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# Is there a role for the community pharmacist in the management of long-term conditions?

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## Abstract

The Government agenda is to move pharmacists away from dispensing medicines from a prescription to the provision of clinical services aimed at managing patients with long-term conditions. This thesis uses the approach defined by the MRC framework for developing complex interventions to ascertain whether there is a pharmacist role in this area.

An initial study was conducted to determine the feasibility of a community pharmacist eczema management support service (PLEEZ). It demonstrated encouraging results, however failed to recruit the required number of participants. A pharmacist focus group indicated that the study had failed because of an insufficient population, overly complex study design and insufficient intervention preparation and training.

Type 2 diabetes was subsequently chosen for the intervention as these patients have an anticipated greater pharmaceutical need and there is a larger available patient population. In line with the MRC framework, appropriate developmental work was then undertaken in the form of a literature review, an audit and a series of focus groups to determine the composition of a novel intervention focused on this condition. These results came together to form the diabetes community pharmacy drop-in clinic comprising the following elements:

- Targeting poorly controlled patients
- A system of referral from the medical practice
- A suitable training programme
- No appointment system
- Additional pharmacist to support
- A focus on adherence and dose optimisation as well as diet and lifestyle advice

The clinics, in five pharmacies, recruited 33 participants providing positive results from the outcomes measured, excellent patient feedback and pharmacist comments that can be used to inform future studies.

The thesis demonstrates that there is a potential role for the community pharmacist in the care of patients with type 2 diabetes, however further, large scale research is needed to confirm whether this is the case.

# Contents

<b>Abstract</b> .....	<b>ii</b>
<b>Contents</b> .....	<b>iii</b>
<b>List of figures</b> .....	<b>vii</b>
<b>List of tables</b> .....	<b>viii</b>
<b>List of Appendices</b> .....	<b>ix</b>
<b>Glossary</b> .....	<b>x</b>
<b>Acknowledgements</b> .....	<b>xi</b>
<b>1 Introduction</b> .....	<b>2</b>
1.1 The history of community pharmacy .....	2
1.2 Government vision for community pharmacy .....	3
1.3 The community pharmacy contract.....	4
1.3.1 <i>Essential Services</i> .....	4
1.3.2 <i>Advanced services</i> .....	5
1.3.3 <i>Enhanced services</i> .....	6
1.4 Provision of community pharmacy contract services .....	7
1.4.1 <i>Community pharmacy workload</i> .....	8
1.4.2 <i>Supervision and skill mix</i> .....	9
1.4.3 <i>Commercial pressures</i> .....	10
1.4.4 <i>Inter-professional working</i> .....	11
1.4.5 <i>Evidence base for current pharmacy services</i> .....	12
1.5 Research into potential pharmacy services .....	15
1.5.1 <i>UK pharmacy practice research</i> .....	15
1.5.2 <i>International community pharmacy research</i> .....	22
1.6 UK community pharmacy research practice.....	27
1.6.1 <i>Perception of research in community pharmacy</i> .....	27
1.6.2 <i>Pharmacist education and training</i> .....	28
1.6.3 <i>Development of complex interventions</i> .....	30
1.7 Conclusion.....	33
<b>2. A randomised controlled trial of a Pharmacist-LEd EcZema management support service (PLEEZ): a feasibility study</b> .....	<b>36</b>
2.1 Introduction .....	36
2.1.1 <i>Eczema</i> .....	36
2.1.2 <i>Educational interventions</i> .....	38
2.2 Aims and objectives .....	42
2.2.1 <i>Aims</i> .....	42
2.2.2 <i>Objectives</i> .....	42
2.3 PLEEZ method .....	43
2.3.1 <i>Pharmacy recruitment</i> .....	43

2.3.2	<i>Communication with the primary care team</i>	43
2.3.3	<i>Pharmacy team training</i>	43
2.3.4	<i>Pharmacist training</i>	43
2.3.5	<i>Inclusion criteria</i>	44
2.3.6	<i>Exclusion criteria</i>	45
2.3.7	<i>Participant recruitment</i>	45
2.3.8	<i>Sample size</i>	46
2.3.9	<i>Randomisation</i>	46
2.3.10	<i>Patient questionnaire</i>	48
2.3.11	<i>The intervention</i>	49
2.3.12	<i>Pharmacist data collection</i>	50
2.3.13	<i>Follow-up data collection</i>	51
2.3.14	<i>Data analysis</i>	51
2.3.15	<i>Amendments to study design</i>	52
2.4	<i>Pharmacist focus group</i>	53
2.4.1	<i>Focus group aims</i>	53
2.4.2	<i>Focus group method</i>	53
2.4.3	<i>Facilitation</i>	53
2.4.4	<i>Topic Guide</i>	54
2.4.5	<i>Focus group analysis</i>	54
2.5	<i>PLEEZ results</i>	56
2.5.1	<i>Feasibility-RCT results</i>	56
2.5.2	<i>Focus group results</i>	59
2.6	<i>PLEEZ discussion</i>	65
2.7	<i>PLEEZ conclusion</i>	72
<b>3</b>	<b>Type 2 diabetes: a perfect disease for community pharmacy?</b>	<b>76</b>
3.1	<i>Prevalence and cost to the NHS</i>	76
3.2	<i>Causes and complications</i>	77
3.3	<i>Evidence and guidelines for treatment</i>	78
3.4	<i>Adherence to treatment</i>	81
3.5	<i>Summary</i>	85
<b>4</b>	<b>Diabetes community pharmacy interventions</b>	<b>87</b>
4.1	<i>Introduction</i>	87
4.2	<i>Aim</i>	87
4.2.1	<i>Objectives</i>	87
4.3	<i>Method</i>	88
4.3.1	<i>Inclusion criteria</i>	88
4.3.2	<i>Exclusion criteria</i>	89
4.4	<i>Search results</i>	89
4.4.1	<i>Included studies</i>	90

4.4.2	<i>Characteristics of excluded studies</i> .....	91
4.4.3	<i>Quality assessment</i> .....	91
4.5	Results .....	92
4.6	Discussion .....	104
4.6.1	<i>Strengths and limitations</i> .....	108
4.7	Conclusion .....	110
<b>5.</b>	<b>An evaluation of prescribing for type 2 diabetes in primary care: optimizing the role of the community pharmacist in the primary healthcare team.....</b>	<b>113</b>
5.1	Introduction .....	113
5.2	Audit method.....	116
5.2.1	<i>Practice selection</i> .....	116
5.2.2	<i>Inclusion criteria</i> .....	116
5.2.3	<i>Sample size justification</i> .....	116
5.2.4	<i>Selection of participants</i> .....	116
5.2.5	<i>Audit standards</i> .....	117
5.2.6	<i>Data collection</i> .....	117
5.3	Audit results.....	119
5.3.1	<i>Clinical outcomes</i> .....	119
5.3.2	<i>Medication</i> .....	121
5.4	Audit discussion .....	123
5.4.1	<i>Limitations</i> .....	125
5.5	Audit conclusion.....	126
<b>6</b>	<b>Focus group discussions with type 2 diabetes patients.....</b>	<b>128</b>
6.1	Introduction .....	128
6.2	Aims and objectives.....	131
6.2.1	<i>Aims</i> .....	131
6.2.2	<i>Objectives</i> .....	131
6.3	Focus group method .....	132
6.3.1	<i>Focus group rationale</i> .....	132
6.3.2	<i>Participant recruitment</i> .....	132
6.3.3	<i>Participant selection</i> .....	133
6.3.4	<i>Topic guide</i> .....	134
6.3.5	<i>Data analysis</i> .....	134
6.4	Focus group results.....	135
6.4.1	<i>The place of pharmacy in the wider primary care team</i> .....	136
6.4.2	<i>The pharmacy as a healthcare destination</i> .....	141
6.5	Focus group discussion .....	146
6.5.1	<i>Strengths and limitations</i> .....	149
6.6	Focus group conclusion .....	151

<b>7</b>	<b>Diabetes Drop-in Clinic: A feasibility study .....</b>	<b>154</b>
7.1	Introduction .....	154
7.2	Aims and Objectives .....	158
7.2.1	<i>Aims</i> .....	158
7.2.2	<i>Objectives</i> .....	158
7.3	Drop-in clinic method .....	159
7.3.1	<i>Ethical Review</i> .....	159
7.3.2	<i>Study Design</i> .....	159
7.3.3	<i>Practice and pharmacy recruitment</i> .....	159
7.3.4	<i>Pharmacist training</i> .....	159
7.3.5	<i>Participant identification</i> .....	160
7.3.6	<i>Participant recruitment and consent</i> .....	161
7.3.7	<i>The drop-in clinic</i> .....	161
7.3.8	<i>Pharmacist data collection</i> .....	162
7.3.9	<i>Patient follow-up questionnaire</i> .....	163
7.3.10	<i>Funding</i> .....	163
7.3.11	<i>Pharmacist interviews</i> .....	163
7.3.12	<i>Sample size calculation</i> .....	164
7.3.13	<i>Data analysis</i> .....	164
7.4	Drop-in clinic results.....	166
7.4.1	<i>Participant demographics</i> .....	166
7.4.2	<i>Baseline and follow-up questionnaire</i> .....	166
7.4.3	<i>Pharmacist data collection</i> .....	172
7.4.4	<i>Feedback questionnaire</i> .....	173
7.4.5	<i>Pharmacist de-brief interviews</i> .....	177
7.5	Drop-in clinic discussion.....	181
7.5.1	<i>Limitations of the study</i> .....	186
7.6	Drop-in clinic conclusion .....	188
<b>8</b>	<b>Overall discussion .....</b>	<b>191</b>
8.1	Conclusions .....	197
8.2	Recommendations for future work .....	198
8.3	Publications and conference presentations arising from the thesis .....	200
<b>9</b>	<b>References .....</b>	<b>202</b>

## List of figures

<b>Figure 1.1</b> The development and evaluation of complex interventions (adapted from MRC 2008) .....	31
<b>Figure 2.1</b> PLEEZ Study design .....	47
<b>Figure 2.2</b> % of patients reporting they had received about the right information or that none was needed for each of the SIMS questions at baseline. ....	58
<b>Figure 2.3</b> Strategy for developing an enhanced pharmacy service as a result of the PLEEZ Eczema service project.....	74
<b>Figure 7.1</b> Responses to the SIMS questionnaire, before: n=33; after: n=26 .....	169
<b>Figure 7.2</b> Responses to Morisky questionnaire, before: n=33; after: n=26 .....	170
<b>Figure 7.3</b> The content of the 33 consultations and whether the topic was raised by the patient or the pharmacist.....	171
<b>Figure 7.4</b> Responses that required a yes/no/not sure answer from the feedback questionnaire.....	175

## List of tables

<b>Table 2.1</b> Intervention content .....	50
<b>Table 2.2</b> Study demographics .....	56
<b>Table 2.3</b> Results from the PLEEZ questionnaire for control and intervention at baseline.....	57
<b>Table 4.1</b> Search terms and results returned.....	90
<b>Table 4.2</b> Definitions for the quality rating system.....	92
<b>Table 4.3</b> Study design.....	93
<b>Table 4.4</b> Training provision for pharmacists .....	96
<b>Table 4.5</b> Inclusion criteria .....	98
<b>Table 4.6</b> Description of intervention .....	100
<b>Table 4.7</b> Ranked studies based on overall quality assessment and outcomes .....	102
<b>Table 5.1</b> Summary of targets for diabetes and the % of patients achieving the desired values .....	113
<b>Table 5.2</b> Practice demographics (QOF 2009-2010 data) .....	120
<b>Table 5.3</b> Adherence to testing criteria (N=194 for all tests).....	121
<b>Table 5.4</b> Patient outcomes.....	121
<b>Table 6.1</b> Participant demographics .....	135
<b>Table 7.1</b> Core findings from previous chapters detailing to rationale for inclusion in the drop-in clinic.....	157
<b>Table 7.2</b> Number of participants recruited in each pharmacy. ....	166
<b>Table 7.3</b> Participant Demographics.....	166
<b>Table 7.4</b> Baseline and follow-up questionnaire data.....	167
<b>Table 7.5</b> Morisky adherence scale change from baseline to follow-up.....	167
<b>Table 7.6</b> Community pharmacy use before and after the study .....	168
<b>Table 7.7</b> Responses to the feedback questionnaire.....	174



## **List of Appendices**

- 1** Protocol and study documentation for PLEEZ
- 2** NHS ethical approval for PLEEZ
- 3** NHS research and Development approval for PLEEZ (with amendments)
- 4** PLEEZ amendment number 1
- 5** PLEEZ amendment number 2
- 6** PLEEZ amendment number 3
- 7** PLEEZ amendment number 4
- 8** PLEEZ focus group information sheet and consent form
- 9** Audit protocol
- 10** NHS R&D approval for audit
- 11** Audit data collection form
- 12** Patient focus groups protocol and supporting documentation
- 13** NHS ethical approval for focus groups
- 14** NHS R&D approval for focus groups
- 15** Diabetes drop-in clinic protocol and supporting documentation
- 16** NHS ethical approval (including amendment number 1) for drop-in clinic
- 17** NHS R&D approval for drop-in clinic

## **Glossary**

AUR	Appliance Use Review
BMI	Body Mass Index
CHD	Coronary Heart Disease
CPD	Continuing Professional Development
CPPE	Centre for Pharmacy Postgraduate Education
CV	Cardiovascular
CVD	Cardiovascular Disease
GMS	General Medical Services
GP	General Practitioner
HbA <sub>1c</sub>	Glycosylated Haemoglobin
LDL	Low Density Lipoprotein
MRC	Medical Research Council
MUR	Medicines Use Review
NDA	National Diabetes Audit
NHS	National Health Service
NICE	National Institute of Health and Clinical Excellence
NMS	New Medicine Service
OTC	Over The Counter
PCP	Pharmaceutical Care Plan
PCT	Primary Care Trust
POM	Prescription Only Medicine
PSNC	Pharmaceutical Services Negotiating Committee
QALY	Quality Adjusted Life Years
QOF	Quality and Outcomes Framework
R&D	Research and Development
RCT	Randomised Controlled Trial
SD	Standard Deviation

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# *Chapter One*

# **1 Introduction**

## **1.1 The history of community pharmacy**

Community pharmacy has been constantly evolving and reacting to the healthcare environment since its inception in the mid-1850s. The profession of pharmacy was created out of the Pharmacy Act 1852 which had been lobbied for by the recently founded Pharmaceutical Society of Great Britain. At this time, the pharmacist was engaged in a wide variety of roles from dispensing medicines from a physician-written prescription to minor surgery and dentistry (Anderson, 2005). It was only with subsequent legislation, surrounding other professions e.g. the Dentists Act 1921, that these latter roles were removed from pharmacists.

One of the most important functions of a pharmacist at this time, and until the founding of the National Health Service (NHS), was to advise and treat patients who could not afford to see a general practitioner (GP). If someone wanted to see a GP, they had to pay for the consultation and then pay for the medicine that either the GP or the pharmacist would dispense. Patients who saw a pharmacist only had to pay for any medicines which they recommended. In a time when universal healthcare had not yet been established and wages were low, this was the only option available to many people.

The transformation in the role of the pharmacist to the one we see today, began with the 1911 National Insurance Act, the forerunner to the NHS. This changed the healthcare landscape so that certain people could see a doctor and then have prescriptions dispensed by a pharmacist for no charge. Within one year of operation, the number of prescriptions dispensed by pharmacists trebled and as a result, pharmacists started to move away from advising patients and towards medicines supply as their main role.

When the NHS was established in 1948, this role transformation was complete. With the advent of free GP consultations for all, most patients chose to access a medical practitioner rather than consult a pharmacist. Consequently, the pharmacist engaged less with patients and more with dispensing medicines from NHS prescriptions which had also significantly increased in number due to the more popular use of medical practitioners. As the NHS evolved, the reliance on community pharmacies for dispensing medicines continued to rise; however, this became more efficient due to the introduction of patient-packs and a reduced need for compounding medicines. In the early 2000s, the Government decided to expand the role of the pharmacist to encompass a more patient-focused approach to their work. This role expansion originates from the notion, outlined by the Nuffield report in 1986, that community pharmacists are well-trained healthcare

professionals with regular interactions with patients but have little impact on their care (The Nuffield Foundation, 1986).

## **1.2 Government vision for community pharmacy**

Today, an average adult visits a community pharmacy 16 times per year with 86% of the population visiting at least once per year, 78% of those for health related reasons (Department of Health, 2008). This figure equates to over 47 million people visiting a community pharmacy at one point during the year and demonstrates the readiness with which the public use community pharmacy. Over the previous decade the UK Government has published three health White Papers outlining its vision for community pharmacy with these figures in mind.

*A Vision for Pharmacy in the new NHS*, in 2003, outlined the Government's overarching view that community pharmacy should be given a clearer NHS identity, as many members of the public view pharmacy as distinct from the NHS rather than an integral part of it (Department of Health, 2003). It set out to develop a new pharmacy contract that placed more emphasis on providing patient services and valued the role of dispensing technicians more in the day-to-day dispensing activities. *Choosing health through pharmacy – a programme for pharmaceutical public health 2005 - 2015* moved this vision forward by establishing the new contract and placing pharmacy, especially community pharmacy, at the heart of the Government's public health strategy. This stated that pharmacists should be involved in improving the public health with a specific focus on long-term conditions in the form of support for self-care together with involvement in disease management as part of the wider primary care team (Department of Health, 2005a).

Long-term conditions affect a significant proportion of the population and can often be life-long and have a detrimental effect on a person's quality of life. In 2007/8 the NHS was treating approximately 1.9 million people for coronary heart disease, 6.9 million for hypertension, 2.1 million for diabetes mellitus and 3.1 million for asthma (The Health and Social Care Information Centre, 2008). The majority of these patients will be treated with medication dispensed by a community pharmacy in primary care which in 2009 cost the NHS £8.5 billion, with each person in the population receiving an average of 17.1 items annually (The Health and Social Care Information Centre, 2010).

The 2005 White Paper also referred to the need for robust research to underpin these new roles, encouraging pharmacists to work with academic institutions to achieve this goal (Department of Health, 2005a). This was further re-enforced in *Pharmacy in England: building on strengths - delivering the future*, published in 2008, which provided greater



detail on implementation, strategy and funding arrangements. This paper also referenced the changes needed to pharmacist education and training, the need to use the pharmacy workforce to better effect and the necessity of improving communication between pharmacists, the public and other healthcare professionals to ensure this role is properly understood. As a result of these White Papers, the community pharmacy contract was re-negotiated in 2005 and detailed a new operational platform and payment structure for the Government vision to account for these new roles (PSNC, 2005).

### 1.3 The community pharmacy contract

In 2005 a new community pharmacy contract was implemented in the United Kingdom (Department of Health, 2005b). Although dispensing formed the core service together with supply of appliances and waste disposal, additional clinical services were, for the first time, recognised in the payment system to community pharmacies. The new pharmacy contract divides services into three categories: essential, advanced and enhanced services. The organisation, provision and payment arrangements for pharmaceutical services differ between the constituent countries of the UK. This following explanation refers to pharmaceutical services in England only.

#### 1.3.1 Essential Services

Community pharmacies are required to demonstrate that they are providing the eight essential services (detailed in box 1) in order to keep their contract with the primary care trust.

#### **Box 1 Essential pharmacy services**

Dispensing	Public health
Repeat dispensing	Signposting
Supply of appliances	Support for self-care
Disposal of unwanted medicines	Clinical governance

These form the core elements of community pharmacy practice and represent the more traditional services that most people associate with community pharmacists and are designed to formalise the pharmacist's role in providing public health advice, health promotion and support for self-care.

Repeat dispensing was introduced as an adjunct to the pharmacist's normal dispensing activities and is a system where up to six-months' worth of prescriptions are kept at the pharmacy, so that when a patient needs their monthly prescription they only have to go to the pharmacy rather than placing a request at their local surgery. The process was designed to make it easier for patients to obtain their repeat prescriptions but it also

provided a valuable opportunity for the pharmacist to engage with, and improve their relationship with, the patient (National Prescribing Centre, 2010). As part of the service the pharmacist should ensure that the patient requires all of the medicines on the prescription before dispensing, thereby, changing the responsibility of community pharmacists to one of monitoring as well as dispensing.

### 1.3.2 Advanced services

Advanced services are those that are agreed nationally between the Department of Health and the Pharmaceutical Services Negotiating Committee (PSNC) and which pharmacy premises and pharmacists have to be accredited to provide. There are currently four nationally agreed advanced services: medicine use reviews (MURs) and prescription intervention (PIs), new medicine service (NMS), appliance use reviews (AURs) and stoma appliance customisation.

MURs are the most prevalent of these services and involve the pharmacist entering into a consultation with a patient about their medicines. This consultation is centred on a patient's adherence to their medicines and any problems they may have in taking them. This could raise problems that can be dealt with by the pharmacy team e.g. patient unable to read the medicine labels and therefore large print labels can be used from then onwards, or by the GP e.g. the patient is experiencing side effects from one of their prescribed medicines. The consultation is designed to last 10-15 minutes and whilst it is not a full clinical review of the medicines, some of the recommendations made to the GP maybe clinical in nature.

In order to be able to provide the MUR service, pharmacists are required to undergo a short training course which details the service specification and provides an overview on consultation techniques that may be useful for conducting this type of conversation with the patient. There are a number of different training courses available ranging from those that can be completed in approximately three hours to those that are more intensive and require the submission of case studies. There is no stipulation as to how long the course must be and how much training a pharmacist must have had before they start to provide the service. All training packages are designed for self-completion and there is no face-to-face element.

The NMS was introduced in October 2011 with the aim of improving adherence to newly-prescribed medicines for certain long-term conditions e.g. hypertension or asthma and is based on proof of concept research by The School of Pharmacy, London and the University of Nottingham (Barber et al., 2004, Clifford et al., 2006, Elliott et al., 2008). The service involves an initial interaction between the patient and pharmacist where consent to

participate in the service is obtained and basic counselling regarding the new medicine is given to the patient. The intervention phase of the service occurs 7-14 days after this initial conversation and is designed to offer patients any advice they may want about their medicine and to discuss any problems or concerns they may have had with taking the medicine so far. Follow-up occurs 14-21 days after the intervention phase and is aimed at making sure the patient is still taking their medicine and that any problems highlighted at the second stage of the service have been resolved to the patient's satisfaction. Both the intervention and follow-up stages can be conducted in person or over the telephone and there is a facility to refer any problems directly back to the patient's GP if necessary. The training requirement for NMS is a self-assessment of the pharmacist's competence to conduct the service which is based on their ability to remember the service specification and a brief appraisal of their own communication skills (PSNC, 2011).

At the end of the year April 2010 – March 2011, 2.1 million MURs had been conducted, 400,000 more than were conducted the year before (The NHS Information Centre, 2011a) with 87.9% of pharmacies providing an average of 219 each, which is just over half of the total allowable number of MURs per pharmacy (400) in any particular year. With the NMS, approximately 6,000 pharmacies are claiming payment for a total of 418,744 interventions provided between October 2011 and July 2012 (PSNC, 2012c), representing just over half of pharmacies conducting this service each month.

### 1.3.3 Enhanced services

These are services commissioned by primary care trusts (PCTs) according to the needs of the local population. The Department of Health has so far specified 19 enhanced services (detailed in box 2) that can be commissioned by PCTs (Department of Health and Welsh Assembly Government, 2012).

#### **Box 2 List of enhanced services**

Schools service	Medication review service
Gluten free food supply	Medicines assessment and compliance support
Home delivery service	On demand specialist drugs
Anticoagulation monitoring	Minor ailment scheme
Disease specific management	Independent prescribing service
Supplementary prescribing	Care home service
Screening service	Patient group direction service
Language access service	Stop smoking
Prescriber support service	Needle and syringe exchange
Supervised administration service	

The training requirement for enhanced services is often more detailed than that for the advanced services and usually comprises a self-directed element e.g. completion of the relevant Centre for Pharmacy Postgraduate Education (CPPE) learning package, along with a face-to-face event provided by the commissioning organisation. These training events are then run at regular intervals to capture any new pharmacists who wish to provide the service but also to act as a refresher for pharmacists currently providing the service.

In total, 30,962 locally enhanced services were provided by community pharmacies in the year 2010-11, an increase of 4.9% on the previous year (The NHS Information Centre, 2011a). This figure is the number of services in operation, not the actual number of patients who used the service. Data relating to the uptake of these services is currently unavailable. The five services that were commissioned the most (number (%) of pharmacies providing the service given in brackets) were stop smoking (6,104 (55.7%)), supervised administration (5,385 (49.2%)), minor ailment service (3,686 (33.7%)), medicines provided through patient group direction (3,552 (32.4%)), and medication review (2,383 (21.8%)). These five services have remained the most popular since enhanced services were introduced in 2005.

For the first time, these enhanced services provide the pharmacist with the opportunity to prescribe medicines both as an independent and supplementary prescriber. In 2010, an evaluation of pharmacist independent prescribing found that between 2-3% of pharmacists were qualified as prescribers and approximately 71% of those were currently using their skills (Latter et al., 2010). However, this report also identifies that although patients and professionals like the idea of non-medical prescribing, only about half of PCTs have a strategy in place to increase their role in the NHS. As of 2012, there are only two documented community pharmacy services that involve the pharmacist (supplementary) prescribing, one in Lincolnshire relating to the supply of oral contraception and one in Tyneside relating to substance misuse (Pharmaceutical Services Negotiating Committee, 2013).

Research suggests that the types of service a pharmacy provides depends on what kind of business they are, with some pharmacies not providing certain services due to the opinions of other customers that use the business e.g. supervised consumption in a supermarket (Bush et al., 2007).

#### **1.4 Provision of community pharmacy contract services**

Despite these innovations in service provision and changes to the pharmacy contract, the pharmacist's core role remains the supply of medicines by prescription and is viewed as

such by many pharmacists (Bryant et al., 2009). Despite the increasing number of services being provided there remains concern from pharmacists, other healthcare professionals and commissioning organisations about the quality, ability to provide and need for some of these new services. The training requirement for these enhanced roles varies significantly and may be one reason why quality and effectiveness is being questioned. However, other factors such as workload, supervision and skill mix, commercial pressures, interprofessional working and evidence base can all be seen to influence the extent to which pharmacists engage with their new roles as providers of patient-focused services. Research that has attempted to explore these factors has largely centred on MURs and how pharmacists have implemented them since their introduction.

#### 1.4.1 Community pharmacy workload

Since the new pharmacy contract, community pharmacists have had to start providing additional patient-focused services against a background of increasing prescription volumes. In 1948, when the NHS was first established, 13,000 pharmacies were dispensing approximately 250 million prescriptions (Anderson, 2007). This has risen to reach 850.7 million prescription items from 10,951 pharmacies in 2010/11 (The NHS Information Centre, 2011a) which was an increase of 4.6% on the previous year, one that is forecast to rise further due to the increasing age of the population (The Office for National Statistics, 2010), increases in the prevalence of certain long term conditions e.g. diabetes (The Health and Social Care Information Centre & The Yorkshire and Humber Public Health Observatory, 2009) and advances in medical technology.

167 out of 280 (59.6%) pharmacists who were surveyed whilst working for one particular multiple pharmacy chain in the UK highlighted at the inception of the pharmacy contract that time constraints would be a major factor in their ability to conduct MURs (Latif and Boardman, 2008). A similar postal questionnaire was posted to a comparable group of pharmacists working in another multiple pharmacy chain in 2009 and a similar response rate returned similar thoughts about time constraints. However, fewer respondents highlighted this as a barrier to performing MURs than in the original survey (Latif et al., 2010) indicating that pharmacists may have become better at integrating service provision into their core dispensing activities.

Latif's other work centred on case studies of two pharmacies providing the MUR service and discovered that in these two pharmacies the workload experienced by the pharmacists may have impacted on their ability to conduct the service (Latif et al., 2011). This aspect of attempting to fit MURs into other tasks associated with community pharmacy e.g. dispensing, is something that has been documented more widely in the

literature (Harding and Wilcock, 2010) and that it is often a struggle to conduct MURs whilst maintaining dispensing volumes (McDonald et al., 2010). This conflict in the requirements of the pharmacist and the reason why workload is an important factor to understand in relation to service provision is largely related to the framework in which community pharmacy operates, with legislation being one of the barriers to the implementation of pharmacy services.

#### 1.4.2 Supervision and skill mix

The Medicines Act 1968 and various Health Acts stipulate that a pharmacist must be in a position to 'supervise' the dispensing of medicines and sales of certain over-the-counter (OTC) medicines personally. This means that the pharmacist must always clinically check a prescription and be in a position to advise and intervene in the sale or supply of medicines should it be necessary (Royal Pharmaceutical Society, 2011). Guidance states that providing pharmacy staff are appropriately qualified, pharmacists do not need to be physically present for certain aspects of the dispensing process (Royal Pharmaceutical Society, 2011). A debate on the supervision rules is underway by the profession to establish to what extent these rules should be amended to allow the pharmacist more freedom to conduct other aspects of their work e.g. provision of pharmacy services (Branford and Phillips, 2010).

These rules have restricted the activities of the pharmacist to only those which take place in the pharmacy and do not take him/her away from the dispensary for long periods of time. Consequently, this has limited the extent to which pharmacists can enter into private consultations with patients away from the dispensary or pharmacy counter and means that, even after seven years of the new contract, they are largely confined to the dispensary, clinically checking prescriptions for most of his/her time. In the cases studies described by Latif et al. previously it is interesting to note that counter staff and dispensers had to make judgement calls about whether they could interrupt a pharmacist's consultation in order for them to check a prescription for a waiting patient (Latif et al., 2011), thereby attempting to balance the medicine-focused and patient-focused role of the community pharmacy.

Better use of the pharmacy team may prove effective at freeing up pharmacist time to concentrate on services. The most recent pharmacy White Paper outlined plans to use the pharmacy workforce to better effect with a suggestion that pharmacy technicians may, in the future, have a role in the sale or supply of medicines (Department of Health, 2008).

Currently, pharmacists have identified that where they have appropriately trained members of staff that can perform activities such as checking prescriptions, it releases

them to engage more with enhanced and advanced services (McDonald et al., 2010). It should also be noted that it is not simply the training of the support staff but the number of them present, as a checking technician requires a number of other support staff (at least two) in order that they can check prescriptions legally and safely (Harding and Wilcock, 2010).

One other aspect that has helped to increase the number of services that are provided is related to the way in which the community pharmacy plans their workload. Most community pharmacies now operate a delivery service and a prescription collection service which means that workload can be planned and the pharmacist is not in a position of having to immediately respond to a patient's prescription request as often (McDonald et al., 2010). This move to a more planned working day has largely been led by multiple pharmacy companies in order to release the pharmacist to provide MURs to increase their income as well as encouraging patients to use the same pharmacy for all of their prescriptions. The incentive to increase the number of services provided was a reduction in the fee paid per item dispensed to pay for the additional service provision. Therefore, pharmacies have to either dispense more medicines or maintain dispensing volume whilst providing services simply to maintain their current income.

#### 1.4.3 Commercial pressures

Bradley et al. discovered that the number of MURs conducted in large multiples differs from that in small independent pharmacies (Bradley et al., 2008). In multiples there is an emphasis on achieving targets for MURs, the 400 limit applied by the Department of Health is seen as an immutable goal with pharmacists being reprimanded if they fall short of this figure (McDonald et al., 2010). Particularly within the large company environment, it is seen as a quantity driven exercise to generate greater profit for the company (McDonald et al., 2010) and pressures are applied to pharmacists to encourage them to achieve this figure (Murphy, 2007).

Bush et al. refer to this as the 'corporatization' of community pharmacy meaning that community pharmacy companies have adopted policies that make sense for the business but not necessarily for the patient or the NHS and that sometimes these professional and commercial responsibilities can conflict with each other (Bush et al., 2009). This pressure from companies to conduct a certain number of MURs may be having an effect on the quality of them with some pharmacists saying they have conducted them when there is not necessarily a need (Wilcock and Harding, 2008). Representatives of organisations responsible for monitoring the number of MURs have also reported that they suspect those pharmacists performing high numbers of MURs may not be conducting good quality reviews something that is also being acknowledged by the medical practices when they

receive the associated paperwork (Bradley et al., 2008). As a result this may be one of the causes for the poor nature of inter-professional working between community pharmacists and GPs.

#### 1.4.4 Inter-professional working

Community pharmacists work in a unique environment in the healthcare sector, namely in isolation. It has been suggested that this isolation can lead to a diminishing of ethical values in a pharmacist's professional practice as they do not interact regularly with other healthcare professionals (Cooper et al., 2009). It has also been suggested that community pharmacists feel subordinate to general practitioners, possibly because many doctors view them as 'shopkeepers' with little to add to the clinical management of the patient (Hughes and McCann, 2003).

This was also enforced in the development of the 2003 general medical services (GMS) contract and the 2005 pharmacy contract. Both contracts were designed with other professions in mind; however, they operate entirely in isolation from each other without taking in to account continuity of care, quality and patient safety (Richardson and Pollock, 2010). There may also be a lack of communication between community pharmacists and GPs with pharmacists suggesting that since the introduction of MURs, interaction with the GP has not altered (Blenkinsopp et al., 2007a). In a survey of community pharmacists and GPs about clinical service provision, both identified that the current funding system does not facilitate inter-professional working and that these services if not linked well together could lead to conflicting information for the patient (Bryant et al., 2009).

In terms of MURs, pharmacists hold the view that GPs place no value on the paperwork that they receive from the consultation and it is thought that GPs are resistant to them because they are merely formalising the role that pharmacists should already be doing but are now getting paid separately for (McDonald et al., 2010). Even when pharmacists submit a copy of the MUR form to the GP, it is often the case that they receive little feedback on the service they have just provided (Wilcock and Harding, 2008).

From the GPs' perspective they found it difficult when the MUR paperwork they were receiving was often not the best quality in terms of the recommendations made (Celino et al., 2007). In a survey conducted in 2007, GPs gave a mixed response to questions relating to MURs calling them useless, noting them as frustrating when pharmacists requested that they measure a patient's blood pressure when it had already been done and conducting MURs on patients whose treatment had not changed in several years and they knew were compliant (Wilcock and Harding, 2007). Community pharmacists do not have access to patient's medical notes and therefore if the patient does not remember



when they last had a blood pressure measurement, it may seem logical for a pharmacist to suggest one on the MUR form, however, this has the possibility of leading to duplication with information that is already present in the medical notes. Therefore, the pharmacist thinks he/she is being helpful where the GP views it as unnecessary interference as the measurement has already been performed. This has also been confirmed in survey research with GPs that demonstrated that over two-thirds of the sample (n=83) thought that pharmacy clinical services would lead to a duplication of work (Bryant et al., 2009).

One factor that may be affecting the level of inter-professional working between the two professions is the evidence base and there is a call for higher quality evidence to support the continued introduction and provision of pharmacy services (Richardson and Pollock, 2010).

#### 1.4.5 Evidence base for current pharmacy services

The most prevalent advanced service currently being performed in community pharmacy is medicine use reviews (MURs). However, the evidence for their benefit for both the patient and the NHS is lacking. There are examples of MUR services that have worked well particularly in the field of asthma, depression and Parkinson's disease.

In an evaluation of an asthma targeted MUR service in Hampshire and the Isle of Wight, Portlock et al. describe how pharmacists identified patients who were non-adherent to their therapy and then helped them to understand their medicines better. From 965 patients who received an MUR and subsequently completed a satisfaction questionnaire, 41% of those patients who were classed as primarily adherent had problems with inhaler technique (secondary non-adherence) and 36% had issues with the beliefs they held about their medicines (Portlock et al., 2009). In the satisfaction questionnaire of attitudes towards the MUR service, 33% of patients said it gave them more confidence, 90% understood more about their treatment and 83% knew more about their condition. This is the purpose of the MUR and the pharmacist is equipped to deal with all the patient issues identified.

This study, whilst extremely encouraging for asthma targeted MURs, demonstrates the importance of appropriate outcome measures. This study did not set out to demonstrate any benefit on asthma symptoms or the cost-effectiveness of the service. Without these two measures it becomes harder to demonstrate the effectiveness of the intervention and/or benefit to the NHS. It also utilised a weak study design, by simply providing the patients with a feedback questionnaire and making no follow-up provision to determine the effect on their asthma symptoms. However, it did provide evidence that targeting patients who potentially require help with their treatments or those who are resistant to treatment

by identifying them from the pharmacy or medical records may be a better group of patients for pharmacists to target. This has been demonstrated to be successful in other pharmacy settings (Lowey et al., 2007). The Isle of Wight project led to the introduction of targeted MURs nationally in 2011 aimed at patients on respiratory medicines (Pharmaceutical Services Negotiating Committee, 2011).

This study was followed in the same region of the UK by the *Evaluation of Inhaler Technique Improvement Project* which aimed to focus on the same group of patients and provided them with two MURs, the second as a follow-up to the first (The Cambridge Consortium, 2012). In this before and after study, 600 patients with asthma and 828 with COPD received MURs which focused on their inhaler technique. As with the previous study and due to poor reporting of the method and results it is difficult to ascertain the benefit on patients despite using sophisticated IT software to collate data and link it to the medical practices.

Both of these studies did focus on providing extra training to the participating pharmacists in order that they could provide the service. For the second project, despite a lack of information explaining what the training consisted of, the authors stated that the training was well received and that pharmacists felt able to deal effectively with patients' concerns (The Cambridge Consortium, 2012).

Other MUR projects have included targeted MURs for depressed patients (Cree, 2010). This project showed positive benefits when conducted by specially trained pharmacists working closely with the GP surgery and highlighted patients who were non-adherent and were experiencing side effects. The MUR covered topics such as what antidepressant the patient has been prescribed, if it was the first treatment course, what information they have already received, side effects and information provision regarding warnings about alcohol and driving. 145 MURs were conducted in nine pharmacies over a period of ten weeks, 54 of which were for patients new to the class of medicine. The study only determined the self-reported content of the MURs from the pharmacists and found that a large majority of patients had not received any additional printed information on their medicines prescribed for depression. As part of the service they referred 37 (25.5%) patients back to the GP for problems such as drug interactions and side effects. No follow-up was provided and no patient satisfaction data was collected.

Parkinson's disease has also been the focus of a study in Greater Manchester where MURs were conducted on those patients prescribed medicines for the condition. The MURs included a series of traffic light questions that alerted the pharmacist to the level of control of the disease. This service resulted in 18 (34%) patients out of a total of 53 being

referred back to the specialist hospital unit with a third of patients reviewed found to have poor control of their Parkinson's disease. Feedback from patients was positive and many did not know that a pharmacist could provide such a service (Colquhoun, 2010a).

In a third study, a team from South Staffordshire demonstrated that targeted domiciliary MURs for patients discharged from a community hospital had a benefit. The project demonstrated that the service, which was performed on 69 patients within seven days of discharge, resulted in fewer admissions to both accident and emergency and the original community hospital as well as an improvement in functional independence, 28 days after discharge (Colquhoun, 2010b). The article does not mention how these figures were ascertained. Finally, from patients who have received an MUR it has been noted that there is only a small, non-significant increase in their satisfaction with information about the medicines as a result of the intervention by the pharmacist (Desborough et al., 2008).

There is, therefore, some evidence to support the continued provision of MURs in community pharmacy. However, this evidence tends to focus on certain disease states and on providing an enhanced-MUR, with the pharmacist equipped with extra tools or training to be able to implement them effectively. All of these studies made increased communication between the pharmacist and GP essential if they were going to be effective. Communication may need to be improved more generally between the two professions in order that the quality of MURs can be improved (Blenkinsopp et al., 2007b, Bradley et al., 2008, Bush et al., 2009) and that targeted MURs that involve the GPs may provide the answer (Livingstone, 2010). However, the majority of studies described demonstrate a weak study design, rarely conducting a follow-up appointment or appropriate clinical measurements to monitor particular conditions. These studies rely either on the self-reporting of outcomes by the pharmacist or satisfaction surveys given to patients after they have experienced the MUR.

In terms of the New Medicine Service, proof of concept research was published before the service was commissioned by the NHS, however, the service that was implemented does not align with the research in a number of ways. In the original article describing the service, patients were recruited by the dispensing pharmacist and then the intervention was performed by telephone by a colleague at the company's head office (Clifford et al., 2006). The head-office pharmacist had received half a day's training on the theory surrounding non-adherence, communication skills and medicine-related problems. As part of the outcome assessment a researcher measured patients' self-reporting of the following question:

*People often miss taking doses of their medicines, for a wide variety of reasons.  
Have you missed any doses of your new medicine, or changed when you take it?*

This was used for the primary outcome measure of adherence and over a period of four weeks' follow-up the intervention group reported better adherence than the control group. This may be due to the increased number of telephone calls being received from the company head office and therefore demonstrating the effect of a social desirability bias.

When the service was implemented nationally, pharmacists were required to undertake no additional training in order to increase their knowledge of the service and communication skills. They had to answer questions on a form to acknowledge themselves as competent to provide the service. All pharmacists then had to conduct all aspects of the service without any additional support, meaning three additional patient interactions per service provided whilst still providing their core dispensing function and other pharmacy services.

This service is undergoing a final evaluation (University of Nottingham, 2012) and the Department of Health has stipulated that the service will be discontinued if there is no proven benefit to the NHS.

This lack of robust evidence together with constraints on time, training, skill mix and inter-professional working have indicated that community pharmacy services may have not been as well received as many may have hoped. In the UK there has been other large-scale research examining whether community pharmacy services provide a benefit to patients. Unfortunately, the evidence for other community pharmacy led services in the UK is largely neutral or incomplete.

## **1.5 Research into potential pharmacy services**

### **1.5.1 UK pharmacy practice research**

The most robust pharmacy studies: RESPECT, HOMER, HEARTMED, MEDMAN and HEART-MOT have not focused on MURs but instead on a targeted intervention on either a particular patient group or disease state. There is a lack of literature examining the role of the community pharmacist in providing pharmacy services, however there is a significant body of work examining the role of the pharmacist in the wider primary care team. These studies have utilised different outcome measures, of different levels of appropriateness, and most have utilised a comparison group and been randomised therefore making the evidence they produce more robust.

The RESPECT (Randomised Evaluation of Shared Prescribing for Elderly people in the Community over Time) study investigated whether shared prescribing between GPs and

community pharmacists improved medication appropriateness in elderly patients (Richmond, 2010). Patients (over 75 years old and on more than five medicines) in five primary care trusts were recruited into a stepped wedge trial design with all patients recruited at the same time and acting as their own controls. The pharmacists had no knowledge of which patients had been recruited until just prior to the start of the intervention as they were recruited by virtue of their medical records at the GP surgery. After a control period, post recruitment, participants were given the intervention by the community pharmacist either in the pharmacy or the patient's home.

The intervention was the implementation of a pharmaceutical care plan (PCP) by the community pharmacist in collaboration with the patient and/or carers and the GP. The pharmacists followed a process to develop the PCP with the patient to determine what (if any) problems there may be with their therapy. Most of the intervention was based on clinical indications for use, presence of adverse drug reactions and the potential for drug interactions. Patients were also given access to medicines adherence aids if this was deemed necessary as well as education regarding their therapy. The intervention lasted 12 months, the study recruited 760 participants of which 551 were included in the final analysis. These participants were recruited from 24 medical practices and 62 community pharmacies provided the service.

In order to conduct this intervention the pharmacist received two days' training provided by two universities. GPs were asked to attend the second training day so that both groups could learn about collaborative working relationships. The pharmacists received training on pharmaceutical care in the elderly as well as learning how to involve patients in the development of pharmaceutical care plans. The training took place just before the start of the intervention group, so that the pharmacists did not forget their newly acquired knowledge.

The primary outcome measure of the study was the medication appropriateness index (MAI) in which an independent pharmacist assigned scores to each patient at various time points during the study. Secondary outcomes included patients' knowledge and compliance, incidence of adverse events and health-related quality of life via the SF-36 questionnaire. The results from the study demonstrate that the pharmacist intervention did not produce a significant result in terms of improvements in medication appropriateness nor did it have any significant effect on the health-related quality of life of the participants. The mean number of reviews conducted by the pharmacist on each patient over the 12 month period of the study ranged from 4.1 to 11.1 between the five different primary care trusts (PCTs).

A cost-effectiveness analysis of their result found that the intervention cost £192 more than standard care per patient or £10,000 per Quality Adjusted Life Year (QALY) (Bojke, 2010). The study highlighted that this estimate means that it is between 79-81% likely to be cost-effective to provide this intervention to patients given the current NICE thresholds of £20,000 - £30,000 per QALY. However, this study was only conducted over a period of twelve months and costs incurred after this time were not factored in and the authors state that this may be likely to underestimate the actual figure for cost-effectiveness. There was also a large degree of uncertainty in the results due to the heterogeneity of the sample which identified that it was possibly more cost effective to treat younger patients on fewer medicines.

The rationale for conducting a cost-effectiveness analysis appears to be lacking as this study produced no significant difference between groups and cost more than standard care to provide. Other disease orientated primary outcomes may have been more appropriate in this study to demonstrate an effect in this group of patients. This may have given a better indication of any patient benefit arising from the study.

The HOMER trial examined the role of pharmacists in medication review post discharge in a patient's home (Holland et al., 2005), was conducted in Norfolk and Suffolk in the UK and used mainly community pharmacists. Twenty-Two Pharmacists were recruited to the study because they held a postgraduate qualification in pharmacy practice or had completed recent continuing professional development (CPD) in therapeutics. They received a two day training course that comprised lectures on adverse drug reactions, prescribing in the elderly and communication skills before they saw any patients.

This study was a randomised controlled trial where the pharmacist visited the patient post-discharge with the aim of performing a medication review. The pharmacist educated the patient and carers about their drugs and liaised with their GPs regarding any changes they felt should be made to their regimen. Any compliance issues were referred to their local community pharmacist. The pharmacist visited again six to eight weeks later to re-enforce any advice given at the beginning and further advise participants. The control group received usual care.

The study identified potential participants in hospital after they had been admitted as an emergency. Patients were eligible to take part if they were about to be discharged to the community, were over 80 years old and were prescribed two or more medicines. The team approached 1399 patients of which 872 patients were recruited and the final analysis was performed on 829. The main outcome measure was hospital re-admissions and the secondary outcome measures were quality of life, deaths and number of GP

home visits. The intervention by pharmacists increased hospital re-admissions by approximately 30% and GP visits by 43% when compared to the control group which could also have increased the number of medicines prescribed. There was no improvement in quality of life as measured by the EQ-5D instrument.

A cost-effectiveness analysis was also performed in this study and stated that the cost per randomised patient of providing the intervention was £124, leading to a total intervention cost of £51,622. Due to the small, non-significant improvement in the EQ-5D the cost per quality adjusted life year (QALY) is £54,454 and considering this and the lack of a reduction in hospital admissions the authors state that further consideration should be given to whether medicines management should be implemented in community pharmacy (Pacini et al., 2007).

This study set out to prove the value pharmacists could have post-discharge from hospital in the elderly, something that it did not achieve. There may be several reasons for this. The biggest criticism of the study and one reason why it failed to show a benefit may be due to the consultation skills of the pharmacist. It has been shown that the pharmacists took a didactic approach to the consultation in the patient's home, giving the patient information and advice that they did not solicit (Salter et al., 2007). The recruitment and training of the pharmacists may have also played a role. There may have not been enough training for the pharmacists for such wide-ranging intervention (this was not a disease-specific intervention) on clinical skills or consultation skills. The authors also note that this intervention may have increased adherence to potentially inappropriate therapy which resulted in an increase in hospital admissions; a full clinical review of the medicines was not part of the study (Holland et al., 2005).

The HOMER study was followed by the HEARTMED study conducted by the same research team which was a disease specific intervention (heart failure) and used the same methodology as HOMER (Holland et al., 2007). The pharmacists received one training course on the organisational and clinical aspects of the study. Half of the pharmacists also attended two evening events aimed at improving their consultation skills. Once recruited to the study, participants were visited at home by the pharmacist in order to review their medicines, educate patients about heart failure as well as providing them with lifestyle advice. Any recommendations for alterations to prescribed therapy were communicated to the GP and compliance problems were fed back to the community pharmacist. The follow-up visit was scheduled in for 6-8 weeks after the initial visit. The control group received usual care.

The recruitment criteria were identical to HOMER with the exception of the age range; HEARTMED recruited patients over the age of 18. 555 patients were approached to participate, 339 randomised and the final analysis performed on 291 participants. The primary outcome measure was hospital emergency admissions with deaths, EQ-5D and a disease specific instrument forming the secondary outcome measures. As with HOMER the primary outcome measure increased (non-significantly) in the intervention group and there were no significant differences between groups for any of the secondary outcome measures.

The results from this study demonstrate that even away from the busy environment of the community pharmacy, pharmacists are not able to have a significant impact on hospital admissions. Patients were recruited from the hospital to which they were admitted with heart failure, which may have helped to recruit a large number of people to the study. However, for this type of study it may not have been appropriate to recruit post-discharge as patients will have already had a medication review whilst as an inpatient. It may therefore be more appropriate and demonstrate a better effect by recruiting directly from the community. There is also another aspect of specialist training required to provide this type of intervention. Many patients will visit a specialist heart failure nurse before leaving hospital and receive information and advice about their condition. When compared to a generalist pharmacist who has received some additional training and who does not implement this training on a regular basis, it may not be a surprise that this study failed to produce significant positive results.

The MEDMAN study, an RCT examining whether a community pharmacist-led medicines management service for patients with coronary heart disease (CHD), was conducted between 2002 and 2004 and recruited 1493 participants in 70 pharmacies across nine primary care organisations (Jaffray et al., 2007a). Pharmacists were provided with a training package developed by CPPE which consisted of a launch event, CHD training and a full day communication event and also included case studies. Participants were randomised to receive the service which consisted of an initial consultation with the pharmacist, who had been given data from their medical record, focussing on therapy, compliance, lifestyle and social support. Those randomised to the control group received usual care from the GP and community pharmacist, although the pharmacist was aware that they were participating in the study.

The primary outcome measures for this study were the percentage of patients receiving appropriate treatment for CHD according to the National Service Framework (NSF), health status and a health economic analysis. The study produced no significant difference between control and intervention in the primary outcome measures of appropriate



treatment or health status. This may be due to the percentage of patients that were already on appropriate treatment at baseline and therefore there may have been little room for improvement. The cost-minimisation analysis demonstrated a significant difference between the control and intervention groups largely due to the training provided to the pharmacists. There were no other improvements in any of the secondary outcome measures apart from the participants satisfaction score in the intervention group.

The failure of this study to produce a significant result may be due to a number of factors. Pharmacists were aware of those participants that were acting as controls and may have approached and treated them differently because of their involvement in the study. A method to avoid this may be to randomise by pharmacy. At the time of the study the Quality and Outcomes Framework (QOF) was being introduced in medical practices which incentivises appropriate prescribing and therefore GPs may have already reviewed all of their patients with CHD. As such, and due to the high number of participants who were already prescribed appropriate therapy at baseline, it may have been more appropriate to selectively target patients who were not conforming to treatment recommendations and focus the intervention on them.

On further analysis of the paperwork that was submitted to the research team by the pharmacists and GPs there appeared to be a lack of consistency in the way pharmacists were completing their paperwork and recommendations (Krska et al., 2008). They discovered that pharmacists were only documenting around a third of potential recommendations to the prescriber including lifestyle issues, potentially ineffective therapy and the need for additional therapy. This may have led to a reduction in the potential effect size that resulted from the study.

Participating pharmacists were also asked about their training for the study as part of the evaluation. The training programme for pharmacists was varied and provided an overview of all aspects needed to conduct the service. 50% of pharmacists at baseline identified that they needed more CHD training in order to feel comfortable providing the service and after this had been completed most felt confident providing the service (Jaffray et al., 2007b). However, over 50% still required more training after these initial sessions to make them fully confident. This resulted in 68% of pharmacists undertaking an additional 10 hours' worth of training outside of the study in order to feel confident to provide the service. At the start, few pharmacists wanted extra training with regards to consultation and communication skills. It is not clear from the data whether it was compulsory for pharmacists to attend the training sessions but considering when this study was conducted, pharmacists were not used to conducting consultations with patients,

documenting advice and making clear recommendations to prescribers and this may have affected the success of the study.

A review of the effect of pharmacist-led medication review on hospital admissions was conducted by Holland et al. in 2008. They found that, in line with the findings from their studies, pharmacist-led medication reviews do not have any effect on reducing hospital admissions or mortality (Holland et al., 2008). This review included 32 studies, eleven of which were conducted by a community pharmacist. Of these eleven, three were conducted by a sole pharmacist, the so called 'super pharmacist'. The only potential benefit that this review identified was that of improved patient knowledge and adherence to medication.

The HEART-MOT service was designed to opportunistically target people who were at risk of cardio-vascular disease (CVD) and provide them with a free risk assessment rather than provide a management service for an existing condition. This study was conducted in community pharmacies in Birmingham and was heavily marketed in pharmacies and surrounding areas (Horgan et al., 2010). No detail was provided on the pharmacists' training for the service, however, they did have to have experience of providing cardio vascular risk assessments before they were allowed to participate. Once enrolled, participants had a full CV risk assessment conducted (blood pressure measurement, non-fasting cholesterol, smoking and diabetes status) in order to calculate their 10 year risk of developing CVD. Patients identified as high risk were referred to their GP for further investigation. There was no follow-up provided to the participants.

From the 1130 participants for whom there were data available, referrals to their GP were made in 70% of cases. Apart from data on the reason for referral, no other outcome measures were used. People were referred for the following reasons: elevated blood pressure, elevated cholesterol levels and when they were found to have an elevated CVD risk (n=201). Patients were required to take a referral sheet to the GP surgery themselves. The results from the study demonstrated that the service targeted hard to reach populations such as men and those patients from deprived areas and ethnic minorities and brought them into the care of the NHS. No outcomes data were collected and therefore the cost-effectiveness of the service could not be determined.

Whilst these studies represent the more robust community pharmacy based research in the UK (with the exception of HEART-MOT) there were wide variations in the selection of outcome measures, delivery of training for the pharmacist for the service and consultation skills, types of intervention and lack of a quality health economics analysis. Only two of

the studies above performed a cost-effectiveness analysis, something that is essential to provide evidence of benefit to the NHS.

The use of appropriate outcome measures is one that dominates the field of health research, not just pharmacy practice. There has been a rise in the use of patient reported outcome measures (PROMs) for studies involving patients as a method of measuring their disease state as it affects them (Dawson et al., 2010). Although beneficial to researchers, PROMs are not the only measures of patient outcomes. The classical clinical indicators e.g. HbA<sub>1c</sub> for diabetes or blood pressure for hypertension still need to be reported alongside PROMs in order that clinicians have all the information about the effect of a particular intervention, something that pharmacy practice research is not alone in omitting (Rahimi et al., 2010). Research methods in pharmacy practice and especially the appropriate selection of outcome measures needs to be improved which is something the Government (Department of Health, 2008) as well as leaders in the field acknowledge (Ambler et al., 2009, Bond, 2008, Simoens, 2008, Walker, 2010).

The other aspect to community pharmacy research that can limit its ability to demonstrate effectiveness is that of intervention design. Most community pharmacy studies conducted in the UK are one-off interventions where the pharmacist is expected to have an effect on patient outcomes after a relatively small amount of time. This may be due to researchers being cognisant of the time pressures faced by community pharmacists and therefore attempting to make the intervention as quick as possible. However, if researchers want to prove the effectiveness of an intervention or service then it needs to be on the same terms as other healthcare professionals. It has already been demonstrated that building the relationship with the patient has benefits to health (Miller and Rollnick, 2002) and pharmacists cannot be expected to build this relationship in such a short period of time. However, in order for this to occur, significant changes to the contractual and operational frameworks in which community pharmacy is conducted will be needed.

### 1.5.2 International community pharmacy research

It is not just in the United Kingdom that research activity and the profession of pharmacy practice has expanded over the past few years. Community pharmacy has also undergone rapid and marked change in other countries around the world in the recent years (de Castro and Correr, 2007, Eickhoff and Schulz, 2006, Guignard and Bugnon, 2006, van Mil, 2005, Westerlund and Bjork, 2006), but most notably in Canada, Australia, New Zealand and the United States. This section will explore community pharmacy and the research conducted in some of these countries.

### 1.5.2.1 Australia / New Zealand

In both Australia and New Zealand, pharmacy is moving towards a much more service orientated profession in conjunction to its dispensing of medicines function. As in the UK, services to address the way in which patients take their medicines are now becoming more common. In fact, in both countries the medicine use review (MUR) now forms an integral part of the community pharmacist's activities.

In New Zealand, the Pharmaceutical Society of New Zealand in 2004 published its vision for pharmacy over the next ten years which outlined the need to change to a service driven, patient-focused profession (Pharmaceutical Society of New Zealand, 2004). Pharmacists have reacted positively to this shift, however, they highlight the need to maintain their original technical and clinical role within the health service (Scahill et al., 2010). In both countries, pharmacists also highlight the lack of research support they receive to highlight the value of pharmacy and problems with remuneration for the new services that they are expected to perform (Scahill et al., 2009, Roberts et al., 2005).

In a study by Saini et al. Australian pharmacists detail that they would be willing to participate in a research project if they had an interest in the research area, a belief that it will benefit the customer and felt that research in the field of pharmacy is actually important. Once again they also highlight that the availability of time is a key consideration as to whether they participate or not (Saini et al., 2006). Nonetheless, the research output from Australia has been promising over the past few years.

Pharmacy practice research in Australia has made significant advances in the fields of diabetes and asthma (Saini et al., 2011). Ines Krass and her colleagues at Sydney University recently conducted *The Pharmacy Diabetes Care Program* in community pharmacies in four areas of Australia (Krass et al., 2007). This RCT was different to most pharmacy studies conducted in the UK by the virtue of the extended nature of the intervention. Participants met with the pharmacist five times over a period of six months. The intervention included a defined protocol and engaged the patients on a variety of topics including self-monitoring of blood glucose, education on all aspects of their disease and medication, adherence support and medication review. Control participants attended the pharmacies for baseline and final data collection which included patient questionnaires.

In order for the pharmacists to deliver the intervention effectively they underwent a two day training course after completing a manual of self-directed learning. This training course comprised all aspects of diabetes care including role-playing exercises and training on the use of blood glucose testing meters.

The study recruited 56 pharmacies in total; 28 intervention and 28 control, with each pharmacy asked to recruit ten patients. This study targeted poorly controlled patients with type 2 diabetes on at least one anti-hyperglycaemic medicine or patients who had multiple co-morbidities such as hypertension or hyperlipidaemia and were prescribed medicines to treat these conditions. HbA<sub>1c</sub> and blood pressure data was confirmed by contacting the GP.

The main outcome measures were mean HbA<sub>1c</sub> systolic and diastolic blood pressure, lipid profile and BMI, with the secondary outcome measures being scores on the EQ-5D quality of life scores. For the main outcome measure of diabetes control, the intervention group had a significantly greater reduction over a period of six months when compared to the control group. There were also reductions in blood pressure, total cholesterol and triglycerides but no significant difference between groups. Health-related quality of life, as measured by the EQ-5D improved significantly in the intervention group when compared to the control group.

This study demonstrated that a prolonged intervention conducted by community pharmacists can be effective in improving a particular disease state. This study was helped by a number of factors: the fact that pharmacies were either providing the intervention or recruiting control patients potentially made it easier for the pharmacists to participate and also helped to reduce the risk of cross-contamination between the groups. Each pharmacy only had to recruit ten patients, which was an achievable target for each pharmacy and because of the high number of pharmacies participating, the overall number of patients remained high as well. This method also helped to demonstrate the potential benefits of many pharmacists and not just a singular pharmacist.

This group of researchers has helped to demonstrate the effectiveness of this type of service on more than one occasion (Krass et al., 2005). They have also used a variety of other methods to measure the effectiveness of the services that they have trialled including cost-effectiveness studies (Taylor et al., 2005) and patient satisfaction with the service (Krass et al., 2009), all of which are discussed in more detail in chapter three.

#### *1.5.2.2 Canada*

Until 2003, community pharmacy research in Canada largely focused on the completion of questionnaires by patients and pharmacists (Sokar-Todd and Einarson, 2003). Again, as in the UK at the same time, Sokar-Todd and Einarson's paper identifies the need to strengthen the design and quality of research studies in the field of community pharmacy. There are, however, examples of good research from Canada, most notably from the

SCRIP (Study of cardiovascular risk intervention by pharmacists) team based at the University of Alberta. This team has performed two RCTs in patients that have high cholesterol (SCRIP) (Tsuyuki et al., 2002) and hypertension with diabetes (SCRIP-HTN) (McLean et al., 2008). Both studies were conducted in community pharmacies in Alberta, Canada by pharmacist and nurse teams.

The SCRIP-HTN study involved the participant attending a clinic at the community pharmacy conducted by the community pharmacist and nurse teams where they would undergo cardiovascular risk reduction counselling. At all points during the article, there is no distinction between the aspects of the service conducted by the pharmacist and those conducted by the nurse. The counselling included measurement and discussion of blood pressure and risks associated with it being high, how their diabetes affects blood pressure and how they could change their lifestyle to improve the control of their disease. They were also given a blood pressure record card where their BP readings were recorded after every consultation. Participants attended a consultation with the pharmacist or nurse every six weeks for a period of 24 weeks.

The pharmacists who participated in the study underwent a training program that included online learning and a case based learning session both based on national guidelines. Recruitment criteria included all patients with diabetes with a blood pressure greater than 130/80mmHg on two visits, two weeks apart. Diabetes was confirmed from the pharmacy records, if a patient had had oral hypoglycaemics medicines for the past six months or more.

The main outcome measure for this study was blood pressure at 24 weeks with secondary outcome measures including the achievement of BP targets, number of medicines prescribed for hypertension and number of patients prescribed an angiotensin converting enzyme inhibitor (ACEI) or similar alternative. At 24 weeks, there was a significantly greater fall in systolic blood pressure in the intervention group (-10.1 mmHg) when compared to the control group (-5.0 mmHg). This effect was much greater if the participant had particularly poorly controlled blood pressure at baseline. The number of patients achieving targets for blood pressure (with co-morbid diabetes) experienced a significantly greater increase in the intervention group.

Both of these studies appear to provide robust evidence for this kind of intervention. However, the lack of definition surrounding the role of the pharmacist and nurse leaves the reader confused as to which aspects the pharmacist is responsible for and therefore the degree to which the results can be attributed to them.

### *1.5.2.3 United States of America*

In the US, Lee and colleagues performed a randomised controlled trial in 200 patients who were on four or more chronic medicines at the Walter Reed Army Medical Center in Washington DC to determine if a pharmacy intervention over a period of six months improved their control of blood pressure and cholesterol levels (Lee et al., 2006).

The study consisted of a run-in phase in which no participants received any educational intervention, instead a baseline adherence measure was performed. Phase one (observation) of the study followed this run-in and all patients participated in this aspect of the study, where they received the educational intervention which included medication education, the provision of adherence aids and regular follow-up every two months. All participants had their medication dispensed in a multidose adherence package that was returned to the pharmacy before the next one was issued. Phase one lasted approximately six months. The initial visit with the pharmacist lasted approximately one hour with subsequent visits lasting up to 30 minutes. After this the participants were randomised to either continue with the pharmaceutical care program or return to usual care which meant the participants returned to having their medicines dispensed as they would have done normally. This phase lasted a further six months for both groups.

Patients were recruited from an outpatients service and a retirement home and were likely to be non-adherent to their medicines due to their age and the number of medicines they were prescribed. No information was given about the training of the pharmacists for the study.

The primary outcome measure was the change in medication adherence as measured by a pill count from the returned multidose package and secondary outcome measures were changes in blood pressure and LDL-cholesterol. At the end of the study, the intervention group had a significantly higher adherence to medication than the control group as well as significantly lower systolic blood pressure. There were no significant changes between groups in diastolic blood pressure and LDL-cholesterol levels.

All of these studies produced a positive result for the role expansion of community pharmacy. However, they demonstrated their effectiveness by allowing the pharmacist and patient time to develop a relationship and therefore have an effect on the condition they were treating. These studies had good clinical and humanistic outcomes and the design was practical enough to allow the pharmacist to conduct them at the same time as performing their normal role.

## 1.6 UK community pharmacy research practice

We have seen that it is possible to conduct good quality research in community pharmacy from international studies, however, as demonstrated, research from UK has largely failed to produce a convincing argument for service expansion. This may be due to issues surrounding perception of research and its impact on practice, education and training and development and testing of research processes in this setting.

### 1.6.1 Perception of research in community pharmacy

Conducting research in the NHS is difficult in all settings but community pharmacy does not lend itself easily to performing research. As previously discussed, community pharmacy is an environment in which pharmacists have to provide clinically focused services alongside maintaining their dispensing function and this can affect their ability to engage from the outset. It may seem logical that research would be low on the list of priorities. Coupled with this the short duration of a visit by a patient to the pharmacy, sometimes only for a matter of minutes when they come to collect their prescription, a researcher can find it difficult to design and recruit patients to a study (Desborough et al., 2008). One other aspect that makes it potentially more difficult for community pharmacists to recruit patients is the process of obtaining consent. In most settings in the NHS, the researcher/clinician has a potential participant in their clinic or practice and can devote a proportion of their time, which is largely protected from interruptions by the patient or staff, to recruit that patient. Community pharmacy is a unique healthcare environment in which it is difficult to obtain consent due to the nature of the work of the community pharmacist and their interactions with patients.

Petty et al. examined this point in more detail when they asked why elderly patients declined to participate in a research project. They found that patients had the following reasons for not participating in the research project that they had been invited to join (Petty et al., 2001):

- Nature of the invitation letter
- Not contactable
- Confusion or lack of understanding
- Unwell
- Unavailability
- Impact of relationship with the doctor
- Desire not to have medication altered
- Perceived simplicity of medication regimen
- Negative attitude to healthcare



- Mistrust of the stated study objectives

With reference to the pharmacist's views on conducting research, some work has already been conducted in this field. The issue of lack of availability of pharmacists' time to provide these extra services repeatedly resurfaces in the literature as, discussed previously, pharmacists are still responsible for checking every prescription that is presented in the pharmacy, which, for a busy pharmacy, can take almost all of their working time. However, as Cvijovic et al. note, in Canadian pharmacy practice research this may be being given by pharmacists as something of an excuse to cover over issues relating to their own reservations about how taking part in research may impact on their 'established work routines' and whether the pharmacist perceives the research to be valuable to them (Cvijovic et al., 2010). In a study that aimed to find out about barriers and perceptions of a particular research project conducted in community pharmacy, they found that "time" and "being too busy" were offered as acceptable excuses to researchers. However, this perhaps masked other issues relating to pharmacists' understanding of a study they might be involved in, the questions they might be asked and also the value they themselves placed on the research. Similar reservations about taking part in research have also been noted for GPs and nurses (Roxburgh, 2006, Salmon et al., 2007).

#### 1.6.2 Pharmacist education and training

In the studies analysed in section 1.5.1 there are three main themes relating to the failure to prove an effect of community pharmacy interventions in the UK all of which are as a result of education and training. These themes centre on whether the pharmacist has the appropriate clinical, consultation and inter-professional skills. All of these are now taught as part of the pharmacy undergraduate degree programme, however, this has only become common in last ten years.

The background to pharmacy education is one of science not practice. When the first pharmacy school was established in 1842 the basis of the course was chemistry (Unknown, 1843), and was an apprenticeship with a minor exam after a period of lectures and a major exam after working as a chemist's assistant for a period of time. There was no formal legislation covering the educational requirements of pharmacists and many chemists and druggists and members of parliament opposed such education in various attempts from 1852 to 1890 (Hansard, 1887). This position altered significantly in the early part of the 20<sup>th</sup> century with enactment of three key pieces of legislation: The Technical Instructions Act 1889, the Pharmacy Act 1908 and the National Insurance Act 1911 (Anderson, 2005). The result was a requirement for people who wanted to train as a

pharmacist to attend a recognised school of pharmacy, undertake relevant work experience and pass examinations set by the Pharmaceutical Society.

Until the 1980s the majority of the pharmacy course remained science-based as pharmacists, at the time, were still required to compound medicines in response to a prescription and therefore required this knowledge. As compounding became less common due to the introduction of original pack dispensing, many pharmacists found that their science based course was not preparing them for the realities of pharmacy in the mid-1980s (The Nuffield Foundation, 1986). The Nuffield Report of 1986 stated that the pharmacy degree should comprise more appropriate teaching to include clinical topics, core science as well as the social aspects of pharmacy e.g. patient behaviours and issues surrounding compliance as well as practical experience.

However, this could only be achieved if the degree course was changed to include more clinical teaching so that they were able to advise patients and prescribers appropriately. This increased teaching that was now required of the pharmacy degree in terms of both clinical and practice subjects was difficult to fit into a three year degree and consequently in 1997, the requirements for registration as a pharmacist changed to a four-year master's degree and a period of pre-registration training post-graduation (12-months).

As a degree pharmacy is funded as a science based degree and not a health degree e.g. medicine. Consequently, the funding available for university education and therefore for clinical placements and significant clinical teaching is limited and the majority of pharmacy schools are still based within faculties of science and not faculties of health (Wright et al., 2006.). The modernising pharmacy careers (MPC) programme board (a division of Medical Education England now Health Education England) is currently examining the possibility of changing the degree course to include, amongst other things, substantial placements and the integration of the pre-registration year into undergraduate training to fall in line with other healthcare professional training (Medical Education England, 2011). It has also recommended that the pharmacy degree course is funded by at least a 12-month clinical supplement in addition to its science funding. Working alongside this, MPC is also examining postgraduate education and training to ensure that pharmacists continue to learn and develop once they have left university (Howe and Wilson, 2012).

These changes to the undergraduate and postgraduate education programmes may provide pharmacists with the improved clinical knowledge and skills to enable them to interact better with other healthcare professionals and patients. However, this only accounts for those pharmacists that are newly qualified. Researchers need to be aware of the need to increase the knowledge and skills of pharmacists that have been qualified for

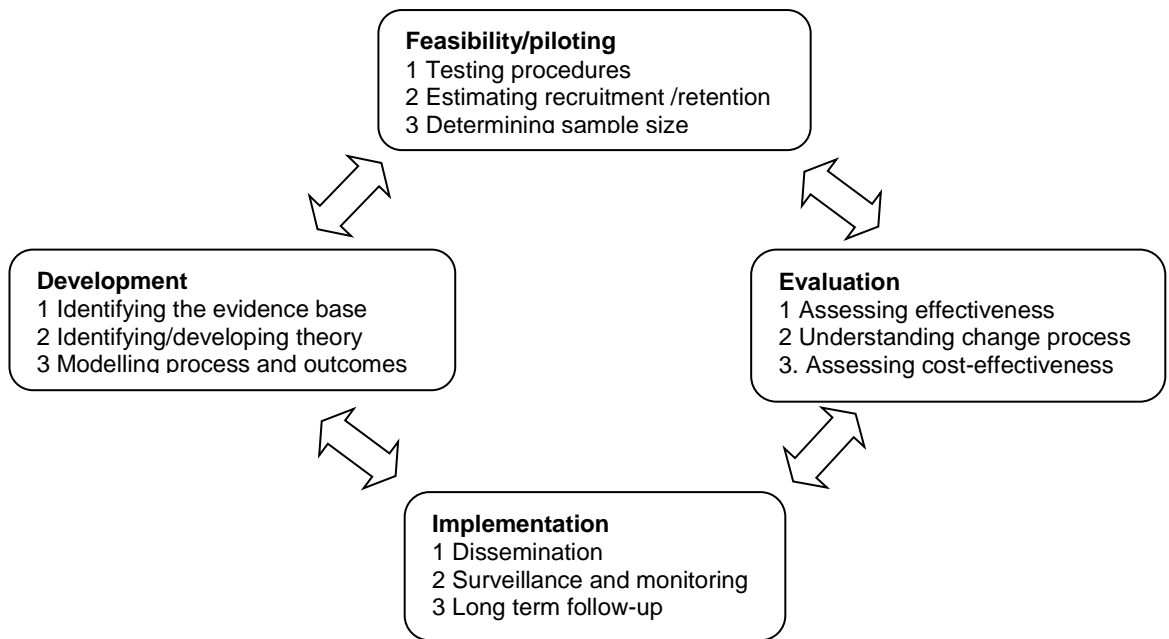
many years and is especially true for consultation and communication skills. In the MEDMAN project examined earlier, pharmacists stated that they had no need for communication skills training, however, the HOMER study found that the pharmacists' intervention may have increased hospital admissions and this is potentially due to their lack of ability to communicate effectively with patients. This may be something that has recently been highlighted as part of a series of focus groups with pharmacists. Pharmacists thought that their consultation skills, built up over a number of years' experience, were adequate for their job and that they required little extra training to account for new techniques to communicate with patients (Al-Nagar et al., 2012). It may also point to the need to train pharmacists more effectively in behaviour change techniques as these vary in their approaches and require specific skills and consultation styles.

### 1.6.3 Development of complex interventions

The other aspect to research that is conducted in the community pharmacy setting in the UK that may lead to a failure of the studies is the lack of preparatory work that is conducted before these projects are performed on a large scale. In 2000 the Medical Research Council published its guide to developing complex interventions in any setting (Medical Research Council, 2000). This was updated in 2008 and defined what constitutes a complex intervention (described in box 3) and what preparatory work should be conducted first. The guidance then states a four stage process for developing and evaluating a complex intervention and this is described in figure 1.1.

**Box 3 Aspects of complexity from the MRC framework (Medical Research Council, 2008)**

- Number of and interactions between components within the experimental and control interventions
- Number and difficulty of behaviours required by those delivering or receiving the intervention
- Number of groups or organisational levels targeted by the intervention
- Number and variability of outcomes
- Degree of flexibility or tailoring of the intervention permitted



**Figure 1.1** The development and evaluation of complex interventions (adapted from MRC 2008)

In the development phase it is important that a review of the literature is performed to identify current research to learn from previous work and to determine what works and what does not in any one particular setting. It is also necessary to conduct preliminary projects to inform the theory surrounding the research being performed. This may include qualitative methods or clinical audit to establish the basis for conducting any intervention.

Feasibility testing and piloting are considered as ‘key elements’ that should be conducted when developing complex interventions (Medical Research Council, 2008). There is little consensus in relation to the definition of feasibility and piloting and therefore the terms are often used interchangeably. However, Arain et al. succinctly describe the differences between the two as follows (Arain et al., 2010):

**Feasibility:** does not necessarily have to be randomised, can be used to detect response rates, number of eligible participants and the willingness of clinicians to recruit and randomise participants. This type of study may not have the same outcome measure as the main RCT.

**Pilot:** small version of the main study to ensure all the components of the study work together as planned by the research team. The data from this study can be added to that of the main study (internal pilot) or removed and used separately (external pilot).

With reference to the studies examined in section 1.5.1, a clinical audit would have identified issues surrounding participant identification for the MEDMAN study and

feasibility testing some of the problems surrounding randomisation and potential contamination. This developmental work can also be used to determine not only the pharmacists' satisfaction with the training provision but also the researcher's viewpoint on whether it appeared adequate enough to enable the pharmacists to conduct the study. The evaluation of the feasibility study is also useful to identify if the appropriate outcome measures have been used and an estimation of the intervention effect size using these measures.

In effect, this means that appropriate testing of small components of the research are essential before conducting a large scale study in an attempt to identify some of the problems that may occur with the project. This is particularly important for research conducted in the community pharmacy setting, as it is a unique healthcare environment that is largely isolated from the rest of the primary care team and as discussed there may be issues surrounding education and training as well as perception to overcome before conducting a full-scale RCT.

## 1.7 Conclusion

Over the period from 1950 to 2000, community pharmacy has remained almost stationary in terms of healthcare provision, preferring to focus on dispensing as its main role. However, in recent years, with the UK government anxious to utilise the pharmacist's skills to better effect within the NHS, their role has started to change into one that is more patient focused and less reliant on dispensing medicines.

This vision for pharmacy in the 21<sup>st</sup> century is important as costs are set to rise in the NHS and pharmacists may provide a more cost-effective use of resources to combat the increasing number of people diagnosed with a long-term condition. Pharmacists are in the ideal location to realise this vision due to the significant and sustained number of interactions between patients and themselves. However, there may be several barriers to achieving this vision which include logistics, inter-professional working and evidence.

Community pharmacists need to work more closely with other healthcare professionals and researchers to better define their role in the wider primary care team. This may come from changes to the undergraduate curriculum that encourages increased inter-professional working from an early stage in a pharmacist's career. It also extends to increasing the education and training provided to pharmacists that are currently qualified as unless they have the appropriate clinical and communication skills other members of the primary care team may not be ready to entrust their patients to the community pharmacist.

Finally, there needs to be an increased effort on providing good quality evidence for community pharmacy services. There needs to be an approach to community pharmacy research that aligns with the MRC framework for developing these types of interventions. This needs to include appropriate preliminary work including literature reviews, clinical audit, qualitative approaches with interested stakeholders and appropriate feasibility and piloting before conducting large scale research in this setting.

The Government has provided community pharmacy with the vision and this thesis will therefore focus on the design and implementation of a novel intervention focused on improving the care of patients with long-term conditions provided by the community pharmacist. The thesis will explore what this intervention should look like and what sort of problems the pharmacist should be discussing with the patient. It will use the MRC framework and attempt to factor in the elements described in this first chapter, including improved interprofessional working, outcome measures and logistics. These will be factored in after preliminary work has been conducted to determine what level of interprofessional working is necessary, which outcome measures are appropriate for the

type of study conducted and what level of support is required to assist the pharmacists in providing such an intervention in the community pharmacy environment.

## *Chapter Two*



## 2. A randomised controlled trial of a Pharmacist-LEd EcZema management support service (PLEEZ): a feasibility study

### 2.1 Introduction

The Government agenda for pharmacy is to expand the role of the community pharmacist in the management of long term conditions. One way of achieving this is via the implementation of enhanced pharmacy services as discussed in chapter one. Most enhanced services in community pharmacy focus on one specific area of concern with which pharmacists have the equipment and ability to assist patients e.g. smoking cessation, emergency hormonal contraception or NHS health checks. One clinical area that aligns with this is the condition of eczema. This condition has a low clinical risk of harm to the patient, does not necessarily require the patient's medical notes and pharmacists would not require excessive clinical training to be able to conduct the service. The National Institute for Health and Clinical Excellence (NICE) guidance for atopic eczema in children also recommends research into educational programmes and adherence to therapy as there is little evidence currently available (National Collaborating Centre for Women's and Children's Health, 2007b). Pharmacists are already familiar with adherence interventions e.g. MUR and therefore eczema may provide the ideal target for an enhanced pharmacy intervention.

#### 2.1.1 Eczema

Atopic eczema is a chronic, relapsing, inflammatory skin condition typically affecting the flexures where it presents as a papular rash; however, affected individuals will generally also have widespread dry skin. The aetiology of eczema is not fully understood but dry, inflamed skin is partially due to an inappropriate immune response resulting in the production of inflammatory mediators which cause damage to the stratum corneum (Kumar and Clark, 2002b). The highly itchy nature of the condition often results in the papular lesions becoming excoriated and thus colonised with *Staph. aureus*, hence impetigo-like lesions are common. In addition to contributing to secondary infections, it is likely that the itchy nature of eczema will result in insomnia (Plotkin, 2004).

Eczema frequently presents in early childhood, improves with age and resolves by adulthood, although it can affect people of any age. UK reported lifetime eczema prevalence in children has ranged from 25% to 41% (Harris, 2007, Kurukulaaratchy et al., 2003) and observation of epidemiological trends have demonstrated a gradual increase in eczema prevalence (Ninan and Russell, 1992).

Given the increasing prevalence of eczema, the costs incurred due to eczema are also set to rise. Estimations of annual eczema associated costs have included the cost of NHS care such as hospital and GP consultations and the cost of therapy. There is also a potential loss of parental income as a result of caring for an ill child. A positive correlation between annual cost and eczema severity has been reported with an analysis of severely affected children reporting a mean annual cost of £740 per child (Herd et al., 1996). Evidence has shown that approximately 80-85% of patients experience mild eczema symptoms, 15-20% experience moderate symptoms and 1-2% the severe form of the disease (Ben-Gashir et al., 2004, Emerson et al., 1998).

The mainstay of treatment is regular emollient and soap substitute use of which numerous varieties are available, however, trials of acceptable rigour evaluating the impact of these emollients are limited. Due to the absence of any trial evidence to demonstrate superiority of one product over another, the recent NICE guideline for the management of eczema in children has recommended that:

“Healthcare professionals should offer a range of different products to children with atopic eczema for topical application and for washing, and children should be encouraged to try out various combinations of topical products. The correct emollient is the one that the child will use.” (NICE, 2007)

This advice is based on a recommendation by the Guideline Development Group (GDG) stating that “adherence to emollient therapy is likely to be key to successful therapy for eczema” (National Collaborating Centre for Women's and Children's Health, 2007a). For adherence to be successful healthcare professionals should take into account the following information when prescribing: any previous adverse reactions to emollients, application frequency and texture of the emollient. Tolerability can change over time and therefore the GDG recommends that patients are reviewed regularly by the care team to check for acceptability and parents monitor children for signs of reduced efficacy over a long period of treatment.

In order for parents and children to achieve this acceptability of their prescribed emollients, any consultation with a healthcare professional must be focused on patient agreement. This is where the GP/nurse actively engage with the patient and/or parent to determine what their preferences are for treatment in a joint decision making process (Cushing and Metcalfe, 2007). There are no current data on whether patients and parents are being offered a choice of emollient but as already mentioned there are a number of reasons why patients may potentially not be using their emollients as prescribed and this can largely be solved through negotiation and agreement with the patient.

It is regularly cited that the frequency of emollient application is central to the efficacy of the product; however, few trials report either the volume or frequency of application recommended. NICE guidelines recommend frequent use in large quantities due to their short lived effect, suggesting 250g per week or more (NICE, 2007). There is a lack of evidence to suggest whether patients are generally adherent to emollient therapy however there is a limited body of evidence to suggest that if emollients are used correctly this can have steroid sparing effect (Grimalt et al., 2007, Lucky et al., 1997) which may be important due to the reasons listed below.

In addition to regular emollient use, topical steroids are generally required as an adjunct to treat exacerbations or in the case of frequent exacerbations, may be used once or twice weekly to prevent flare ups (NICE, 2007). There is considerable evidence supporting the improved outcomes associated with steroid use compared to emollient alone (Hanifin et al., 1998, Lupton et al., 1982, Stalder et al., 1994). Whilst the benefits are clearly demonstrable, steroid induced adverse effects can be very damaging with children being more susceptible than adults (BNF 60, 2010). Adverse effects include local irritation and skin depigmentation or discolouration and extremely rarely Cushing's syndrome and growth retardation and likelihood is directly associated with the frequency and volume of use (Hengge et al., 2006). Such risks have been demonstrated to cause carers and parents to become anxious about the use of topical steroids on children (Woodford et al., 2001, Zuberbier et al., 2006), resulting in non-adherence to prescribed recommendations either in the form of infrequent or non-use (Charman et al., 2000). Particular lay beliefs that have been reported include 'they should only be used to treat severe eczema' and that they are 'too dangerous' to be used on children (Fischer, 1996). The frequency of emollient application can be reduced by the appropriate use of emollients even when there is no exacerbation of eczema symptoms. However, data has been published that show in one area of Scotland over half of those children under 6 years old prescribed a topical steroid were not prescribed an emollient (Santer et al., 2006).

### 2.1.2 Educational interventions

The problems associated with adherence to eczema therapy such as patient acceptability of emollients and lay perceptions of the risks and benefits associated with topical steroid use have resulted in a number of interventions to address the issue of non-adherence to therapy with educational interventions the most frequently reported. A recommendation taken from the NICE guidelines for eczema management in children is outlined below:

“Healthcare professionals should spend time educating children with atopic eczema and their parents or carers about atopic eczema and its treatment. They

should provide information in verbal and written forms, with practical demonstrations which are reinforced at every consultation, and should cover: how much of the treatments to use, how often to apply treatments, when and how to step treatment up or down and how to treat infected atopic eczema (NICE, 2007)".

There is little good quality research to assess the effectiveness of an educational intervention on outcomes associated with atopic eczema in children (National Collaborating Centre for Women's and Children's Health, 2007b). In Germany, two RCTs have demonstrated the benefit of parental and children's education on the long-term control of their disease (Staab et al., 2006, Staab et al., 2002). The 2002 study included children with a confirmed diagnosis of atopic dermatitis of more than four months duration with a SCORAD score of >20 (Staab et al., 2002). The SCORAD index measures the severity of eczema/dermatitis with a score <15 indicating mild disease, 15-40 moderate and >40 indicating severe disease (European Task Force on Atopic Dermatitis, 1993). No power calculation was conducted for this study. The participants completed an initial questionnaire that included questions on medical history, health-related quality of life and coping. Participants were then randomised to the control or intervention groups. The intervention consisted of a six-week educational programme provided by paediatricians, dieticians and psychologists. The sessions ran once a week in the evening and lasted approximately 2 hours. As well as education, parents were asked to share personal experiences and were given the opportunity to practice new skills. There was no detail provided with regard to the location of study and how many of the multi-professional team were present at each session.

At the one-year follow-up, 145 participants were included in the analysis. The SCORAD score had decreased by 20 points in the intervention group and 16 points in the control group, however, the intervention group showed an increased ability to adapt to disease severity as shown by an increased use of steroids for inflammation and 82% of participants still using regular skin care therapy compared to 67% in the control group. The research also suggested that this type of intervention may have a positive effect on the coping ability of parents of children with the disease.

In Staab's 2006 study, the structured education programme was more clearly defined and was age-related (Staab et al., 2006). Participants were recruited from seven hospitals and were randomised to control or a multi-professional team intervention. The three target groups for the intervention were parents (children from 3 months to 7 years), parents and children (8-12 years) and adolescents (13-18 years). The power calculation conducted for this study indicated that each group required 125 participants, a total of 750 for the whole study.

The programme followed a similar pattern to their previous study but in this study the multi-professional team underwent a 40-hour training programme to qualify for the study. Each of the consultations followed a manual that had been developed previously to ensure that all of the core topics were covered. These topics included basic medical information about atopic dermatitis, stress management, dealing with itching and scratching and sleep disturbances, avoidance of trigger factors, food allergies and coping. This was accompanied in the final consultation with a self-management plan. Consequently, this ensured the fidelity of the intervention across all sites and all education providers.

Staab recruited 992 participants of which 823 (446 randomised to intervention and 377 control) were included in the final one-year analysis. The results from this study indicate a significant improvement in eczema severity scores (a reduction of between -16.0 to -19.7 in the intervention groups vs a reduction of -5.2 to -12.2 in the control group) as well as an improvement in the parent's quality of life as a result of the intervention in all age groups. In all age groups this was the difference between the severe and moderate form of the disease. This study demonstrated that tailored, age-dependent education, aimed at parents, parents and children or adolescents, was significantly more effective than usual care.

In the UK, the only RCT available in this area of research is by Chinn et al. This examined the effect of a single dermatology nurse consultation on children's quality of life (Chinn et al., 2002). Participants were identified by screening the medical records at the local medical practice for those patients with a registered diagnosis of atopic eczema up to the age of 16 years. Each eligible family was posted two questionnaires: the family dermatitis index and an age-appropriate, validated quality of life index, plus a consent form. Participants returning a completed consent form and questionnaires were randomised to receive the intervention or usual care. Those in the intervention group were asked to attend an appointment with the dermatology nurse within two weeks. Both groups were then posted a follow-up questionnaire at six and 14 weeks.

The content of the consultation focused on the participant's understanding of eczema, practical demonstrations of application technique, avoidance of allergens and irritants, advice on bathing and the use of emollients at school. This was re-enforced with written information and the participants were offered continued support via telephone or further appointments.

The study demonstrated no significant improvement in quality of life of the 235 children that participated. This may be due to the 'one-off' nature of the intervention or may imply that education is not enough and that an intervention that utilises a particular consultation technique e.g. motivational interviewing may be more beneficial.

In relation to the role of the pharmacist no RCT data are available, however, one UK study demonstrates an increase in the frequency of emollient application leading to a reduction in irritability and itch as a result of a pharmacist intervention (Carr, 2007). This study involved parents attending an appointment with a pharmacist, when the pharmacy was quiet e.g. lunchtime, to discuss their children's eczema management using a standardised approach. The study was conducted in ten community pharmacies. The pharmacist discussed current treatment, patterns of use of emollients and tested the parent's application technique on their children. The intervention lasted approximately 10 to 15 minutes. Fifty participants were recruited and from the baseline questionnaire it was identified that only a small number (20%) had been shown how to apply their emollients by a GP or nurse and only 10% were actually applying them correctly. This also identified other areas where parents were confused about their child's treatment e.g. mixing up steroid and emollient creams.

The intervention demonstrated a small reduction in itching (mean difference: 1.48 (0.65 – 2.30) on a 0-10 scale with 0 meaning no symptoms and 10 the worst symptoms) and irritability (mean difference: 1.23 (0.06 – 2.09) on the same scale) as well as increasing the correct use of emollients. Parental feedback described the service as extremely helpful or quite helpful.

Following on from successful RCTs in Germany and a lack of robust evidence in the UK, this chapter will focus on the development and testing of an RCT aimed at improving the management and support for patients with atopic eczema. The intervention will focus on aspects of the studies mentioned above whilst factoring in current NICE guidance in relation to eczema educational interventions.

For this project we will feasibility test an RCT methodology, in line with the conclusions from the previous chapter to enable us in the future to determine the effect of a community pharmacist-led eczema management support service in the community pharmacy setting.

## **2.2 Aims and objectives**

### 2.2.1 Aims

- To feasibility test and pilot a randomised controlled trial methodology to examine the effects of a community pharmacist-led eczema management support service.
- To determine the acceptability of conducting RCT research in the community pharmacy setting.

### 2.2.2 Objectives

Trial the methodological approach and service design in order to ascertain the:

- recruitment rate by pharmacists
- appropriateness of the training programme
- suitability of the inclusion criteria and randomisation protocol
- appropriate questionnaire design for completion by parents/guardians
- appropriate outcome measures
- acceptability and completion rate of study documentation

## **2.3 PLEEZ method**

The protocol for PLEEZ and supporting documentation is included in appendix one. The flow of participants through the study is illustrated by figure 2.1. Research governance and ethical committee approval were obtained from Hertfordshire NHS Research Ethics Committee (appendix two) and NHS Norfolk Research and Development Department (appendix three) prior to commencing data collection. This study was funded by a grant from Numark Ltd, a representative organisation of independent pharmacies.

### **2.3.1 Pharmacy recruitment**

Eligible Numark pharmacies in one primary care trust PCT area with a consultation room were identified and approached by me. Pharmacies were remunerated for all activities associated with the study including participant recruitment, delivering the intervention and data collection. Pharmacists and pharmacy staff received a free dinner as a thank you for attending the training evening.

### **2.3.2 Communication with the primary care team**

All prescribers associated with the participating pharmacies were contacted by telephone or e-mail by myself prior to trial commencement to provide information on the study and obtain consent for their patients to be approached for trial participation. Any pharmacist interventions delivered as part of the trial were communicated to the primary care team (general practitioners and / nurses responsible for the eczema management of a patient) via a notification form. Prescribers were familiarised with this notification form prior to trial commencement in order that they were aware of what to expect to receive from the pharmacist as a result of a consultation with the patient and parent/guardian.

### **2.3.3 Pharmacy team training**

Participating pharmacies identified up to two members of the team to be responsible for the study (excluding the pharmacist). These team members attended the training session conducted by me and a fellow researcher, which covered the study protocol, participant recruitment (including gaining consent) and data collection.

### **2.3.4 Pharmacist training**

Pharmacist training involved completion of a CPPE developed common skin condition training package prior to attendance at a training evening. The learning outcomes for the CPPE pack were:

- identify skin conditions that must be referred for diagnosis and/or treatment
- advise confidently on effective use of over the counter (OTC) and prescription-only (POM) products



- access local, regional, national and international information resources and support
- describe the possible roles of the pharmacist in the multidisciplinary dermatology care team (CPPE, 2007)

Eczema focused training developed in conjunction with the Norfolk and Norwich NHS Foundation Trust and NHS Norfolk was provided to pharmacists by a NHS Norfolk eczema specialist nurse. The nurse re-enforced topics covered by the CPPE training package in relation to eczema and also provided samples of creams and ointments for the pharmacists and pharmacy staff to try. The nurse also provided practical advice such as the definition of 'sparingly' in relation to the application of steroid creams. A practical demonstration of application technique took place with the pharmacists and staff given the opportunity to practice the technique for themselves.

Training in consultation skills was provided on the same occasion and was underpinned by techniques designed to explore patient beliefs and concerns as well as motivating adherence to prescribed therapy. The training included an overview on some basic consultation techniques such as:

- open questions
- reflective listening
- decision balance/summarising
- key question
- self-efficacy for treatment.

The training also covered the structure of the consultation from agenda setting to the time frame which lasted approximately three hours.

Additional training was provided to the pharmacists on the study paperwork and consent in the subsequent time leading up to the commencement of the trial. This was in response to feedback that the pharmacy staff did not feel particularly confident about roles asked of them for the study. This was provided by me on the training evening and as required by the phamacists.

### 2.3.5 Inclusion criteria

Due to the increased prevalence of eczema in this age group, children aged 0-10 years were targeted as potential participants. A dermatology registrar at the Norfolk and Norwich University Hospital assisted with defining the inclusion criteria for the study. The majority of feedback concerned the inclusion criteria of a confirmed diagnosis of eczema. Many

patients may be using topical steroids and emollients for conditions other than eczema and to recruit participants solely based on their prescribed medication without confirming their diagnosis would be inappropriate for this particular intervention. The decision was also taken to narrow the recruitment criteria to include only those patients receiving topical treatment. This was decided based on feedback that patients on systemic therapy would generally be managed by the dermatology team at the hospital rather than the GP.

A final criterion for inclusion in the study was the requirement that patients had to have been receiving medicines from the pharmacy for three months prior to recruitment due to the intention to collect data on adherence to emollient and steroid therapy in the three months preceding study enrolment.

#### *2.3.5.1 Summary inclusion criteria*

- Child aged 0-10 years
- Currently receiving topical treatment for diagnosed eczema
- Provides written informed consent
- Has been attending the pharmacy with prescriptions for eczema medication for at least three months before recruitment

#### *2.3.6 Exclusion criteria*

There were limited exclusion criteria for the study; however two were important for practical reasons. The inability to speak or read English was included as it was seen as impractical to provide the pharmacies with appropriate translation equipment/support for this particular group of patients.

Following feedback from the dermatology registrar, the decision was taken to exclude other skin conditions and infected eczema as these would complicate the intervention and it was not within the remit of the intervention to be actively treating infected eczema, rather addressing adherence issues on the part of the patient.

#### *2.3.6.1 Summary exclusion criteria*

Unable to understand written and / or spoken English

Any other diagnosed skin conditions or infected eczema

#### *2.3.7 Participant recruitment*

All parents or guardians who presented at the pharmacy with a prescription for an emollient or a steroid topical preparation for their child, were asked if the patient had been diagnosed with eczema by a doctor. Potential participants who had been previously

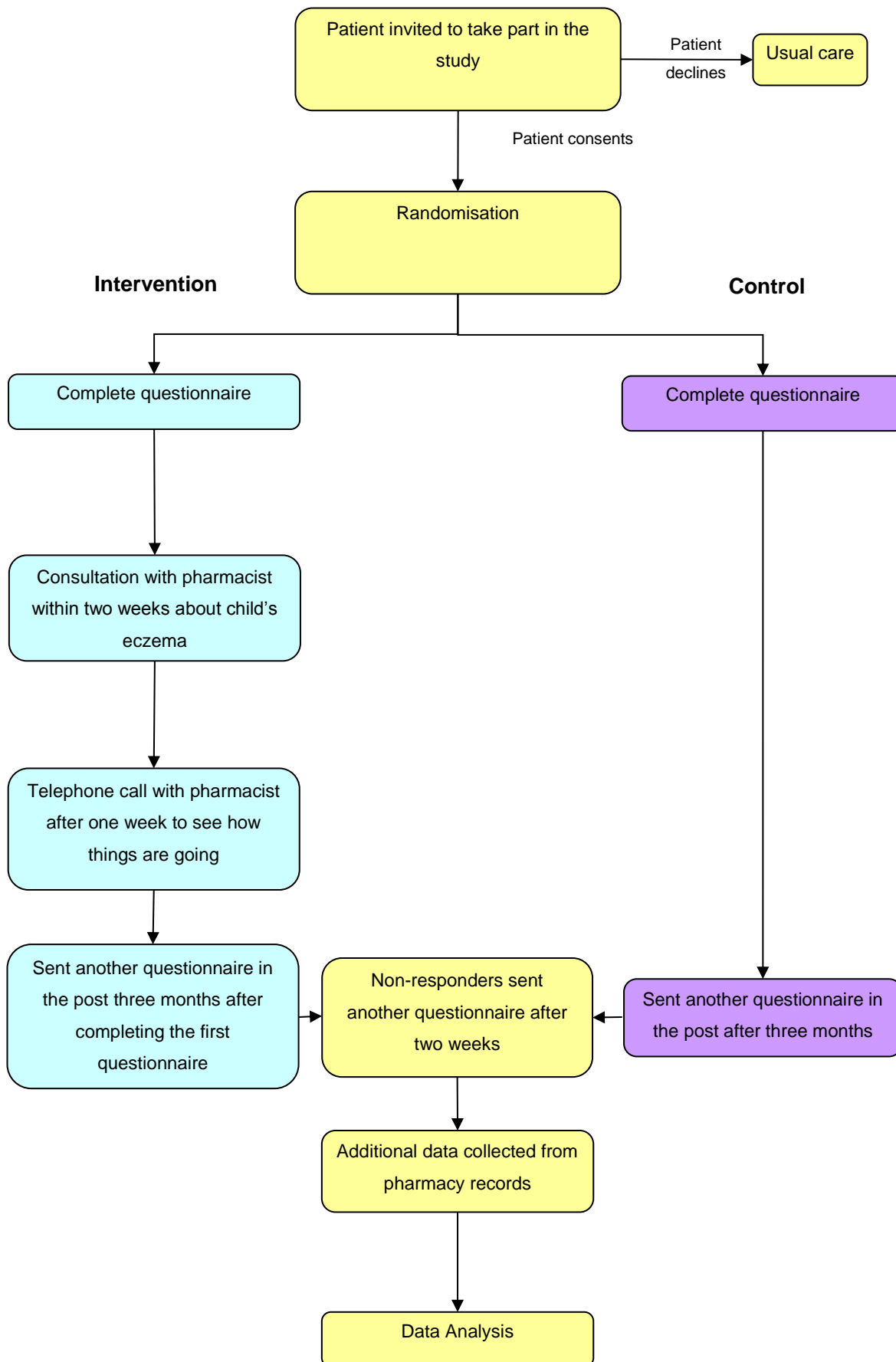
prescribed these products had their pharmacy records 'flagged' to alert staff when they presented at the pharmacy that they may be suitable to invite to the study. The pharmacy staff or pharmacist approached the potential participant and provided them with an information sheet: one aimed at the parent/guardian and the other aimed at the child. Potential participants were free to take the information sheet away with them to consider participation. All parents or guardians who consented to participate were asked to complete a written consent form on behalf of their child and if the child was aged 6-10 years the child was asked to sign an assent form. This was again completed by the trained pharmacy staff or the pharmacist. All pharmacists had the option of sending a letter to potential participants alerting them to the service as a result of identifying them from their pharmacy medication record.

### 2.3.8 Sample size

The aim of this study was to recruit 100 participants (50 in each group). This data was to be used to inform formal sample size estimation for a larger RCT designed to determine whether the intervention has a significant impact on the primary outcome measure of Children's Dermatology Life Quality Index (CDLQI). The effect size of the primary outcome measure from this study would be used to estimate the sample size necessary for a larger study to identify a difference between intervention and control with 90% power and 5% significance.

### 2.3.9 Randomisation

Once participants had provided informed consent they were randomised by an automated telephone randomisation service. The pharmacy staff telephoned the automated randomisation service where some basic details were recorded and the participant allocated to the intervention or control group. The allocation was stratified by pharmacy to ensure approximately equal numbers of intervention and control participants in each pharmacy. Due to the potentially small number of participants, randomisation was conducted in permuted blocks of 4 or 6. All participants were allocated a study number and the encryption form linking the patient details to the study number was kept separately under each pharmacy's usual storage procedures. Only anonymised data were sent to myself as I was not directly involved in the care of the patient.



**Figure 2.1** PLEEZ Study design

### 2.3.10 Patient questionnaire

Participants in both the intervention and control groups completed a baseline questionnaire. This questionnaire was designed specifically for this project and includes previously validated questionnaires on adherence (Morisky et al., 1986), quality of life (Lewis-Jones and Finlay, 1995), beliefs about medicines (Horne et al., 1999) and satisfaction with information about medicines (Horne et al., 2001) in addition to some basic demographic questions.

#### 2.3.10.1 *The Beliefs about Medicines Questionnaire (BMQ)*

There are two versions of the BMQ: specific and general. They are both designed to elicit patients' necessity for and concerns about their medicines or medicines in general. This study used the specific version of the questionnaire. It contains ten items that are rated on a 5-point likert scale from 5 = strongly agree to 1 = strongly disagree (Horne et al., 1999). The questions consist of five that are aimed at identifying the necessity with which the patient views their medicine and five that identify their concerns. These are then scored according to their group and a difference between the groups (necessity and concerns) is calculated. Once calculated, this difference is a good indicator of non-adherence in chronic conditions (Horne and Weinman, 1999), specifically intentional non-adherence as patients who attribute more weight to the concerns about taking their medicines rather than the necessity for them are more likely to not take them as prescribed (Clifford et al., 2008). This finding has been characterised in several disease states e.g. rheumatoid arthritis (Neame and Hammond, 2005) and severe mental disorder (Jónsdóttir et al., 2009) and drug specific regimens e.g. the use of antidepressants (Russell and Kazantzis, 2008) and inhaled corticosteroids (Menckeberg et al., 2008).

For this study, two copies of the BMQ were placed in the questionnaire; one for topical steroids and one for emollients.

#### 2.3.10.2 *The Morisky Adherence self-report scale*

The Morisky medication adherence scale is a validated scale designed to measure adherence. Two versions exist: a four item questionnaire (Morisky et al., 1986) and an eight item questionnaire (Morisky et al., 2008). All questions contain a yes/no answer apart from the last question on the eight item version which is a 5-point likert scale. The questions are phrased in a way that discourage patients from answering in the affirmative automatically, thereby encouraging them to think harder about each question to produce a more accurate response. The eight item questionnaire has been shown to be a more sensitive measure than the four item version (Morisky et al., 2008) and has been demonstrated to provide a consistent result when compared to other adherence measures such as pharmacy fill rates (Krousel-Wood et al., 2009). The usefulness of the measure

has been demonstrated in a variety of settings from ulcerative colitis (Bernick and Kane, 2010) and hypertension (Krousel-Wood and Frohlich, 2010) to bipolar disorder (Jarman et al., 2010) however, at the time of conducting the study large scale validation data for the 8-item version was unavailable. Therefore, in this study I decided to use the validated, four-item questionnaire which also minimised participant questionnaire burden and thus aimed to maximise response rate.

For this study, two copies of Morisky were placed in the questionnaire; one for topical steroids and one for emollients.

#### 2.3.10.3 *The Children's Dermatology Life quality index (CDLQI)*

The Dermatology Life Quality Index is an extensively used tool to measure how symptoms affect the participant's quality of life (Finlay and Khan, 1994). It has been used in a wide variety of different skin conditions and translated into numerous languages for use around the world (Basma et al., 2008). It has been developed into a version that is suitable for use in children (Lewis-Jones and Finlay, 1995) and infants (Lewis-Jones et al., 2001) along with a cartoon version (Holme et al., 2003). The children's version contains ten questions each with a possible answer of 'not at all/ not relevant', 'a little', 'a lot' and 'very much'. It is scored out of 30 with higher scores indicating greater impairment to quality of life. It is also recommended for use by clinicians in the most recent NICE guidance for atopic eczema when diagnosing and assessing eczema severity (NICE, 2007).

#### 2.3.10.4 *The Satisfaction with Information about Medicines Scale (SIMS)*

This is a validated questionnaire that helps determine a patient's satisfaction with the information they have received regarding their prescribed medication. It is a 17-item tool which asks patients to rate the amount of information they have received about their medicines as 'too much', 'about right', 'too little', 'none received' and 'none needed' (Horne et al., 2001). The answers 'too much', 'too little' and 'none received' are attributed a value of 0 and the answers 'about right' and 'none needed' are given a value of 1. A high score then indicates a high level of satisfaction with the information the patient has received about their medicines. This scale can be further divided into two subscales: action and usage of medication (questions 1-9) and potential problems of medication (questions 10-17). The version of SIMS that was used in this study did not contain the questions referring to alcohol intake and sexual activity as this was aimed at children and therefore would not have been appropriate.

#### 2.3.11 The intervention

Participants randomised to the intervention group had an appointment for a consultation arranged with the pharmacist at a mutually agreeable time within the following two weeks

post randomisation. The participant and parent or guardian were taken to the consultation room with the pharmacist for the eczema management support session. The pharmacist used the previously completed baseline questionnaire to inform the consultation which was targeted at the participant's needs, thus consultations comprised of core content and possibly additional aspects in response to individual need. Table 2.1 summarises the content of the consultations and is based on previous published research and current NICE guidance (NICE, 2007). If the parent/guardian expressed an interest in trying another cream/ointment for preference, the pharmacist was able to provide the parent/guardian with the smallest samples of NHS Norfolk formulary listed creams.

One week post consultation, the pharmacist contacted the participant to discuss their progress with implementing any recommendations, offer any further advice and co-ordinate any prescription changes if needed. If changes were necessary or participants preferred a different emollient, the pharmacist was provided with a notification form to send to the GP. Multiple visits to the community pharmacist were seen as potentially difficult to conduct so therefore this method was seen as a compromise that may have made study implementation easier at the outset.

Core items discussed with all participants	Additional items addressed in response to individual need
Current topical eczema management	Demonstration of steroid and emollient application technique
Frequency and volume of emollient use	Advice regarding future management strategies
Frequency and volume of steroid use	Lifestyle advice and food allergies
Discussion of application technique	Provision of emollient samples to try for preference

**Table 2.1** Intervention content

Pharmacists were paid per patient that was recruited, which included the intervention and paperwork completion. This money was paid to the pharmacists via their membership subscriptions with the Numark organisation and not via the University of East Anglia.

### 2.3.12 Pharmacist data collection

A bespoke data collection form was developed for pharmacists to document the areas of discussion with the parent / guardian together with data from patient medication records to determine the use of eczema related products over the previous three months and the three months during the trial.

### 2.3.13 Follow-up data collection

After three months, a second questionnaire containing the same measures as the baseline questionnaire was sent to both the intervention and control group participants by the pharmacy concerned with their care. The questionnaires were sent back by the participants directly to me, who informed the pharmacy upon receipt. Non-responders were sent a second posting after two weeks.

### 2.3.14 Data analysis

For the primary outcome measure (CDLQI) the magnitude of difference and variance between intervention and control groups was analysed. The study was not powered as this was a feasibility study. Morisky reported adherence, was dichotomised into adherence/partial adherence. Therefore, if four 'no' answers were entered into the questionnaire, then the patient was deemed to be adherent. If there were one or more 'yes' answers, then the patient was classed as partially adherent (Morisky et al., 1986).



### 2.3.15 Amendments to study design

This study was commenced at the start of my PhD and the basic protocol and overall study design had already been developed prior to my joining the research team.

During the initial phases of the study the pharmacists involved highlighted problems with the protocol and documentation and it became clear that recruiting the required number of participants was going to be difficult. Therefore, I decided to submit applications to the ethics committee for changes to the study protocol. Approval was obtained for each amendment (appendices four to seven).

#### *Amendment number 1*

This amendment focused on aspects of the study that participating pharmacists and I highlighted that had been missed from the original documentation. This included amending the information sheet to include details about the follow-up telephone call from the pharmacist, the addition of two more boxes on the data collection form to ascertain what the pharmacist had discussed with the patient during the consultation. It was also decided to invite two members of the pharmacy staff, instead of one, to the training evening to account for sickness during the study period.

#### *Amendment number 2*

This amendment was aimed at increasing uptake of the service. It extended the time available to pharmacists to recruit participants and also allowed them to send a letter to patients identified from the pharmacy medication record, informing them of the service.

#### *Amendment number 3*

This amendment extended the recruitment criteria to include adults over the age of 18. It introduced further information sheets, consent forms and questionnaires revised to reflect this potential new group of participants. It also increased the data collection period for the study further.

#### *Amendment number 4*

The final amendment for the study was submitted after the main study had been halted due to low recruitment of participants. This amendment allowed me to invite pharmacists to a focus group to determine the reasons for a low recruitment rate and how this could be improved for further research projects. A new information sheet and consent form was developed for the pharmacists (appendix eight).

## **2.4 Pharmacist focus group**

During the time when the eczema RCT was still running, I had conversations with each of the participating pharmacists to gain a sense of whether they thought I could do anything to increase the numbers of participants being recruited to the study. These conversations highlighted considerable diversity between different pharmacists in what they thought were the problems with the study. It emerged that not all of the pharmacists were approaching the research in the same way and in their practice they also had different ways of fitting it in to their daily routine, with varying degrees of success. Therefore, it was decided to ask them all to take part in a group discussion to examine areas of agreement or differences in engaging with the research and their reasons for these.

### **2.4.1 Focus group aims**

To characterise the views of pharmacists involved in a community pharmacy RCT in terms of why they participated in the research, their views on the mechanics of the study and how they think this kind of research fits into community pharmacy practice.

### **2.4.2 Focus group method**

Ethics and Governance approval was received prior to conducting the focus group. A group discussion (or focus group) was chosen as a means to encourage interactive discussions between participants. At this point, I wanted to elicit the views of pharmacists on participating in an RCT and how the project methodology could be refined to reflect these. This fits the 'problem-solving' notion put forward by Kamberelis & Dimitriadis in suggesting that "problems cannot be solved by individuals alone" (Kamberelis and Dimitriadis, 2007). Opening and introductory questions were used along with open questions to facilitate the focus group discussion as described in Krueger and Casey (Krueger and Casey, 2009) with the facilitator joining in the conversation.

#### *2.4.2.1 Inclusion criteria*

The inclusion criteria for the focus group were as follows:

- Community pharmacist
- Working in the independent sector
- Participated in the original eczema RCT

### **2.4.3 Facilitation**

The focus group was moderated by two members of the research team not associated with the day-to-day running of the RCT project and members of a wider research group (the UEA Medicines Management Research Team). I decided not to take part in the focus group as this may have affected the participants' responses to questions about the researcher's own conduct during the study. Both of the researchers present for the focus

group had observed and acted as secondary facilitators at previous sessions in other studies. The session was conducted at the University and the participants were provided with refreshments.

#### 2.4.4 Topic Guide

The focus group facilitator was given a set of questions by me to ask the pharmacists during the focus group. The questions had been piloted with a pharmacist who was unable to attend the focus group to determine if they were likely to provide the kinds of answers I was seeking in terms of reasons for the study failing. These questions sought to elicit a wide range of reasons for taking part in the trial, the barriers experienced to their participating fully in research and the benefits that they expected and actually received from taking part in the research. The following questions were asked to the group:

- What was your initial motivation to take part in the study?
- What are your thoughts on the training provided?
- What are your thoughts about the support that you received?
- What was your general impression of the study?
- More generally, what are your thoughts on the current trend of pharmacists providing more services while still maintaining their original functions e.g. dispensing?

The participating pharmacists were given prior information about the general topics to be discussed in the participant information sheet and were each asked to sign a consent form before the focus group could begin. The session was audio-recorded, transcribed by myself and then checked by the assistant facilitator for accuracy. The transcript was then analysed independently by myself and a fellow researcher using thematic analysis directed at identifying any common themes expressed over the course of the focus group discussions.

#### 2.4.5 Focus group analysis

The transcript was independently coded by me and a fellow researcher according to the principles of thematic analysis (Braun and Clarke, 2006). We met to discuss the findings and agree final themes. Any disagreement was discussed and a consensus reached based on referral back to the original transcript.

##### 2.4.5.1 *Thematic analysis*

Thematic analysis is one of the most widely used frameworks for analysing qualitative data, especially for novice researchers as it minimally organises the data in an attempt to understand what is being said by the participants (Braun and Clarke, 2006). Until relatively recently, thematic analysis, although used ubiquitously, was poorly defined. Braun and

Clarke in 2006 attempted to define thematic analysis as the process described below in order to standardise the approach and make it more accessible to novice researchers.

The process of thematic analysis as described by Braun and Clarke:

1. Familiarise yourself with your data e.g. transcription and reading
2. Generating initial codes
3. Searching for themes e.g. organising codes into groups, starting to identify themes
4. Reviewing themes e.g. checking themes match with the originally generated codes
5. Defining and naming themes
6. Producing the report

It is stated that constant reference at all stages to the original transcript is essential as this will help the researcher determine the level of themes and subthemes and confirm that these are relevant to what was said in the transcript and have not been taken out of context during the coding process. The use of thematic maps is highlighted as a process that can be used to develop themes and determine where they lie in the bigger picture of the research question.

Computer software was not used to conduct the analysis. Coding started with the first line of the transcript and continued on every line until the last. Not every line was individually coded because some lines were included in more than one code or were encompassed in codes spanning more than one line e.g. long passages of text; however, a consistent effort was made to code as much as possible. This returned 219 codes in total. These were then typed up with a reference number to consistently locate which part of the text they came from and cut out to set each code onto its own small piece of paper. These codes were then arranged to reflect their degree of conceptual commonality with others e.g. all the 'time-related' codes were grouped together. This initially produced eleven themes, some of which were subsequently further combined where differences did not appear as clear. The overall theme for each collection of codes was decided without reference to the original questions posed during the focus group. A second researcher also coded the transcript and identified themes independently of myself. We met to discuss emerging themes and to ensure all themes had been identified.

To help highlight both commonalities and differences identified in the analysis between the pharmacists' views, selected quotes are presented in the results section.

## 2.5 PLEEZ results

### 2.5.1 Feasibility-RCT results

Seven pharmacists and pharmacies were recruited to the study, two in a rural location, two in a small town and three in a city. After nine months and a lack of recruited participants, the study was halted. Nine participants, from the initial target of 100, were recruited of which five were in the intervention group and four in the control group from just three pharmacies (six in one pharmacy, two in a second and one in a third pharmacy). Table 2.2 describes the study demographics. The recruitment period lasted from mid-September 2009 until May 2010, however, all of the recruitment of participants occurred between the start and mid-December 2009.

Follow-up data from the returned questionnaires, were only available for four control participants (100%) and three out of the five (60%) intervention participants. The outcome measures demonstrated no improvement for the control participants. All three intervention participants, however, showed an improvement in adherence, as measured by the Morisky scale (Morisky et al., 1986). One patient also demonstrated improved knowledge about their medicines after the consultation with the pharmacist. All questionnaires that were completed at baseline and returned to me were completed in full. The data from the baseline questionnaires are detailed in table 2.3 with further examination of the combined (intervention and control) SIMS results in figure 2.2.

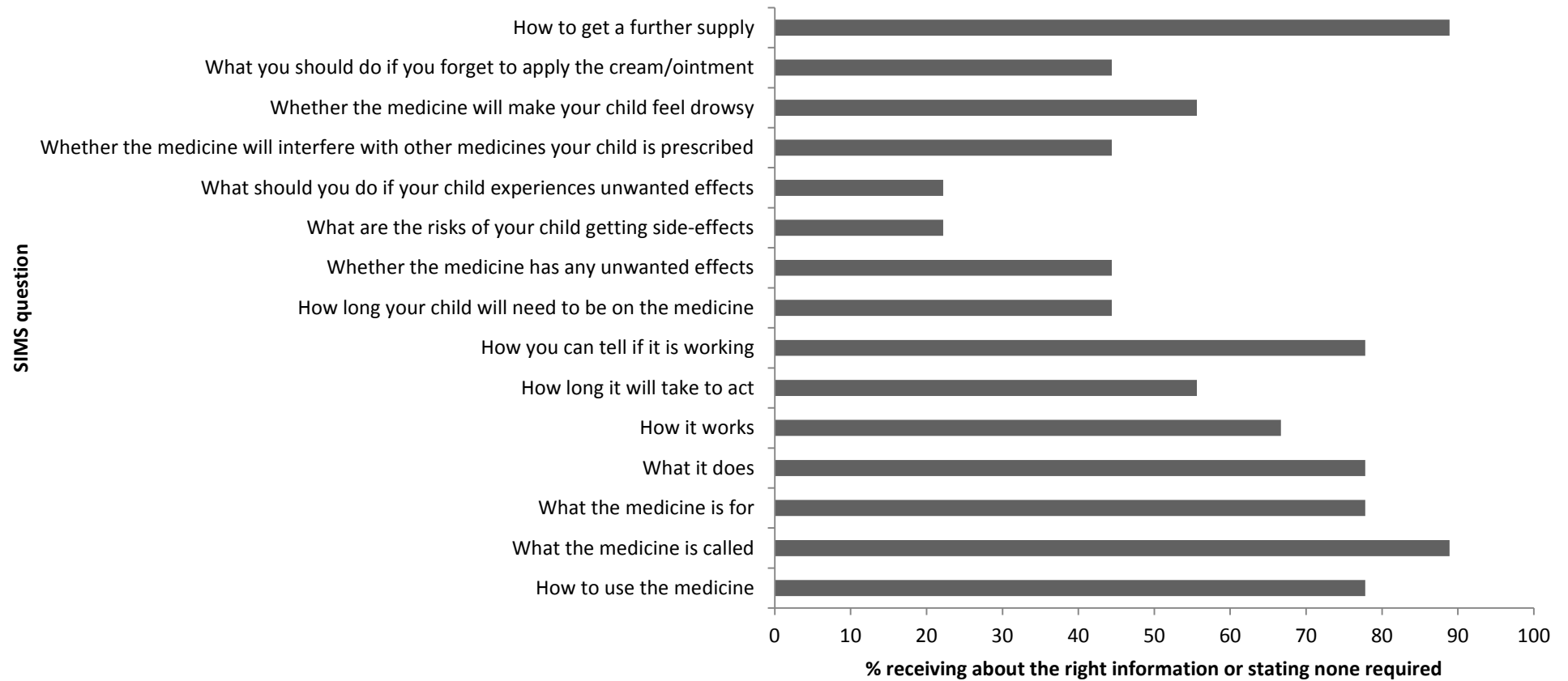
Data collection by other means failed due to the pharmacists not completing the appropriate paperwork as per study design. This paperwork included the pharmacist data collection form and as such aspects of the study e.g. content of consultation and level of emollient and steroid use could not be characterised.

Participant demographics	Measure	Control	Intervention
Number of participants	Number	4	5
Age (months)	Mean (SD)	21.2 (12.4)	33.0 (30.4)
Gender	Number (%)	2 (50%) male	3 (60%) male
Family history of eczema	Number (%)	1 (25%)	4 (80%)
GP or nurse contacts in the previous three months	Mean (SD)	1.0 (0.8)	1.7 (3.3)

**Table 2.2** Study demographics

Questionnaire	Measure	Control	Intervention
CDLQI ( <i>n</i> =4)	Mean score (SD)	4.8 (4.5)	3.9 (2.7)
BMQ differential – Steroid ( <i>n</i> =3)	Mean score (SD)	0.3 (3.8)	4.2 (5.7)
BMQ differential – Emollient ( <i>n</i> =4)	Mean score (SD)	8.25 (2.5)	4.8 (5.3)
Morisky – Steroid ( <i>n</i> =3)	% adherent	0	20
Morisky – Emollient ( <i>n</i> =4)	% adherent	50	20
SIMS ( <i>n</i> =4)( <i>max</i> = 15)	Mean score (SD)	6.25 (3.8)	11.4 (2.9)

**Table 2.3** Results from the PLEEZ questionnaire for control and intervention at baseline



**Figure 2.2** % of patients reporting they had received about the right information or that none was needed for each of the SIMS questions at baseline.

### 2.5.2 Focus group results

Four pharmacists agreed to participate in the focus group, three declined. The three participating pharmacists who declined cited strong family or personal reasons for not doing so. Of the pharmacists who did take part, there were equal numbers of men and women. All participating pharmacists were aged between 40 and 60 years. One worked in a city pharmacy, one in a pharmacy located in a small town and two in villages.

The focus group produced seven themes: GPs, the balance between professions, paperwork, trial design, timing, frustration and impact and reasons. There was a sense of a lack of engagement by the GP practices which was reflected by the experience of pharmacists within the group:

“the bizarre thing is that we have a very good working relationship with the surgery but when it came to this particular trial obviously went to the practice manager first with that, then had to go the partners but the partners weren’t interested... they were just saying oh yes we’ll get round to it, we’ll get round to it ....and they never got round to it because they didn’t see, they said yeah go see a pharmacist, whatever they want to do, fine we’re behind it but to actually get the senior partner and a quorum decision to say yes this is, and send someone to talk about the trial, it was not a priority” **(Ph3 male, pharmacist in a small town)**

“it was a bit like them [GPs] flicking a fly [pharmacists] off the shelves... it was of no consequence to them” **(Ph2, female, pharmacist in a village)**

The purpose of gaining consent from the GPs was to involve them in the project from the start. As part of the project they may have received documentation requesting a change to a patient’s regimen and therefore it was important to inform them of this before progressing with the study. However, the general view of all the participating pharmacists was that because eczema, as a disease, was not high on their medical practice’s list of priorities, then it was not seen by the GP as warranting the time taken to actually give consent to let the pharmacist approach their patients. In most cases it took repeated telephone calls and e-mails to obtain consent from the medical practice.

Other factors relating to GPs included having a lack of interest in research and pharmacists expressing disagreement with GPs’ priorities such as “putting money before patients”. It was suggested by one pharmacist that when it came to their providing a service to patients in the community pharmacy, unless the GP was paid for it as well, GPs did not want to engage with it, as with medicine use reviews (MURs).



Most of the pharmacists also commented on the balance of power between the two professions, saying that the GPs had an unfair advantage when it came to recruiting patients for an NHS service that both professions were conducting e.g. health checks, and that the pharmacist was probably not being considered by patients as the most suitable person to conduct this type of service.

“...there’s only a finite number of people you can do and the surgery have actually written to their patients about it all they’re going to respond to the surgery more to the surgery than the pharmacy” **(Ph3)**

However, two out of the four pharmacists present also stressed the need to work collaboratively with GPs to decrease their workload and so to free up time for more urgent clinical problems. They saw this as being achieved through such services as minor ailments in the community pharmacy.

“...by the time they’ve [GPs] got to them it’s [eczema] flared up, that’s the problem, they’ve only gone there [surgery] because it is a real problem, but if we can get it the other way round they [GPs] would need to see them half the time would they?”  
**(Ph1, female, pharmacist in a village)**

In relation to the trial design and paperwork, all the pharmacists expressed the view that they wanted the patient/ potential participant to be able to have as near usual a pharmacy-based experience as possible. This meant coming in and having the kind of conversation with the pharmacist they would usually have, without the need for any paperwork. They also felt that the length, layout and colour scheme of the paperwork was a disincentive to taking part in the study.

“... sheer amount of paperwork and I think it’s coming at a time when whatever we do is paperwork and it’s a bit of a turn off really” **(Ph2)**

“think of it on the side of the patient or the guardian they don’t understand consent, they don’t understand the paperwork, they just want to walk into the pharmacy like they do every single day and speak to the pharmacist and be given the advice that we were giving, they don’t want this, oh can you fill this form in before we talk about this.... straight away turns em off” **(Ph3)**

One of the pharmacists recognised the need for most of the paperwork but went on to point out practical problems with its layout, colour scheme and content.

“I don’t wanna be sitting there thinking is it one of these forms, even getting them to fill out one form, and then going oh you’ve got the wrong form. I think that side of things could have been better” **(Ph3)**

When providing pharmacy services, pharmacists are generally used to obtaining verbal consent from the patients, however, this study required written consent, and this was not something that any of the pharmacists were used to. Three pharmacists went on to express a need for this process to be made as easy and simple as possible so that they and the participant can get on with the intervention and the participant does not lose interest. The everyday practice of community pharmacy is that patients will often only come in for a matter of moments to pick up their prescription, so that they saw keeping patients in the pharmacy for a substantial amount of time to read and sign all of the informed consent forms as a considerable disincentive for the potential participant.

“look with MURs [medicine use reviews] we have a verbal consent before we start and it makes it much easier” **(Ph1)**

“I think from my point of view erm a little bit of naivety from myself because I’ve not really been involved with the, the erm the mechanics of the trial before, so therefore as pharmacists we are very much hands-on, we’re dealing with patients all the time, we’re responding to symptoms, we’re doing it there and then, that’s what the patient wants, suddenly to have the bureaucracy of the trial which is obviously is necessary.... I wasn’t expecting that.” **(Ph3)**

This quote illustrates the discomfort of this pharmacist with introducing a new and unfamiliar procedure into their usual interaction with patients, and something that they did not see as being part of care to patients.

This particular study focused on children with eczema as this is known to be the age group with the highest prevalence (Harris, 2007, Kurukulaaratchy et al., 2003). However, all the pharmacists who participated in the focus group found this to be very restrictive in excluding adults and alongside the other inclusion/exclusion criteria e.g. the requirement to have received medicines from their pharmacy for three months prior to recruitment, saw this as further reducing an already small number of potential participants who might be approached.

“it was the age to start with... the very first idea of this study I thought there would be lots of people but when you actually look at it, there wasn't , I think I had 7, I had a list of 7.” **(Ph1)**

The study protocol had suggested that counter assistants could recruit patients to the study, which one of the pharmacists felt was a mistake.

“actually engaging our staff to actually gain the consent and how to ask patients, influencing in the right way as trials needed, y'know asking you staff to do the initial consent was quite difficult y'know” **(Ph4, male, pharmacist in a city)**

Because the pharmacist had decided to recruit the patients to the study as well as conducting the intervention he saw this as increasing his workload in an already busy pharmacy which meant he had to withdraw from the study at an earlier stage.

Another area of concern for some of the pharmacists was the lack of any intervention for the control participants. The pharmacists (not used to participating in this type of study) felt uncomfortable providing the intervention for only half the participants and felt it necessary to say to the patient they would provide them with the intervention once the study had finished.

“it's very difficult to get them to do all the sign up and then say I'm awfully sorry but I can't do you at the moment... we sort of decided that if we had any that went erm that weren't randomised to be seen immediately, we would say well y'know we'll do yours after the trial and have the discussion” **(Ph2)**

The timing of the study was another theme that could now be seen to surface throughout the course of the focus group discussion. The time of year when the study was being conducted at “it was the middle of the summer holiday” **(Ph1)** then when there were delays to starting “...made it running on towards Christmas then” **(Ph2)**. There are times in the year when community pharmacies are naturally busy e.g. in the approach to Christmas, or quiet e.g. in the summer holidays and this could affect whether a) the pharmacist has time to engage fully with a study or b) there are any patients to recruit to the study. The employment status of these particular pharmacists may also have had an impact on the issue of timing. All of these pharmacists owned their own pharmacy and as such would have had constraints on their time that other pharmacists (those that work for multiple chains) would not have had.

The pharmacists also experienced frustration from delays to the research process, they felt they just wanted to get on with doing the research. The pharmacists' frustration arose from the time it took for the amendments to be approved, the volume of paperwork that they had to deal with, the issues surrounding the perceived lack of services to the control group, the consenting process and sense of some of the pharmacists that they were competing for patients with dispensing doctors, so again there was the non-level playing field "all the time we're up against this doctor dispensing bit" **(Ph2)**.

Finally, all the participating pharmacists clearly articulated how they found being part of a research study a valuable experience which had even benefitted their practice and increased their awareness of the necessity of research in community pharmacy as well as building their enthusiasm. All the pharmacists saw becoming involved as offering a chance to engage with a different population that they did not see very often, here, children and young parents. The pharmacists also saw the condition of eczema as not being managed particularly well by the current care team so that offering or evidencing the intervention might lead to them having a positive effect on the patient-participants' condition.

"I had seen so many prescriptions and and I could see that it really wasn't being erm used that the products that they were being prescribed were not being used and you could also tell by the repeat forms, what they were picking and using and then if they'd come back for steroids because they weren't using emollients, I think, and actually this was an opportunity to actually get them to sit down and talk to them and do something positive for them" **(Ph1)**

The pharmacists also noticed an impact on their practice, using the RCT study training evening to gain knowledge to apply to other patients not in the study.

"you know I feel the same, I didn't get any patients out it and I had to hand it back but the fact that I learnt what I learnt from the [training] evening into help not just the child but maybe the adults having some of the problems" **(Ph4)**

"I do find I actually spent more time with the patients who did not come forward for the trial and I am making more of a difference that way, so for me personally I'm doing better than I was beforehand and hopefully my patients are better for it, so you see the rationale a bit more because you're looking at the whole picture now rather than just an odd script that coming through the door. So we've, I've benefitted from it and patients I have dealt with have benefitted from it but not the trial" **(Ph1)**.

All of these points demonstrate that these particular pharmacists, after participating in a study, acknowledge the benefits to their practice even after the study had finished and one pharmacist even stated “it hasn’t dampened my enthusiasm for trying it again” **(Ph1)**.

## 2.6 PLEEZ discussion

This feasibility study recruited nine participants over a nine month period with all participants recruited from three pharmacies in the initial three months of the study until mid-December. This demonstrates that although possible to conduct an RCT in community pharmacy there was a failure to recruit a large enough number of participants. This may be due to a variety of factors, including study design, but largely centred on the process of recruitment itself. No information was collected on how many patients were approached to participate in the study and therefore a recruitment rate cannot be determined. I also had no access to the number in the patient population and as such a recruitment rate for the available population is not calculable for this study. In future an analysis of community pharmacy patient medication records or GP medical systems prior to study implementation would be able to identify this information. This lack of recruitment demonstrates a problem with the inclusion criteria that is discussed more fully later in this section. This may indicate that an independent researcher, present in the pharmacy, may be more appropriate than expecting a pharmacist to recruit patients and document refusals.

The results from the small number of questionnaires do provide some reassurance that it was appropriate to target this group of patients. In both groups at baseline, a high proportion of participants stated that they had unmet needs for information about their child's therapy relating to side effects, interactions, what to do if they forgot to use the cream/ointment and the length of treatment required for their child.

All the questionnaires were fully completed when returned to me which implies that their design was appropriate for this group of participants. The outcome measures selected also provided a wide range of characteristics affected by eczema and demonstrated a slight change between baseline and follow-up with the exception of the health-related quality of life measure which did not demonstrate a change. However, the baseline values for both groups were small, indicating a low impact on quality of life at the start and in order to demonstrate a benefit it may be prudent to target patients with more severe eczema with this type of intervention, however this may make recruitment more difficult.

None of the other study documentation (pharmacist data collection form or GP referral form) was completed and this may be due to a lack of understanding on the part of the pharmacist as to what was required of them or it may be a lack of time available to them to complete the paperwork. Both this and the problems with recruitment could be rectified by placing an independent researcher in the pharmacy at the same time as the study is being conducted. As well as recruiting patients and consenting them for the study this researcher could collect the necessary data from the pharmacy. However, this was not

possible in this study due to the part-time nature of myself and the lack of funding for such support.

Focus group discussions demonstrated that participating pharmacists had similar ideas about what they wanted for their patients who may participate in a community pharmacy study. An overarching theme threading through the focus group data was that pharmacists wanted the patient taking part in the research study to have as near “usual” experience of community pharmacy as possible. However, this may be a surprisingly unambitious aspiration considering that the usual experience of patients in community pharmacy settings consists of one-off opportunistic interventions, usually over-the-counter in front of other customers/patients. The trial intervention was based on using a consultation room and attempted to move the pharmacist into a more clinical/advisory role away from the dispensary or counter, almost formalising the consultation with the patient. It centred on building rapport with a patient and advising them after a lengthy discussion related to their eczema medicines. This is not normal practice for some pharmacists including some of the pharmacists who participated in our study and may suggest that future interventions need to include more support (both in terms of training and locum support) for participants in managing such changes.

The level to which these pharmacists could engage with these ‘lengthy’ consultations with patients was limited. Evidence has shown that pharmacists are experiencing ever growing pressures at work from the increase in prescription items and the requirement to provide this type of enhanced service (Hassell et al., 2011). In the previous 10 years the number of prescription items has increased by over 157% to 850 million items whilst the number of pharmacies has only increased by 12.3% (The NHS Information Centre, 2011a). This implies the time available to pharmacists to participate in research maybe limited and is likely to be given a lower priority than their day-to-day activities. Thus, researchers should be cognisant of this and make arrangements for the adequate locum-cover or researcher-support of a pharmacist who is participating in a study to increase their commitment to the research. This researcher could act as the recruiter for the study in the pharmacy in order that the pharmacist does not have to engage in the consenting process. This may also remove certain issues surrounding selection bias if the pharmacist was to recruit their own participants. However, this support must be at a level that can be realistically implemented within the current funding arrangements for community pharmacy if the service was to be commissioned by the NHS.

Pharmacists in our study also expressed reservations about its design. Using RCT methodology may provide the best quality evidence (Gomm et al., 2006); however, it may

not be appropriate in a particular setting due to practical aspects associated with implementation.

The randomised controlled trial (RCT) methodology is classed as the 'gold standard' when it comes to proving the effectiveness of a healthcare intervention in the setting in which it is conducted (Gomm et al., 2006). The RCT is the only design which guards against most of the methodological errors associated with confounding and bias. RCTs can be blinded (where the participant does not know which treatment they are receiving), double-blinded (where the participant and physician do not know the allocation) or not blinded at all. There is evidence to demonstrate that studies that are not blinded tend to over-estimate the effect size of the intervention by around 17% (Schulz et al., 1995). In community pharmacy research, it is often not feasible to blind participants or pharmacists and therefore most studies in this setting remain unblinded. To ensure that RCTs are conducted on a methodologically sound basis the CONSORT (Consolidated Standards of Reporting Trials) statement was developed and provides a checklist that aims to assess the rigour of an RCT from the randomisation method to reporting of the results (Moher et al., 2001).

It has been suggested in the literature that more thought be given to using observational studies and other research methods that are easier and more practical in nature to implement than the RCT (Black, 1996). For this particular type of research in this setting, a before and after study or a stepped-wedge design may have been more appropriate. A stepped wedge design is one where all participants receive the intervention; however the timing of the intervention depends on which group the participant is randomised to (Brown and Lilford, 2006). Each group starts the intervention at a different time point with all those except the initial group having a control period of varying length before the intervention is provided.

Being naïve about the study design was a fault that one pharmacist identified himself and indicates not only a shortfall in the training provided to these particular pharmacists but also to a lack of pharmacist's general knowledge about methodologies available to researchers. Therefore, greater training needs to be given to pharmacists who participate in studies that are using unfamiliar research designs to explain the necessity of the processes involved and more support to implement these processes in the working environment. This training should include basics such as the need for consent, why certain research designs are being used and what type of evidence they will provide for an intervention. This was not included in the training provided to our pharmacists. Pharmacists may then be able to engage much better with these studies in the future.



There may also be a need to investigate, more widely, the knowledge and understanding of research methods by the general population of pharmacists.

In this study the randomisation database itself worked successfully, however, the problem occurred with the pharmacists' unwillingness to accept the decision of the randomisation system and to provide the service at a later date. This could have been identified through an appropriate qualitative study before commencement of the full study. If an independent researcher had been present to recruit participants this may have ameliorated pharmacists' views towards this particular research design and the effect it would have had on their patients.

For the practical aspect of the study, lack of engagement from, and poor communication with the GP medical practice is a common problem encountered by community pharmacists (Blenkinsopp et al., 2007b, Bradley et al., 2008, Bush et al., 2009). Many research studies either need to gain consent from a particular practice to approach patients, due to the nature of the intervention with medication (as in our study), or need the practice to identify potential participants on their behalf. Problems seem to arise because GPs may not see the need to become involved and would prefer to leave the pharmacist to do what they would normally do i.e. approach patients as they see fit. Therefore, they do not see the need for consent to be given and this can create barriers in the initial phase of any community pharmacy study. This can potentially be addressed by closer working between the research team, the medical practice and the community pharmacist to identify groups of patients that would benefit from this type of intervention in the future. In retrospect, there was little need to gain consent from the medical practice for this study as it was low risk and mirrored services that are already being conducted in community pharmacy e.g. MURs.

One aspect of the study that could be seen to impact on the level of engagement from the medical practice was the choice of disease state i.e. eczema. This condition is not featured on any targets e.g. Quality and Outcomes Framework (QOF), that medical practices have to achieve and there is evidence to suggest that in one group of patients (those with diabetes mellitus) that the QOF incentive system improves clinical and process outcomes (Khunti et al., 2007). This may imply that prescribers become more interested in those patients for whom they are financially rewarded for treating. This, together with the potential perception that pharmacists are already conducting this type of intervention, may not have helped in gaining consent to approach their patients.

The pharmacists highlighted that although anecdotally at the start they thought they had a lot of patients that would meet the inclusion criteria, at the time of recruitment into the

study this number was far lower than originally anticipated. Eczema affects approximately 16.5% of the population from 0-12 years of age (NICE, 2008) and therefore the actual number of patients available to the study was not an issue. Pharmacists may have found it difficult to approach patients within the confines of the protocol, which may be as a result of poor preparatory work in helping them to identify patients that may be suitable for the study. Appropriate mechanisms, that were not used in this study, should be in place when designing research studies to determine the potential number of participants before the study commences. One way of achieving this would be to use the QOF database (for more prevalent conditions) to ascertain exact number of patients that are registered with a particular condition at the outset of the design stage. This would also allow a recruitment rate to be calculated. Another method would be to involve the medical practice by asking them to perform a search of their records to create a list of patients that could be targeted by them to attend the clinic. This would also be useful in determining a response rate.

Issues surrounding documentation for the study could be seen to be related to the study design in that the pharmacists should have received much more training and help on how to use it appropriately. However, it also points to a need to test study documentation prior to commencement to determine if any alterations can be made to allow the participating pharmacists and patients to complete it quickly and easily. It is not practical to expect pharmacists (or any healthcare professional) to commence a study protocol without the appropriate support from the research team in the initial phases of the research. In future studies it may be prudent to have a researcher present when the pharmacist is in the early stage of recruiting patients and providing the intervention so that if any support is required it can be provided instantly. Once the pharmacist is familiar with the paperwork and processes, the support can be slowly reduced but should always be available should they require it.

In terms of data collection, the questionnaire used for the study was also highlighted as part of the pharmacists' problems with the paperwork and none of the data from the pharmacy medication record or consultation was collected even though they were paid for data collection. The questionnaire contained BMQ, Morisky, SIMS and CDLQI which may have made the questionnaire too long and may have put pharmacists off recruiting participants with the thought of having to ask participants to complete it. In future it may be prudent to reduce the questionnaire length so that it contains the minimum required for the study so that participants can complete it quickly before any consultation. No other data were collected by the pharmacists. This, again, points to the need for increased researcher support at the time of providing the intervention so that either the pharmacists can be reminded of what data need to be collected and have the time to do so or the researcher can obtain the data independently of the pharmacist.

The training aspect of the study that focused on eczema was well received; referenced by comments from the pharmacists that stated they felt in a better position to advise patients of all ages not just children. This means that the training they received was at a general level and therefore they felt they could use it for all patients. The study documentation training fell short of the pharmacists' needs and no reference was made to the consultation skills training. More should be made of these elements in future along with a longer session, on more than one occasion, to facilitate this.

There is little research examining how pharmacists approach research and what problems they encounter in terms of participation although Cvijovic et al. explore this in a Canadian context. These problems include a perceived lack of time, fear of modifying established work patterns and a perceived lack of value attributed to research participation (Cvijovic et al., 2010). In this study pharmacists stated they had a lack of time to conduct the research, however the research team explored this and discovered that the research took very little time to complete. This excuse of time was reportedly given to mask the other underlying issues with the Canadian study already mentioned. Whilst giving time as a reason for non-completion of the study, our pharmacists also elaborated in some depth on other reasons that may be responsible for the failure of this study. However, it was also clear that they remained enthusiastic about the idea of taking part in research in general, even though some of them had not known what to expect at the outset.

Examining the problematic issues raised in the context of their usual practice may provide some very practical guidance for redesigning such trials in the future. These problems also fit with the current literature explaining why *patients* do not want to participate in community pharmacy research, as described in chapter one. Patients cite reasons for non-participation in a community pharmacy research project as confusion or lack of understanding of the research, unavailability and most importantly the impact on the relationship with their GP (Petty et al., 2001). It may therefore point to an issue regarding relationships, not only the GP-pharmacist but also GP-patient and patient-pharmacist as to why community pharmacy RCTs are potentially difficult to conduct and these should be investigated further.

Even though this study examined a limited amount of data from a focus group whose membership was restricted to pharmacists from the independent sector it still produced rich data on the varying reasons for a lack of recruitment of participants for this particular study. The small number of independent pharmacists that participated were able to offer a diversity of views which helped identify a range of related problems in the study that they had encountered. This process has made visible the reasons for conducting the focus

groups: determining whether I could have increased the number of participants, what the problems were and how the individual pharmacists fitted the study into their daily routine and these were largely answered by the focus group discussion and its subsequent analysis of the data it produced. It may be prudent in future research to conduct this type of focus group before the main research project even enters the design phase. However, this will still only produce certain insights into practical aspects of conducting research that can be 'predicted'. It will not allow researchers to anticipate and predict everything and that is why feasibility testing, piloting and subsequent follow-up will remain an important aspect of the research framework for developing complex interventions.

With a lack of time and the opportunistic nature of the pharmacist's interaction with patients it is clear to see that this study was always going to struggle to recruit participants. The recruitment process of approaching patients ad-hoc – when they had spare time to do so, determining the correct paperwork, explaining the study and obtaining informed consent, all before speaking to the patient about their eczema, may have been too much. In future, more thought needs to be given to the important stage of a research study. In this project, the presence of a researcher in the pharmacy may have helped address some of these problems. In the community pharmacy setting this study has demonstrated that it may be impractical to expect the pharmacist to act as recruiter and the intervention provider at the same time.

## **2.7 PLEEZ conclusion**

In deliberately setting out to test study processes this project would have benefitted from even greater preparation such as an appropriately designed feasibility study to assess aspects of the study such as recruitment rate, documentation, support requirement and practical implementation of the project in the community pharmacy setting and then conduct a separate pilot designed with information from the first study. This study attempted to combine both into one. The patient outcomes may be encouraging but further research will need to be conducted to determine the effect of this kind of community pharmacy service.

The reasons for conducting the study in this group of patients: concerns about treatment, the need for appropriate therapy management and the need for education have all been confirmed by the participants that were recruited to the study and their answers to the initial questionnaire. In conducting this study the potential reasons why community pharmacy research may prove difficult have been highlighted.

The pharmacists raised several practice specific problems that prevented them from participating fully. This did not, however, alter their enthusiasm for the study or the impact the study training had on their other patients that were not recruited.

One important theme that emerged was the need for greater researcher support either in the form of extra training or being present with them in the pharmacy to recruit potential participants or collect the necessary data. It is important that when designing such studies researchers understand the 'real life' pressures that community pharmacists are under and take steps to alleviate further pressures applied by participation in research. The inclusion of greater support may also remove a component of selection bias and allow researchers to obtain full sets of data.

In terms of the study design, pharmacists clearly had concerns regarding the nature of a control group and felt uneasy about it. Better training in the area of research methods to enable pharmacists to understand the necessity of certain methodologies may help alleviate some of these anxieties. Alternatively, changing the research design to one that may be more appropriate could be an option in future studies.

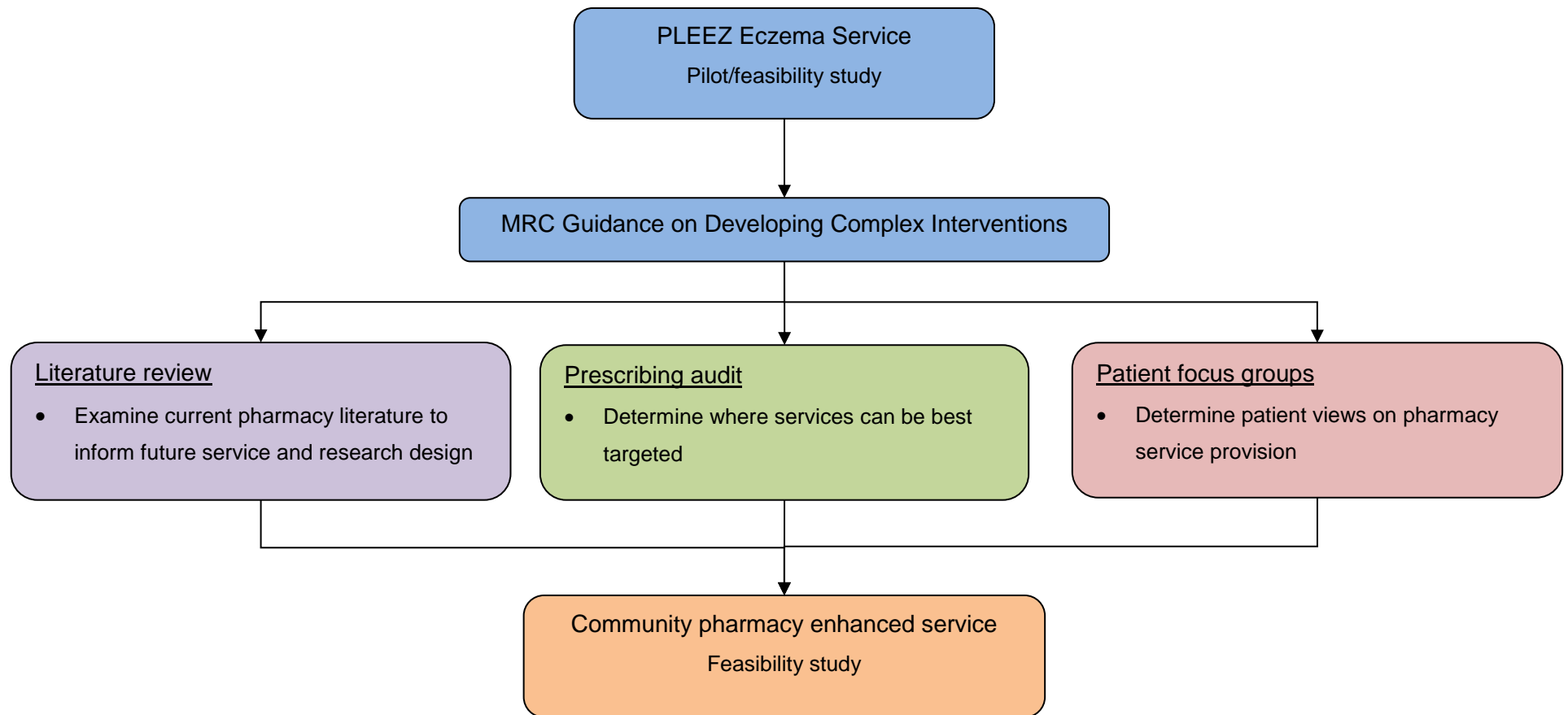
Better communication with the medical practice by both the community pharmacist and the researcher is central to a successful study. In this case it may have resulted in better identification of likely numbers of participants that were available for the study. As such it is important to identify at the outset, not only the number of participants but also their needs for any kind of intervention. This may take the form of meetings with the specialist

nurse or GP at the practice to gain an idea of the scope of the problem in a particular group or it may be in the form of an audit to determine where any intervention would be best targeted.

This point of determining where an intervention should be targeted goes further than collecting data, either quantitative or qualitative, from the medical practice. Current literature and comments from the pharmacists in our focus group indicate that patients may have views on which healthcare professional they prefer to be treated by and which one they are most likely to engage with in order to improve their health. Further work should therefore be undertaken to determine how this triumvirate relationship between the pharmacist, patient and GP affects the extent to which patients are likely to engage with services provided by the community pharmacy. This allows the research team to begin designing novel services with patients in mind, something that is high on the agenda of funding bodies such as the National Institute of Health Research (NIHR, 2012).

If this project were to be conducted again, the main amendment would be the presence of an independent researcher to recruit participants and complete study paperwork. This would mean the pharmacist could focus on the consultation and aspects of the data collection process would not be missed. This revised study would also not contain a control group as it would be testing the feasibility of the service/research and not examining a difference in effect between two groups. There would also be greater involvement of the medical practice with potential signposting of patients to the service either by mailing those identified through their medical records or referral from the GP.

All of these aspects, views and data can then be used to design an intervention that is appropriate for the patient and one that they are likely to engage with. It should be one that does not duplicate work being conducted by the medical practice, targets the appropriate group of patients and most importantly is successful when initiated in the unique setting of the community pharmacy. The strategy for designing a new community pharmacy intervention will factor in these considerations along with the most recent MRC guidance on complex interventions. This strategy is illustrated in figure 2 and is one that will be used for the remainder of this thesis



**Figure 2.3** Strategy for developing an enhanced pharmacy service as a result of the PLEEZ Eczema service project.

# *Chapter Three*



### **3 Type 2 diabetes: a perfect disease for community pharmacy?**

In the development stage of a novel complex intervention, the MRC states that researchers should identify the appropriate evidence base in order to develop theory and processes to inform the study design (Medical Research Council, 2008). One way of achieving this is to conduct a systematic review of the literature, which is the focus of this and the next chapter.

Chapter two demonstrated that in the community pharmacy setting a number of factors need to be considered when choosing a disease state on which to focus a novel intervention. There needs to be a large enough population affected to ensure a high recruitment rate, it needs to be predominantly treated in primary care and it should be high on the medical practice's list of priorities in order for them to engage in the research.

Type 2 diabetes meets all these requirements: accurate figures can be obtained about local prevalence, if patients are not prescribed insulin then it is generally treated in primary care; and as part of the Quality and Outcomes Framework (QOF) it is a high priority for the medical practice. With the complexity of the condition and therefore the number of areas the pharmacist may be able to target together with the number of visits this group of patients make to the pharmacy to collect their medicines; we decided to focus on designing an intervention for this condition.

#### **3.1 Prevalence and cost to the NHS**

There are an estimated 17.5 million people diagnosed with a long-term condition in the UK (Department of Health, 2005a); of which 2.3 million (4.3% prevalence) have diabetes (The NHS Information Centre, 2011c). The prevalence has risen from 3.6% to its current figure since 2005/6 and is predicted to rise further over the next few years as a result of the obesity epidemic with the estimated number of people with diabetes reaching 3.2 million (5.9% prevalence) by 2020. According to the United Kingdom Prospective Diabetes Study (UKPDS) it affects proportionally more Indian-Asians (10%) and Afro-Caribbeans (8%) than are present in the normal population (4% and 2% respectively) (Davis, 2008). The majority of patients (85%) are diagnosed with type 2 diabetes which is largely controlled by oral medication.

The expenditure on type 2 diabetes in the NHS is estimated to be £1.3 billion with total costs to society estimated to be five times this figure through loss of income due to time off work and caring for those who have the severe form of the condition (NICE, 2009a). In 2010/11 the total cost of prescribing for diabetes (both type 1 and type 2) reached £725.1 million an increase of 11.7% on the previous year with the number of items prescribed

rising by 7.8% to 38.3 million (The NHS Information Centre, 2011c). This figure is, in part, comprised of the following:

- £259.1 million on antidiabetic drugs – a 30.6% rise from the previous year
  - 14.1 million prescriptions for metformin – an increase of over 70% from 2005/6.
- £152.6 million on blood glucose monitoring – an increase of £10 million on 2009/10

### **3.2 Causes and complications**

Type 2 diabetes is caused by the reduction of insulin production or the resistance to insulin in the periphery. In terms of insulin production, pancreatic beta cells are generally performing at a suboptimal level and are not producing the required level of insulin for the body. As well as converting glucose to glycogen, decreasing gluconeogenesis and decreasing glycogen breakdown, insulin also performs a central role in the movement of glucose across the cell membrane in the peripheral tissue. Insulin activates its receptor on the membranes of muscle and fat cells which enables the GLUT-4 glucose transporter to facilitate the movement of glucose inside the cell. In type 2 diabetes, these receptors can become resistant to insulin which will lead to reduced glucose intake into the cells, leaving them with a deficit of energy and increased blood glucose concentration (Kumar and Clark, 2002a).

This is a condition that usually develops over a long period of time, to the extent that patients will not always be aware that they have the condition and is the reason for the large number of people that have the condition but are not aware of it, the so-called 'missing million' (Diabetes UK, 2010). These patients will have an increased frequency of hyperglycaemia but may have few or none of the classic symptoms (Walker and Edwards, 2003). The common symptoms of type 2 diabetes are polyuria, polydipsia, blurred vision and very often weight loss despite an increase in appetite. The other symptoms that can present include chronic skin infections, pruritus or vaginitis. Caught at this stage it can be treated effectively to reduce the incidence of complications. However, in some cases patients may have started to develop complications and still have no idea that they have the condition. If a patient is asymptomatic the only method of ascertaining whether they have type 2 diabetes would be to perform a blood glucose test. This may be an opportunistic random test carried out, for example, in a pharmacy or as part of a routine medical practice visit for an unrelated condition. If the results of the random test fall outside the normal expected range then a fasting test should be performed to ascertain whether the patient has the condition. The internationally recognised reference ranges to indicate a diagnosis of diabetes are (WHO and IDF, 2006):

- Random plasma glucose concentration >11.1mmol/L

- Fasting plasma glucose concentration >7.0mmol/L

It is always advisable to perform the test twice on separate occasions and there may be a need to perform a further 2-hour post glucose load test. This is a test where the patient is given 75g of anhydrous glucose and 2 hours later the blood glucose concentration is tested. Anything over 11.1mmol/L indicates a diagnosis of diabetes.

There are many complications arising from having poorly controlled diabetes and these can fall into two categories: macrovascular and microvascular. The macrovascular complications include increased risk of myocardial infarction, stroke and foot amputation. Hypertension is also a risk factor for these complications and as such it is important to simultaneously maintain blood pressure control in the care of diabetes patients to reduce the risk further.

Increased microvascular blood glucose concentrations over a long period of time can lead to damage of the small blood vessels in the retina, renal glomerulus and nerve sheaths which can lead to microvascular complications such as neuropathy, nephropathy and retinopathy respectively (Kumar and Clark, 2002a). Neuropathy is usually associated with complications in the feet and can lead to pain and weakness in the legs and feet. In men it is also associated with impotence. Nephropathy, caused as a result of enlargement of the kidneys and high glomerular filtration rate (Walker and Edwards, 2003), may lead to renal insufficiency whilst retinopathy usually presents with a simple blurring of the vision and if left untreated may lead to blindness. Developing retinopathy as a result of diabetes is one of the leading causes of blindness in the UK in the under-65s (Kumar and Clark, 2002a).

In terms of secondary care, patients with diabetes are more likely to be admitted to hospital as an emergency and once there will stay longer than a general inpatient by an average of three days and of those patients admitted specifically for their diabetes, 47% were admitted with active foot disease (a complication arising out of poor glucose control) requiring extensive treatment (The NHS Information Centre, 2012). Therefore, in order to reduce admissions, length of stay and complications it is important that patients with type 2 diabetes receive the appropriate preventative care from the NHS in order to reduce further (more costly) intervention.

### **3.3 Evidence and guidelines for treatment**

In order for patients to reduce the complications experienced as a result of having type 2 diabetes the National Institute for Health and Clinical Excellence (NICE) has developed guidelines for the treatment of type 2 diabetes and places targets on clinical outcomes such as blood glucose and blood pressure which are listed below (NICE, 2009b):

HbA <sub>1c</sub> :	<59 mmol/mol or 7.5%
Blood pressure:	<140/80 mmHg or <130/80 mmHg if kidney, eye or cerebrovascular damage is present.
Total cholesterol:	<4.0 mmol/L
LDL-cholesterol:	<2.0 mmol/L

Any reduction in HbA<sub>1c</sub> levels (the long-term measure of blood glucose control) can improve the risk of developing microvascular and macrovascular complications (Stratton et al., 2000) and that early control particularly, can help reduce the long-term complications developed as a result of having the condition (Holman et al., 2008). There is however, now an evidence base for not intensively treating diabetes to a level below 48 mmol/mol or 6.5%. Research has demonstrated that intensive treatment leads to increased all-cause mortality and CV-related deaths along with increased episodes of hypoglycaemia (ADVANCE Collaborative Group et al., 2008, ACCORD Study Group et al., 2008) and significant weight gain (ACCORD Study Group et al., 2008).

The drug of choice for first line treatment is metformin, which is particularly effective for obese patients as it is known to cause anorexia. Alternatively, sulphonylureas e.g. Gliclazide can be used in those patients for whom weight is not a problem. NICE recommends a stepwise approach to the management of blood glucose; once a patient's HbA<sub>1c</sub> level increases above a certain threshold it directs the prescriber to initiate further therapy. This can be a combination of metformin and sulphonylurea or the addition of one of the following:

- thiazolidinedione e.g. pioglitazone;
- dipeptidylpeptidase-4 inhibitor e.g. sitagliptin or vildagliptin;
- acarbose;
- glucagon-like peptide-1 mimics e.g. exenatide or liraglutide;
- or insulin (as a final option)

which can result in a patient being prescribed several medicines in an attempt to control their blood glucose.

Unless prescribed insulin, it is not routinely recommended for patients with type 2 diabetes to self-test their blood glucose levels (NICE, 2009b). This is based on evidence stating that self-monitoring of blood glucose, with its significant cost implications, only leads to a moderate reduction in blood glucose and can lead to increased anxiety and depression (Farmer et al., 2007, O'Kane et al., 2008, Simon et al., 2008). However, patients may find

it a comfort to test their blood glucose once or twice a week to determine an approximate reading for their own knowledge. It may also prove useful for newly diagnosed patients who are in the process of discovering how their diet and lifestyle can affect their blood glucose levels. This group of patients may then be receiving prescriptions for test strips along with the associated lancets and testing machines. Patients may not always know how to use these machines and therefore the pharmacist may be asked to guide them on their use.

The importance of good blood pressure control cannot be understated in patients with type 2 diabetes (Stearne et al., 1998) as it has been demonstrated to provide a similar reduction in the development of the same complications associated with the control of blood glucose (Sehestedt et al., 2011), however there may be differences in which one is better to treat intensively on the disease development and progression in each patient (Bartnik and Cosentino, 2009). The standard treatment for patients with type 2 diabetes and hypertension is to initiate an angiotension-converting enzyme (ACE) inhibitor or equivalent if these are not tolerated. Again, NICE state a stepwise approach to the management of hypertension in these patients and for those that are severely affected then it may result in four or more medicines being prescribed concurrently.

There are a further two medicine-related interventions in these patients: lipid-lowering drugs and anti-thrombotics. The evidence base for total cholesterol and LDL-cholesterol reduction in patients with type 2 diabetes is clear. For every mmol/L reduction in low-density lipoprotein cholesterol (LDL-C) there is a reduction in all-cause mortality by 12%, CHD death by 19%, stroke by 17% and the incidence of a first major coronary event in the diabetic sub-population by 26% (Baigent et al., 2005). It has been demonstrated that statins have a significant effect at lowering the LDL-C level in patients with type 2 diabetes (Haffner et al., 1998, Shepherd et al., 2006) and therefore NICE recommends that each patient should be prescribed a statin as a matter of routine to lower their cholesterol.

The evidence base for anti-thrombotic therapy is not as clear and there may be little benefit of prescribing aspirin to patients who have not yet experienced a myocardial infarction or stroke (De Berardis et al., 2009, Zhang et al., 2010). However, many patients are prescribed it as the evidence base has developed over recent years and NICE currently recommends prescribing it as primary prevention in those patients over 50 and those under 50 with significant other cardiovascular risk factors.

In combination with all of these medicines to treat the 'core' elements of type 2 diabetes, patients may often be prescribed other medicines to treat co-morbid conditions or complications as a result of having the disease. These can include treatments for

neuropathic pain e.g. paracetamol or amitriptyline or impotence e.g. sildenafil (NICE, 2009b).

Even with all of these treatments available only 66.5% of patients achieved a target HbA<sub>1c</sub> of 59 mmol/mol, 60.7% achieved a blood pressure of 140/80 mmHg and 40.9% reached a target of 4.0 mmol/L for total cholesterol (The NHS Information Centre, 2011b). Medical practices are encouraged to achieve these targets via the implementation of the Quality and Outcomes Framework (QOF), an incentive scheme run by the NHS. Medical practices are incentivised monetarily for such aspects of diabetes care as (BMA and NHS Employers, 2011):

- compiling a list of those patients within the practice that have been diagnosed with diabetes
- performing clinical tests at regular (pre-specified) intervals
- the number of patients achieving national targets for measures such as blood glucose, blood pressure and lipids
- the medication prescribed to patients with certain complications arising from the disease
- the number of patients to have received the influenza vaccine.

The number of medicines prescribed may indicate that adherence to regimens may be a problem in this group of patients and that this may be contributing to a lack of control. This is an area that the community pharmacist, who will be seeing the patient regularly when they collect their medicines, may have an impact on.

### **3.4 Adherence to treatment**

It is estimated that 50% of patients do not take their prescribed medication correctly (Sackett and Snow, 1979) and research has shown that this causes, or is the reason for, between 11% and 30% of drug related hospital admissions (Col et al., 1990, Wasserfallen et al., 2001). Non-adherence is the term used to describe the extent to which a patient's behaviour does not correspond with agreed recommendations from a healthcare provider (WHO, 2003). The reasons for such patient behaviours have been widely researched and it is believed that it arises from both unintentional and intentional actions (Vermeire et al., 2001).

Intentional non-adherence is where a patient has decided not to take their prescribed medicines due to factors such as side effects, perceived lack of effect of treatment or disbelief in their diagnosis. Unintentional non-adherence occurs when factors such as dexterity, lack of mobility or lack of understanding prevent the patient from either collecting

their medicines from the pharmacy or accessing their tablets e.g. if they are contained in small bottles with child resistant lids. This also includes cognitive impairment such as memory loss in dementia patients or patients with learning difficulties. The pharmacist can have an impact in addressing unintentional non-adherence through the provision of a delivery service, large print labels and compliance aids. Efforts to address intentional non-adherence have focused on improved physician-patient communication (Martin et al., 2005) and other educational interventions using different consultation techniques such as motivational interviewing and behaviour change counselling (Easthall et al., 2012). However, no single intervention has been found to be better than others at tackling this problem (Peterson et al., 2003).

Adherence can be further subdivided into primary non-adherence and secondary non-adherence. Primary non-adherence is where patients do not collect their prescribed medicines from the pharmacy and secondary non-adherence is where they do not follow the prescribed regimen (Donovan and Blake, 1992).

There are several methods for measuring adherence including self-report e.g. the Morisky questionnaires, prescription re-fill counts and electronic monitoring e.g. MEMS. There is no consensus on the gold standard for measuring adherence (Smith et al., 2010), however there appears to be an agreement that self-report methods are less reliable than pill counts or electronic monitoring (Adams et al., 1999, Guénette et al., 2005). When monitoring adherence, it has been suggested that two methods are used together in an effort to triangulate the results produced (Vitolins et al., 2000).

Adherence to treatment by patients plays an important role in the metabolic control of type 2 diabetes. Schectman et al. demonstrated that every 10% increase in adherence was associated with a 0.19% lower HbA<sub>1c</sub> level (Schectman et al., 2002) and a lower HbA<sub>1c</sub> level has been demonstrated to lead to a reduction in the incidence of diabetic complications (UK Prospective Diabetes Study (UKPDS) Group, 1998).

In 2004, Cramer performed a review of the literature examining the adherence to diabetes medication and found a wide variation in results both from retrospective and prospective studies (Cramer, 2004). In the studies that used retrospective prescription refill data from health databases the mean adherence ranged from 36 to 93% and certain studies highlighted that once-daily regimens had higher adherence rates than twice-daily (Dezii et al., 2002) and monotherapy displayed higher adherence characteristics than polytherapy (Ciechanowski et al., 2000). In the prospective analysis, all studies used the Medication Event Monitoring System (MEMS) to monitor adherence. This produced a much narrower range for adherence of 61 – 85% of doses taken and again certain studies provided

evidence to suggest that adherence decreases as the number of daily doses increases (Paes et al., 1997). One study compared electronic monitoring with self-reporting adherence and found that there was a discrepancy between the two (74.5% vs 92.4% adherent respectively) (Matsuyama et al., 1993), with self-reporting being less valid.

Evidence from Sweden suggests that adherence is good in patients with diabetes with almost 90% of patients classed as adherent (taking 80% of the prescribed doses) to treatment, as measured by large scale prescription refill data (n=171,220 patients) (Haupt et al., 2009). Conversely, in Scotland, Donnan et al. found that prescription refill data from 2920 patients demonstrated that only 31% of patients prescribed only a sulphonylurea and 34% prescribed metformin alone were classed as adequately adherent (taking >90% of prescribed doses) with poorer adherence associated with an increase in the daily number of tablets and when co-medication was added to the sulphonylurea regimen (Donnan et al., 2002). This has been confirmed in 1,815 patients in the US who displayed lower adherence rates from prescription refill data when a second medicine was added to their monotherapy than when it was changed to a fixed-dose combination medicine (54% vs 77% respectively) (Farmer et al., 2005). This is something that is confirmed more widely in the literature for other conditions (Claxton et al., 2001).

Therefore it has been demonstrated that adherence may be a problem in this group of patients, the full extent of which has yet to be determined, with self-report methods potentially over-estimating the figure. This research has shown that the number of medicines and number of daily doses a patient has to take directly impacts on their level of adherence. However, as suggested earlier, the extent to which a patient adheres to treatment may be affected by a number of other factors. Non-adherence has been suggested to be as a result of the patient not understanding the need for the medicine, the occurrence of any side effects or deciding that the medicine has no perceived effect and they therefore stop taking it (Grant et al., 2003). There is also some limited evidence to suggest that the just the perception of side effects may impact on intentional non-adherence (Chao et al., 2007).

However, in patients with diabetes there is evidence to suggest that there is strong motivation to take prescribed medicines as patients can observe them having an effect through an improvement in their blood glucose measurements (Farmer et al., 2005, Lawton et al., 2008). In both of these studies, experiencing side effects from medication was found to have a negligible effect on the extent to which a patient is likely to adhere to treatment.



Most concerns about diabetes medication appear to focus on weight gain as a result of taking the medicine, what to do when doses are missed, the increased cardiovascular risk as a result of taking certain medicines and how they will continue to manage their regimens if their routine changes. These were all perceived to have an effect on the level of a patient's adherence to treatment (Hauber et al., 2009, Lawton et al., 2008, Farmer et al., 2005).

Other factors that have been shown to have some impact on adherence rates in this group of patients are: age, lower socio-demographic status, shorter duration of disease and lack of complications (Bezie et al., 2006) along with a potential link between diabetes, depression and non-adherence (Park et al., 2004).

The evidence regarding adherence to medication in diabetes patients suggests that there may be a problem trying to persuade patients to take their medicines as prescribed. One consequence of this could be the large proportion of patients that fail to achieve national targets for diabetes control. The evidence appears to suggest that a simplification of medication regimens and improved information provision aimed at addressing concerns over side effects, missed doses, routine changes and cardiovascular risk may help to improve adherence in this group of patients. These are all topics which a pharmacist, with appropriate counselling on medication and improved communication with the prescriber should be able to address in the community pharmacy setting.

### **3.5 Summary**

With the number of medicines and devices prescribed for diabetes and co-morbid conditions, patients with type 2 diabetes will visit their community pharmacy on a regular basis and this provides an opportunity for a novel intervention. As discussed, these patients may have significant concerns or needs for information about their medicines or disease that the community pharmacist may be able to address via an adherence-based intervention. Together with this the explicit guidelines produced by NICE for the treatment of type 2 diabetes also provide a background for clinical interventions that can be suggested to the primary care team by the pharmacist. These guidelines are stepwise and cover most aspects of diabetes care and there is therefore the potential for the long term management of patients to be moved to the pharmacist provided they remain within these limits. The use of the QOF incentive scheme for medical practices would also be of use in any future study/service. Any help that the community pharmacist can provide to this group of patients may also help the medical practice to achieve their targets more easily. It could also be an advantage when trying to engage practices in research projects that involve the community pharmacist.

The next stage in this thesis is to examine the current evidence base for such a community pharmacy service from the UK and abroad.



*Chapter Four*

## **4 Diabetes community pharmacy interventions**

### **4.1 Introduction**

There have been many interventions developed in the UK and internationally to assist patients in controlling their diabetes, most notably in the UK these have included the X-PERT and DESMOND studies (Davies et al., 2008, Deakin et al., 2006). These have involved multi-professional teams in a variety of settings, and have provided encouraging results with regard to education provision and its effect on diabetic control. This type of educational intervention has been delivered and evaluated by community pharmacists both in the UK and internationally and the next section will examine these in more detail.

### **4.2 Aim**

A literature search was performed to identify published research articles which examined the effect of a community pharmacy based service on patients with type 2 diabetes. This was performed to learn from other trial designs and to identify what worked successfully and what did not in order that this can be factored in to the design of our novel intervention. There was also a need to identify any UK research in this area to avoid duplication and determine if this work could be conducted within the current community pharmacy operational framework.

#### **4.2.1 Objectives**

To identify:

- the presence of UK-based and international studies conducted in this group of patients in this setting
- the trial design of each of the included studies
- the training provision for pharmacists
- the inclusion criteria applied to potential participants
- the content and duration of the interventions
- whether these types of interventions have been effective
- the quality of the research conducted in this group of patients in this setting

### **4.3 Method**

The following databases were searched for relevant articles: OVID (AMED, Medline, Embase, PsychINFO), CINAHL, Scopus, Web of Knowledge and the Cochrane Database. These databases were selected due to their specialism in the area of medicine, nursing and allied health as well as being general literature databases that list the major journals that are likely to publish research in the field of interest.

The terms used for this literature search are identified in the results section together with the number of articles returned by the individual databases. These terms were identified using previously identified articles and MeSH terms. Each term was searched for in the title and abstract listed on the database, apart from Web of Knowledge where the search was only conducted in the title and CINAHL where the search was conducted in the abstract only. This was due to constraints on the database search engines.

Once identified, the articles were downloaded to the Endnote referencing programme for further screening. A first screen was used to remove duplicates and those articles that clearly did not fit the inclusion criteria from their title. A second, more detailed screening, involving the abstract was then performed using the inclusion and exclusion criteria.

#### **4.3.1 Inclusion criteria**

This literature review focuses on the role of the community pharmacist in the management of patients with type 2 diabetes. Therefore, it is appropriate that all those included are performed by a community pharmacist working in a community pharmacy and not a clinical pharmacist working in the community. Some studies were conducted in health clinics or hospitals and this does not reflect the current situation in UK community pharmacy. The community pharmacy setting in the UK is defined by its primary role of medicines supply and not clinical service provision. This places limitations on the role of the community pharmacist that pharmacists in other settings will not experience e.g. dispensing and advising customers over-the-counter. It is also a place where the pharmacist is the only healthcare professional present and therefore there is limited scope to discuss medical problems with other members of the healthcare team. It is for these reasons that this review will focus specifically on the community pharmacy and not the community pharmacist operating in other environments.

Many studies also involved a pharmacist as part of a wider healthcare team and it is difficult to determine exactly what affect the pharmacist alone had on these patients and whether any effect could be attributed to the pharmacist or another healthcare professional e.g. certified diabetes educator.

Further specification required the review to contain only studies that were conducted in patients with type 2 diabetes. This is due to the differing nature of the two types of diabetes. Type 1 is generally managed by the secondary care team and it may not therefore be appropriate to develop a role for the community pharmacist in this area due to the increased complexity of any intervention which would be centred on a patient's insulin management. As a result of this, pharmacists may require a significant training programme that may not be feasible to perform in this setting. Type 2 diabetes is managed largely in primary care with oral medication and the community pharmacist will see this group of patients regularly and will be in a position to contact the medical team should it be necessary.

For this review, it was decided to include only studies that reported HbA<sub>1c</sub> as an outcome measure, either primary or secondary. This is due to the importance of this measure of blood glucose as an indication of control of the disease and the likelihood of developing complications.

As demonstrated in chapter two, it may be hard to conduct RCT research in this setting therefore any research methodology will be accepted. Studies must also have an abstract available for screening. Conference presentations were also included in the literature review.

#### *4.3.1.1 Summary inclusion criteria*

- Intervention performed solely by a community pharmacist
- Conducted in patients with type 2 diabetes
- Conducted in the community pharmacy setting
- Reported HbA<sub>1c</sub> as an outcome measure
- Used any type of research methodology
- Abstract available

#### *4.3.2 Exclusion criteria*

I did not have the facilities to translate articles that were published in a foreign language, therefore these paper were excluded if an English version could not be sourced.

#### *4.3.2.1 Summary exclusion criteria*

Articles not written or available in English

### **4.4 Search results**

The literature search was performed up to and including December 2011. Table 4.1 details the terms used and the number of hits returned by each of the search engines.

Search number	Terms	Database			
		OVID	SCOPUS	CINAHL & MEDLINE	Web of knowledge
1	Pharmac*	1,139,640	923,123	379,881	543,625
2	Pharmacist*	53,234	54,263	14,869	15,360
3	1 or 2	1,139,640	923,122	37,988	543,625
4	Community	691,113	722,024	266,529	365,163
5	Retail	12,387	26,672	4,418	10,844
6	High street	234	15,364	83	265
7	4 or 5 or 6	702,794	761,683	270,668	376,253
8	3 and 7	24,626	18,941	9,438	4,333
9	Adult onset diabet*	1,012	13,056	353	479
10	Type 2 diabet*	135,151	118,585	59,169	97,926
11	Ketosis resistant diabet*	22	51	5	21
12	Maturity onset diabet*	3,458	2,595	1,297	976
13	Non-insulin dependent diabet*	21,133	105,752	8,816	13,906
14	Noninsulin dependent diabet*	2,810		1,152	854
15	Slow onset diabet*	9	519	4	24
16	Stable diabet*	260	8,061	87	338
17	Type II diabet*	15,105	20,047	5,681	10,966
18	NIDDM	14,648	7,986	6,703	8,953
19	9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18	177,635	172,865	76,815	131,818
20	8 and 19	312	319	108	22
21	Remove duplicates	206			14

**Table 4.1** Search terms and results returned

The Cochrane Database returned no relevant studies or reviews.

#### 4.4.1 Included studies

After detailed searching, 30 articles required further reading of the full paper to determine appropriateness for inclusion of which eight articles were subsequently deemed appropriate (Correr et al., 2011, Krass et al., 2007, Mehuys et al., 2011, Oyetayo et al., 2011, Taylor et al., 2005, Wermeille et al., 2004, Fornos et al., 2006, Krass et al., 2011). One study, conducted by Wermeille et al. should have been excluded as it appears that the actual consultation with the patient took place in the medical practice for 'space reasons'. However, I felt that it would be useful to include as it was the only UK study

published in this area at the time of the literature search and it would be helpful to compare to other countries. I believe that the intention of the study team was to perform the project in the community pharmacy had there been a suitable space and that if this project was performed today it would have been possible for them to achieve this.

#### 4.4.2 Characteristics of excluded studies

A number of studies from the US and Australia were excluded based on the setting in which they were conducted. Some of these studies, including DiabetesCare, the Diabetes Ten City Challenge and The Ashville Project (Cranor et al., 2003, Fera et al., 2009, Odegard et al., 2005, Krass et al., 2006, Johnson et al., 2008), were conducted in community medical facilities by a community pharmacist; however, this setting does not reflect the current UK setting of community pharmacy and they were therefore excluded. These three studies either used an observational design or a pre-test post-test methodology and between them recruited 1313 participants. Three Swedish studies were also excluded because they were conducted by community pharmacists in conjunction with a diabetes nurse and away from the community pharmacy setting (Sarkadi and Rosenqvist, 1999, Sarkadi and Rosenqvist, 2004, Sarkadi et al., 2005).

Certain studies were excluded based on their chosen outcome measure of fasting plasma glucose (Turnacilar et al., 2009, Adepu et al., 2007). This is not seen as a good measure of the long term control of a patient as it only references a patient's glucose level over the preceding 12 hours. To provide some comparability, we only included studies which reported appropriate clinical outcomes and consequently studies that reported fasting plasma glucose, health-related quality of life and intermediate outcomes such as knowledge or satisfaction (Malathy et al., 2011, Mitchell et al., 2011) were excluded.

#### 4.4.3 Quality assessment

The aspects of individual studies included are described with reference to study design (table 4.3), training provision (table 4.4), inclusion criteria (table 4.5) and intervention design (table 4.6). A quality assessment is provided in each table which is used to determine which factors may be related to better outcomes and individual rating systems are described in detail in table 4.2. This rating system was developed in collaboration with the supervisory team to provide clarity on the different aspects of each study and to aid presentation of results. The system has not been validated in the literature.



	☆ = Poor	☆☆ = Moderate	☆☆☆ = Good	Table reference
Study design	Controlled trial	Randomised OR achieved recruitment target	Randomised AND achieved recruitment target	4.3
Training provision	No input	Acquired all knowledge face-to-face	Addition of role play sessions	4.4
Inclusion criteria	Some recruitment criteria	Based on HbA <sub>1C</sub>	Based on HbA <sub>1C</sub> and number of medicines	4.5
Intervention content	Small number of interventions	Large number of interventions, covered small number of topics	Many interventions covering all aspects of diabetes care	4.6

**Table 4.2** Definitions for the quality rating system

#### 4.5 Results

There were differences between the studies in terms of the magnitude of change in the clinical outcome measures and this may have been due to the different approaches to the intervention and the research process. These differences are summarised in each subsequent table and collated in table 4.7 where they are ranked in order of overall quality. Study design is examined first in table 4.3.

Author	Date	Location	Controlled	Before/after	Randomised	Power	Anticipated effect size	Number of anticipated participants	Number of actual participants	Quality
Correr	2011	Brazil	✓						161	☆
Fornos	2006	Spain	✓			80%	10% relative difference between groups	110	114	☆☆
Krass	2007	Australia	✓		✓*	90%	0.5% absolute reduction	360	335	☆☆
Krass	2011	Australia	✓		✓*	90%	0.5% absolute reduction	320	387	☆☆☆
Mehuys	2011	Belgium	✓		✓*	80%	0.5% absolute reduction	256	288	☆☆☆
Oyetayo	2011	US		✓					126	-
Taylor	2005	Australia	✓						239	☆
Wermeille	2004	UK		✓					62	-

**Table 4.3** Study design

\*Randomisation performed by pharmacy; one ☆ for each of the following criteria: controlled trial; randomised; achieved recruitment target.

Correr et al. performed a non-randomised study in Brazil that was based on a pharmacotherapy follow-up programme (PFU) and provides detailed information regarding the intervention provided to the participants and the training provided to the pharmacists. This study recruited six pharmacies of which two self-selected to be in the control group, purely based on the pharmacist's preference which may have influenced the result as the more motivated pharmacists were providing the service. There was little explanation of the participant drop-out rate, which in this study was 40.3%.

The reporting of the RCT by Fornos et al. was extensive and provided significant detailed information. The study had 80% power to detect a 10% relative difference in HbA<sub>1C</sub> between groups at follow-up, which was achieved with the appropriate number of participants recruited. The intervention was extensively described along with the training requirements for the pharmacists who also attended regular sessions where drug-related problems were discussed and intervention fidelity was assessed. The study also reported other clinical and humanistic outcomes in addition to HbA<sub>1C</sub>, which all demonstrated a positive effect of the intervention.

The group of researchers in Australia have developed and tested a number of community pharmacy diabetes interventions (Krass et al., 2007, Krass et al., 2011, Taylor et al., 2005, Armour et al., 2004) as well as patient perceptions of such a service (Mitchell et al., 2011). Both studies provide extensive information regarding the intervention provided to participants and the training provided to pharmacists. They both include detailed inclusion criteria and power calculations although the 2011 study over-recruited. They both also report other clinical and humanistic outcomes on which the interventions have a limited positive effect.

The group's 2005 study was similar to the subsequent two with respect to training with the addition that the research team visited the pharmacies to assess intervention fidelity (Taylor et al., 2005). It is not clear if this was performed in the 2007 or 2011 studies or what the outcomes of these visits were.

To demonstrate that these studies can have a beneficial effect to the patient is important, however, it must also be affordable to the health service in which it is conducted. Only one of the studies reviewed also published a cost-effectiveness analysis of their service. Taylor et al. calculated that the additional cost of providing their service was approximately \$A383 per patient for the first nine months of the service and that this achieved an HbA<sub>1C</sub> reduction of 0.46% (Taylor et al., 2005). For every 1% reduction in HbA<sub>1C</sub>, the risk of developing any long term complications diminishes by 21%, myocardial

infarction by 14% and microvascular complications by 37% (Stratton et al., 2000) which could lead to significant cost savings to the NHS.

Mehuys et al. over-recruited for their power calculation, recruiting a total of 288 when only 256 were required. In this study the intervention was well described, however, the training requirement of the pharmacists was not clear from the article. A lack of description of training undertaken by the pharmacists was also a problem with the article by Oyetayo et al. This was classed as a 'live four-hour educational session' but did not describe where this took place or what was covered. This study included no power calculation and experienced a drop-out rate of 65%, the reasons for which were not explained.

Wermeille's 2005 study was the only one to be conducted in the UK. It was a prospective pre-test post-test design that identified participants through their pharmacy medication records. Each participant recruited attended an interview at baseline and again at 24 weeks and had a pharmaceutical care plan (PCP) developed for them by the community pharmacist. This PCP, generated after the first interview was reviewed by a second community pharmacist and two academic pharmacists before being discussed with the participant's GP. The second interview was designed to assess whether the PCP had been implemented. During both interviews the participant's knowledge was tested, medication adherence measured and a blood pressure measurement was taken.

The training provision provides an overview of the extra training the participating pharmacists had to undergo in order to provide their respective services. This is described in table 4.4 below.

Author	Date	Delivery			Content					Quality
		Self-directed learning	Face to face training	Role play	Diabetes knowledge	Measurement techniques	Guidelines	Study design	Regular monitoring	
Correr	2011		✓		✓	✓		✓		☆☆
Fornos	2006		✓		✓	✓		✓	✓	☆☆
Krass	2007	✓	✓	✓	✓	✓		✓		☆☆☆
Krass	2011	✓	✓	✓	✓	✓		✓		☆☆☆
Mehuys	2011		✓		✓		✓	✓		☆☆
Oyetayo	2011		✓		✓			✓		☆☆
Taylor	2005	✓	✓		✓	✓		✓	✓	☆☆
Wermeille	2004	No information provided								☆

**Table 4.4** Training provision for pharmacists

☆ = no input; ☆☆ = all knowledge acquired face to face but no role play; ☆☆☆ = training included role play

In four out of the eight studies the training for the pharmacists followed a similar pattern of self-directed learning e.g. a diabetes manual, followed by a training session held usually at the university that lasted anywhere from eight hours to two days. Two of the studies (Mehuys et al., 2011, Wermeille et al., 2004) provided little or no information about the training they required the pharmacists to attend and in the final two studies one held a university training session (Correr et al., 2011) and one conducted a live four-hour face to face training session with an endocrinologist and specialist pharmacist (Oyetayo et al., 2011).

All of these training sessions covered the basics of diabetes, the complications and prognosis of the disease, medication used to treat diabetes, an overview and practical demonstration of diagnostic equipment (if required for the study) and information about the study protocol e.g. details on the pharmacotherapy follow-up programme. *Fornos et al.* included as part of the on-going training, regular sessions where pharmacists could present and discuss drug related problems that they had identified during the course of the study. For Taylor et al. consistence was important across all the pharmacies and therefore the participating pharmacists were visited by the research team after their attendance at the training session to ensure consistency within the programme.

All of the studies recruited participants based on different aspects of their diabetes care and therefore it is useful to understand the inclusion criteria and how this may affect the outcome of the study. Inclusion criteria are detailed in table 4.5.

Author	Date	Recruitment based on:					Quality
		Prescription of oral diabetes medicines	Age	HbA <sub>1c</sub>	Medical practice confirmation of results before recruitment	Comments	
Correr	2011	✓	✓			>30 years old	☆
Fornos	2006	✓				OHAs >12 months	☆
Krass	2007	✓		✓	✓	>7.5% + 1 OHA or insulin OR >7.0% + 1 OHA and other medicine for hypertension, angina or lipids	☆☆☆
Krass	2011			✓	✓	>7.0%	☆☆
Mehuys	2011	✓	✓			45-75 years old, OHAs >12 months BMI >25, approached consecutively	☆
Oyetayo	2011					Hispanic	☆
Taylor	2005	✓	✓			<85 years old >3 medicines	☆
Wermeille	2004	✓	✓			>40 years old	☆

**Table 4.5** Inclusion criteria

☆ = some recruitment criteria; ☆☆ =based on HbA<sub>1c</sub>; ☆☆☆ = recruitment based on HbA<sub>1c</sub> and number of medicines

With reference to the inclusion criteria, all of the studies apart from two (Krass et al., 2011, Oyetayo et al., 2011) used whether a patient was receiving oral medicines to treat type 2 diabetes to screen eligible participants. Two studies (Krass et al., 2007, Krass et al., 2011) included HbA<sub>1C</sub> as a criterion for inclusion; the patient had to be poorly controlled before participating. Both studies utilised a control group for comparison and produced a significantly greater decrease in HbA<sub>1C</sub> in the intervention group when compared to the other studies. Oyetayo et al. did not recruit using HbA<sub>1C</sub> results; however, they did perform a sub-analysis on their data to account for those patients that were poorly controlled at the start. These patients achieved a significant decrease in the HbA<sub>1C</sub> result compared the non-significant result seen in all participants.

Finally, intervention design is detailed in table 4.6.



Author	Date	Number of consultations	Length of intervention	Content			Action		Quality
				Adherence	D&L	DRP	Monitoring	Referral	
Correr	2011	12	12 months	✓		✓		✓	☆☆
Fornos	2006	13	13 months	✓	✓	✓	✓	✓	☆☆☆
Krass	2007	5	6 months	✓	✓	✓	✓	✓	☆☆☆
Krass	2011	4 or 6	6 or 12 months respectively	✓	✓	✓	✓	✓	☆☆☆
Mehuys	2011	Each visit	6 months	✓	✓				☆☆
Oyetayo	2011	4	12 months	✓	✓	✓	✓	✓	☆☆☆
Taylor	2005	7	9 months	✓	✓	✓	✓	✓	☆☆☆
Wermeille	2004	2	24 – 28 weeks	✓		✓		✓	☆

**Table 4.6** Description of intervention

D&L: diet and lifestyle; DRP: drug related problems; ☆ = short duration, small number of interventions; ☆☆ = large number of interventions, covered small number of topics; ☆☆☆ = large number of interventions, covered all aspects of diabetes care

There is no common theme threading through the design of these interventions that clearly produces improvements to HbA<sub>1C</sub>. However, most of them cover the same topics in the consultation and most follow roughly the same pattern; a service that has multiple consultations with the participant over an extended period of time. The content of the consultation was approximately the same for all of the included studies and covered aspects such as diabetes and its complications, medicines and their correct use, lifestyle and diet advice and adherence advice.

Nearly all of the studies sought to see the patient as part of the intervention anywhere between once every month to once every three months for up to 1 year with some studies having an intensive intervention at the start which then tapered off as the year progressed. Only one study did not follow this model instead interviewing the patient at the start of the study and providing them with the necessary information they wanted and then re-interviewing at the end (24-28 weeks later) to collect the follow-up data (Wermeille et al., 2004).

In terms of the length of follow-up and the number of clinics provided as part of the intervention, Krass's 2011 study sought to determine the ideal length of time for an intervention such as this. One group received four visits over six months and the other group received six visits over 12 months. Both arms were followed up at 18 months and both demonstrated a 0.9% decrease in HbA<sub>1C</sub> over this period. The first group did demonstrate a slight worsening of control over the follow-up period, however this was still significantly lower than the baseline figure.

These studies all produced varying drop-out rates from 2-65%. Those with the best drop-out rates engaged with their participants on a regular (usually monthly) basis to encourage them to continue attending the service. The total length of the intervention (from baseline to final follow-up) appeared to have no effect on the rate of attrition in this group of patients.

A final aspect that appears useful in these studies is the apparent integration of the community pharmacist into the primary care team. All apart from one of these studies had some level of referral system in place to liaise with the patient's physician. However, the extent of the pharmacist-doctor communication differed with some only providing advice to the prescriber, some simply referring patients and others actively working with the prescriber to identify and solve drug-related problems.

The overall rating for each study is provided in table 4.7 where they are ranked in order of quality.

Author	Date	Star rating (see individual table):				Outcome	P-value	Comments
		Design (4.3)	Training (4.4)	Inclusion criteria (4.5)	Intervention (4.6)			
Krass	2007	☆☆	☆☆☆	☆☆☆	☆☆☆	-1.0% (-0.8 to -1.3)	<0.01	(int vs cont diff)
Krass	2011	☆☆☆	☆☆☆	☆☆	☆☆☆	No difference	0.98	Comparison of 6- month and 12-month groups; -0.9% (-0.7 to -1.1 in both groups)
Mehuys	2011	☆☆☆	☆☆	☆	☆☆	-0.5% (0.1 to 0.9)	0.009	(difference between groups); p<0.001 (within intervention group); -0.6% (-0.3 - -0.9) (intervention)
Fornos	2006	☆☆	☆☆	☆	☆☆☆	-0.5%	<0.001	8.4% (1.8) to 7.9% (1.7); control group increased
Taylor	2005	☆	☆☆☆	☆	☆☆☆	-0.46%	0.02	7.86% (1.37) to 7.40% (1.34) (intervention); Control: 7.41 (1.14) to 7.38 (1.08); p=0.81
Oyetayo	2011	-	☆☆	☆	☆☆☆	-0.2%	0.516	(patients not at goal values: -0.6% (p=0.006))
Correr	2011	☆	☆☆	☆	☆☆	-2.2% vs -0.3%	<0.001	(-2.8 to -1.6) vs (-0.8 to 0.2)
Wermeille	2004	-	☆	☆	☆	-0.8% (-1.1 to -0.5);	<0.001	

**Table 4.7** Ranked studies based on overall quality assessment and outcomes

All the studies included produced encouraging results to support the inclusion of the community pharmacist in the care of patients with type 2 diabetes. The eight studies in this review recruited a combined 1849 patients with type 2 diabetes and 1366 of those were included in final analyses. Seven of the eight studies produced a significant result in terms of HbA<sub>1c</sub> reduction either in the form of a significant decrease in the intervention group or a significant difference between the control group and intervention group at the end of the study. One of these studies (Mehuys et al., 2011) achieved a significant difference between groups at the end of the intervention period but this was not sustained in the extended 18-month follow-up period. One study (Oyetayo et al., 2011) found no significant fall in HbA<sub>1c</sub> as a result of participating in the study. However, when a second analysis was conducted on those patients entering the study with an above target HbA<sub>1c</sub> reading, the reduction over the course of the study became significant.

Falls in other clinical outcome measures such as blood pressure, total cholesterol and triglycerides were recorded in six out of the nine studies with two studies not reporting any other clinical outcomes (Mehuys et al., 2011, Taylor et al., 2005). Five studies reported humanistic outcomes; with the diabetes pharmacy interventions having positive effects on diabetes knowledge, health-related quality of life and self-management activities. One study reported no significant improvement in quality of life (Krass et al., 2011) and one study reported no significant improvement in adherence despite a significant fall in HbA<sub>1c</sub> (Wermeille et al., 2004).

## 4.6 Discussion

This review has identified a number of successful community pharmacy interventions aimed at improving the care of patients with type 2 diabetes. However, there is a lack of data to suggest whether a targeted diabetes intervention could work within the current UK community pharmacy contractual and operational framework. The only UK study included was conducted in a manner that would not be possible to implement on a larger scale and therefore does not provide an accurate assessment of the role of the pharmacist in the care of these patients. There are several problems that arise from this study. This study provides no information on the training the pharmacists were given and did not include a power calculation on which they based their sample size. The study demonstrated a significant fall in HbA<sub>1C</sub> levels in 59 participants but was delivered in the medical practice for 'space' reasons. Whilst this does not meet the inclusion criteria for this review, the study was conducted at a time when it was not commonplace for pharmacies to have their own private space for counselling patients. If conducted today, this study would almost certainly have been conducted within the community pharmacy. This, along with the review of the pharmaceutical care plan by three other pharmacists, does not align with the current operational framework which is in place for UK community pharmacy. If this service was extended to other pharmacies then it would potentially become impractical very quickly due to the other professionals needed to verify to the PCP from the originating pharmacist.

The extent to which the pharmacist accessed the medical records of the participant is also unclear which poses an important challenge from a community pharmacist's perspective. If the pharmacist needed access to medical records then a mechanism would have to exist to ensure better communication between the medical team and the community pharmacy in order for the pharmacist to view this information.

The interviews (as described in the article) also provide cause for concern as they appeared to be knowledge testing rather than where the participant was allowed to express concerns or problems with their treatment. Most of the pharmaceutical care issues could potentially have been identified by examining their personal record held at the medical practice rather than interviewing the participant.

Inclusion in this review has been useful as it demonstrates that, to date, there has not been a large scale community pharmacy diabetes study performed in the UK. It would therefore be appropriate to design such a novel intervention based on the processes examined in the international research but with the UK community pharmacy setting in mind. This is an important point as the UK primary care sector is distinctly different from models of care internationally. In the UK, the work of managing patients with diabetes

primarily lies with the practice nurse in the medical practice, with the GP being called in to deal with “difficult” patients. Primary care nurses are generally less expensive to employ than a community pharmacist and GP and therefore based on cost alone it may appear more sensible to leave the management to this group of patients to other healthcare professionals rather than a more expensive community pharmacist. The practice nurse is a role that has been developed heavily over the past ten years in the UK primary care setting and as such is one of the reasons why they have become more involved in the care of this group of patients. This is not the case in other countries, including some of those explored in this section and therefore may limit the generalisability of the results to the UK setting.

Despite the lack of UK evidence, this review has provided a large amount of international evidence regarding the type of intervention that is likely to benefit patients, the training associated with that intervention and the types of patients that should be targeted to achieve the optimal results. It is clear from this evidence that the most successful studies are those that recruit a large number of pharmacies and ask them to approach a small number of patients to participate in the intervention.

Three studies randomised participants to control or intervention at the level of the pharmacy and not the patient. This cluster approach to randomisation is one that can reduce contamination between the participants in each arm of the study as well as providing practical benefits for the pharmacists involved, in that they only have to train for one set of processes. However, although practical in this particular setting, cluster randomised trials may not always be the best design as they may introduce selection bias and often greater sample sizes are required (Torgerson, 2001) and this can result in lower statistical precision during analysis (Donner and Klar, 2004). Both the Belgian study and two of those from Australia recruited a large number of pharmacies and asked them to recruit a small number of participants. This appears to have worked at achieving, even surpassing, their recruitment targets and may provide an assessment of whether a programme such as this would be feasible in community pharmacies on a national scale. As described in chapter two, in the PLEEZ study, some pharmacists found it uncomfortable providing the intervention and control as they felt it was depriving their patients of a service. If randomisation is performed at the pharmacy level then this may contribute to relieving these concerns.

One aspect that is central to the success of these studies is the training programme provided by the research team. For many pharmacists, services such as these may be new roles for them and therefore it is essential that they are provided with both the knowledge and the means to convey that knowledge to the participant e.g. role play or

consultation skills. This needs to be factored into study design and, importantly, if a cost-effectiveness analysis is performed, the ongoing costs should be taken into account as the guidelines for treatment are constantly changing and pharmacists will need to be kept up-to-date.

The level of training given to the pharmacist may impact on how well participants perform over the course of the study. From the studies identified, it appears that training of pharmacists may need to be two-fold. The first aspect is a self-directed learning package and the second is a face-to-face element with the study co-ordinators to explain the research. Self-directed learning may be less effective whereas face-to-face enables the pharmacists to become familiar with practical application of the knowledge. This final aspect also included input from other healthcare professionals to help explain local practice and clarify aspects of the self-directed learning.

Most advanced and enhanced services in the UK require a degree of self-directed learning but the face-to-face element varies depending on the service. With medicine use reviews (MURs), pharmacists are able to provide the service if they have undertaken the short online training and assessment exercise lasting approximately three hours (CPPE, 2012) whilst the new medicine service only requires pharmacists to self-assess their competency without any additional training before providing the service (PSNC, 2012b). For enhanced services, most primary care trusts require pharmacists to have undertaken a self-directed learning package, usually provided by the Centre for Pharmacy Postgraduate Education (CPPE), and then attend a short training session of approximately three hours. These services are generally one-off opportunistic interventions and as such may only require a small amount of training, however, the services identified as part of this review require much longer and more in-depth training and the extent to which pharmacists in the UK will engage with this, in terms of availability and practicality, needs to be determined.

The inclusion criteria for these studies indicate that it may be better to target those patients most in need of a reduction in HbA<sub>1c</sub> levels. For the same cost of the intervention it would appear that targeting those patients who are poorly controlled provides a greater opportunity to not only reduce their HbA<sub>1c</sub> level but to reduce it further than those patients who are well controlled at baseline. In a public health system such as the NHS this would provide better use of restricted financial resources. Targeting patients via their medication seems appropriate as the patient can be identified through the pharmacy's own medication records; however, it gives no indication as to the level of control the patient is currently experiencing. It may, therefore, be appropriate to use this method of identifying potential participants and then confirm their inclusion using HbA<sub>1c</sub> data from the medical

records. This may indicate a better use of resources as they are focused on those with greatest need.

In these studies all of this clinical information had to be obtained from the patient's general practitioner before they commenced participation on the study which may have added time and costs to the programme that other studies did not have. Setting up a similar service in the UK would require increased collaboration between the patient's medical practice and the community pharmacy, which may increase the patient's perceived value of the service and provide a more focused intervention. This could be achieved with the use of Summary Care Records, due to be introduced in the UK, or a referral and feedback system between the medical practice and community pharmacy.

The successful studies often involve the pharmacist meeting the patient on a regular basis over a period of months or years. These interventions appear to work well, however, they lack definition and the pharmacists in each study appear to cover every aspect of the condition of diabetes when conversing with their patients. This may be necessary; however, it would be prudent to determine if an intervention covering such a wide variety of topics could be reduced to fewer 'core' topics and still be effective. This also has implications for cost as a longer intervention will be more expensive to implement. None of these studies provided information on the length of each consultation and therefore if studies like these were to be conducted in the UK then a measurement of time spent with the pharmacist may be useful in defining cost more effectively.

The published work by Krass et al. in 2007 and 2011 demonstrates a good approach to this type of research. The service itself aligns with current treatment pathways in Australia and aims to add to the service provided by the patient's physician rather than duplicating it. However, Krass and Taylor in their three interventions provided their participants with blood glucose testing devices and at each consultation downloaded the results from the meters onto the pharmacy computers. These results then formed the core content of the consultations and the pharmacists used them to develop goals that were agreed with the participant. The use of blood glucose monitors, whilst helpful for pharmacists to aid goal setting for patients, does not seem essential for the significant reduction in blood glucose levels. Other studies that are included in this review have not used this particular tool and have still demonstrated a significant effect. It is not current UK guidance to recommend the use of self-monitoring devices in patients that are non-insulin controlled and this will have an impact on the design of any future pharmacy services (NICE, 2009b).

The study by Mehuys, as part of the intervention, also included point of care testing for clinical parameters, which may not be something that pharmacists are used to performing



and therefore may not be representative of the community pharmacy environment around the world. In the UK, it may be more appropriate to obtain this information from the medical practice.

Only two of the included studies test the intervention provision once they have trained the pharmacists. The study conducted by Fornos includes regular meetings to discuss progress and outcomes and focuses on case-based discussions between the participating pharmacists to ensure they are all providing similar information. Krass's 2007 study focusses on the research team making visits to the pharmacies to ensure that they are adhering to the study protocol. They also maintain regular contact with them to keep them informed and motivated about the study (Krass et al., 2007). This aspect of intervention fidelity checking is important as it ensures not only that the pharmacists are all following the study protocol correctly but that they are providing consistent advice to their participants. Some form of this should be factored into the design of our novel intervention.

The only cost-effectiveness analysis conducted was performed from the health system perspective and therefore did not include the societal costs of type 2 diabetes, which may be important in this group of patients (Taylor et al., 2005). The analysis was only performed over the course of the nine months of the study and the authors acknowledge that given the long-term nature of the condition this may need to be revisited in the future. The authors also identify that they did not include the cost of training and although this is just an initial factor in the analysis, if the service was to be implemented these costs may become significant and ongoing.

In summary the studies identified here have provided positive evidence for the inclusion of the community pharmacist in the care of patients with type 2 diabetes. The HbA<sub>1c</sub> reductions ranged from 0.2% to over 2% with the three highest quality studies suggesting that a reduction of between 0.5% and 1.0% could be realistically achieved in this setting. The quality of the evidence presented varies but most provide a good basis on which to design a novel intervention that could be developed for the UK community pharmacy setting.

#### 4.6.1 Strengths and limitations

This review identified a number of significant published articles relating to the effectiveness of community pharmacy diabetes services in a systematic manner. It has identified the current evidence base for this type of community pharmacy service and, importantly, the salient aspects of each project to determine which would need to be considered when developing my own community pharmacy diabetes clinic.

However, although these studies were examined and compared to each other, steps could have been taken to increase the reliability of the results produced. Following the PRISMA guidelines for systematic review and meta-analysis reporting (Moher et al., 2009) there are a number of steps that could have been taken to improve the quality of this review.

In any robust systematic review, study identification and data extraction should be undertaken independently by two researchers. This was not the case in this review due to funding and time constraints. In terms of data extraction, a standardised document should be developed to ensure the same information from each study is reviewed. Again, this was not the case in this review as all data extraction and review were performed by one researcher. Finally, bias e.g. publication or selective reporting in these studies has not been assessed.

If this review was to be conducted again, then a full systematic review with meta-analysis would need to be conducted according to the principles stated in the PRISMA guidelines.

## 4.7 Conclusion

From the evidence presented, appropriately trained community pharmacists have demonstrated the ability to improve clinical outcomes associated with diabetes, however, there still remains a lack of evidence as to whether this is the case in the UK. In developing a novel community pharmacy service a comprehensive training programme, clear inclusion criteria and an intervention that has multiple interactions with the pharmacist over an extended period of time may be the most effective way of improving the control of these patients. However, the extent to which these factors align with the current community pharmacy contractual and operational framework is unknown and requires further research.

To undertake a randomised controlled trial in the UK, the following factors would need to be considered:

### *Randomisation at the level of the pharmacy*

This review has demonstrated that those studies that have randomised at the level of the pharmacy produced the most positive results and have had no problems with recruitment. This may have also been due to the small recruitment target set for each pharmacy, which should also be considered for future studies.

### *Training provision*

All of the included had some aspect of face-to-face learning usually with the two studies that demonstrated the most positive result having aspects of self-directed learning and role play to re-enforce the information provided.

### *Targeting of poorly controlled patients*

The need to target poorly controlled patients was emphasised by the two highest quality studies and the sub-analysis conducted in one article and their associated decrease in HbA<sub>1c</sub>. As stated in the discussion, targeting these patients may provide a better allocation of resources in a publicly funded healthcare system.

### *Multiple consultations*

All of the studies had a significant number of consultations with patients over sustained period of time to achieve the results that were reported. This is a clear theme emerging from the review and may or may not be possible to implement in the UK community pharmacy setting.

### *Improved communication*

Improved communication between the medical practice and community pharmacy was a central component to each of the interventions whether for identifying patients, discussing pharmaceutical care or for the referral of patients whom the community pharmacist could not manage.

However, more work still needs to be conducted to determine what a pharmacist consultation with these patients would consist of as the studies explored here have failed to narrow down the focus of the intervention.



*Chapter Five*

## 5. An evaluation of prescribing for type 2 diabetes in primary care: optimizing the role of the community pharmacist in the primary healthcare team.

### 5.1 Introduction

The care of patients with long term conditions centres around prescribing, monitoring, adherence and the provision of general information relating to the prevention of related conditions and lifestyle and diet advice. This chapter will focus on the prescribing and monitoring aspects of the management of patients with type 2 diabetes to determine if the community pharmacist may have a role in these areas of their care.

In the UK, the National Diabetes Audit (NDA) is conducted annually to determine national and local figures for the number of patients that are achieving goals for treatment with reference to blood glucose, blood pressure and lipids (The NHS Information Centre, 2011b). It also characterises the spending on medicines and devices both nationally and by PCT area, however, it does not provide detail as to whether a patient is being prescribed their medicines in line with national guidance. Nationally, the NDA shows a large population for whom control is not being achieved (The NHS Information Centre, 2011b). As described in the chapter three, it is important that these patients achieve control as this can decrease their cardiovascular (CV) risk as well as renal, ocular and neuropathic complications. A summary of the target levels and the percentage of patients achieving those targets is provided in table 1.

Measure	Target value	% of patient achieving target value
HbA <sub>1c</sub>	<59 mmol/mol	66.5
Blood pressure	<140/80 mmHg	60.7
Total cholesterol	<5.0 mmol/L	78.3
(more stringent target)	<4.0 mmol/L	40.9

**Table 5.1** Summary of targets for diabetes and the % of patients achieving the desired values

From this data there is clear evidence that these patients, particularly with reference to blood pressure control and total cholesterol reduction may need further support to help them achieve these targets. Some areas that have emerged from the review conducted in chapter four is that of medication management and identification of drug-related problems by the pharmacist and liaising with the patient's physician about possible changes to their treatment plan. However, in the UK there have been little data to suggest whether there is a problem with the prescribing in primary care associated with type 2 diabetes and certain co-morbid conditions and whether this may be impacting on the level of control of some patients. Therefore, it is unclear, from a UK perspective, whether the pharmacist should

be involved in this aspect of a patient's treatment. With reference to prescribing in type 2 diabetes, the areas that a pharmacist could target are: drug selection, dose optimisation, monitoring and adherence to treatment.

The National Institute of Health and Clinical Excellence (NICE) has issued guidance on drug selection and management of type 2 diabetes including complications and co-morbid conditions such as hypertension and hyperlipidaemia (NICE, 2009b). These guidance documents provide specific, evidence based and cost-effective treatment options for patients at various stages of their disease. It is important that these documents are adhered to by prescribers so that patients receive the best possible care and the NHS obtains the best possible value from the medicines that are prescribed. Currently in the UK, there is evidence examining the adherence to NICE guidance for other conditions such as type 1 diabetes in children (Edge et al., 2005), epilepsy in children (Chinthapalli et al., 2008), head injuries (Shravat et al., 2006), the use of COX-2 NSAIDs (Price-Forbes et al., 2005) and various other conditions (Sheldon et al., 2004). However, there appears to be no published audits of adherence to type 2 diabetes guidance in primary care.

Within primary care, the management of patients with diabetes is the principal responsibility of the specialist practice nurse with support from the patient's doctor. Other professions within the primary care team have defined roles in the care of such patients e.g. the dietician and the podiatrist. The community pharmacist, part of the wider primary care team, will see the patient on a regular, monthly basis when they collect their medicines but does not have a defined role other than that of medicines supply.

As a result of monthly prescription collections, community pharmacists have the opportunity to develop a long-term relationship with these patients including those that may not be attending the medical practice. There is therefore an opportunity to improve the use of the medicines, the condition and resulting co-morbidities. Pharmacists are already providing adherence based interventions such as medicine use reviews (MURs) and the new medicine service (NMS), however, these focus on a patient's ability to take their medicines and are not clinically focused. This audit will help determine the necessity for clinical medication review in a community pharmacist consultation.

Clinical audit is a useful tool aimed at identifying where there may be problems with an established care process and where treatments do or do not follow relevant current guidelines. It is distinct from research and service evaluations in that these focus on producing knowledge to develop guidelines or policy, or aim to describe the state of a service at one particular time in one particular location respectively (National Clinical Audit

Advisory Group, 2009). In this scenario, NICE guidance will be used as the benchmark for the audit standards.

The purpose of the audit was to determine whether prescribing is in accordance with NICE guidance, patients are adequately controlled and identify any areas where role of the community pharmacist in the primary healthcare team could be refined.



## **5.2 Audit method**

### **5.2.1 Practice selection**

The protocol for this audit is included in appendix nine. Approval for the audit was sought from NHS Norfolk's Research and Development department (appendix 10). NHS Norfolk's prescribing advisors identified ten practices as potential participants in the audit based on their likelihood of participation. Each practice was approached by the relevant prescribing advisor to seek consent to participate. Once agreed, an alphabetical list of all patients at each practice that met the following inclusion criteria was obtained from the practice manager for the researcher.

### **5.2.2 Inclusion criteria**

This audit focused on the adherence of prescribers to NICE guidance for type 2 diabetes. The guidance was originally issued in 2008 and then partially updated in 2009. Before this point there were five separate guidelines that covered the different aspects of care for patients with the condition and certain co-morbidities. The audit focused on the most recent guidance and as such patients who were only recently diagnosed were included as their treatment would be based on the current algorithms. Selecting only those patients who had been diagnosed since 2008 would have potentially reduced the patient population to select from, however, as prescribing practices change it was decided to only go back five years to account for this.

It was also decided to exclude those patients under the age of 18 and those prescribed with insulin as these patients are generally managed by the secondary care team.

#### *5.2.2.1 Summary inclusion and exclusion criteria*

- Confirmed diagnosis of type 2 diabetes within the previous five years
- Aged over 18
- Not prescribed insulin

### **5.2.3 Sample size justification**

With a sample size of 250 the confidence interval around a proportion of 10% non-adherence to NICE guidance would be  $\pm 3.72$  and around a 50% proportion would be  $\pm 6.20$ .

### **5.2.4 Selection of participants**

A random number generator was used to select 25 patients from the alphabetical list provided in each participating practice. If there were fewer than 25 patients eligible then all patients were used. Once a patient was selected, the date of diagnosis, age and medication prescribed was checked to ensure that the patient met the inclusion criteria.

### 5.2.5 Audit standards

100% adherence to NICE guidance for the management of type 2 diabetes in terms of clinical monitoring intervals and achievement of target levels where provided by NICE for HbA<sub>1C</sub>, blood pressure, weight, cardiovascular risk, renal function, lipids, retinal and neurological examinations.

The clinical monitoring criteria state that HbA<sub>1C</sub> and blood pressure measurements should be conducted at least every six months. This frequency rises if the patient is not well controlled for either one of these parameters. The other clinical measurements should occur at least once every 12 months. The target levels for HbA<sub>1C</sub>, blood pressure and lipids are defined in chapter three, however they are summarised in box 4.2.

#### **Box 4.1 NICE target levels**

HbA <sub>1C</sub> :	<59 mmol/mol or 7.5%
Blood pressure:	<140/80 mmHg or <130/80 mmHg if renal, eye or cerebrovascular damage is present.
Total cholesterol:	<4.0 mmol/L
LDL-cholesterol:	<2.0 mmol/L

100% adherence to NICE guidance for prescribed therapy in accordance with a stepwise management approach for diabetes and co-morbid conditions covered by Clinical Guideline 87 (NICE, 2009b) will also be assessed. The stepwise approach to the management of type 2 diabetes and the supporting evidence has also discussed in more detail in chapter three.

### 5.2.6 Data collection

Records were reviewed to determine whether the patient had received the appropriate number of clinical tests in the previous 12 months. A two week allowance for non-attendance at the practice was incorporated. This means that if the patient was due for a blood test two weeks either side of the audit date then data were considered as present. Data were not collected to allow the calculation of renal function.

Medication prescribed for the treatment of diabetes was recorded together with the sequence in which it was initiated and whether there was a clinical need for that medicine i.e. was a patient's HbA<sub>1C</sub> level high enough to justify initiation of a new medicine. Information obtained on blood pressure medication was used to determine whether a patient with hypertension and diabetes was prescribed an angiotensin converting enzyme (ACE) inhibitor or angiotensin II receptor antagonist .

The audit tool (appendix 11) was tested prior to data collection by one of the practice managers to determine if it was possible to collect all the data I set out to collect. This information was fed back to me in order that alterations to the tool could be made. The audit tool consisted of three pages of tables designed for efficient completion. The first page was provided for recording information regarding clinical measures and outcomes, the second; information on diabetes prescribing and the third, information on prescribing in co-morbidities. A code system was used for medicines and class of medicines that made it easier when entering onto the database for analysis. Data were collected and entered by one researcher (MT) for all patients and practices.

## **5.3 Audit results**

### **5.3.1 Clinical outcomes**

Nine practices agreed to participate in the audit from which data for 194 patients were collected. These practices represented a spread in total antidiabetic spending per head and a variation of scores on the Quality and Outcomes Framework (QOF) indicator DM5 (number of patients that had received an HbA<sub>1c</sub> blood test within the previous 15 months). The team achieved a good distribution of practices in terms of dispensing/non-dispensing practices and a mixture of rural, town and city practices, as shown in table 5.2. The mean (SD) age in years for patients was 65.13 (12.1) and the mean (SD) length of time since diagnosis was 29 (17.4) months.

Table 5.3 summarises adherence to the audit standards for the clinical tests and the number of patients achieving targets for those parameters. Practices performed well for the number of patients with a recorded weight, lipid profile and renal function, however, for HbA<sub>1c</sub>, blood pressure and cardiovascular (CV) risk practices were lower than the target 100 % adherence standard set by this audit.

The breakdown of clinical results, cardiovascular risk and BMI is shown in table 5.4 and demonstrates the large number of patients that remain uncontrolled with their diabetes especially with respect to blood pressure and total cholesterol. This table also demonstrates that 86% of those patients audited were classed as overweight or obese and 69% had a cardiovascular risk greater than 20%.

Practice	N	No. of patients on the diabetes register (% of practice population)	QOF indicator DM5 result (centile)	Dispensing / non-dispensing	Location
1	25	269 (4.9%)	68	Dispensing	Rural
2	22	336 (4.2%)	73	Dispensing	Rural
3	25	261 (3.7%)	85	Dispensing	Rural
4	24	133 (4.3%)	76	Non-dispensing	City
5	13	171 (3.0%)	42	Non-dispensing	City
6	25	178 (4.2%)	68	Dispensing	Rural
7	10	300 (4.1%)	42	Dispensing	Town
8	25	261 (4.0%)	75	Non-dispensing	City
9	25	403 (4.1%)	29	Non-dispensing	City
Total	194	2312 (4.0%)			

**Table 5.2** Practice demographics (QOF 2009-2010 data)

NICE Criterion	Recommended frequency of test (months)	% Adherence to monitoring frequency (95% CI)
HbA <sub>1c</sub> measurement	6	79.4 (73.7 – 85.1)
BP measurement	6	71.6 (65.3 – 77.9)
Weight & BMI measurement	12	92.3 (88.5 – 96.1)
Cardiovascular risk assessment	12	31.4 (24.9 – 37.9)
Lipid measurements	12	95.4 (92.5 – 98.3)
Renal function	12	93.3 (89.8 – 96.8)

**Table 5.3** Adherence to testing criteria (N=194 for all tests)

Clinical Test	Number of patients (%) with recorded value	Adherence to NICE standard % (95% CI)
HbA <sub>1c</sub> <58 mmol/mol (7.5%)	194 (100)	82.4 (77.0 – 87.8)
Blood pressure < 140/80 mmHg	194 (100)	61.3 (54.3 – 68.3)
Lipids <4.0 mmol/L	194 (100)	47.4 (40.3 – 54.5)
	Number of patients (%) with recorded value	% (95% CI) of patients with recorded value
BMI	186 (95.9)	
Underweight/ideal weight		14.0 (9.0 – 19.0)
Overweight		28.0 (21.5 – 34.5)
Obese		31.2 (24.5 – 37.9)
Morbidly obese		26.9 (20.5 – 33.3)
Cardiovascular risk assessment	29 (14.9)	
<10%		6.9 (-2.3 – 16.1)
10-20%		24.1 (8.5 – 39.7)
>20%		69.0 (52.2 – 85.8)

**Table 5.4** Patient outcomes

### 5.3.2 Medication

One hundred and thirty nine (71.6%) patients were prescribed at least one medicine to manage their diabetes, 38 (19.6%) patients were prescribed two medicines and four (2.1%) patients were treated with three oral antihyperglycaemics. Fifty five (28.4%) patients were not prescribed any medicines for their diabetes and were presumed to be controlled by diet alone of which only three patients were classed as uncontrolled. All first, second and third line therapies matched NICE recommendations. In 36 out of the 38 patients who were prescribed second line therapy, their HbA<sub>1c</sub> level was sufficiently high

at the time of initiation (>6.5%) to warrant that addition. For third line therapy, three out of four patients met the NICE recommendations for additional therapy (HbA<sub>1c</sub> >7.5%).

For those prescribed a Thiazolidinedione or DPP-4 inhibitor, NICE states there must have been a 0.5% drop in their HbA<sub>1c</sub> level after six months of treatment for it to be continued. This was the case in four out of the twelve prescribing incidences. Two did not see a decrease, of which one was stopped and one was not. Data were unavailable for the remaining patients as they had only been recently prescribed.

A total of 135 patients were prescribed at least one medicine for hypertension of which 118 (87.4%) were prescribed an ACE inhibitor or angiotensin II receptor antagonist. There were 37 (27.4%) patients prescribed a  $\beta$ -blocker, currently 4<sup>th</sup> line in NICE guidance and not recommended due to their effect on carbohydrate metabolism.

Finally, 74.7% of patients were prescribed a lipid-lowering medication and 39.7% of patients were prescribed an anti-thrombotic medication e.g. aspirin. In patients who had un-controlled lipid levels (total cholesterol level >4.0 mmol/L; n=101) 38.6% were not prescribed any lipid-lowering medication.

#### **5.4 Audit discussion**

From the results it can be seen that there is generally good adherence to the audit standards with reference to NICE guidance. The majority of patients were undergoing the appropriate clinical tests at the recommended intervals and the medicines for diabetes and blood pressure were being prescribed in accordance with recommendations made by NICE. The discussion of this audit, and where the pharmacist may have a role, centres on managing cardiovascular risk, medication dosage and adherence as these have been identified as potential gaps in current care.

The reporting of CV risk assessments varied according to practice and therefore further research would be warranted to determine the exact figure. The majority of data required to perform a CV risk assessment was found in patient records. This deficit in reporting could therefore be rectified by the appropriate use of software within the medical practice. Currently, many community pharmacies are providing a CV risk assessment service or health-check enhanced service aimed at primary prevention of cardiovascular events (PSNC, 2012a) and are aimed at a population that would not ordinarily interact with the medical practice. The patients audited here already have all of the details needed to perform a CV-risk assessment recorded at the medical practice therefore it may not be appropriate for pharmacists to unnecessarily measure these patients for a second time when all of the information required has already been obtained.

However, of the patients that did have a documented CV risk, 70% were in the high category. CV risk is composed of several factors such as blood pressure and total cholesterol and once identified and appropriately communicated to the pharmacist, evidence has shown that they may have a role in reducing this risk by modification of blood pressure and lipid-lowering therapy (Lowey et al., 2007). This study was conducted in a hospital setting and therefore further work would need to be conducted to determine if the results are generalisable to the community pharmacy setting.

In this audit over four-fifths of participants were classed as either overweight or obese. With the link between increased weight and increased blood pressure firmly established (Stamler et al., 1978), it may also be appropriate to target weight management as a proxy to reducing blood pressure and therefore CV risk. There is some promising evidence that weight management clinics in community pharmacy can produce significant results, however these need to be investigated further (Blenkinsopp et al., 2008).

All medicines to treat diabetes were prescribed in line with the most recent NICE guidance and if a patient required an additional medicine to control their HbA<sub>1c</sub> level, this was initiated at the appropriate time interval. Medication to treat hypertension was simply listed



on the audit tool and not sequenced as with diabetes medication, due to the complex nature of a patient's condition and that some of the medicines had been prescribed pre-diabetes diagnosis therefore making it difficult to compare to the NICE guidance. This finding has been confirmed in previous research (Simoens et al., 2009). However, at the point at which the audit was conducted the majority of patients were prescribed ACE inhibitors or ARBs which is ideally first line therapy for patients with type 2 diabetes due to its reno-protective effects.

The low prescribing rate of aspirin may be a reflection of the recent evidence that it has limited benefit for primary prevention of cardiovascular events in diabetes (Chunyu et al., 2010, De Berardis et al., 2009). However, it may be appropriate for pharmacists to approach patients to ascertain if they are aware of this new evidence and if they have discussed it with the GP or practice nurse.

In terms of control of lipid levels, there were 25.3% of patients not prescribed a statin and of those classed as uncontrolled (n=101) almost 40% had no prescription for a lipid lowering medication. This is a routine medication for patients with type 2 diabetes apart from those that are under the age of 40 and who have a low cardiovascular risk profile.

With reference to monitoring, approximately one fifth of patients did not receive a blood glucose measurement and almost a third of patients did not receive a blood pressure measurement at least every six months. Blood pressure monitoring is a service widely available within community pharmacies and therefore, with appropriate communication systems between medical practices and pharmacies, may be a means for pharmacy to contribute to adherence to NICE guidance.

The monitoring results indicate that there are still a number of patients who are not controlled on their current medications with reference to HbA<sub>1c</sub> (approximately one fifth), blood pressure (approximately two fifths) and cholesterol (over half). This may be due to inadequate dose titration by the prescriber (data that was not collected), the need for additional medicines to be prescribed, current medicines are not working or the patient is non-adherent.

This audit set out to determine if any gaps in care could be identified in terms of prescribing for type 2 diabetes. It demonstrated that the prescribing of medicines is in line with NICE guidance, although information was not obtained regarding doses. Therefore, this implies that there may be little role for the community pharmacist in changing the medicines prescribed for diabetes. The audit does not, however, provide information regarding dose optimisation or adherence in this group of patients. If it is found that there

is a problem with either of these, in future work, then dose optimisation may require the use of the patient's medical record and therefore it may be appropriate for this aspect of care to be conducted by a healthcare professional at the medical practice e.g. GP, practice nurse or primary care pharmacist. However, adherence is an aspect of care that may not require the use of the medical record and could potentially be conducted by community pharmacist as well as those professionals in the medical practice.

Through regular attendance at the pharmacy to collect their medicines, it may be appropriate for the community pharmacist to become more involved with these patients. In response to a significant lack of therapy effectiveness, through patients not taking their medicines, the Government has introduced brief pharmacist-led, adherence-focused interventions e.g. medicine use reviews and the new medicine service to increase the responsibility placed on the pharmacist in patients with long-term conditions. However, these new services do not have a robust evidence base supporting their implementation.

In conjunction with this, it may also be appropriate for community pharmacists to become involved in blood pressure management with its associated effect on the development of diabetic complications and cardiovascular risk. Pharmacists have already demonstrated that they can perform this type of management service in the hospital setting; however, the extent to which community pharmacists, in the current contractual and operational framework, could achieve the same results may be limited.

These aspects of care that have been identified as appropriate for the community pharmacist to conduct could also be beneficial to the medical practice as well as the patient. The pharmacist could contribute to the medical practice's targets on the Quality and Outcomes Framework (QOF) by measuring blood pressure, managing weight and managing cardiovascular risk. This information could then be fed back to the practice which may lead to increased collaboration between the two groups of professionals.

#### 5.4.1 Limitations

This audit was only conducted in nine practices in Norfolk and therefore the results have limited generalisability. The audit covered the medicines prescribed for diabetes and co-morbid conditions. It did not include other aspects of care covered by the NICE guidance such as smoking status or lifestyle advice given to the patient. Half the practices audited were dispensing practices and as such patients will not have access to a community pharmacist and ways of building a model for these patients need to be considered.

All of the audit results were communicated to the medical practices involved. However, due to time and funding constraints there is no plan to re-audit.

## 5.5 Audit conclusion

Prescribing for type 2 diabetes is generally in line with national guidance. There are, however, still uncontrolled patients and this may be due to lack of dose titration, the need for further medicines to control their condition or adherence problems on the part of the patient. The community pharmacist, who has the opportunity to interact with the patient on a monthly basis when they collect their prescription, may have a role in improving adherence in uncontrolled patients due to their access to the patient medication record and experience at providing similar services. In future they may be able to identify these patients by the use of summary care records that are being phased in across the country. However, for this to be effective, good lines of communication between themselves and the medical practices would be required.

The audit has demonstrated that it may not be appropriate for community pharmacists to be conducting CV-risk assessments on this group of patients as most of the data already exist in medical practice records. However, it may be appropriate for pharmacists to target those patients that have already been identified as having a high CV risk and provide weight management, blood pressure and lipid-lowering management services to them, if the medical practice referred such patients to the community pharmacy.

In terms of developing an intervention for patients with type 2 diabetes to be delivered in the community pharmacy, the pharmacist should be targeting poorly controlled patients as these are the patients who are most likely to gain long term benefits from a reduction in HbA<sub>1c</sub>, blood pressure or lipids. At present, these patients would need to be identified from medical practice records as community pharmacists do not have the ability to identify their level of control. The intervention should be focused on either adherence which is already conducted as part of the MUR service. Any new type of service may be a more advanced version of the MUR, something which community pharmacists are already familiar with and may require little additional training to perform.

In this chapter, the aspects of an intervention that would be appropriate for a community pharmacist to conduct have been discussed. The next chapter will discuss the patients' perspectives on the role of the community pharmacist in their care. It is important that this is characterised so that a service is designed with patients in mind and is something that they are likely to engage with.

 *Chapter Six*

## **6 Focus group discussions with type 2 diabetes patients**

### **6.1 Introduction**

The next stage in the development of this complex intervention involves approaching patients to ascertain their views and experiences of their community pharmacist and the role they play in their care. This will be central to understanding where a particular intervention would be best targeted and whether patients with this condition would engage with such a service to help them control their diabetes. It will also prove useful as there is a lack of UK literature available to ascertain the conditions under which such a service would be viable with patients in the context of the NHS.

As previously discussed, the main government vision for community pharmacy in the UK is for pharmacists to assume greater responsibility for the management of medicines for patients with long-term conditions including diabetes (Department of Health, 2008). To achieve this transformation, public perception of the role of the community pharmacist may also need to be changed as many people still view the main role of the pharmacist as one of medicines supply (Gidman et al., 2012).

The limited research available on patient perceptions of community pharmacists suggests that they are currently not considered the primary source of information about health matters, but do have a role in relation to the provision of advice related to medicines supply (Anderson et al., 2004). Whilst some patients report an educational benefit from the services a pharmacist provides (Johansson et al., 2009), others prefer to see their own doctor about matters relating to their health and treatment (Hibbert et al., 2002, Salter et al., 2007).

Much of the available UK evidence for patient satisfaction with the pharmacist derives from questionnaires completed by patient research participants (Bissell et al., 2008, Tinelli et al., 2007), which is informative but does not provide us with perception held by the general public or even regular pharmacy visitors. A survey of patients participating in a randomised controlled trial of a medication management service reported both positive and negative comments regarding the involvement of the pharmacist in their care (Bissell et al., 2008). They liked how the pharmacists appeared to listen to them for longer than they expected the GP would do and found it a good source of reassurance that another healthcare professional was interested in their care. Some were surprised at how much the pharmacist knew about the medicines they were taking. However, when considering whether the pharmacist should make recommendations to the GP for their treatment they expressed more anxiety, citing concerns regarding drug companies' influence on pharmacists, and their need to make profit and so preferred that the GP should make the

final judgements on any treatment recommendations. As discussed in chapter one, findings from Tinelli et al. also confirm this preference, shared by over three quarters of participants (n=1355) in their study who still prefer to discuss their medicines with their physician, even after a pharmacist intervention (Tinelli et al., 2007).

In a recent US study by McAuley et al. patients with epilepsy were asked to complete a questionnaire about their perception of the current and future role of the pharmacist in their care. Patients used their pharmacist for information about drug interactions and side effects, with fewer patients wanting to discuss their condition, adherence and impact on their lifestyle (McAuley et al., 2009). Many patients (n=75) in the survey identified that the pharmacist had the knowledge and time to discuss with them their epilepsy medicines and the condition but was impeded from doing so by the space that is available to them in the pharmacy.

Most recently, research was conducted in the US to ascertain the patient's perspectives on information they wanted about their medicines and the barriers to asking pharmacists questions. In brief face-to-face interviews (n=600) in the pharmacy setting, participants were asked to comment on the role of the pharmacist and what information they desired from them at the initial dispensing of a medicine and the repeat dispensing of a medicine. Participants generally sought information such as basic instructions for use, adverse effects and drug interactions. However, participants collecting repeat medicines; mainly sought information about repeats remaining on their prescription with relatively few wanting a reiteration of the initial information. The barriers to asking pharmacists questions fell into two categories: patient and pharmacist-related. The patient barriers included fear or embarrassment, lacking initiative, having no need for any information and time constraints. The barriers perceived as relating to the pharmacist were being unapproachable and not being seen as a credible information source. Participants again highlighted their trust in the physician to provide most of their information but also that by speaking to the pharmacist they were in some way going against their doctor (Krueger and Hermansen-Kobulnicky, 2011).

Specific patient groups have highlighted where they view the role of the pharmacist and this largely depends on their personal experience. Patients also have an idea about how far this role extends to the greater management of their condition with most indicating that they still need the physician to be involved in their care if they are to trust what the pharmacist is doing for them. This is important information if the government's vision for pharmacy, as described in previous chapters, is to be realised in patients with long-term conditions.

Patients with diabetes, particularly those who are newly diagnosed, often do not understand the seriousness of their condition. They assume they can control it themselves until they reach a point at which they start developing symptoms or complications and this can have an impact on the extent to which they seek advice from healthcare professionals (Thoolen et al., 2008). It has been suggested that clear plans for treatment and information provision to patients with diabetes is both helpful and has an impact on behaviour (Peel et al., 2004, Polonsky et al., 2010). In patients who are prescribed insulin (for type 1 and type 2 diabetes) this is particularly important as adherence barriers include time available to inject, emotional problems or embarrassment and that less restrictive regimens that take account of a patient's lifestyle may improve blood glucose results (Peyrot et al., 2012). There is also evidence to suggest that patients who experience episodes of hypoglycaemia have greater levels of fear and worry about their condition (Williams et al., 2012).

The perceptions of patients with diabetes regarding the current and future role of the community pharmacist in the UK in addressing some of these problems have not been ascertained. If community pharmacists are to assume a greater role in the management of long-term conditions, understanding the patient perspective will help to facilitate this role change. This chapter will examine patient perspectives on the current and future roles of the community pharmacist in the management of type 2 diabetes.

## **6.2 Aims and objectives**

### **6.2.1 Aims**

To describe the relationship between a community pharmacist and patients with type 2 diabetes and where patients see the pharmacist having the greatest role in their healthcare in the future.

### **6.2.2 Objectives**

The objectives of the focus groups were to understand:

- how diabetes affects patients' lives
- when and in what situation patients would deem it appropriate to see the pharmacist and what bearing their condition has on this decision
- the extent to which patients interact with different healthcare professionals when discussing their diabetes
- the personal experiences of patients with the community pharmacist
- the view of patients regarding the community pharmacy environment
- how patients see the role of the pharmacist developing



### **6.3 Focus group method**

The protocol and supporting documentation for this study are included in appendix 12. This study received UK ethical approval from the Cambridgeshire National Health Service (NHS) Research Ethics Committee (appendix 13) and governance approval from NHS Norfolk's Research and Development Committee in 2011 (appendix 14).

#### **6.3.1 Focus group rationale**

The data that I was aiming to collect revolved around patients' current experiences and thoughts on the future role of the community pharmacist. I had anecdotal knowledge from my practice, that many patients would have experiences of the community pharmacy that were limited to the collection of their prescription. Therefore, focus groups with patients were chosen as a method in order to collect data on their experiences but also to explore how they viewed other patients' experiences of interacting with the pharmacist. The aim of the project was not to gain an in-depth knowledge of the patient's own experiences but rather to understand the norms of this group of patients when visiting and interacting with the pharmacy support staff and pharmacist. Focus groups can encourage group discussion and debate about the topics raised and highlight a wider range of experiences and understanding (Kitzinger, 1995). They can also be more useful at exploring criticism than in-depth interviews as participants may be more likely to express diverse and contrasting views in a group setting than one-to-one (Kitzinger, 1995). This debate can lead to explication of personal processes and norms that otherwise may have gone unchallenged in an individual interview. I was not looking for a one-size-fits-all approach to be generated at the end of each focus group discussion or, overall, for this study. Rather, the focus groups were seen as providing contextualising information to understand how a variety of patients' recent experiences may have affected their diverse perceptions of the community pharmacist and pharmacy.

#### **6.3.2 Participant recruitment**

I gained the agreement of 20 community pharmacies in Norfolk to assist in the recruitment of patients. These included small independent pharmacies, large multiples (chains) and supermarkets in a variety of locations across the county. Patients that presented at one of the pharmacies with a prescription for a medicine to treat type 2 diabetes were informed about the study and given an information sheet by the pharmacist. If they were interested in participating, they were given a consent form to complete in their own time. This was returned directly to me. Pharmacists distributed most of the information sheets they had been given (n=32 for each pharmacy). Potential participants were asked to complete a series of demographic questions on the reverse of the consent form. These asked about age, gender, length of time since diagnosis and number of medicines on their repeat prescription form.

Once the consent form had been received, participants were entered into a pool from which participants were selected for each focus group based on their answers to the demographic questions. The reasons for selecting the four demographic characteristics on which to base sampling are detailed below:

**Gender:** There is evidence to suggest that men and women cope differently with type 2 diabetes and that it can impact on their ability to handle the condition (Svenningsson et al., 2011).

**Age:** As age increases, a patient is more likely to be prescribed more medicines (Skegg et al., 1977) and therefore may have a more in-depth experience of visiting the pharmacy and interacting with pharmacists.

**Number of medicines prescribed:** If patients are prescribed more medicines they may be visiting the pharmacy more often and interacting with the pharmacist.

**Length of time since diagnosis:** Those patients who have been diagnosed with a long-term condition for more years may have had the opportunity for more involvement with the pharmacist as they will have visited the pharmacy on more occasions since diagnosis.

Ethnicity was not chosen as demographic data for Norfolk suggested that it may be difficult to recruit on the basis of ethnic background (Norfolk County Council, 2004). Each of the participants was given a £10 voucher as a thank you for attending.

### 6.3.3 Participant selection

Data were collected over three months between May and July 2011. For the initial focus group, maximum variation sampling (Patton, 2002) was used to gain an overview of the widest variety of participants' views and experiences. While eight was the maximum target number of participants in each focus group, inability to attend and non-attendance resulted in eight participants in the first focus group, seven in the second, six in the third and four in the fourth. The sampling strategy was informed by a process of constant comparative analysis. After initial analysis of the second focus group, which highlighted the potential relevance of repeated visits to the pharmacy to patients' views, the decision was taken to invite only those participants who had either been diagnosed for a long period of time or those that were prescribed a high number of medicines. The aim was to determine whether specific views and experiences were more likely to be shared to patients with an extensive experience of visiting the pharmacy. The subsequent fourth group returned to a general sample to verify the findings from the previous groups. No new themes emerged from analysis of the fourth focus group's data, indicating that data saturation was likely to have been achieved.

#### 6.3.4 Topic guide

During the focus groups, participants were asked open questions about their current experiences of the pharmacist and what they thought the future role of the pharmacist should be. Their views were elicited by using a set of small scenarios of common pharmacy experiences (set out in Box 1.) derived from my personal experiences of working in community pharmacy and the current literature on novel pharmacy services directed at this group of patients. Scenario 3 was based on research conducted by *Krass et al.* in Australia which indicated that a person-centred, flexible intervention had a positive effect on a patient's sense of control of their condition (Krass et al., 2007). These scenarios were used to stimulate discussion around the research question as many participants will have had diverse experiences likely to reflect those indicated in one or more of these scenarios.

#### **Box 1: Scenarios used to stimulate discussion**

**Scenario 1:** You pick up your prescription from the pharmacy once a month, a counter assistant hands it to you and you never speak to the pharmacist.

**Scenario 2:** As number 1 except once a year you have a chat with the pharmacist about your medicines in the pharmacy consultation room.

**Scenario 3:** As number 2 except patients with poorly controlled diabetes have more consultations with the pharmacist to try and improve their condition. The number of consultations would be based on patient need over a period of about 4-6 months.

#### 6.3.5 Data analysis

All focus groups were audio-recorded and transcribed by me. The transcripts were analysed independently using the principles of thematic analysis (Braun and Clarke, 2006) without reference to the original material by two researchers (myself and my supervisor). Thematic analysis is a widely used framework for analysis of meanings derived from qualitative data as it can summarise key features of a large body of data whilst offering 'thick description' of the data set (Braun and Clarke, 2006). The thematic analysis process is described previously in chapter two. No software was used to analyse the data.

We met several times during the study to discuss and agree the emergent themes, this was completed in the final meeting. If there was a discrepancy between the views of the researchers, discussion was held and a compromise achieved based on reference to the original data. The final report was independently checked for consistency with the transcripts and themes by two researchers (myself and my supervisor). Disagreements were resolved by discussion amongst ourselves and the wider research team.

## 6.4 Focus group results

Forty-four patients were consented from whom 25 participants were recruited and attended one of the four focus groups. The remaining participants were not selected either as the demographic information made them less suitable, or they were unable to attend one of the focus groups. Participant characteristics are detailed in Table 6.1.

Focus group	Participant number	Demographics			
		Age (years)	Gender	Length of time since diagnosis (years)	Number of medicines on repeat list
1	1	61-70	M	5+	2
	2	61-70	M	5+	6
	3	51-60	M	5+	10
	4	51-60	F	5+	8
	5	51-60	F	5+	4
	6	71-80	M	5+	10
	7	61-70	F	1-2	5
	8	71-80	F	2-5	3
2	1	41-50	M	1-2	2
	2	61-70	M	2-5	4
	3	61-70	F	2-5	4
	4	71-80	M	5+	11
	5	61-70	M	5+	7
	6	61-70	F	5+	5
	7	61-70	F	5+	8
3	1	61-70	F	5+	10
	2	61-70	M	2-5	9
	3	61-70	F	5+	10
	4	71-80	M	5+	18
	5	71-80	M	5+	9
	6	71-80	F	5+	11
4	1	51-60	M	1-2	6
	2	51-60	F	0-1	5
	3	61-70	F	5+	3
	4	51-60	M	5+	13

**Table 6.1** Participant demographics

Participant data from the four focus groups, provided accounts of varied experiences of the community pharmacy and views about the role of the community pharmacist in their

care. These views fell into two broad themes: the place of pharmacy in the wider primary care team and the pharmacy as a healthcare destination.

#### 6.4.1 The place of pharmacy in the wider primary care team

##### *The need for information*

Many participants in our focus groups expressed their needs for information about their disease, medicines and lifestyle. Some were quite knowledgeable about their condition, but still described occasions where they would have liked more information or advice and the opportunity to seek this from an appropriate healthcare professional. This information included advice on diet, side effects of medicines, interactions between medicines (including over-the-counter preparations) and alternatives to their currently prescribed therapy. They also wanted to know why they were prescribed so many medicines, and why they were prescribed them, particularly when first diagnosed.

“I felt as if I had gone from being healthy and no tablets to all of a sudden, I must be, well I have got all these tablets and I don’t really want them erm coz my blood pressure is ok, it’s a little bit on the high side, but needed to come down but probably if I wasn’t diabetic I wouldn’t have been put on anything erm and the same with statins and I felt quite vulnerable really.” **(F3, FG4 (female number 3, focus group 4)**

Here, this participant is pointing up the suddenness and quite intimidating prescription of medicines for not only their diabetes but also other conditions. This participant’s lack of understanding as to why these medicines have been prescribed might reflect a collective failure to provide information by any of the various healthcare professionals involved in this participant’s care.

One theme that emerged emphatically from all focus groups concerned taking responsibility for their own condition especially with regards to managing their blood glucose levels and that they had occasional needs for advice from an appropriate healthcare professional to be able to achieve this.

“I feel that part of type 2 diabetes is managing a lot of it yourself to some extent with guidance from the GP and the pharmacist” **(F7, FG2)**

All participants identified the need for some formal regular review of the control of their diabetes to provide them with the information they needed to prevent developing complications. In one case, during the first focus group, participants themselves

expressed anxieties when one of them revealed that they had not received a review in some time:

“I think you had better go to the doctors and stamp your feet, it doesn't seem like they're doing it properly at all” (**F3, FG1**) and “that's the only way you know you're looking after yourself, if not how do you know that you're... I'm quite concerned for you actually” (**M1, FG1**).

Such comments emphasised the intense feeling in relation to this topic. Some participants specifically identified the need for an alternative source of information to the GP because they were not always available when the need arose.

“if you want to talk to somebody about the problem, coz sometimes with diabetes you do have problems, you can't not always get to the doctor coz as good as he is and you really want someone to be able to speak to.” (**M1, FG1**)

All of these types of information requests and topics contained within them could be addressed within the professional competence of the community pharmacist, however, whether these participants would be likely to approach the pharmacist for advice on these topics depended on a variety of factors including: perceived expertise of the pharmacist, their perception of the healthcare hierarchy, their experiences of the medical practice and the healthcare environment the pharmacy setting provides.

#### *Perceived expertise of the pharmacist*

All participants identified that the primary expertise of the community pharmacist was medicines supply and advice regarding over-the-counter preparations and the interactions with their prescribed medicines.

“if you want to query anything you want to take, like I'm not a very good traveller on the sea so I wanted some tablets to take for sea sickness so I asked him [the pharmacist] and you could say what would go with the tablets I was taking” (**F3, FG3**)

There were differing views about how much further the pharmacist's role extended to advising on prescription medicines and disease advice. Their perceptions of pharmacist expertise appeared to vary with their length of time since diagnosis and the number of medicines prescribed. Participants who had lived with the condition for a long time or were prescribed a large number of medicines acknowledged the pharmacist as someone with greater expertise than the doctor or nurse when discussing medication. These 'more

experienced' participants viewed the pharmacy as somewhere they could obtain much of the advice they wanted, that was easy and convenient to access and felt that if the pharmacist could not deal with the problem they could rely on them to refer patients to the doctor or nurse.

“you can't always get in to see your doctor, that quickly but I mean er you know you can just whip in there and they will at least give you a good bit of advice if you know nothing else” **(F6, FG2)**

However, there was still general unease, even in this group as well as those with less experience, of wanting to talk to the pharmacist about, or acknowledge their ability to provide advice on, the condition of diabetes.

“the thing to do with pharmacists is that I wouldn't necessarily go to my pharmacist and ask about my erm health around my diabetes I would go and ask “I have got a raging cold can I take this?”, and that's where I find my pharmacist really helpful” **(F5, FG1)**

“you know if I've got a bad cold or something, that would be the pharmacy but like discussing anything else that certainly wouldn't be the pharmacist” **(F3, FG2)**

This highlights the perceived expertise of the pharmacist as someone who can help and advise patients with regards to over-the-counter medicines and minor ailments but whom they would not approach for advice regarding their diabetes. A potential reason for this is explored in the next section.

#### *Experiences of the medical practice*

In all focus groups it was apparent that those participants who had a good relationship with, and received all their information from, the medical practice had little desire to seek further information from the pharmacist beyond that of prescription supply and over-the-counter requests. Even after hearing positive experiences of other participants' information they had doubts about whether the pharmacist was the right person to approach for advice about prescription medicines or their condition.

“she [the nurse] explains in great detail what that's for and if there's any side effects then ring me, which when I first started taking it I did, took a couple of weeks, just made a phone call, obviously she was busy, she phoned me back and hour or two later and made another suggestion so there's no need to go to the pharmacist, just make a phone call” **(F3, FG2)**

Conversely, those who described either a poor relationship with their medical practice or having received little information from them identified the pharmacy as their first port of call as they continued see them regularly to pick up their prescriptions and they found it easy to ask them questions.

“well I find our pharmacist very very good I mean he’s far better than my doctor , we could talk to him can’t we and he’ll help you, he know most things and erm he’s just brilliant you know. We can talk to him about things we couldn’t with the doctor or the practice nurse and he just... help quite a bit with the different things, if he can help you he will, he is brilliant” **(F6, FG3)**

However, even those participants who identified the pharmacist as their first port of call, would not necessarily act on advice without first confirming it with their doctor. This is something that can be explained by examining their perception of the healthcare hierarchy.

#### *The healthcare hierarchy*

Participants saw it as extremely important to take note of whether advice given by someone needed to take into account a health professional’s position in what they saw as a healthcare hierarchy when deciding whether to act on advice that a professional gave them. Participants tended to view their GP as the ‘controller’ of their medical care and that he/she was the person who took overall responsibility for treatment and care for their condition. This appeared to impact on whether they felt comfortable approaching other professionals and most therefore suggested that they would need the doctor to validate the role of the pharmacist in their care before they could commit to any advice the pharmacist had given them. Participants stated they would be unwilling to let the pharmacist change their prescription medicines unless the doctor had agreed that this was the correct thing to do and had assessed the situation themselves.

“if the pharmacist suggests it to you then you go to the doctor with it and that suggestion but I would be reluctant to rely entirely on the pharmacists decision that this is different, that this is better or... I wouldn’t take advice from a pharmacist without, especially over the change of medication, without seeing the doctor but then I have got a very good doctor as well” **(M4, FG2)**

This participant appears happy to have received advice from the pharmacist but the extent to which he acts on it depends on the relationship with the doctor, in his case a good one,



and therefore that means he will have to pass this through them before he can proceed with implementation.

“If I’ve got a problem with managing my diabetes I go to my diabetic nurse or the doctor because for me I would want to know what it is that’s causing the problem... I’d be asking about do I need to increase the tablets erm or do I need to go onto insulin or something like that, whatever the situation might be I can’t imagine I could go to the pharmacist to do it because that’s not what I’ve really thought that pharmacists do, pharmacists manage the medication and hand it out and they are kind of behind the scenes boys if you like” **(M4, FG4)**

These participants are commenting on what seems to them the anomalous positioning of pharmacist’s authority in the primary care team especially with regards to medicines management. They may have the knowledge to be able to advise patients with regards to medicines, side effects, interactions and supply, however they do not have the ability to make these usually small, distinct changes to their treatment. This does not necessarily extend to advice regarding their condition; they view this as the primary responsibility of the GP and not the pharmacist. As the previous participant highlighted, the types of queries a patient may have are often longer and more complex than the issues they may have surrounding medication. Therefore the GP, with more information, such as blood test results, is acknowledged as being in a better position to advise them.

In relation to pharmacy service provision, whilst some participants had already experienced being offered and had participated willingly in the medicine use review (MUR), an adherence-focused pharmacy service, some said they would want a doctor to refer them to the pharmacist if, as a patient, they were to perceive any benefit to it and if they were to engage with it fully. Repeatedly in the focus groups, participants refer to ‘joined up care’ and at present their perception of the pharmacist is of them offering isolated, and sometimes duplicating, interventions.

“I’ve been offered it [MUR] but very nicely declined it, I didn’t feel I needed it, having been seen down at the surgery and stuff, I have been offered it” **(F3, FG4)**

Again, participants wanted the doctor to initiate and validate pharmacist-led interventions.

“if the doctor referred me I’d be happy but if the pharmacist just took it on himself I wouldn’t be happy... but I would think if the doctor said go and see the pharmacist to discuss it that would be good.” **(F1, FG3)**

For these participants to engage fully with the pharmacist and to understand what their role may be in the primary care team, pharmacists would need to be seen as more integrated within the team whilst still maintaining the position of the doctor as overall 'controller' of their medical care. For most participants, pharmacy is seen to occupy a unique place in the primary care team in relation to medicines supply and over-the-counter advice, which is recognised as their primary role. Participants with more experience of interacting with pharmacists are more willing for them to become involved in wider aspects of their care, with the proviso that it could be seen to be 'joined up' with the work of the rest of the primary care team and that they understood why the pharmacist was becoming involved and what they could add. However, it is important to note all participants had reservations as to how this could be achieved in the current community pharmacy environment.

#### 6.4.2 The pharmacy as a healthcare destination

Since 2005, community pharmacy has had to become more patient-focused, however, it is clear seven years after the commencement of the new pharmacy contract, that our participants still had concerns about the pharmacy being somewhere they would be willing to discuss private medical problems. These concerns relate to space, time, privacy and relationships with the pharmacist. However, this was also a topic on which there was marked diversity between different participants' perspectives regarding what they perceived as acceptable or as their priorities.

The starkest contrasts were in their diverse views on supermarket pharmacies and 'local' pharmacies. Many participants thought that supermarkets lacked the privacy to enable them to fully discuss their medical problems with the pharmacist. Others thought that the supermarket pharmacy was ideal for their convenience. However, all pharmacies (supermarket and 'local') came under critical scrutiny as being less likely to allow discussions to be conducted with sufficient privacy. So the supermarket pharmacy environment might be equated with the supermarket counter.

"Occasionally I have gone to the supermarket pharmacy... they'll start talking openly in a supermarket, over the counter to you about your condition. Now, I don't want to do that, I don't want other people listening to what my problems are... It's that lack of privacy that I don't like, discussing over the counter that I don't like that I think that's awful" (M4, FG4)

However, other participants saw any crowded place, including the medical practice pharmacy as being at least as restrictive in terms of privacy.

“I mean if I went to the one at the medical practice it’s not a big pharmacy, and quite often it’s packed with people so you’re still going to be standing there at the counter and it’s all people listening so I can’t see there’s any difference, not for me.” **(F2, FG4)**

For others, any loud conversation conducted in earshot of anyone else would be public.

“erm its erm quite a public place. If the pharmacist speaks to you, you’re in earshot of everybody else.” **(M1, FG1)**

These quotes illustrate the public nature of the pharmacy environment and the discomfort caused with discussing medical problems in this setting. Compared to the medical practice, with private consultation rooms as standard, it is not surprising that participants identified their absence in the pharmacy environment as a flaw for conducting confidential conversations. This lack of a suitable, formal and uninterrupted consultation space also appeared to impact on whether participants were likely to request a conversation with the pharmacist.

Participants also highlighted the visibly multiple calls on the pharmacist’s time and how this might affect their availability to answer any questions they may have. This lack of a formal individual appointment time also impacted on whether they were likely to approach the pharmacist for advice.

“it seems very intrusive to take him away from his job to do something that I feel is not part of what his job is, it, I always view the pharmacist as someone who gives you your medicine, mixes it up for you if necessary and dispense it to you as the doctor has prescribed it and you take it as prescribed and I would view the doctors surgery is the place to go for advice and not the pharmacist” **(M1, FG1)**

Giving dedicated time to individual patients is not seen as part of the pharmacist’s professional public role, so much so that talking to the pharmacist can be seen as “taking them away from their job”.

“in my experience I not seen the pharmacist at all, I mean they’re just so busy, you know, and er you feel you are imposing if you say to him can I have a word about this?” **(M2, FG2)**

The pharmacy environment itself is seen as too busy a place to be individual-focused.

**5:** ...everybody that go in the chemist is always asking questions

**6:** oh he's always talking to somebody

**5:** always so busy, always! And that's only a small little chemist but that always busy and run off their feet sometimes" **(M5 & F6, FG3)**

Whether community pharmacists were actually and equally busy over the course of the working day was not discussed during the focus groups however, it was an important and commonly-shared perception. In primary care, pharmacists are the sole profession where patients can observe them conducting almost every part of their job, from dispensing to advising patients on the counter. No other profession experiences this in primary care and it appears to undermine the possibility that patients feel they can approach the pharmacist to obtain the advice they may need to control their condition more effectively. This perception appeared to be moderated slightly if the participants knew their pharmacist and therefore knew more about the terms under which they could be approached for advice.

Despite the qualifications and limitations in their perceptions of circumstances in which they might seek advice from pharmacists, all participants saw the pharmacist-patient relationship as extremely important. To enable this relationship to exist, participants pointed to the need for the pharmacist either to be there all the time, or to be able see a regular face, and for both the patient and the pharmacist to know each other's names. This was viewed as central for patients to be able to trust the advice that was being given to them or to seek advice from the pharmacy in the first instance.

"the relationship part of it is very important, it's the trust got to build, you can't just have the locum pharmacist coming in and you know he knows nothing about you... you build that relationship before you put your trust in them." **(F7, FG1)**

This quote highlights a distinction made between locum and regular pharmacists. While there is no assertion of any difference in their clinical abilities, it is the regular pharmacist's knowledge of patient specifics that the participant views as important, something that they see the locum as lacking.

"I find it much easier to go in if you know the pharmacist... if I go in with any queries or anything and you know I'll say to the assistant you know can I just speak to [the pharmacist] and he'll come through and we'll discuss things" **(M4, FG3)**

This participant focuses on the impetus to go and ask the pharmacist questions. He implies that there is an initial barrier to asking questions, which is one of knowing each

other which would make it difficult to approach a pharmacist if they did not know them already.

“it is a convenience and because you know him like, you know your pharmacist, he is more like a friend” **(F3, FG3)**

This highlights a potential difference in the relationship dynamics between the patient and pharmacist and the patient and GP in viewing the pharmacist as more of a friend than a formal healthcare professional and potentially more approachable.

Those participants that had experienced a consultation with the pharmacist made some interesting points about the space and environment in which it was conducted and their thoughts about being initially invited for a consultation with the pharmacist which they did not necessarily know how to interpret at first.

“a bit strange, yeah a bit strange but yeah fine yeah that’s that’s not a problem or an issue at the end of the day. I rather know, I’d rather make sure I know what I’m taking, rather than not know what I’m taking” **(M3, FG1)**

They might view the pharmacy consulting space as not recognisable as an official part of the activity

“so we’ll go back into the little back room there” **(F6, FG2)**

The occasion and the space could be so unfamiliar that it might even convey an air of the patient themselves having “broken the rules”

“she called me into the consultation room and I thought why, why am I being called in here? You know I go to the diabetic nurse every six months they’re quite happy and I was a bit why is this happening and you sort of sit in this private room as if you have done something really naughty” **(F1, FG3)**

These quotes explain a little about the perception of the consultation room as also being seen as an ambiguous environment to conduct private conversations about health management. They indicate how these participants were unaware of the existence of a private area in the pharmacy. They also pointed to the need for pharmacists to explain more about why they might be asking patients to enter into the ‘little’ room so that they don’t feel like it is ‘strange’ or that they have been ‘naughty’.

Finally, this next participant had no previous experience of interacting with the pharmacist and had described his work as “all I see him as dispensing” and viewed the consultation room itself as somewhere very much out-of-bounds since it was a place “to give drug addicts the privacy to take their methadone”. However, after listening to the comments from other focus group participants she altered her view to observe that it could be worthwhile under certain conditions:

“...if you are going to use the pharmacist, it would be very useful and would help you understand more about your condition and about your tablets, and the doctors don’t have time for that, but I would want to do that in a consultation room. I would want a pre-arranged appointment and I would want to build a relationship with the particular pharmacist because otherwise I don’t think the benefit would be there”

**(F7, FG1)**

This participant encapsulates views held by other participants in a similar situation, once they knew more about the pharmacy and had formed an idea where the pharmacist’s expertise could be beneficial to them from other participants, they were prepared to moderate their views and consider the pharmacist as a professional that may be valuable in their care providing certain criteria were met.

## 6.5 Focus group discussion

The findings from this series of focus groups involving patients with type 2 diabetes indicates that they do perceive pharmacists as an essential part of the wider healthcare team, particularly with reference to allaying patients' anxiety regarding over-the-counter medicines and matters associated with the ordering of prescriptions. These are roles that have long been associated with community pharmacists and it could be expected that patients would be more familiar with these rather than recent changes in service provision that might have impacted less on their own healthcare experiences of the pharmacy.

This group of patients clearly articulated their need to control their diabetes themselves and the importance they attached to self-monitoring was evident. This was reflected by all participants and not just those that had experienced complications or symptoms as identified elsewhere in the literature (Thoolen et al., 2008). However, when seeking information about their condition, they did not necessarily see the pharmacist as their first port-of-call for healthcare advice. This has been confirmed in other research that demonstrates pharmacists do not serve as the primary healthcare resource for patients (Anderson et al., 2004). Our participants seeking information and advice would normally first approach their doctor or nurse as these professionals could make any necessary changes to medication or treatment plans. If, for some reason this were not possible either due to a problematic relationship between them or being unable to obtain an appointment, then the pharmacist became the next port of call.

Our participants viewed the doctor as the 'controller' of their medication in a strictly-observed health hierarchy so that they did not want to go against any treatment recommendations made by their doctor by obtaining advice from the pharmacist. They saw approaching the pharmacist as violating the natural line of treatment. Urban et al. have previously identified that pharmacists believe it is difficult to recruit patients for an MUR as they may be concerned about advice provided that conflicts with their GP's (Urban et al., 2008). Bissell et al. identified it in relation to accepting a pharmacist's treatment recommendation as part of a community pharmacy medicines management service, again viewing the GP as the 'health professional in charge' of their medicines but also citing worries about the commercial interest of pharmacies and their need to make money (Bissell et al., 2008). Participants also referred to what they saw as the isolated position of the pharmacist within primary care, as they did not see them as fully integrated with the rest of the primary care team. In characterising what the pharmacist could provide they highlighted it as lacking in joined up care and as duplicating services they received from the medical practice. This aligns with other research that has highlighted the isolated working practices and environment of the community pharmacy (Cooper et al., 2009) and

is something that, professionally, community pharmacists may be limited as to what they can alter.

However, their discussions also made clear that participants were not simply 'anti-pharmacist'; it was more that they did not have a clear understanding of where pharmacist expertise could be useful to them in managing their condition. Participants identified that, for their view to change, pharmacists needed to become more integrated into the primary care team with better communication between the different professionals. Such communication would include being referred by the doctor to the pharmacist, so validating the pharmacist's input whilst not deviating from what they saw as the natural line of treatment as well as developing procedures so that the pharmacist can communicate information back to the doctor if necessary without the patient having to visit the medical practice.

However, even if this improved method of communication was to be developed, participants still have many reservations about the pharmacy as a suitable place for obtaining comprehensive, confidential healthcare advice that they could act on with confidence. It is perhaps surprising that seven years after the new pharmacy contract in England was implemented, pharmacies have not adapted sufficiently to create an appropriate environment in which patients feel comfortable asking personal medical questions.

Our participants highlighted that pharmacies are busy places, often full of patients collecting prescriptions or asking the pharmacist questions and this may have an impact on whether and when they feel it is appropriate to ask for advice. Cowley and Gidman's similar research on what the general public think about community pharmacist consultations suggests the perception that pharmacists are too busy to engage with patients (Cowley and Gidman, 2011). Our research seems to support at least part of this idea in that our participants saw pharmacists as lacking individually-available time but while they did not see pharmacists as unable to engage with patients, this view did influence whether they were likely to approach the pharmacist for detailed, personal health management-related information.

Pharmacists' public role and professional knowledge were not clearly understood by patients in identifying which of their questions pharmacists can appropriately answer. Participants identified the existence of a relationship between the pharmacist and patient as another criterion for their being willing to engage with the pharmacist; or with any services in the community pharmacy. They prioritise the need for a 'regular face' before they would begin to trust the pharmacist. They saw it as vital that pharmacists should



know their patients and their histories before entering into discussions about their condition or for them to accept any advice or recommendations that the pharmacist might make during a consultation.

In terms of the pharmacy environment, most pharmacies cannot offer the privacy that this group of patients was seen to prefer to enable them to adequately discuss their medical condition. Even the consultation room, with which most pharmacies are now equipped, did not escape criticism. The 'little room' as it was described is often used as stock storage space and was often small and cramped (Rapport et al., 2009). Some patients reported wondering why they had been taken into the room, fearing they had done something wrong or identifying it as somewhere stigmatised groups such as drug addicts might be treated. This gives the impression that community pharmacy services and the consultation room are still not used routinely by patients and as a result they are still wary of them and what to expect once in there. Pharmacists may assume that patients are aware of the consultation room and what it entails, and that the patient is automatically comfortable and happy with these consultations as they will view them as similar to those they will have encountered in their medical practice. However, in previous research patients have identified the opposite citing a small room and a lack of knowledge about why they were asked into the room in the first instance, suggesting that pharmacists are not explaining to patients the purpose of the encounter and setting (Iqbal and Wood, 2010). These findings underline the further work the profession may be need to do to demonstrate to patients what the community pharmacy consultation room is like and how it can be used.

Viewing all of these features of both the pharmacy and pharmacist together, highlights many changes the community pharmacist and the wider healthcare team will need to make if patients with diabetes, or others with chronic conditions, are going to confidently and effectively engage with new pharmacy services and see the pharmacist as a credible healthcare professional. This may involve changing the perception of the pharmacist by patients but also, and possibly more importantly, changing the way pharmacists work and are paid by the NHS. Changes to the national pharmacy contract may be appropriate to ensure pharmacists have the time and space to not only engage effectively with patients but also members of the wider primary healthcare team.

### 6.5.1 Strengths and limitations

This study focused on the experiences and perceptions of patients with type 2 diabetes relating to the community pharmacy. These outcomes demonstrate that a focus group method could enable participants to articulate, debate and share common and different perspectives and experiences with each other to allow the researcher to examine how these develop in this group of participants (Kitzinger, 1995). The study only recruited 25 purposively-selected participants, which would not reflect the whole range of patients with diabetes visiting the community pharmacy, however, the nature of the study required participants to be aware of their experiences in this setting in order to be able to discuss them knowledgeably and therefore this 'self-selection' may not be a significant bias. The purposive sampling strategy enabled me to capture diversity in a range of conceptually-relevant characteristics such as length of diagnosis and number of medicines prescribed.

A key limitation with this study was that it could not include the views and experiences of patients with type 2 diabetes who do not interact with the pharmacy or the pharmacist. Gaining these views would have helped provide insights into what factors would make them engage with the pharmacist about their condition and why they do not currently engage with even basic pharmacy services. Accessing and studying the views of this group would call for a different study using different methods. The perspectives found here are also limited to the UK which may differ from perspectives in other countries which may have different organisational structures in which community pharmacy operates (Farris et al., 2005).

Another limitation of this study was the necessity to allow the pharmacists to select potential participants from those presenting in the pharmacy which may have led to 'cherry-picking' of patients. This could have been avoided by placing a researcher in the pharmacy to recruit directly or posting out an information sheet and consent form to all those patients with type 2 diabetes registered with the pharmacy or medical practice. This, however, still would not have removed the self-selection bias of this study as the pharmacy staff would still have had to ask patients for permission to allow the researcher to approach them.

The focus group was conducted by a pharmacist and the participants were aware of this from the outset. This may have impacted on their ability to speak freely, however, all were informed at the beginning that they were free to say anything they wished and that nothing would leave the room or affect their care. To help address this problem, the first focus group was also moderated by an experienced, non-pharmacist, qualitative researcher to ensure that the main researcher did not lead the participants into providing certain

answers. The secondary moderator was comfortable with the first focus group and for subsequent groups a second non-pharmacist researcher assisted with the sessions.

## 6.6 Focus group conclusion

When designing a novel community pharmacy intervention, researchers need to be aware of patients' currently held beliefs and practices which will inform the relevance and acceptability of the design to them. In the series of focus groups examined here, participants drawing on their experience of living with diabetes indicated that the pharmacy is not yet acceptable to them as an environment where wider healthcare conversations can be seen as readily or appropriately conducted. While these patients acknowledge that the pharmacist will have a wealth of expertise relevant to administration, supply, side effects and interactions of medicines, because they see pharmacists as isolated from the rest of the primary care team they are less comfortable with taking up community pharmacist interventions which they see as possibly disrupting treatment by the participant's established care team. Pharmacists have long-established roles as suppliers of prescription and over-the-counter medicines. However, if this is to change to include more condition-led management of complex long term conditions such as type 2 diabetes it seems that changes in the national pharmacy contract and working practices will be needed which can ensure that the community pharmacist becomes more fully integrated within the wider care team and, importantly, in the pharmacy environment in which these interactions take place. Any assumption by pharmacists that patients view the consultation room as simply a small medical practice rather than a completely different environment may need to be challenged.

These focus groups have proved useful in establishing not only the sort of topics patients are willing to speak to the pharmacist about but also who and how patients are identified for the research project. It has highlighted the need to involve the medical practice from the outset of targeting patients and for some kind of referral system from them to the community pharmacy. Without this, participants in our focus groups have told us they would be unlikely to engage with the project.

Issues surrounding the pharmacy environment may be impractical to address in a study being designed here, however, the perception of the pharmacist as 'busy' can be addressed. Participants identified that there may be a need for additional pharmacist support so that they did not feel they were taking them away from their 'core' dispensing role.

The final aspect highlighted by participants involved access to the pharmacist. They liked the ease and convenience of speaking to the pharmacist and the lack of need for appointment bookings. In the intervention developed as a result of this work, access and convenience need to be maintained in order to retain the incentive for the patient to visit the pharmacy.

The subsequent study, detailed in the following chapter, will include all of these features in an attempt to create a successful intervention in the community pharmacy setting.

# *Chapter Seven*

## **7 Diabetes Drop-in Clinic: A feasibility study**

### **7.1 Introduction**

The preceding chapters have focused on preliminary work aimed at developing a complex intervention designed to complement that advocated by the 2008 MRC framework (Medical Research Council, 2008). This process has involved a systematic literature review, an audit of prescribing in primary care and a series of focus group discussions and has assisted in the definition and structure of the intervention and the target population described in this chapter.

The literature review described how patients are often prescribed a significant number of medicines for type 2 diabetes and its co-morbid conditions and that they may have concerns and questions about their treatment that may affect whether they take those medicines as prescribed. Non-adherence in this group of patients has been shown to be influenced by a number of factors including the number of medicines prescribed, the number of daily doses, the patient's understanding of the regime and the perception of side effects and the likelihood of experiencing them.

The community pharmacist is ideally positioned to be able to address these problems both in terms of their specialist knowledge and the frequency with which they will see these patients, demonstrated by the evidence provided in chapter four. These studies highlighted several factors that should be considered before any novel intervention is trialled, namely the training provision for pharmacists, the inclusion criteria and the intervention design. Any service developed in the UK also needs to assimilate itself with the current care team and the wider NHS. Evidence from the literature review implies that training for pharmacists should involve an element of self-directed learning together with a face-to-face training session provided by the university covering aspects such as consultation techniques, local treatment guidelines and information on the study processes.

The content of the consultations analysed in chapter four's review of the literature provided little information in relation to which 'core' areas the pharmacist should be focussing on e.g. diet and lifestyle, adherence or drug-related problems. As such, most of these consultations were wide ranging in the topics covered with patients. In the future it may be appropriate to narrow down the focus of the pharmacist's consultation; however, at this point there is a lack of common data to suggest what this should be.

In terms of attempting to address this issue of consultation focus, an audit of prescribing in type 2 diabetes was conducted to determine if it were appropriate for the pharmacist to

become involved in this aspect of a patient's treatment. Chapter five demonstrated that prescribing for type 2 diabetes is generally in line with the most recent NICE guidance. However, this audit and the annual National Diabetes Audit provide evidence to suggest that there are still a large number of patients for whom control cannot be achieved and this may be due to lack of dose titration, the need for further medicines to control their condition or sub-optimal adherence. If problematic, dose optimisation may need to take place in the medical practice but it may be appropriate to address sub-optimal adherence in the community pharmacy as they are already equipped to provide this type of service.

Again if problematic, the audit identified that the community pharmacist may not only have a role in adherence but also in managing cardiovascular risk, blood pressure measurement and weight. For a community pharmacist to be able to target these patients, effective lines of communication between the medical practice and community pharmacy would be required. At present, with the delay of the introduction of summary care records in community pharmacies, pharmacists would need to rely on the direct referral of poorly controlled patients from the medical practice to the pharmacy in order to target these patients.

In the series of focus groups described in chapter six, participants drawing on their experience of living with diabetes indicated that they would be willing to engage with a service aimed at improving their condition providing that it met certain criteria. The first of which was the inclusion of the medical practice and their doctor in any treatment or service offered by the community pharmacy. Participants saw it as necessary in terms of validating the knowledge of the pharmacist but also not violating the natural line of treatment between them and the doctor.

As discussed in chapter six, issues surrounding the pharmacy environment may be impractical to address in a study being designed here, however, the perception of the pharmacist as 'busy' can be addressed. Participants identified that there may be a need for additional pharmacist support so that they did not feel they were taking them away from their 'core' dispensing role. The final criterion highlighted by participants involved access to the pharmacist. They liked the ease and convenience of speaking to the pharmacist and the lack of need for appointment bookings. In the intervention developed as a result of this work, access and convenience need to be maintained in order to retain the incentive for the patient to visit the pharmacy.

All of this information from the literature review, audit and patient focus groups has been brought together to develop the idea of a diabetes drop-in clinic in the community



pharmacy setting. This service will pull together the core findings from the work conducted as demonstrated in table 7.1 below.

Core finding	Rationale for inclusion
Targeting poorly controlled patients	Studies in the literature review that worked best targeted poorly controlled patients. The audit identified along with the literature identified that there were a significant number of patients who were uncontrolled with respect to blood glucose, blood pressure and total cholesterol.
A system of referral from the medical practice to the community pharmacy	Focus group participants identified this aspect as essential if they were to engage with the community pharmacist in relation to their diabetes. The PLEEZ study identified that relying solely on pharmacists to recruit participants opportunistically may not be an appropriate approach for this kind of service.
A training programme that has a self-directed learning aspect as well as face-to-face sessions.	The pharmacists in PLEEZ highlighted that they liked the training provided to them as part of the service and in the studies detailed in the literature review most utilised this approach.
No appointment system	Focus group participants have identified this as a benefit to community pharmacy and it should try to be incorporated into any service developed.
An additional pharmacist to provide support to the service pharmacist	The introduction demonstrated that a significant concern for pharmacists is time available to conduct a service. The PLEEZ study failed to recruit participants, potentially due to the lack of support provided to the pharmacist whilst they were providing the service. Focus group participants also identified that pharmacists “appear busy” all the time and they feel as

	though they are imposing on them if they were to ask a question. This finding may help to limit that feeling.
A focus on adherence as well as diet and lifestyle advice	The literature review identified that pharmacists could provide a service that encompassed all of these items and produce positive results. The audit ruled out the inclusion of changing medication and providing screening for cardiovascular risk.

**Table 7.1** Core findings from previous chapters detailing to rationale for inclusion in the drop-in clinic

As a result of the work conducted in chapter two and working within the MRC framework for developing complex interventions, this chapter will focus on testing the feasibility of the diabetes drop-in clinic that comprises all of the elements listed above together with assessing whether this service is acceptable to both patients and pharmacists.

## 7.2 Aims and Objectives

### 7.2.1 Aims

The overall aim for my research in this area is to determine whether a community pharmacy diabetes drop-in clinic improves the care of patients with type 2 diabetes. The aim for this initial study is:

- To determine whether a pharmacy diabetes drop-in clinic is feasible and acceptable to patients with poorly controlled diabetes.

### 7.2.2 Objectives

To determine:

- the feasibility of a community pharmacy drop-in clinic for poorly controlled diabetes patients
- recruitment methods and rate of participation in the drop-in clinic
- the characteristics of patients accessing the service and identify their needs
- the ability of service recipients to complete the follow-up questionnaires
- the potential effect on the following potential outcome measures:
  - BMQ
  - SIMS
  - Morisky
  - Community pharmacy utilisation
- the most suitable outcome measures
- the suitability of the questionnaires for informing the consultation
- the content of the intervention
- the acceptability of the service to patients and pharmacists
- the acceptability of the research design in terms of
  - recruitment methods
  - training provision
  - questionnaire design
  - locum support

### **7.3 Drop-in clinic method**

#### 7.3.1 Ethical Review

The protocol and supporting documentation are included in appendix 15. This study was given approval to commence from Essex NHS Research Ethics Committee (appendix 16) and NHS Norfolk Research and Development committee (appendix 17). The substantial amendment paperwork is also included (appendix 16) as a result of requested changes from NHS Norfolk.

#### 7.3.2 Study Design

The diabetes pharmacy drop in clinic specifically targeted patients who were poorly controlled with respect to HbA<sub>1c</sub>, blood pressure or lipids. The clinic was conducted in five pharmacies with the regular pharmacist in the private consultation room.

#### 7.3.3 Practice and pharmacy recruitment

In conjunction with the local primary care trust, the researchers identified potential independent community pharmacies where the study could be conducted. This study was partly funded by an organisation that represents independent community pharmacies and therefore this was the reason for selecting only these pharmacies initially. The pharmacies were selected based on convenience and their proximity to a medical practice (all were co-located together). Once these sites were identified, the researchers approached both the pharmacy and the medical practice and arranged meetings to discuss the project and seek consent to participate in the study. After discussion with the Local Pharmaceutical Committee, and to ensure fairness to all community pharmacies in the area, those in the vicinity of the previously identified independent pharmacy were invited to participate as well, this resulted in two additional pharmacies being recruited that were part of a multiple pharmacy chain.

#### 7.3.4 Pharmacist training

Pharmacists were required to complete the CPPE Diabetes Management training package and have read the NICE guidance for the management of type 2 diabetes before undergoing a training session conducted by me. The pharmacists were paid to complete this training and took approximately 10 hours to complete. The learning outcomes of the training package were as follows (CPPE, 2010):

- identify risk factors associated with developing diabetes
- distinguish between type 1 and type 2 diabetes
- describe best practice in managing patients with type 1 and type 2 diabetes
- understand and monitor various parameters which are used to judge metabolic control

- make recommendations to prevent the complications of diabetes or manage them should they occur
- enhance the contribution made to the care of people with diabetes.

Once this was completed, the researcher visited each pharmacist and undertook a short (one-hour) training session aimed at contextualising the study by presenting the results from the patient focus group discussions along with information about the study design. Excerpts from the focus groups were used to highlight real concerns that patients may have and how they felt they should be dealt with. Consultation skills were not addressed as part of the training as there were limited funds available and part of the aim of the project was to determine if this was necessary.

### 7.3.5 Participant identification

The medical practice was asked to identify poorly controlled patients subject to the following criteria:

- Confirmed diagnosis of type 2 diabetes
- Aged > 18 years
- Poorly controlled with respect to the following QOF outcomes:
  - Patients not achieving QOF indicator DM26 (HbA<sub>1c</sub> < 59 mmol/mol) AND/OR
  - Patients not achieving QOF indicator DM31 (BP < 140/80 mmHg) AND/OR
  - Patients not achieving QOF indicator DM17 (TC < 5 mmol/L)

From the generated list of patients, the medical practice was asked to remove the following patients:

- Those patients on the QOF dementia register
- Those patients on the QOF palliative care register
- Those patients who have been exception reported for QOF

The medical practice was also permitted to remove any patient that, in their experience, would not be suitable for the service e.g. those that they knew were housebound or resident in a care home.

For all identified patients the researcher provided the medical practice with pre-filled envelopes enclosing a letter from the practice partners and a leaflet advertising the service and they were asked to mail these to patients identified. The leaflet contained information including clinic times and what was involved when patients attended the pharmacy. The researcher had no access to medical records for this process. In order to

test the need for a repeat mailing, one medical practice was asked to send a second letter out to all potential participants identified. Another medical practice was asked to send out a repeat mailing to a select number of participants based on the experience of the practice as to whether they thought they would attend the clinic and the third medical practice did not send out a repeat copy of the invitation letter.

#### 7.3.6 Participant recruitment and consent

The leaflet advertising the service contained a consent section on the back that the patient were asked to bring along to the clinic. In the case of forgetting, they were asked to complete a consent form before the consultation could commence. The pharmacist, researcher or pharmacy staff were available to assist the patient in completing the consent form and subsequent questionnaires should they need any help. Once the patient had consented, the consent/data collection form was detached from the information leaflet so that the patient could keep that section and the pharmacist could keep the consent form. The participant, researcher and medical practice were also be given copies of the consent form if they requested it.

#### 7.3.7 The drop-in clinic

The clinic was conducted for a four-hour period once a week for four weeks (six weeks in one pharmacy). The patient also had the opportunity to visit the pharmacy outside of the clinic times but was informed that they may have to wait a short while to see the pharmacist.

The patient was then asked to complete a short questionnaire containing three validated questionnaires: the Beliefs about Medicines Questionnaire (BMQ) (Horne et al., 1999), the Satisfaction with Information about Medicines questionnaire (SIMS) (Horne et al., 2001) and Morisky measure of adherence (Morisky et al., 1986) all of which have been described previously. Data was also collected regarding how many times and why they have used the community pharmacy over the preceding three months.

Once the participant had completed these, the pharmacist started the consultation. The content of all the consultations was negotiated between the pharmacist and the patient based on the needs of the patient and the responses to the questionnaire. This could have included questions relating to their disease, lifestyle and diet or medicines. The breadth and depth of the discussion was not dictated to the pharmacists. They were asked to let the patient lead the consultation and use the baseline questionnaire to inform any discussions as necessary. The questionnaire had been shown to the pharmacist during the training session to allow themselves to become familiar with it. The different elements were explained and how these might be useful in guiding the consultation.

The information sheet provided to the participants suggested that this was a one-off clinic and gave no impression that they had to attend the clinic on multiple occasions. However, there were no restrictions on how many times they were allowed to attend over the course of the study if they found it beneficial. No time limit in terms of length of consultation was suggested to the pharmacists.

If necessary, the pharmacist was able to liaise with the prescriber and discuss any potential changes that the pharmacist thought would be beneficial to the patient. Prescription changes were agreed by the participant, pharmacist and prescriber and were arranged by the pharmacist in conjunction with the medical practice staff.

The patient then completed a feedback questionnaire post consultation which contained questions regarding the conduct of the pharmacist, the surroundings in which the consultation occurred and their opinions on the consultation. The patient was asked to post the completed questionnaire directly to me at the university to manage social desirability bias which could result from posting to the community pharmacy. At the end of the questionnaire, there was an option for patients to include their telephone number so that should any aspects of their answers need clarification, I was able to contact them. It was made clear on the questionnaire that by giving their telephone number they were consenting to me calling them for clarification.

#### 7.3.8 Pharmacist data collection

The pharmacist collected information from the participant including age, gender and postcode and called the medical practice after the consultation to obtain the following information required to complete the data collection form:

- Most recent HbA<sub>1C</sub>, blood pressure and total cholesterol results
- Number of medicines prescribed
- Length of time since diagnosis

The pharmacists were asked to describe the contents of the consultation with the participant using a tick box form which included space to write any additional comments if needed. Information such as length of the consultation, the topics of discussion, alterations to the care received from the pharmacy and any changes requested from the medical practice were sought in this form.

### 7.3.9 Patient follow-up questionnaire

Three months after the consultation, the patient was asked to complete a repeat of the baseline questionnaire. This was posted to their address by the researcher, contained only the patient number and was returned in a pre-paid envelope to the University. The researcher kept track of which patients were due to receive a questionnaire and if they had returned it. If they did not return the questionnaire within two weeks, they were sent a follow-up.

### 7.3.10 Funding

The medical practice was paid a set fee for participating in the evaluation. The pharmacy received free locum support from myself on the day of the clinic and were paid per patient that attended the drop-in clinic to a maximum of 40 between the five pharmacies.

### 7.3.11 Pharmacist interviews

As part of the follow-up to the study, pharmacists were interviewed to determine their views on the drop-in clinic, patient interaction and the study design. These 'de-brief' interviews asked pharmacists to comment on the following areas to inform the design for a subsequent pilot study:

The service:

- What was your general impression of the service?
- Did you have enough time to prepare for the service?
- What did you think of the delivery and content of the consultations?
- How do you think the service benefitted:
  - Patients?
  - Relationship with the medical practice?
  - You personally?
- What impact do you think the pharmacy environment has on this kind of service?
- How has your practice changed as a result of providing the service?

The research:

- What are your thoughts about the research design?
- What was your impression of the targeting of patients for this study?
- What did you think of the conduct of the research and the research team?
- What did you think of the paperwork for the study?
- What did you think about liaising with the medical practice?
- Do you think the data collected for the study was appropriate?



Other questions were asked where necessary to clarify remarks made to me. These interviews were held at a convenient location and time for the pharmacists and were audio-recorded and transcribed verbatim by me. They were analysed using content analysis with reference to the original questions initially by me in conjunction with my supervisor.

#### 7.3.12 Sample size calculation

As this was a feasibility study a formal sample size calculation was not performed. However, based on the previous research described in chapter four it was deemed sensible to only ask each pharmacy to recruit a small number of participants. Therefore an initial target of 40 was set to allow each pharmacy to recruit eight participants.

#### 7.3.13 Data analysis

The data were analysed using the Statistical Package for Social Sciences (SPSS) version 18. All demographic and clinical data from the participants were analysed using descriptive statistics. Each section of the questionnaires was assigned a score according to the respective validated tool and was then analysed using descriptive statistics to identify any differences between baseline and follow-up. Appropriate parametric and non-parametric tests were used to determine the statistical significance of any differences. The BMQ questionnaire was analysed in terms of the necessity and concerns scale as well as the differential score with the SIMS questionnaire analysed in terms of the action and usage section and potential problems section as well as the total score. Adherence was dichotomised into adherent and partially adherent. A 'yes' response to any of the Morisky questions implied the participant was partially adherent. McNemar's test was used to determine any significant difference in adherence between baseline and follow-up. This was used as it tests the difference between two related groups, when nominal data have been used (Field, 2009). It needs to be used when you have two dichotomous variables (adherent/partially adherent) and they are related to each other (before and after). This test was also used to determine any differences in the community pharmacy use section of the questionnaire.

The free-type sections of the questionnaires were summarised and a selection are presented as an overview of the data. All views will be represented. The pharmacist interviews were transcribed and coded by the researcher and themes were developed using content analysis. A second researcher also read the transcripts and familiarised themselves with the participants responses. The two researchers then had discussions surrounding the themes to arrive at a consensus and resolve any conflicting views.

#### 7.3.13.1 *Null hypothesis*

No difference will exist between baseline and follow-up for the following measures:

- BMQ necessity, concerns and differential scores
- SIMS action and usage, potential problems and total scores
- Morisky, change in adherent behaviour
- Frequency of visits to the community pharmacy and interacting with the pharmacist
- Topics of conversation with the pharmacist

#### 7.3.13.2 *Content analysis*

Content analysis involves breaking individual interviews down into units of analysis usually determined by the questions asked of the participants (Graneheim and Lundman, 2004). In our interviews the units of analysis are: training provision, conduct of the service, the study paperwork and the benefits arising out of the study. These units of analysis contain all the references made in all the interviews and are formed together in one text for analysis. This text is then progressively coded until categories, subthemes and themes are established. These interviews will be analysed using a deductive approach as described in the literature (Elo and Kyngäs, 2008). This is due to the researchers knowledge of where problems may have occurred from work conducted in previous chapters. The themes were discussed between two researchers who had reviewed the text independently and consensus was sought.

## 7.4 Drop-in clinic results

### 7.4.1 Participant demographics

Five pharmacies and three medical practices were recruited in three locations across Norfolk. The pharmacies dispensed the majority of the prescriptions issued by their associated medical practices. The medical practices identified and posted the invitation letter and information sheet to 342 potential participants. Thirty-three participants (9.6% response rate) were recruited in four of the five pharmacies as detailed in table 7.1. The demographics of the recruited participants are detailed in table 7.2. The participants postcode was used to determine distance travelled to the clinic. Of those that attended, 44.5% were uncontrolled with respect to blood glucose, 74.1% for systolic blood pressure, 81.5% for diastolic blood pressure and 48.1% for total cholesterol with some patients being uncontrolled for multiple measures.

Pharmacy	Number of participants recruited	Repeat mailing?
1	12	Yes
2	7	Yes
3	8	No
4	6	No
5	0	Yes
<b>Total</b>	<b>33</b>	

**Table 7.2** Number of participants recruited in each pharmacy.

	N	Mean (SD)	% of patients controlled
Distance travelled to clinic (miles)	33	3.1 (2.7)	n/a
Most recent HbA <sub>1c</sub> result (mmol/mol)	27*	63.5 (13.2)	55.5
Most recent SBP result (mmHg)	27*	133.6 (21.7)	25.9
Most recent DBP result (mmHg)	27*	78.8 (16.1)	18.5
Most recent total cholesterol result (mmol/L)	27*	4.4 (1.4)	51.9
Number of medicines prescribed	29*	8.8 (4.2)	n/a
Years since diagnosis	29*	8.1 (5.0)	n/a

**Table 7.3** Participant Demographics

\*Data unobtainable for some participants presenting at pharmacy 4. SBP: systolic blood pressure; DBP: diastolic blood pressure; data normally distributed

### 7.4.2 Baseline and follow-up questionnaire

All participants completed the baseline questionnaire and I received 26 follow-up questionnaires, data from which are presented in tables 7.3 and 7.4 with figures 7.1 and 7.2 illustrating the responses to the SIMS and Morisky questionnaires respectively before and after the intervention. The final part of the questionnaire asked for information

regarding pharmacy use before and after the study, the results of which are detailed in table 7.5.

Measure	Before N=33 (median (quartiles))*	After N=26 (median (quartiles))*	p-value <sup>#</sup>
BMQ – necessity scale /25	20 (17 – 23)	20 (17 – 22)	0.674
BMQ – concerns scale /25	14 (11 – 18)	16 (12.75 – 18)	0.445
BMQ – differential score	6 (2 – 9)	4.5 (-0.25 – 8.25)	0.500
SIMS – actions and usage score /9	7 (4 – 8)	7 (5 – 9)	0.117
SIMS – potential problems score /8	4 (2.5 – 7)	5.5 (2.25 – 7.25)	0.940
SIMS – total score /17	11 (8 – 13)	11 (7.75 – 16)	0.558

**Table 7.4** Baseline and follow-up questionnaire data

<sup>#</sup>Wilcoxon signed-ranks test for all variables; BMQ: beliefs about medicines; SIMS: satisfaction with information about medicines scale

	Baseline (n=33)	Follow-up (n=26)
Adherent	61.5%	76.9%
Partially adherent	38.5%	23.1%

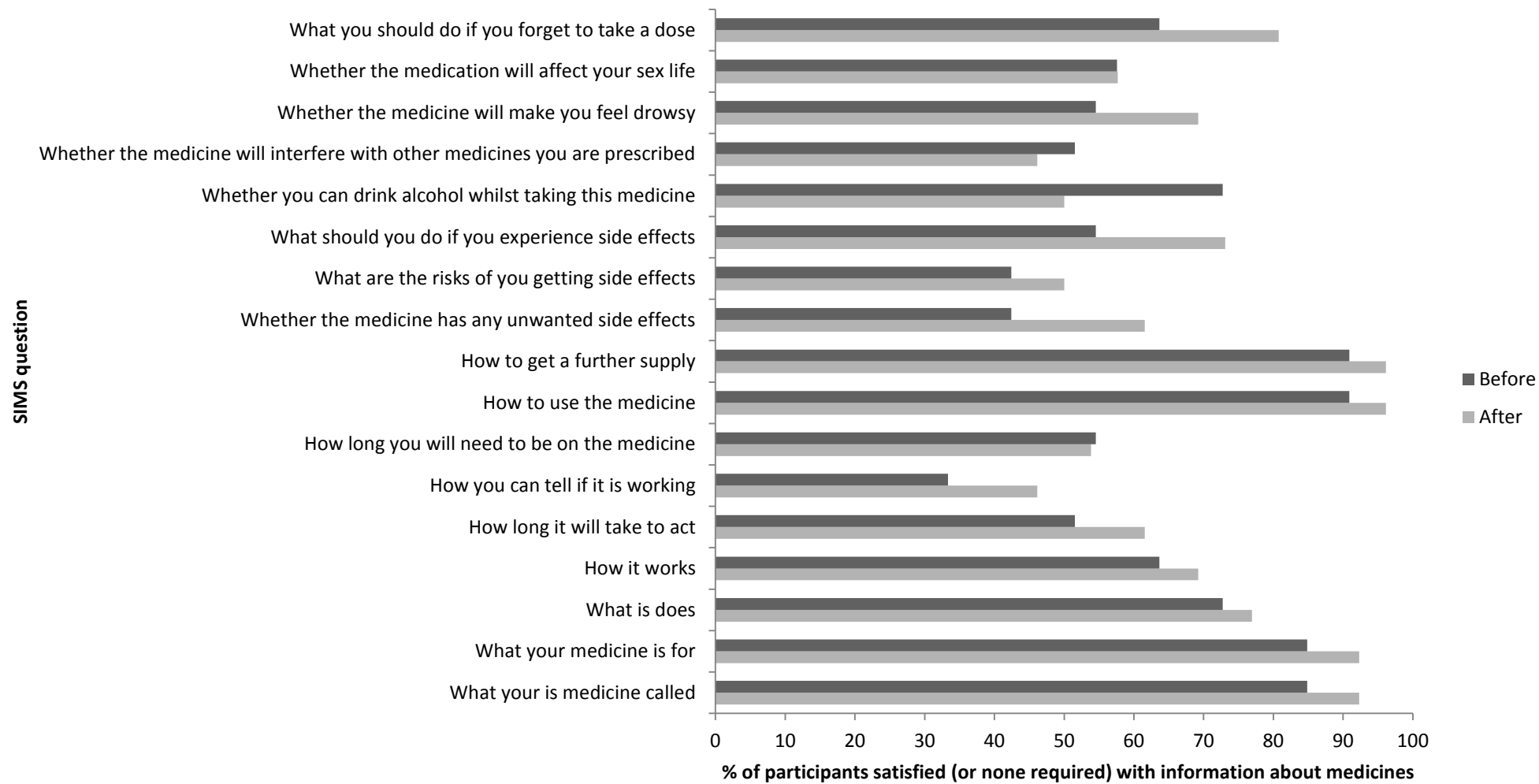
**Table 7.5** Morisky adherence scale change from baseline to follow-up

P=0.219; McNemar's test

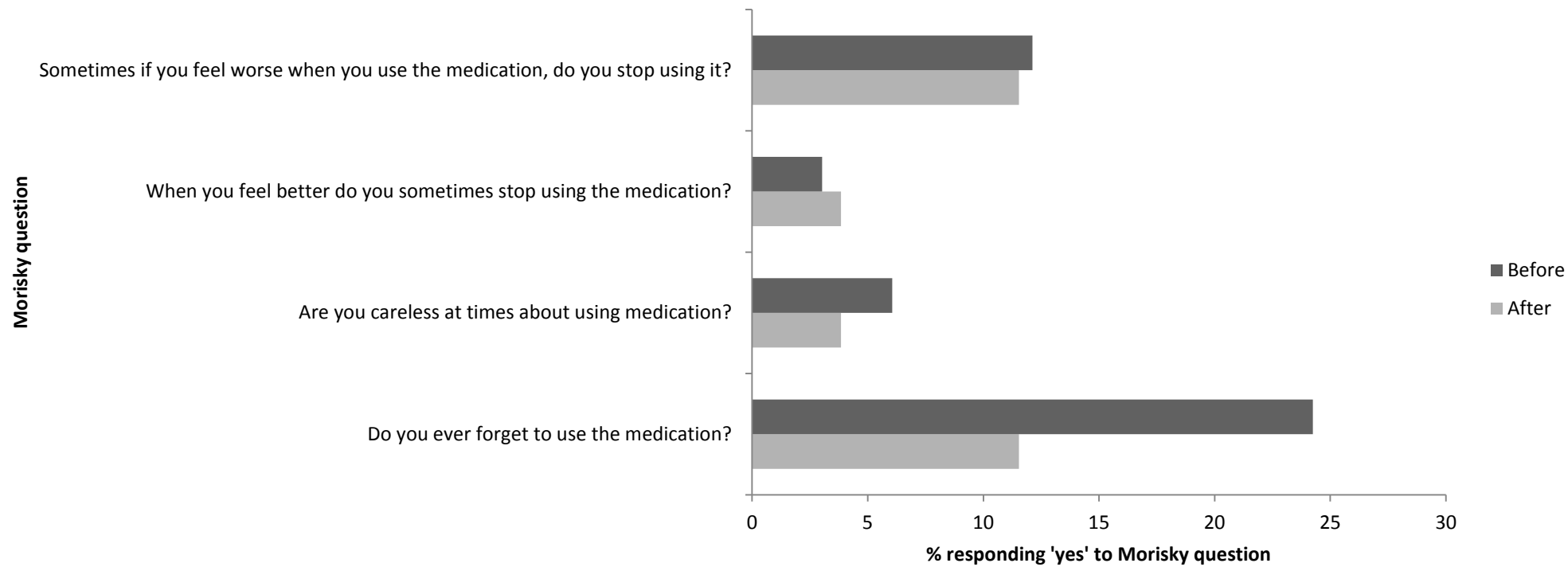
Not counting today, how many times in the last three months have you:	Before n=33 Mean (SD)	After n=26 Mean (SD)	p-value
Visited the pharmacy	3.37 (2.82)	3.37 (2.65)	0.454*
Spoken to the pharmacist	0.96 (1.54)	1.91 (2.51)	0.134*
What have you spoken to the pharmacist about?	% responding 'yes'	% responding 'yes'	
Your condition	0	38.5	0.002 <sup>#</sup>
Your medication	15.2	34.6	0.070 <sup>#</sup>
Over-the-counter advice	18.2	23.1	0.500 <sup>#</sup>
Lifestyle	6.1	19.2	0.219 <sup>#</sup>
Dietary advice	9.1	26.9	0.063 <sup>#</sup>
Other medical conditions	12.1	26.9	0.125 <sup>#</sup>
Minor ailments	9.1	19.2	0.250 <sup>#</sup>
Medicine supply	21.2	53.8	0.004 <sup>#</sup>

**Table 7.6** Community pharmacy use before and after the study

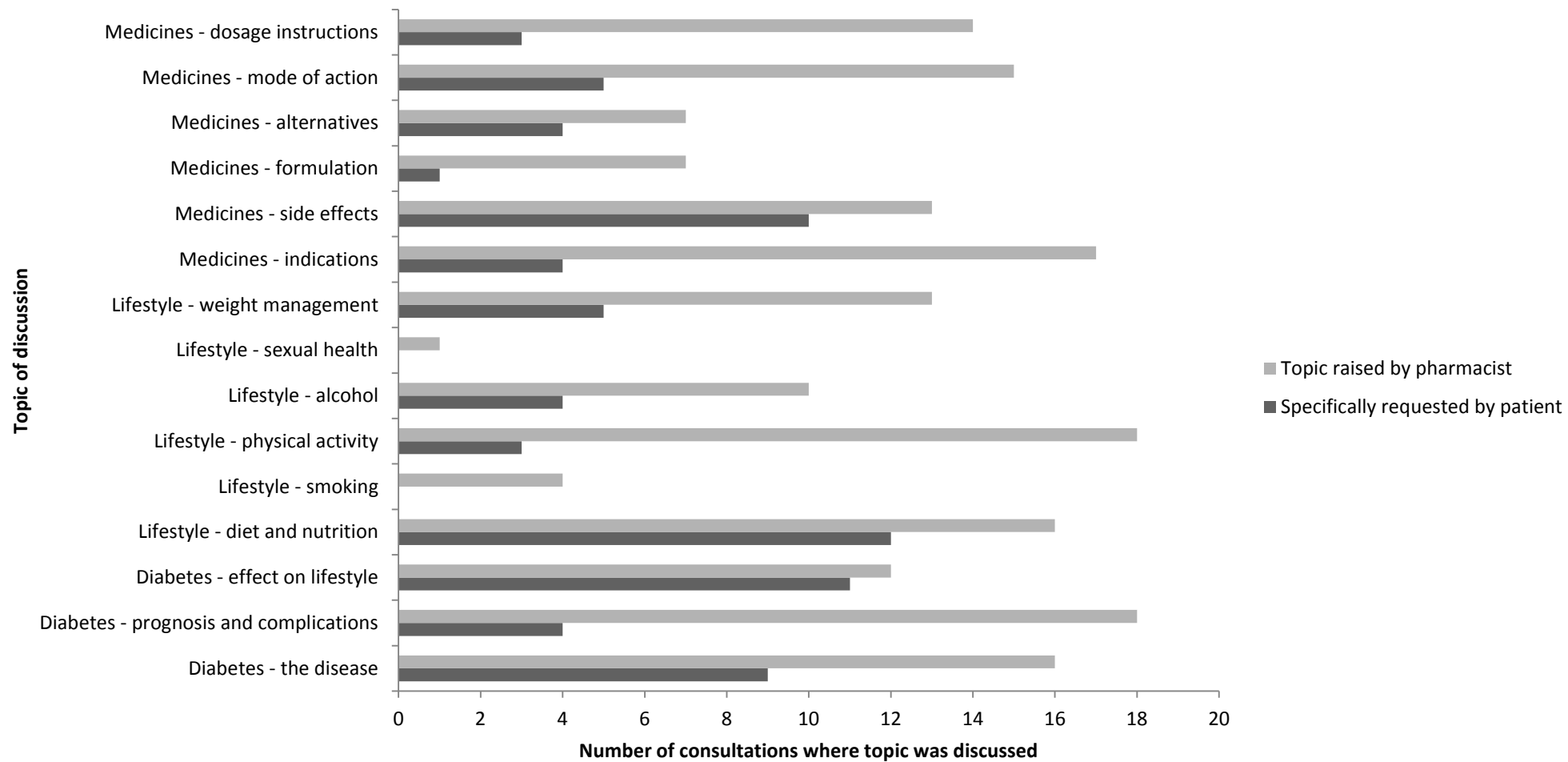
<sup>#</sup>McNemar's test; \*Paired samples t-test



**Figure 7.1** Responses to the SIMS questionnaire, before: n=33; after: n=26



**Figure 7.2** Responses to Morisky questionnaire, before: n=33; after: n=26



**Figure 7.3** The content of the 33 consultations and whether the topic was raised by the patient or the pharmacist.



### 7.4.3 Pharmacist data collection

The mean (SD) time for the consultation was 32.5 (12.0) minutes but ranged from 15 minutes to 65 minutes. Out of the 33 consultations, the topics covered are illustrated in figure 7.3 with the free type sections summarised below.

#### *Other information requested by the patient*

Most of this additional information requested by the patient involved the use of devices and monitoring of blood glucose. Participants wanted more information on the use of their test strips and needles (if they were prescribed insulin) together with information about what to do in the case of a hypoglycaemic episode. Other information that was requested related to correct portion size, alternatives to the medicines they were currently prescribed and why they were still taking oral medicines when they have recently been prescribed insulin.

#### *Other information raised by the pharmacist*

The pharmacists felt it necessary to discuss additional points such as the recently changed Driver and Vehicle Licensing Agency's (DVLA) requirements for patients with diabetes as well as adherence to treatment recommendations. In a number of participants this revealed a lack of adherence to therapy of which two examples are provided below:

- Participant had been prescribed gliclazide 80mg three times a day and was only taking half a tablet in the morning.
- Participant only taking one metformin twice a day when they should have been taking two twice a day.

#### *Alterations requested of the pharmacy*

The changes that the pharmacists thought they could enact themselves in the pharmacy were limited to adherence aids, providing information leaflets on appropriate diet and lifestyle changes, offering a delivery service and removing a participant from the managed repeat service.

#### *Alterations requested of the medical practice*

The pharmacists identified a number of clinical problems that needed to be addressed by the medical practice in addition to informing them if a patient was not taking their medication as prescribed. These issues are listed below:

- Participant needs a review of their current medication
- Participant has reported not receiving a blood test and diabetes review in some time.
- Request for an alternative cholesterol medication

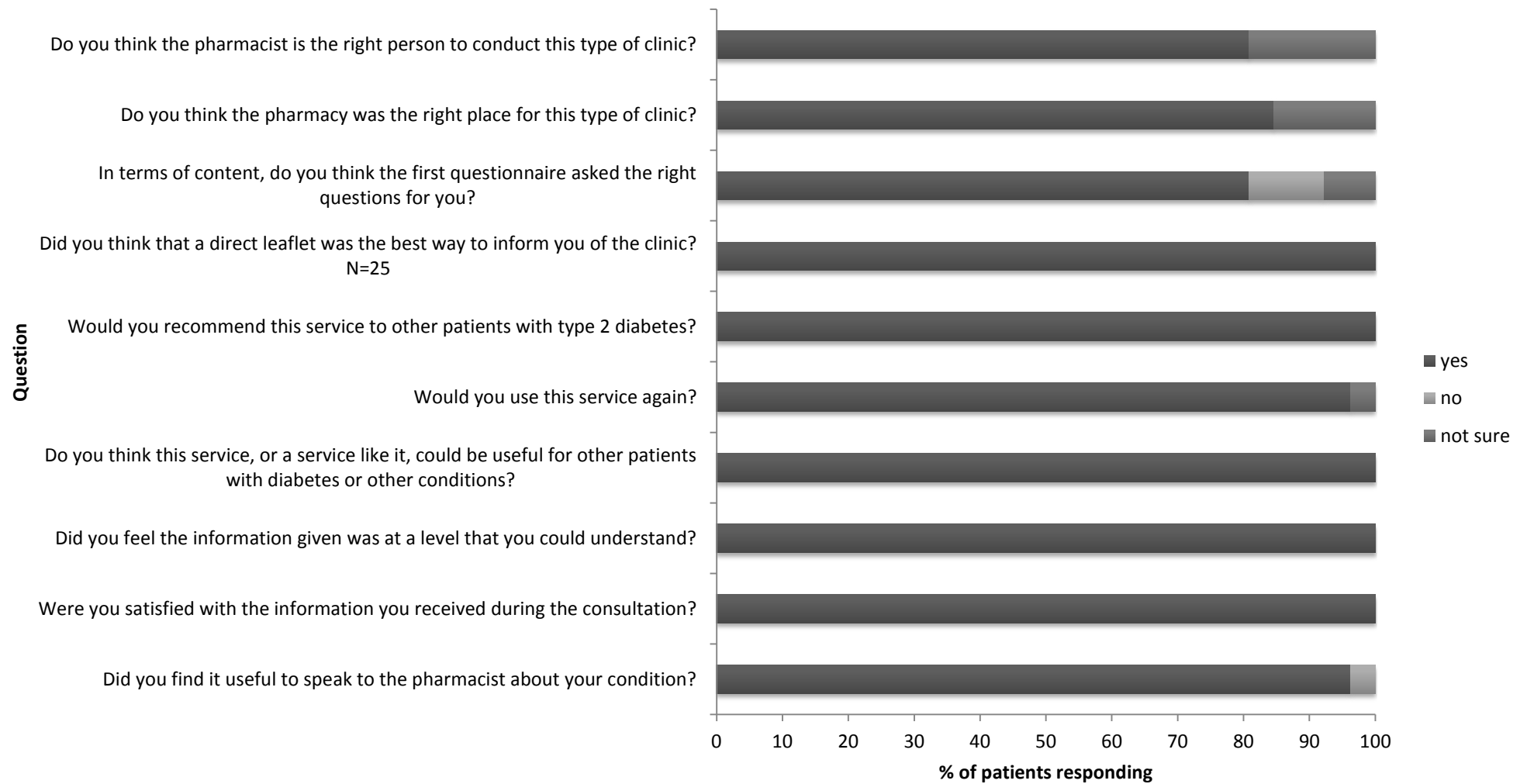
- Participant may require calcium and vitamin D prescribed as they are currently taking Bonviva and long term steroids
- Participant is uncontrolled, is overweight and has not been prescribed metformin. Recommendation to add metformin to current therapy
- Alter metformin dose from two twice a day to two modified-release tablets in the morning to aid compliance
- Increase quantity prescribed as dose has increased and participant keeps running out of tablets.

#### 7.4.4 Feedback questionnaire

Participants were asked to complete a feedback questionnaire after the consultation and post it back to me at the university. In total, 27 completed questionnaires were returned and the results are summarised in table 7.6 and figure 7.4.

Questions	Questionnaire responses (%)				
	Very good	Good	Average	Poor	Very poor
What was your general impression of the service you received today?	74.1	25.9	0	0	0
What did you think of the invitation and leaflet telling you about the diabetes clinic?	42.3	57.7	0	0	0
How much do you think attending the drop in clinic will help you manage your diabetes?	A lot 55.6	Some help 40.7	A small amount 3.7	No help 0	
Would this service make you more or less likely to consult a pharmacist in future about other conditions?	More likely 59.3	About the same 37.0	Less likely 3.7	Not sure 0	
What did you think about the length of time for the consultation?	Too long 11.1	About right 88.9	Too short 0		
In terms of length, what did you think of the first questionnaire?	15.4	86.4	0		

**Table 7.7** Responses to the feedback questionnaire



**Figure 7.4** Responses that required a yes/no/not sure answer from the feedback questionnaire

At the end of the questionnaire there were five boxes for participants to free-type comments. Participants were impressed that the pharmacist appeared to know what they were talking about and that they were able to talk to them without any time pressure and in a manner that they found approachable and professional. They identified that the pharmacist had the time to sit and discuss their problems in a way that helped to reassure them about their condition and provide advice to them in a way they could understand. However, one quote demonstrated that the participant was aware of the limitations of the service as the pharmacist still had to refer to other healthcare professionals to alter treatment regimens:

“Good but needed to refer to the 'diabetes' nurse for direction of prescription”.

Two of the pharmacies held their consultations in the medical practice due to space restrictions and they received positive feedback. Participants in the pharmacy consultation rooms highlighted that there may still need to be some work done to convince them that it is a place where they would feel totally comfortable.

Apart from two negative comments about the clinic being a waste of time, most participants were extremely positive about their experiences in the clinic and thought that it should be available to all patients with diabetes.

“The pharmacy diabetic clinic is a brilliant idea and I sincerely hope it takes off big time, I for one would use it.”

“Pharmacists seem to be more approachable than doctors and speak to patients on their level so that they do not feel intimidated. More information can be gleaned this way. Feel that this service would be invaluable. A consulting room would need to be earmarked due to lack of space in this pharmacy.”

Overall, from all the responses, participants identified this as a valuable service, helping to reassure them and provide them with advice and information on alternatives in an environment where they could take their time and get the most out of the opportunity to sit down with a well-trained, knowledgeable healthcare professional.

#### 7.4.5 Pharmacist de-brief interviews

The pharmacist debrief interviews centred on four areas of discussion: training provision, conduct of the service, the study paperwork and the benefits arising from the service.

##### *Training provision*

The participating pharmacists identified that the training provision for the service which consisted of a self-directed learning package and a short face-to-face training session was adequate to cover their needs for the study.

“the training that you did here was brilliant I mean, convenient was the thing so no travel for me which is absolutely brilliant so but yeah very straight forward, you got it clearly set out, what you had done, why you had got to this stage, I thought it very clear, very good and I could see why you had set the study up as it was so thought that was really good.” **Pharmacist 1**

Pharmacists refer to the training as informative and some stated that it gave them the confidence to provide the service and that it was good to re-cap knowledge that they had not revisited for some time. As part of the face-to-face element, pharmacists were informed of the previous work from the focus groups with patients. This helped them to contextualise the clinic within their practice and tailor their consultations with this information in mind. There was, however, one aspect of training that two of the pharmacists thought could have improved: interaction with other participating pharmacists and healthcare professionals. One pharmacist identified that, in her opinion, interaction with her peers would have been useful to determine how each of them was going to implement the service and what they had learnt as a result of the training in diabetes and study documentation thus far whereas another pharmacist wanted interaction with other healthcare professionals.

“I personally would’ve liked... time with either the diabetes nurse or one of the doctors at the practice er just to clarify er sort of their guidelines and what they were trying to achieve with their patients.” **Pharmacist 3**

There was a need for this pharmacist to integrate further with the medical practice and determine their patterns and guidelines for treatment as he did not want to go against the wishes of the practice nurse or GP when making suggestions to them for treatment alterations.

##### *Conduct of the service*

In terms of providing the service, pharmacists identified that due to the nature of the clinics, they had very little time to prepare for the consultation. None of the pharmacists viewed this as a problem with some even highlighting that it helped them to not lead the conversation, instead allowing the patient to dictate the direction of topics as they had no prior information. Once in the consultation, pharmacists identified a number of topics that patients wanted to cover and these varied for each pharmacist.

“Quite a few people wanted to know about like the prognosis of diabetes, I thought that was quite interesting that they didn’t quite realise that they would be on medication for like a long time” **Pharmacist 2**

This pharmacist appeared surprised at the content of the consultation, expecting participants to focus on medicines but instead wanting to discuss other matters surrounding their condition. With the pharmacist below, their perception was that participants just wanted reassurance that they were doing the right things to control their diabetes.

“I think most people came with some ideas, some had things they just wanted reassurances about other people just came to say their diabetes is fine and explain their medications and... some had directed questions they wanted, some just came along because it was a clinic and it was something they are interested in...” **Pharmacist 5**

“it was good to just sort of talk through the diet and each person I guess had some myths that they were following that weren’t particularly true so I think you know that was good” **Pharmacist 3**

The pharmacists felt that because of this wide variation in topics covered during the consultation, this meant they were sat with the patient for an extended period of time, which they felt had its benefits but could only be achieved because another pharmacist was covering their dispensary workload.

“They don’t normally get to spend a long time talking to the doctor or nurse, they are often rushed, so they liked the idea of coming whenever it suited them and having a open length of time just to discuss any problems with their diabetes, I think it’s quite well received by patients...I think it would be very difficult to run that kind of service if I didn’t have any locum cover or second pharmacist cover... they [patients] feel less intimidated disturbing what you are doing.” **Pharmacist 5**

This statement confirmed that the pharmacists would not have been able to conduct this service had a second pharmacist not been available to them, it allowed them to focus on the needs of the patient as well as completing all of the relevant paperwork required for the study.

### *Study paperwork*

Despite most of the questionnaires being completed in full and the follow-up questionnaires returned to me, some of the pharmacists identified a number of problems with their design and wording.

“they [the patient] didn’t always understand the questions erm you know if they were asked how they feel about this or what they think about this” **Pharmacist 2**

“I think some people found the questionnaires difficult to fill in... Maybe I would have posted the questionnaire with the original invite to the clinic and people could have had that would have prompted people to go away and have a think about things that they didn’t know before the clinic and they might have come with more ideas of things they wanted to discuss” **Pharmacist 5**

Here the pharmacists were concerned that although the questionnaire was composed of smaller, validated questionnaires that have been used many times by other researchers, these patients at times seemed to struggle with some of the concepts. They acknowledge that this may have been as a result of the questionnaire wording but also the fact that they had to complete it in the pharmacy before seeing the pharmacist. In their opinion this reduced the time they had to think about the questions and therefore it may have been more appropriate to send the questionnaire to them with the original letter and information sheet.

Pharmacists also liked the nature of the data collection form as they were able to tick boxes for most elements and this reduced the amount of time they had to devote to completing this form which meant that unlike the PLEEZ study described in chapter two all of the paperwork that the pharmacist was required to complete was done so in full.

### *Benefits arising out of the study*

Pharmacists identified that participating in this study had benefits to patients, themselves as healthcare professionals and their interaction with the medical practice. Pharmacists



highlighted that a positive aspect of the study was that they had had participants return to them after the consultation to update them on their progress, which is something that, as pharmacists, they are not used to. They also identified that it increased the awareness of the pharmacy as the first port of call with reference to their medical condition and that could only be a good thing for all healthcare professionals involved in their care.

“I mean we’ve already had somebody come in this morning to say how his levels, his readings have improved as a result of just having a chat. I think it is fantastic if we can do it in future and if there is the ability for pharmacists to get away from checking prescriptions and providing a service like this its great” **Pharmacist 4**

Most pharmacists highlighted that participating in the study was beneficial to their wider practice as well as the drop-in clinic and that it had given them more confidence to speak to this group of patients. One final benefit that was highlighted was the increased collaboration with the medical practice.

“I think it has strengthened the link with the diabetes nurses coz a lot of the time we have had further questions about a patient whose medication I couldn’t change and I’ve referred to the diabetes nurse... there has been 3 or 4 different interventions which have all been beneficial to the patient... it’s a been a good link” **Pharmacist 5**

“I can only imagine that this the surgery seeing us carrying out these services would be good, it would be good for them, and it does help them, hopefully if the results are good and there is an improvement in people’s controls then it will only be of benefit to them coz they have got their targets as well we can help them do that” **Pharmacist 4**

All of the pharmacists saw this kind of service as benefitting the relationship with the medical practice and demonstrating where the community pharmacist could help when trying to control patients with type 2 diabetes. They also stated that this would help to raise the profile of pharmacy more generally within the medical practice, which could only be good for pharmacy.

## **7.5 Drop-in clinic discussion**

The primary aim of this study was to determine if a drop in clinic aimed at patients with poorly controlled type 2 diabetes and conducted in the community pharmacy was feasible and acceptable to patients and pharmacists.

This was successfully achieved with the drop-in clinic recruiting 33 poorly controlled participants via the medical practice. The study achieved a response rate of 9.6% from the postal invitation, something that has implications for generalisability of the results. A low response rate such as this may imply that only motivated patients were encouraged to participate in the study and therefore these patients may not be representative of the wider population with diabetes. This response rate for also has implications for calculating the required number of participants for a larger study. A low rate will mean any larger study will have to identify a significant number of patients to invite to the study without necessarily increasing the generalisability of the results.

All recruitment methods (comprising the different levels of follow-up mailings between the medical practices) produced approximately the same number of participants and therefore one particular method cannot be preferred from these results. The rate of recruitment using these methods of identifying and alerting potential participants to the study is in line with other published work using a similar approach (Gardner et al., 2011) however it is still low and further work may need to be undertaken to determine how this can be increased. Further work will also need to be undertaken to determine the most appropriate recruitment criteria and methods of identification of potential participants. In this group of patients the QOF cut-off that was used in this study is set at a level of 59 mmol/mol. This may not be appropriate for all patients and clinicians may have identified certain patients for whom targeting below this level would be inappropriate. This may be resolved by greater involvement of clinicians at the outset of a study to determine the most appropriate recruitment criteria in this group of patients.

The questionnaire was completed by all 33 participants at baseline and was returned by 26 (78.8%) three months later as a response to follow-up mailing. This rate of drop-out from the study is within the range taken from the studies detailed in chapter three (2-65%). The questionnaire results from baseline to follow-up demonstrated no differences except a slight increase in the BMQ concerns scale, an increase in the SIMS potential problems score and that five participants that were classed as partially adherent before the clinic became adherent at follow-up. This study was not powered and it can be seen that only differences of greater than 30% were found to be significant. The aim of this chapter was to estimate the effect size in the selected outcome measures.

Closer inspection of the baseline data from the Morisky and SIMS questionnaires demonstrates that in this group of participants almost a quarter reported sometimes forgetting to take their medicines and an eighth stopped taking their medicines if it made them feel worse. It also highlighted that many participants were not satisfied with the level of information received in relation to side effects, the nature and risk of experiencing them, how long the medicine will take to act, how you can tell it is working and whether their medicines will interfere with each other. This provides an indication that this was an appropriate group of patients to target as they were either not using their medicines appropriately or they may have had further information needs.

Results suggested that although there was no increase in the frequency of visits to the community pharmacy there was an increase in the number of times participants spoke to the pharmacist. At baseline, participants wanted to speak about their medicines, over-the-counter remedies and prescription supply whilst at follow-up this changed to include a full range of enquires not just related to these three areas with significant changes to the number of participants wanting to speak about their condition and medicines supply. In terms of the number of consultations this intervention provided it suggests that pharmacists are comfortable with providing a single intervention to patients. However, if this study is to align with the outcomes from the previous chapters then it appears that an approach that factors in multiple consultations may be needed. In this study a single consultation was used to determine whether pharmacists were capable of providing a diabetes-focused service to patients and whether the training and support put in place was adequate. It was also due to the resource and time restrictions that were in place. Now that we have this information it may be possible to further define the intervention and feasibility test some of the components that have not been tested here.

In terms of the appropriateness of the validated questionnaires forming part of the larger questionnaire, participants found some of these questions slightly ambiguous and were not sure what they were 'supposed' to answer. The questionnaire responses produced little change in all of the measures from baseline to follow-up and it may be prudent to alter the design and composition for future use. It may be more accurate and less time consuming for the participant to use prescription refill rates to calculate adherence rather than a questionnaire. If conducted on a larger scale and to enable a cost-utility analysis to be performed a health-related quality of life questionnaire e.g. EQ-5D or the SF-36 questionnaire (Brazier et al., 1992, The EuroQol Group, 1990) would also need to be included. The outcomes used may, in this study, be appropriate as intermediate measures, helpful in informing training requirements and the content of the intervention.

However, for a larger study they could be changed to HbA<sub>1c</sub>, health-related quality of life and prescription refill rates as this would provide a better indication of the effect on the patient at the same time as removing some of the questionnaire burden.

Most pharmacists identified that they let the participant lead the consultation and only used the questionnaire when the participant appeared to think they had been called in and didn't have any particular topics they wished to discuss. Most pharmacists stated they quickly reviewed the questionnaire towards the end of the consultation to ensure nothing had been overlooked.

The consultations themselves lasted significantly longer than GP consultations (Carr-Hill et al., 1998) with the mean time at approximately 32 minutes. This allowed the pharmacist to spend a longer time with the participants discussing all aspects of their care but may prove an expensive intervention if conducted more widely. The cost, per 32 minutes, for the pharmacist intervention is £71.13 which compares to £28.27 for a nurse in a general practice, £26.13 for a nurse specialist, £53.33 for a nurse practitioner and £117.87 for a general practitioner (Curtis, 2012). This therefore means that although the intervention was less expensive than a GP consultation, it was significantly more expensive than a nurse consultation. This could have implications for this type of community pharmacy service in primary care and means that there will need to be a further defining of the intervention in order to make it distinct from current nurse provision, which is less expensive.

Over 90% of participants felt it was useful to speak to the pharmacist about their diabetes and that the length of the consultation was about right. Participants identified that they were satisfied with the information they received and that it was given to them in a way they could understand. There is evidence to suggest, from GP consultations, that the longer the time spent with a patient the more satisfied they will be and more likely they will follow any recommendations made (Ogden et al., 2004), however, this may refer to quality time (in the patient's view) rather than actual time (Cape, 2002).

All aspects of diabetes were covered from the condition itself to prognosis, diet and lifestyle to medicines with pharmacists identifying the most popular topics raised by the participant as:

- Diabetes – the disease
- Diabetes – the effect on lifestyle
- Lifestyle – diet and nutrition

- Medicines – side effects

As a result of the consultations, pharmacists made a number of recommendations (n = 20) for either the pharmacy to implement or to the prescribing team at the medical practices. Some of these involved formulation and dose changes to facilitate improved adherence to treatment, changes to prescribed quantity and on one occasion the pharmacist identified that the participant should have been prescribed a statin and discussed this with them. Most of the changes were focused on the patient's diabetes, however, on a number of occasions this expanded to include some of their other conditions, highlighting the pharmacist's confidence in providing the intervention and making recommendations to the GP. However, it may be necessary to provide the pharmacists with detailed consultation skills in an attempt to keep them on the topic of diabetes and to reduce the overall length of the interaction.

In terms of participant feedback, the majority had a good impression of the service, with over 90% saying that they thought it would help them to manage their diabetes. The impression of the pharmacist also improved with nearly 60% saying it would make them more likely to consult a pharmacist in the future, 100% stating that this kind of service should be available to patients with diabetes and other conditions and that they would recommend the service to others.

Consultation time was noticed and commented upon by participants with many of them identifying on their satisfaction questionnaires that the pharmacist did not appear to rush them and was not distracted by other work in the dispensary. Participants also identified that the pharmacists appeared knowledgeable, professional and approachable with some participants highlighting that the doctor and nurse don't have the time to sit with them and answer all their questions so it was beneficial to have time with the pharmacist.

In terms of the space in which the consultation was conducted, two pharmacists used rooms in the medical practice next door to the pharmacy for practical reasons. The other two pharmacies used their own consultation rooms and a couple of participants referred to these as small and cluttered and wondered if it could have been a bit more private.

Finally, from the de-brief interviews, pharmacists stated that they enjoyed providing the drop-in clinic as it allowed them to use the knowledge that they had learnt from their training, it allowed them to interact with patients more formally and for longer and they especially enjoyed the feedback and hearing from patients about their progress once the study had finished.

Some of the pharmacists highlighted that although they liked the method of recruiting the participants, it meant that they had no idea who was going to present for the clinic and what their circumstances were. One pharmacist, who had access to the patient's medical record, suggested that it may be useful to target patients in an ad-hoc way as well as posting an invitation to them. This pharmacist is unusual in that most community pharmacies do not have access to this data and therefore cannot tell whether a patient is poorly controlled or not. Another aspect one pharmacist identified was the potential need to stagger the posting of the invitations to prevent a sudden influx of patients on the day of the first clinic. Although this did not happen, it is a valuable consideration to retain for future, larger studies.

Pharmacists identified that the training was sufficient to prepare them for consultations with patients with the CPPE package being well received and covering all the topics necessary. Some pharmacists found it extremely beneficial for their day-to-day practice as well as the drop-in clinic. Pharmacists also highlighted that the face-to-face training was useful as it provided a context to the study that allowed pharmacists to tailor their conversations with patients. As a result of this training, they had a good understanding of the study procedures and paperwork and with the researcher being present at every clinic it gave the pharmacists the opportunity to focus on completing that documentation in full with support available if necessary.

One aspect to the training that the pharmacists would have liked more of was interaction with other pharmacists and healthcare professionals involved in the study. This was to provide two benefits: to interact with other pharmacists involved in the study in order to understand their perspective and how they were going to implement it in their practice, and other healthcare professionals, notably the GP and practice nurse, to understand local guidelines and targets for treatment. This last point would have been useful to ensure an integrated strategy for treating these patients between the community pharmacy and medical practice.

In terms of feedback on the questionnaire from the pharmacists, they believed that some of the questions particularly in the BMQ section were ambiguous and that it could have been easier to complete with one pharmacist saying it was also too long. However, this was not identified by the participants' feedback with the majority saying that the questionnaire was the right length and asked the right questions for them.

The other issue identified with the questionnaire was the method of administering it at baseline; pharmacists thought that it may have put participants under pressure to complete it in a short period of time and that it may have been better to send it out with the postal invitation instead. This would have allowed the participants to think about the answers more carefully and then come to the consultation with a more informed idea about what they wanted to discuss. They also felt that the answers from the first and second questionnaires may have differed because of the different setting in which it was completed. However, this method of administering the questionnaire may have reduced the response rate even further.

In terms of the feedback on the consultation, the pharmacists identified that one of the most important aspects to the service was the locum support provided as part of the research. This enabled them to focus on the patient and not feel distracted by events in the dispensary.

This study has demonstrated that pharmacists are able to provide a diabetes drop-in clinic in the community pharmacy setting and that it will attract poorly controlled patients referred from their medical practice. It has provided information for a larger study such as the appropriate method of recruitment, response rate, topics covered during the consultation and has alluded to the kind of interactions the pharmacist may have with the medical practice when requesting changes to medication. It has also demonstrated the need to re-design the questionnaire and potentially shorten it to one validated health-related quality of life measure coupled with clinical measures and prescription re-fill rates as outcome measures.

#### 7.5.1 Limitations of the study

In terms of a feasibility testing, this study has been successful. The medical practices were willing to refer patients to the service, pharmacists could conduct the consultations and patients find them acceptable and are willing to engage with the process. However, this study could only be conducted with the researcher support that allowed the pharmacist to spend the length of time they did with the participants and is unclear how manageable this would be on a larger scale.

In a larger study, the primary outcome measure would be HbA<sub>1c</sub> and this would need to be collected for sometime after the end of the study and any changes made requested by the pharmacist as a result of the clinic would need to be followed-up to determine their implementation rate. The extent to which both of these can be achieved was not tested during this study. To inform a larger study a pilot study would be required with HbA<sub>1c</sub> as

an outcome measure or good evidence from the published literature. Adherence was characterised using a self-report method which may be less reliable than other forms of adherence measurement e.g. prescription refill data. Again, the extent to which this data could be collected would need to be tested in any subsequent pilot study.

From the literature review in chapter four, it was identified that a successful intervention in this group of patients may require multiple consultations over an extended period of time. This study did not examine that scenario in a UK context and therefore further feasibility testing may be required to ascertain if this would be possible.



## **7.6 Drop-in clinic conclusion**

This study of a community pharmacist diabetes drop-in clinic has demonstrated that the concept is feasible within the setting and is acceptable to both participants and pharmacists. This service identified patients that were poorly controlled of which some were non-adherent to their treatment and some may have had concerns about taking their medicines. The pharmacists in our study aimed to address these problems and in view of the participant's feedback succeeded in appearing knowledgeable and engaged with their needs as a patient. The clinic helped to improve the number of participants classed as adherent as well as providing clinical recommendations to the medical practice.

The pharmacists spent longer with the participants during the consultation than their GP or practice nurse would do normally and covered almost every aspect of their diabetes care. This helped to establish a relationship between the pharmacist and participant that, from the feedback, they both found valuable. The pharmacists also made a number of clinical recommendations as a result of the study that they had discussed and agreed with the participant before approaching the prescriber. These recommendations were made in line with national guidance that the pharmacists had been provided with as part of the training for the study.

Pharmacists suggested the questionnaire provided little help in guiding the conversation and they let the patient lead the discussion. However, it may be appropriate in future to include an element of consultation skills training in order that the pharmacists can balance this aspect of time and content in a sustainable way for a larger number of participants. The consultations lasted for an extended period of time and covered topics that are potentially already covered by a nurse-led service that is significantly cheaper.

In future, the use of the questionnaire may need to be adjusted in terms of content and time of completion. In order to obtain a more considered answer it may be more appropriate to provide the participant with the questionnaire before they arrive at the pharmacy. This may mean that the patient has more time to think about the answers and the information needs they may have before consulting with the pharmacist. However, it may also be appropriate to determine appropriate measures for inclusion such as health-related quality of life rather than adherence, which can be measured in other ways.

One of the main aspects of this study that assisted its successful completion was the presence of a researcher in the community pharmacy at the time of the clinics. This locum support allowed the pharmacist to concentrate solely on providing the clinics and focusing

their attention on the participant. Without this support, the study may have replicated the RCT conducted in chapter two.

After visiting the clinic, there was a small positive change in the perception of the pharmacist as someone with the knowledge to be able to assist these patients manage their condition. This was referenced by the increase in the number of variety of discussions between the two. Pharmacists also felt that it had helped them to interact with the medical practice and patients in a way that was not usual for their practice. As part of future training it may be appropriate to include the medical practice in the training aspect of the study in order that pharmacists can understand their priorities for care in this group of patients.

This study has demonstrated that this type of clinic is feasible in the UK community pharmacy setting. However, further changes would need to be made to ensure that this service does not duplicate those that are already being provided in the primary care setting and an increased cost to the NHS.

 *Chapter Eight*

## 8 Overall discussion

The original aim for my PhD was to determine whether there was a role for the community pharmacist in the management of long term conditions. On reflection, this has not been achieved as part of this process. However, the work contained within this thesis has contributed to the definitions of both 'role' and 'management' within this aim even though it does not provide an answer to the original question. It has helped to identify that the pharmacist's 'role' needs to take into account other healthcare professionals in the UK primary care setting. It has highlighted that although the pharmacist may have a role in the management of these conditions this role cannot be simply put in place without due consideration of other healthcare professionals. The term 'management' has been further defined in terms of what the pharmacist could and should be focusing on as part of their consultations with patients. The audit ruled out certain aspects to a pharmacist intervention, including that of changing medication. Pharmacists in the intervention, without direction, focused on adherence as well as diet and lifestyle advice and information about their condition. This implies that any pharmacist intervention relates to more information provision than altering current therapy.

One research question that has been answered relates to defining aspects of community pharmacy that form a conducive environment in which to conduct research to provide evidence for the role of the pharmacist. This is in reference to the need to have appropriate support mechanisms in place for a community pharmacist to perform research. This means researcher or locum support to free the pharmacist from their routine tasks and allow them to spend time with the patient. It also relates to the identification of participants, as pharmacists, if left to recruit by themselves, may not be able to successfully perform the required processes as part of the research. This will result in disengagement and poor recruitment of participants.

The evidence contained within this thesis provides a backbone on which to conduct further research in the community pharmacy setting. It has detailed that before conducting research into a particular intervention, researchers need to conduct preliminary work to consider where and to whom the intervention should be targeted. This thesis has identified that it would be more appropriate to target poorly controlled patients, it has provided some definition to a pharmacist intervention and has tested that intervention for acceptability. However, there is still more to add to this 'backbone' particularly with reference to the context of primary care and the pharmacist's role within that team and the content of the intervention. These aspects need to be researched more thoroughly before progressing with a definitive study.

It has attempted to define the concept of 'management' in patients with long term conditions as potentially one of information provision, as well as interacting with them to determine where they foresee the role of the community pharmacist in their care. Neither of these concepts have been explored in the UK before. The novel intervention has provided evidence, not of the effectiveness of the pharmacy service but of the feasibility of conducting such research in this setting and the considerations that need to be made in doing so. In conducting research in this setting, researchers need to be aware of the time and working constraints of community pharmacists when asking them to participate in a study. This will have implications for recruitment and provision of any intervention if it is not factored into the design of such work. We also need to be aware of the place of not just community pharmacy in the wider primary care team but also the place and role of the other healthcare professionals. In this case, the position of the practice nurse has particular importance for the provision of a community pharmacy service.

The Government vision for community pharmacy is to move from a medicines-supply role to a more patient-focused approach by providing services aimed at managing long-term conditions. This vision has been re-enforced in several White Papers and it is now the responsibility of higher education institutions and community pharmacy itself to provide the evidence required to aid service implementation on a larger scale.

The work in this thesis has discussed the current evidence base for community pharmacy services as well as published research examining new roles for the pharmacist. Published evidence of research in this area has either been lacking or when it has been conducted appropriately has often produced a negative result for the role of the pharmacist. This lack of a significant evidence base for community pharmacy services may be as a result of several factors that influence the ability to be able to conduct research which include the perception of research by pharmacists and patients, the extent to which pharmacists understand the processes behind research, the level of knowledge they currently have and the approach that researchers take to conducting studies in this setting.

Leading on from this, the work in this thesis has been heavily influenced by the MRC framework for developing complex interventions in order that we could design a novel and robust community pharmacy intervention, that pharmacists could provide and patients would engage with. This started with the PLEEZ study which was a feasibility study that aimed to test whether an RCT could be used in community pharmacy to examine the effects of a pharmacist-led eczema support service. This seemed, at the time, to be the most appropriate approach to take as a first step before conducting a full scale RCT. However, the study failed due to a number of factors that could have been easily identified

with appropriate preliminary work and predicted with a more robust analysis of the MRC framework before conducting feasibility testing. This work may have identified that this approach to community pharmacy research was always going to lead to poor results and that problems such as pharmacist support and study paperwork were central to a successful recruitment process.

At this point, I revisited the MRC framework and planned a series of preliminary projects prior to the design and implementation of a feasibility study. These projects included a literature review, an audit and a set of focus groups, the aim of which was to inform the design and content of the final project. The first change to be made was to the target disease state. We needed to focus on a disease state that will guarantee any future service a large number of potential participants as well as being targeted by the medical practice. Type 2 diabetes was chosen as it aligned with both of these requirements: a large number of diagnosed and poorly controlled patients and it is subject to the QOF targeting system.

The literature review, audit and focus groups all occurred at the same time as described in the figure at the end of chapter two. The literature review examined the current treatment options and evidence surrounding type 2 diabetes and went on to detail the current evidence base from the UK and internationally regarding community pharmacist interventions in this area. The aim of this was to identify those trial designs from other studies that worked well and those that did not to determine what could be used in our study. This review indicated that the most successful studies could conduct an RCT in community pharmacy but if it were to be successful randomisation had to occur at the pharmacy and not the patient level. This will increase the size of any trial but may produce a more manageable and successful study. In terms of training provision, again the most successful studies provided the pharmacists with an extensive training programme aimed at increasing their clinical knowledge along with their communication and consultation skills. The inclusion criteria for these studies indicated that recruitment based on HbA<sub>1c</sub> levels is useful in targeting those patients that are poorly controlled with respect to their diabetes. It also demonstrated that this kind of targeting of patients is possible but that close working with the medical practice would be necessary to achieve it. Finally, the interventions provided to the patients were all conducted over a period of months with repeated visits to the community pharmacist and covered all aspects of their condition.

The review was successful in identifying the design elements of a study that we wanted to conduct in the UK community pharmacy setting. However, the consultation content was wide ranging and the aim of the audit was to determine if such a consultation was

necessary in the context of the UK NHS. This was important as the role of the diabetic nurse specialist is clearly defined in the UK and it may have implications on whether the international studies identified can simply be transferred to the UK community pharmacy setting. The audit aimed to determine if prescribing for type 2 diabetes in primary care was in line with national guidance. The results demonstrate that this is largely the case in terms of the medicines prescribed for diabetes. However, there are still a large number of patients that remain uncontrolled with respect to blood glucose, blood pressure and lipids. The audit demonstrated that the pharmacist may have a role in providing services to these patients centred on the modification of cardiovascular risk, managing blood pressure or adherence support.

Finally, the diabetes patient focus groups identified that patients value the input and expertise of the community pharmacist in their care especially in relation to information about side effects and interactions with over-the-counter medicines. However, they highlighted that they would be uneasy with community pharmacists conducting interventions aimed at addressing the control of their condition unless their medical practice had sanctioned their involvement. This was important for a number of reasons including the need for patients not to violate their perceived natural line of treatment and the need for GPs, as controllers of their medical care, to validate the role of the pharmacist in the primary care team. They also identified that it was important for the pharmacist to be able to communicate any intervention outcomes directly to the prescriber rather than the patient having to return to the medical practice to relay information.

Participants in the focus groups also highlighted some important information regarding the community pharmacy environment as a place where they receive healthcare advice. After seven years of the new pharmacy contract, it appears that our participants still have reservations about the privacy available in the community pharmacy and the ability of the pharmacist to engage with them as they perceived them as 'always busy' in the dispensary.

All of this work helped to inform the design of the diabetes drop-in clinic which was conducted in five community pharmacies in Norfolk. The study factored the following elements into the design (as described more fully in chapter seven):

- Targeting poorly controlled patients
- A system of referral from the medical practice to the community pharmacy
- A training programme for the participating pharmacists
- An access system which did not require an appointment

- An additional pharmacist to provide support to the service pharmacist
- A focus on adherence as well as diet and lifestyle advice.

This drop-in clinic produced excellent results with 33 patients attending one of the sessions in four of the five pharmacies, encouraging results from the outcome measures tested, positive patient feedback and comments from the pharmacists during their de-brief interviews that can be used to inform future studies.

Pharmacists were able to cover a wide variety of topics during the extended consultations with patients. Patients acknowledged that the pharmacist had the knowledge, communication skills and professionalism to give them confidence in the information they received from the consultation and they would like it to be more widely available to patients with diabetes. The study also demonstrated a slight increase in the number of times patients spoke to the pharmacist and the topics about which they were prepared to speak to them. However, the consultation lasted for a significant period of time and at times ventured on to topics not associated with diabetes. This may point to the need to provide the pharmacist with consultation skills training in order to conduct a more focused conversation with the patient.

At the same time the drop-in clinic was being conducted, a similar study had been published which had also been conducted in the UK. This study was based in Hertfordshire and used an RCT methodology in two pharmacies (Ali et al., 2012). The pharmacists were provided with an eight hour training package at the University of Hertfordshire (UH) that included workshops with a consultant diabetologist and a specialist diabetes nurse. Participants were alerted to the service using posters, leaflets, referred from the GP/nurse or identified at prescription dispensing. Those approached and asked to participate were over 18 years old, had no significant co-morbidity, were not involved in other research, were able to attend regular visits and had an HbA<sub>1c</sub> > 53mmol/mol (7.0%). This final measurement was conducted in the pharmacy and sent to an external testing company for analysis.

The intervention involved regular monitoring and consultations with the community pharmacist for 12 months; a total of six consultations. It consisted of a targeted MUR if appropriate, lifestyle modification and referral to the GP if necessary. It also included education about diabetes and its complications and a review of the patient's medicines.

The UH study aimed to recruit 30 participants in total however the power calculation used to ascertain this figure does not align with other studies that have reported in this area and



have been discussed in chapter four. The study actually recruited 48 participants and included 46 in the final analysis which is encouraging as it demonstrates that patients were willing to attend all the sessions over an extended period of time. The results from the study indicated a significant difference in HbA<sub>1c</sub> between the intervention and control groups. There were also significant differences in other clinical outcome measures along with health-related quality of life, diabetes knowledge test, BMQ-necessity and concerns scores and SIMS.

This study aligned well with the studies described in the literature review especially in relation to the number of consultations. This team demonstrated that it was possible to conduct multiple consultations with patients over an extended period of time. My study used a single consultation due to resource and time allocation. However, it may be prudent to determine which approach is better at improving the care of patients as one will be significantly less expensive than the other.

All of this work has advanced the understanding of what the role of the pharmacists may entail, however, it has largely failed to factor in the primary care context. The degree to which any pharmacist intervention is implemented will rely on the gaps in care currently provided by other healthcare professionals. Further work needs to be undertaken to find this niche for the community pharmacist and design an intervention around this.

## 8.1 Conclusions

The work in this thesis has demonstrated that there are still a significant number of patients for whom diabetic control cannot be achieved. These patients could potentially benefit from a community pharmacist-led service aimed at improving their care. In the past there have been problems with conducting research in the community pharmacy setting or have demonstrated negative results and this thesis has attempted to unpack these problems and factor them into the design of a new intervention.

The results from this intervention, and the thesis as a whole, pose important questions in relation to the role of the community pharmacist in the management of patients with long-term conditions. The work conducted internationally cannot simply be transferred to the UK setting in the hope that it will lead to the improvement of patient care. This is largely due to the increased role that nurses play in UK primary care. The intervention tested here is a case in point. All of the subjects that were discussed with the pharmacist during an extended consultation were those that could have been discussed easily with the practice nurse, with a dedicated consultation space and access to medical notes. This highlights two important issues in relation to community pharmacist services. The first issue relates to intervention definition. With many patients still uncontrolled in the current primary care environment, it may be appropriate for the community pharmacist to become involved in their care. However, this cannot simply be duplication of services but in a different setting as it has implications for cost to the NHS. Further work needs to be conducted to determine the exact gaps in patient care and where the pharmacist niche occurs for any intervention to be accepted by the wider primary care team and patients alike.

The second relates to consultation skills and the need for pharmacists to be given the knowledge to be able to focus a consultation better. During my study pharmacists spent more time with patients than GPs or nurses. This may be necessary, but as it has significant cost implications, an investigation to determine the need for and potential for implementation of greater consultation skills training should be conducted.

Although this work set out to answer a broad question about the role of the pharmacist in patients with long-term conditions, it has actually answered another question regarding the definition of both the role and management in relation to the pharmacist and the context of primary care in the UK. This raises further questions regarding the intervention definition, pharmacist niche and pharmacist consultation skills that all need to be addressed in order to provide a clear view of what the pharmacist can bring to the table that is distinct from what is currently available.

## 8.2 Recommendations for future work

Further preliminary work to be performed before a definitive RCT:

- Perform a full, systematic review and meta-analysis of the available literature examining the role of the community pharmacist in the care of patients with type 2 diabetes. This would be to formalise the findings from chapter four.
- Triangulation of focus group data by the use of a widely administered questionnaire to patients with type 2 diabetes, developed using that data.

This will assist in determining whether the views detailed in the focus group chapter are more widely held in the population of patients with type 2 diabetes. This will assist in the validation of the focus group findings.

- Qualitative interviews or focus groups with other healthcare professionals about their views and perceptions of the current treatment/management gaps in the care of patients with type 2 diabetes.

This will help to determine where there are current gaps in the care of patients with type 2 diabetes. This information can then be used to ensure that any pharmacist intervention does not duplicate a service conducted by other healthcare professionals or provides a service that could be conducted by a less expensive healthcare professional e.g. practice nurse.

- A larger audit in a greater number of medical practices encompassing the findings from chapter five.

This will attempt to capture information on medication doses as well as adherence as measured by prescription issue. This needs to be conducted to further define the intervention in terms of the consultation topics that should be addressed by the pharmacist. This audit will provide a better indication of the prescribing practices in this group of patients and whether there are any gaps in care. The reason for capturing adherence at the medical practice is that it will be more accurate than patient self-report and will determine if this is indeed a problem in this group of patients.

- Appropriate quantitative and qualitative work to understand pharmacists' current consultation skills and where they perceive any gaps in knowledge.

This will help to understand the current practices surrounding pharmacist consultation skills. This mixed methods approach will involve conversations (preferably focus groups due to the nature of the data required) with pharmacists about their perception for the

need for good consultation skills when speaking to patients but also work to characterise the consultation process as it happens. This may take the form of observational research of pharmacists conducting consultations and assessing their performance against a standard grading scheme. This will assist in understanding how pharmacists conduct a consultation and if there are any needs for further training.

Definitive study:

- Perform a pilot study of a diabetes drop-in clinic in community pharmacy. The decision to perform this pilot study will rest on whether the above further work conducted refines the questions posed at the end of the thesis with regards to intervention definition and consultation skills. If no further intervention detail can be obtained then a follow-on study will not be necessary as it will be a repeat of the intervention described within this thesis. If, however, further definition to the intervention provided by the pharmacist can be obtained and it can align with the UK primary care setting, a pilot study will be performed. This pilot study will also have to factor in multiple consultations and collect HbA<sub>1C</sub> data as the primary outcome measure.

The most important aspect of this work to be conducted first will be the further definition of the intervention and how this aligns with current primary care practices and healthcare professionals.

### 8.3 Publications and conference presentations arising from the thesis

#### Peer-reviewed Journals

**Twigg MJ**, Poland F, Bhattacharya D, Desborough JA, Wright D; The current and future roles of community pharmacists: the views and experiences of patients with type 2 diabetes. *Research in Social and Administrative Pharmacy*. (*In Press*)

**Twigg MJ**, Bhattacharya D, Poland F, Desborough JA, Wright D; (2012) The views of pharmacists who participated in a community pharmacy RCT; *International Journal of Pharmacy Practice* (*In Press*)

**Twigg MJ**, Bhattacharya D, Desborough JA, Wright D; (2012) Is there a role for pharmacists in the management of patients with type 2 diabetes? An audit of prescribing in primary care. *Primary Care Research and Development* (*In Press*)

#### Published Conference Abstracts

**Twigg MJ**, Poland F, Bhattacharya D, Desborough JA, Wright DJ (2012) Patients' perceptions of the current and future roles of the community pharmacist in type 2 diabetes care. *International Journal of Pharmacy Practice* 20 (Suppl. 1) 5-15 (Oral presentation at HSRPP 2012)

**Twigg M**, Bhattacharya D, Desborough JA, Wright DJ (2011) Adherence to NICE guidance for prescribing in type 2 diabetes in primary care. *International Journal of Pharmacy Practice*, 19, 38-64. (Poster at RPS 2011)

 *Chapter Nine*

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# *Appendices*

**■ ■ ■** *Appendix One*



## Protocol

A randomised controlled trial of a Pharmacist LEd EcZema management support service (PLEEZ). A pilot study

Version 7

March 2009

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## 1. Introduction

Atopic eczema is a chronic, relapsing, inflammatory skin condition typically affecting the flexures where it presents as a papular rash, however, affected individuals will generally also have widespread dry skin. The aetiology of eczema is not fully understood but dry, inflamed skin is partially due to an inappropriate immune response resulting in the production of inflammatory mediators which cause damage to the stratum corneum. The highly itchy nature of the condition often results in the papular lesions becoming excoriated and thus colonised with *Staph. aureus*, hence impetigo is common. In addition to contributing to secondary infections, the itchy nature of eczema produces considerable insomnia.

Eczema frequently presents in early childhood, improves with age and resolves by adulthood. UK reported lifetime eczema prevalence in children has ranged from 25% to 41%.[1, 2] and observation of epidemiological trends have demonstrated a gradual increase in eczema prevalence over the past 10 years.[3]

Given the increasing prevalence of eczema, the costs incurred due to eczema are also set to rise. Estimations of annual eczema associated costs have included the cost of NHS care such as hospital and GP consultations and the cost of therapy. Additionally, loss of income due to caring for an ill child has been estimated. A positive correlation between annual cost and eczema severity has been reported with an analysis of severely affected children reporting a mean annual cost of £740 per child.[4]

The mainstay of treatment is regular emollient and soap substitute use of which numerous varieties are available, however, trials of acceptable rigour evaluating the impact of these emollients are limited. Due to the absence of any trial evidence to demonstrate superiority of one product over another, the recent National Institute for Health and Clinical Excellence (NICE) guideline for the management of eczema in children has recommended that:

'Healthcare professionals should offer a range of different products to children with atopic eczema for topical application and for washing, and children should be encouraged to try out various combinations of topical products. The correct emollient is the one that the child will use.'

It is regularly cited that the frequency of emollient application is crucial to the efficacy of the product, however, few trials report either the volume or frequency of application recommended.

NICE guidelines recommend frequent use in large quantities due to their short lived effect, suggesting 250g per week or more. [5] Furthermore, the guidelines stipulate that "Adherence to emollient treatment is the key to successful therapy for atopic eczema".

There is considerable evidence supporting the improved outcomes associated with steroid use compared to emollient alone. [6-8] In addition to regular emollient use, topical steroids are therefore generally required as an adjunct to treat exacerbations or in the case of frequent exacerbations, may be used once or twice weekly to prevent flare ups. [5] Whilst the benefits are clearly demonstrable, steroid induced adverse effects can be very damaging with children being more susceptible than adults. Adverse effects range from local irritation and skin depigmentation or discolouration to Cushing syndrome and growth retardation and likelihood is directly associated with the frequency and volume of use.[9] Such risks have been demonstrated to cause carers and parents to become anxious about the use of topical steroids on children, resulting non-adherence to prescribed recommendations either in the form of infrequent or non use. Particular lay beliefs that have been reported include 'they should only be used to treat severe eczema' and that they are 'too dangerous' to be used on children.[10]

The problems associated with adherence to eczema therapy such as patient acceptability of emollients and lay perceptions of the risks and benefits associated with topical steroid use have resulted in a number of interventions to address the issue of non-adherence to therapy. Educational interventions are the most frequently reported. A recommendation taken from the NICE guidelines for eczema management in children is outlined in the box below:

The [National Institute for Health and Clinical Excellence guideline](#) (NICE) for the management of atopic eczema in children issued in 2006

Healthcare professionals should spend time educating children with atopic eczema and their parents or carers about atopic eczema and its treatment. They should provide information in verbal and written forms, with practical demonstrations, and should cover:

- how much of the treatments to use
- how often to apply treatments
- when and how to step treatment up or down
- how to treat infected atopic eczema.

This should be reinforced at every consultation, addressing factors that affect adherence.

Given the higher incidence of eczema in children compared with adults, it is unsurprising that interventions have largely focussed on this age group. Eczema educational programmes have been demonstrated to enhance clinical outcome from therapy.[11-13] This has been associated with either an increase in emollient or steroid use, thus a better utilisation of prescribed therapy. A community pharmacist intervention provides the additional advantage of improved access to healthcare via availability out of surgery hours such as evenings and weekend.[14] A pilot trial involving community pharmacists providing educational support to children and parents has demonstrated a small, significant improvement in symptom severity post intervention. This intervention, however, was focussed simply on increasing emollient use, research has demonstrated that up to 80% of parents and carers of children are concerned about the side effects of topical corticosteroids with 25% reporting discontinuing use due to the associated anxiety.[5] It is therefore essential that interventions emphasise the importance and value of both emollient and steroid appropriate use.

## **2.1 Aims**

- Define the methodological approach and service design of a pharmacist led eczema management support service.
- Enable a formal power calculation to be conducted for a Phase III randomised controlled trial via estimating the magnitude of difference and variance between intervention and control in terms of the following primary outcome measures:
  - Satisfaction with Information about Medicines received (SIMS)
  - Children's Dermatology Life Quality Index (CDLQI)

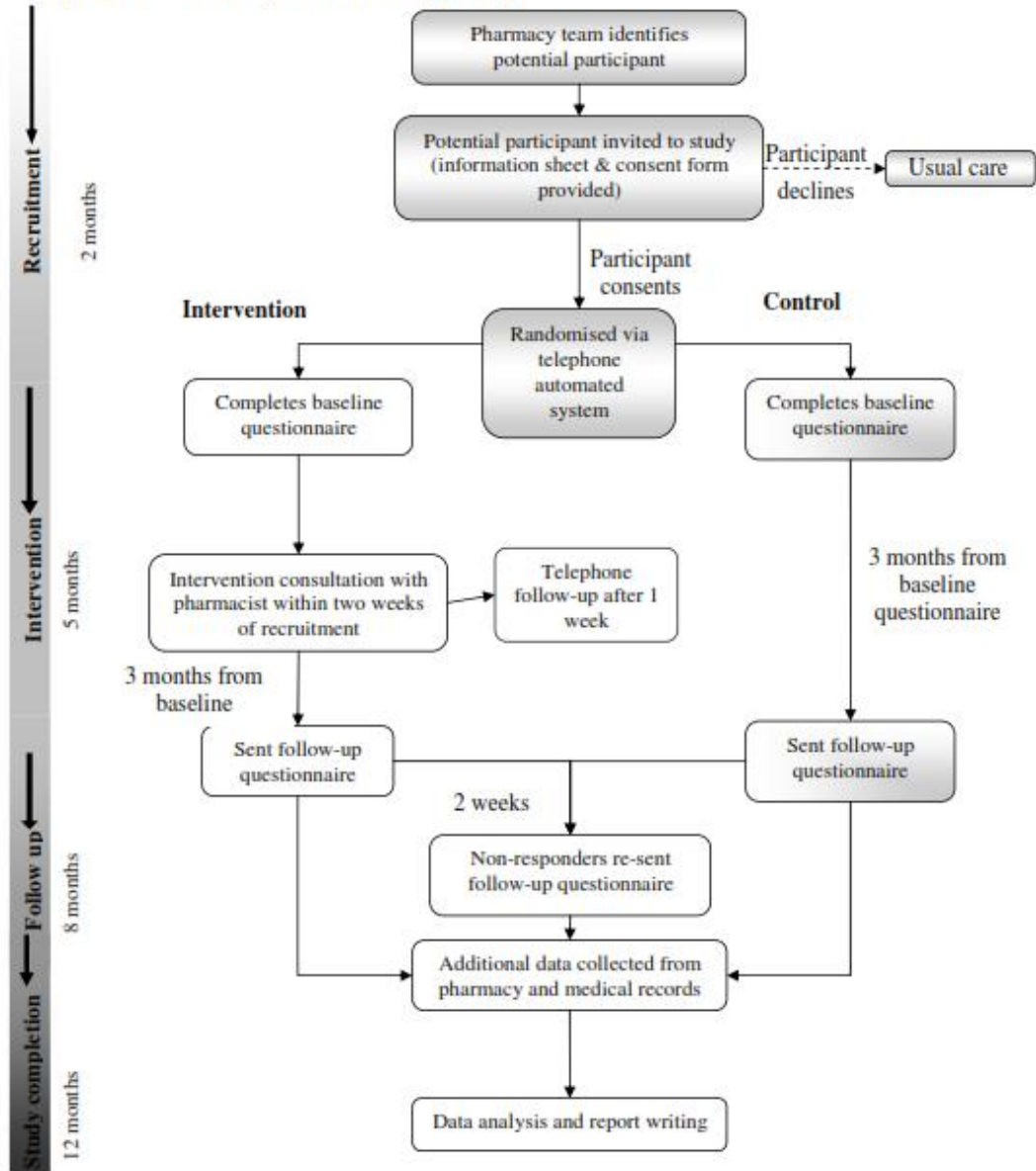
## **2.2 Objectives**

- Trial the methodological approach and service design in terms of the following:
  - questionnaire design
  - patient and pharmacist recruitment
  - pharmacist training provision

### 3 Method

The study will employ a randomised controlled trial (RCT) design to determine the impact of this pilot pharmacist led eczema management service. The flow of participants through the study will follow the chart illustrated in figure 1. Research governance and ethical committee approval will be obtained prior to commencing data collection as per the timeline in figure 2.

**Figure 1 Flow of patients through study**



**Figure 2 Gantt Chart**

	Jan '09	Feb	Mar	Apr	May	Jun	Jul	Aug	Sept	Oct	Nov	Dec	Jan '10	Feb	Mar
Literature review															
Governance & Ethics review															
Recruitment of pharmacies															
Training															
Recruitment of patients															
Trial period*															
Follow-up questionnaire(s) sent out															
Additional data collected from pharmacies															
Data analysis and report writing															

\*The trial period is three months, however, participants recruited at the start of the recruitment period will receive their baseline questionnaire and (if necessary) their intervention as soon as they consent to take part. Therefore, the trial period will last three months after the last possible date of recruitment.

### **3.1 Pharmacy recruitment**

All Numark Pharmacies in one PCT area with a consultation room will be invited to participate. Eligible pharmacies will be identified and approached by the research team at the University of East Anglia. Pharmacies will be remunerated for all activities associated with the study including participant recruitment, delivering the intervention and data collection. Ten pharmacies will be required to participate in this pilot study.

### **3.2 Primary Care Trust (PCT) involvement**

The methodology for this phase II trial has been developed in collaboration with NHS Norfolk and the Norfolk and Norwich Foundation NHS trust. Particular input has been sought with respect to defining age range of participants and the range of emollient samples to offer patients to ensure that they are in accordance with PCT formulary. They have also, supported the development of methods to communicate pharmacy recommendations to the primary care team, to ensure continuity of care.

### **3.3 Communication with the primary care team**

The trial will be introduced to prescribers via a routine NHS Norfolk lead prescribers meeting plus a dedicated skin management meeting delivered by NHS Norfolk. In addition all prescribers associated with the participating pharmacies will also be contacted by mail prior to trial commencement to provide information on the study and obtain consent for their patients to be approached for trial participation. Any pharmacist interventions as a course of the trial will be communicated to the primary care team (general practitioners and / nurses responsible for the eczema management of a patient) via a notification form (appendix 1). Prescribers will be familiarised with this notification form prior to trial commencement in order that they are aware of what to expect to receive from the pharmacist as a result of a consultation with the patient and parent/guardian.

### **3.4 Pharmacy team training**

Participating pharmacies will identify one member of the team to be responsible for the study (excluding the pharmacist). This team member will be trained in the study protocol, participant recruitment (including gaining consent) and data collection by a member of the research team. The designated team member will be the main point of contact for the research team.

### **3.5 Pharmacist training**

Eczema focussed training developed in conjunction with the Norfolk and Norwich NHS Foundation Trust and NHS Norfolk will be provided to pharmacists by a NHS Norfolk eczema specialist nurse.



Pharmacist training will involve completion of a Centre for Postgraduate Pharmacy Education developed Eczema training package prior to attendance at a training evening which will include eczema related clinical topics in addition to training in application of emollients and steroids. Training in consultation skills will be provided on a separate occasion and will be underpinned by techniques designed to explore patient beliefs and concerns plus motivate adherence to prescribed therapy.

### **3.6 Participant recruitment**

All parents or guardians who present at the pharmacy with a prescription for an emollient or a steroid topical preparation for their child, will be asked if the patient has been diagnosed with eczema by a doctor. Potential participants who have been previously prescribed these products will also have their records 'flagged' to alert staff when they present at the pharmacy that they may be suitable to invite to the study. The study will be explained to them and they will be provided with an information sheet: one aimed at the parent/guardian and the other aimed at the child (appendices 2 & 3). Potential participants will be free to take the information sheet away with them to consider participation. All parents or guardians who consent to participation will be asked to complete a written consent form on behalf of their child (appendix 4) and if the child is aged 6-10 years they will be asked to sign an assent form (appendix 5).

The recruiting of participants, providing information on the study and obtaining informed consent will be undertaken by a nominated member of the pharmacy staff. This member of staff will have been trained in the study design and also how to obtain informed consent from potential participants.

It is anticipated that the recruitment period will be 2 months according to the inclusion and exclusion criteria listed below:

#### **3.6.1 Inclusion criteria**

- Currently receiving topical treatment for diagnosed eczema
- Provides written informed consent
- Has been attending the pharmacy with prescriptions for eczema medication for at least three months before recruitment

#### **3.6.2 Exclusion criteria**

- Unable to understand written and / or spoken English
- Any other diagnosed skin conditions

### 3.7 Randomisation

All participants that provide informed consent will then be randomised by an automated telephone randomisation service. The pharmacy staff will phone the automated randomisation service where some basic details will be recorded and the participant allocated to the intervention or control group. The allocation will be stratified by pharmacy to ensure approximately equal numbers of intervention and control patients in each pharmacy. Participants randomised to the control group will be asked to complete the baseline questionnaire (appendix 6) at this point. Those participants in the intervention group will have the intervention appointment arranged, however, they will still be asked to fill out a baseline questionnaire at the point of recruitment into the study (appendix 6).

### 3.8 The intervention

Participants randomised to the intervention group will have an appointment for a consultation arranged with the pharmacist at a mutually agreeable time within the following two weeks. The participant and parent or guardian will be taken to the consultation room with the pharmacist for the eczema management support session which will last up to 30 minutes. The pharmacist will use the previously completed baseline questionnaire to inform the consultation which will be targeted at the participant's needs, thus consultations will comprise of core content and possibly additional aspects in response to individual need. Table 1 summarises the content of the consultations.

**Table 1. Intervention content**

<b>Core items discussed with all participants</b>	<b>Additional items addressed in response to individual need</b>
Current topical eczema management	Demonstration of steroid and emollient application technique
Frequency and volume of emollient use	Advice regarding future management strategies
Frequency and volume of steroid use	Lifestyle advice
Technique of application	Provision of emollient samples to try for preference

One week post consultation, the pharmacist will contact the participant to discuss their progress with implementing any recommendations, offer any further advice and co-ordinate any prescription changes if needed.

### 3.9 Referral Criteria

If the pharmacist suspects infection i.e. weeping or crusting, the patient will be referred back to the general practitioner for assessment.

### 3.10 Focus Groups

When the parent/guardian signs the consent form they will be asked to tick a box to say whether they would be interested in participating in a focus group held by the research team at UEA. If they tick this box, they will be contacted by the pharmacy concerned with their care after the trial has ended and asked formally if they would like to participate in a focus group. If they agree, the pharmacy will send them an information sheet (appendix 7) and consent form (appendix 8). The consent form will then be returned to the researchers who can contact the participants directly to inform them of the time and location of the focus group.

The intention is to recruit a purposive sample of sixteen participants to ensure wide representation of the pharmacies involved and outcomes achieved. This group of sixteen will be split to form two focus groups of eight people. The researchers will contact the pharmacies to ask them to call all of the participants at their pharmacy who suggested they would be interested in taking part in the focus group. This initial telephone call will allow the pharmacy to gain verbal consent from the participants for the researchers to obtain their names and addresses to send the information sheet and questionnaire out to them. The consent forms will be sent back to the researchers who will randomly choose ten people (one from each pharmacy) to participate in the groups.

The focus group discussions will be recorded and the following areas will be discussed:

- General discussion about managing eczema
- General impression of the trial
- Method of recruiting the participants
- Design and information contained within the information sheets and consent forms
- Design and information contained within the questionnaire
- Time and ease of questionnaire completion
- Identify any benefit or service improvement needed.

### **3.11 Data collection**

#### 3.11.1 Patient questionnaire

Participants in both the intervention and control groups will complete a baseline questionnaire (appendix 6). This questionnaire has been designed specifically for this project and includes previously validated questionnaires on adherence, quality of life and satisfaction with information about medicines in addition to some basic demographic questions.

- a) The Beliefs about Medicines Questionnaire (BMQ)

The BMQ is a tool used to assess how important a patient or in this case a parent/guardian thinks a medicine is to their children's life and how much of an impact it has on it.

b) The Morisky Adherence self-report scale

The Morisky medication adherence scale is a validated scale designed to measure adherence. It consists of four yes/no questions regarding past medication use which is used to identify problems and barriers to adherence.

c) The Children's Dermatology Life quality index (CDLQI)

The Children's Dermatology Life Quality Index is an extensively used tool to measure how symptoms affect the participant's quality of life. It is scored out of 30 with higher scores indicating greater impairment.

d) The satisfaction with information about medicines scale (SIMS)

This is a validated questionnaire that helps determine a patient's satisfaction with the information they have received regarding their prescribed medication. It is a 15-item which asks patients to rate the amount of information they have received as 'too much', 'about right', 'too little', 'none received' and 'none needed'.

After three months, a second questionnaire (appendix 6) containing the same measures as the baseline questionnaire will be sent to both the intervention and control group participants by the pharmacy concerned with their care. The questionnaires will be sent back by the participants directly to the research team, who will inform the pharmacy when they have responded. Non-responders will be sent a second posting after two weeks with a final follow-up phone call after a further two weeks to maximise response.

### 3.11.2 Pharmacist Consultation

After the consultation, the pharmacist will record the areas of discussion with the parent / guardian and will record these on both the GP notification form (appendix 1) and the data collection form (appendix 9). If the parent/guardian expresses an interest in trying another cream/ointment for preference, the pharmacist will be able to provide the parent/guardian with samples of NHS Norfolk formulary listed creams. Data taken from patient medication records at each participant's pharmacy will be used to determine the use of eczema related products over the previous three months and the three months during the trial.

All participants will be allocated a study number and the encryption form linking the patient details to the study number will be kept separately under each pharmacies usual storage procedures. Only anonymised data will be sent to researchers not directly involved in the care of the patient.

### **3.12 Sample size**

A sample of 100 patients (50 in each group) will be recruited for this pilot study. The results of this study will then be used to enable estimation of variation in response between each group. This data will then inform a formal sample size estimation for a randomised controlled trial designed to determine whether the intervention has a significant impact on the primary outcome measure which will be SIMS and the CDLQI.

### **3.13 Data analysis**

The participant population will be characterised using appropriate descriptive statistics. For each of the subsections of the questionnaire, appropriate parametric and non-parametric tests will be used to determine the differences in the change in response. For the primary outcome measures (SIMS and CDLQI) the magnitude of difference and variance between intervention and control groups will be analysed. The study is not powered therefore no statistical tests can be performed. In terms of adherence, this will be dichotomised into adherence/partial adherence. Therefore, if four 'no' answers are entered into the questionnaire then the patient will be deemed to be adherent. If there is one or more 'yes' answers then the patient will be classed as partially adherent.

### **3.14 Dissemination**

The study results will be presented to NHS Norfolk and published in a peer reviewed journal.

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## **5. Appendices**

1. GP Notification Form
2. Adult Information sheet
3. Children's Information Sheet
4. Parental Consent Form
5. Children's Assent Form
6. Questionnaire
7. Focus Group Information Sheet
8. Focus Group Consent Form
9. Data Collection Form

# Appendix One



Pharmacist Led Eczema Management Support Service (PLEEZ). A Pilot Study.

**General Practitioner Notification Form**

**Patient Details Prescriber Details**

Name: GP Name:  
Address: Surgery Address:

Tel. No: Date of Consultation:

**Pharmacy Details**

Pharmacist: Pharmacy Tel. No:  
Pharmacy Address: Pharmacy Stamp:

Dear ,

As previously discussed with you, I have undertaken a consultation with the above patient in my pharmacy on the date shown, with reference to their eczema management. I have discussed with the patient options for the future management of their eczema and would like to put forward the suggestions listed overleaf for your consideration. I have explained to the patient that the decision to make any changes rests with you as the prescriber and they understand this. All suggestions are in line with the current PCT skin formulary and PCT guidance and were developed in conjunction with the Norfolk and Norwich University Hospital. I would be happy to discuss any of the suggestions I have put forward in more detail should you wish to. Thank you once again for taking the time to participate in the study.

Yours Sincerely,

*(To the pharmacist: please attach the final sheet of the data collection form)*

# Appendix Two

**Pharmacist Led Eczema Management Support Service (PLEEZ). A Pilot Study.**

**Invitation to participate in a research project.**

You and your child are invited to participate in a trial service jointly conducted by Numark pharmacy, the University of East Anglia, NHS Norfolk and the Norfolk and Norwich University Hospital. The trial is being conducted as part of a PhD student project and is designed to find out whether a service to eczema patients provided by the pharmacist is beneficial. The service that is being tested involves the pharmacist providing information to you (the parent or guardian) about the current use of your child's medication and how to achieve the best result from it. Your local GP and health authority are aware that this trial service is taking place and are happy for you to be asked to take part.

Before you decide to take part you need to understand why the research is being done and what it would involve for you and your child. Please take the time to read the following information carefully and talk to others about the study if you wish.

**Why has my child been chosen?**

Your child has been chosen to take part in the project due to the medications they have been prescribed by the doctor or nurse. They have also been chosen for their age (0-10 years) as this is the age group that are most affected by eczema.

**What happens if I agree for my child to take part in the study?**

If you agree for your child to take part then you will be asked to talk through the project with your child and then sign a consent form on their behalf. If they are aged 6-10 years they will be asked to sign a document as well (although this is not essential). During the course of the project you will be asked to fill out two questionnaires (three months apart) relating to your child's eczema. After the first one, you will be randomly put in to one of two groups: intervention or control. This is basically a coin-toss to decide which group you will be put in. If you are in the intervention group, an appointment will be arranged for a convenient time in the next two weeks for you to sit down with the pharmacist for roughly 30 minutes to discuss your child's eczema and if any changes can be made to improve your child's eczema symptoms (you may bring your child along to this discussion). If you are assigned to the control group, your child will receive the normal service from the pharmacist and if you have questions about

your child's medication –

the pharmacist will still be able to answer these in the normal way. Three months later, you will be asked to fill in the second questionnaire and return it.

**What disadvantages are there?**

We do not anticipate any disadvantages to your child participating in this project, apart from the time it takes for the consultation.

**Will my doctor know that I am taking part?**

We will ask you to consent to the pharmacist passing on any information or advice that you receive, to your doctor. This may just be for their information or it may be because the pharmacist thinks you would be better suited to another cream/ointment and would like to suggest a medication change to your doctor.

**What happens when the project ends?**

When the project ends a variety of data will be collected and analysed by the University of East Anglia to determine if the pilot service was a success. A copy of the final report will be available upon request.

**Confidentiality- will anybody be able to gain information about me from this project?**

The researchers at the University of East Anglia will not be able to access any personal information regarding your child. Similarly, no personal data relating to your child will be published in any form. Only the pharmacy staff, who would normally have access to this confidential information, will be able to identify your child through their records on the pharmacy computer.

**It is alright not to participate and you can withdraw from the study at any time without reason. Your child's medical care will not be affected in any way if you decide not to participate in this study.**

*Thank You*

If you have any further questions about this project please do not hesitate to contact the UEA Medicines Management Team on 01603 593391. Alternatively, you can obtain independent advice from the following sources: Patient Advice and Liaison Service on 01603 289036

## Appendix Three

## PLEEZ – Children's Information Sheet

The creams you use for your skin are there to help you fight your skin problem and it is important that your parent/guardian puts these on properly and that they are the right ones for you. We would like to see if a chat between your parent/guardian and the lady/man in the pharmacy makes your skin problem any better.

### What will I have to do?

Your parent/guardian will be asked to give permission for the lady/man who works in the pharmacy to ask them about you and how you feel about your eczema. They will also ask about the creams that you use on your skin. So, you will have to do nothing unless your parent/guardian asks you any questions about your skin.



### What will my parent/guardian have to do?

Your parent/guardian will be asked to complete a piece of paper with some questions on it, possibly with your help. Then, they will have a chat with the lady/man from the pharmacy about you and your skin problem. This could last up to half-an-hour. In a few months time they will then be asked to answer some more questions about you.



### Will anybody else know that I am taking part?

Nobody else will know that you or your parent/guardian are taking part unless it is necessary. Your doctor has agreed to you taking part in this project.



### Will my skin problems get worse?

We will try to make your skin problem better so that it doesn't bother you as much as it might do now.

### What do I do if I do not want to take part?

Just inform your parents/guardian if you do not want to take part and they will tell the lady/man at the pharmacy.

PLEEZ Children's Information Sheet Version 2 (February 2009)

## Appendix Four

Pharmacist LEd EcZema Management Support Service (PLEEZ). A Pilot Study.

**Parental Consent Form**

Study number  (Assigned by research team)

**If you wish to be involved, please initial each box and complete the details at the bottom of the form. Once completed, please return to the pharmacist/ pharmacy team member that is looking after you in the envelope provided:-**

- 1. I confirm that I have read and understand the information sheet dated Feb 2009 Version 3 for the above study and have had the opportunity to ask questions.
- 2. I understand that my child's participation is voluntary and that I am free to withdraw my child at any time without my medical care or legal rights being affected.
- 3. I am willing to allow access to my child's health care records but understand that strict confidentiality will be maintained.
- 4. I agree for my child to take part in the above study and recognise that they are not able to consent for themselves.
- 5. I agree that information relating to the advice and any possible treatment changes can be communicated to the doctor as necessary.

.....  
Name of patient

.....      ...../...../.....      .....

Name of parent/guardian      Date      Signature

Please tick here and provide your telephone number if you agree to being contacted  to take part in a discussion about the trial, after it has finished.

Telephone number:.....



# Appendix Five

Pharmacist LEd Eczema Management Support Service (PLEEZ). A Pilot Study.

**Assent Form for Children Aged 6-10**

Study number  (Assigned by research team)

(To be completed by the child and their parent/guardian)

Child (or if unable, parent on their behalf) /young person to circle all they agree with:

Have you read (or had read to you) about this project?	Yes/No
Has somebody else explained this project to you?	Yes/No
Do you understand what this project is about?	Yes/No
Have you asked all the questions you want?	Yes/No
Have you had your questions answered in a way you understand?	Yes/No
Do you understand it's OK to stop taking part at any time?	Yes/No
Are you happy to take part?	Yes/No

If any answers are 'no' or you don't want to take part, don't sign your name!

If you do want to take part, you can write your name below

Your name \_\_\_\_\_

Date \_\_\_\_\_

The pharmacist/pharmacy team member who explained this project to you needs to sign too:

Print Name \_\_\_\_\_

Sign \_\_\_\_\_

Date \_\_\_\_\_

Thank you for your help.

# Appendix Six

Study Number

# Pharmacist led eczema support service A pilot study

## Guidance on completing this questionnaire

- This questionnaire is designed to take less than 10 minutes to complete and is completely anonymous
- Please tick one box **only** in response to each question unless requested to do so otherwise
- Please complete **all** sections in the questionnaire to the best of your knowledge
- Once completed please return in the stamped addressed envelope provided

**UEA** University of  
East Anglia

NUNMARK PHARMACISTS  
PUTTING YOUR HEALTH FIRST

Norfolk and Norwich University Hospitals **NHS**  
NHS Foundation Trust

**NHS**  
Norfolk

## Section One: How eczema affects your child's life

*What impact has the eczema had on your child's quality of life?*

	<b>Tick one box for each of the questions below.</b>	<b>All the time</b>	<b>A lot</b>	<b>A Little</b>	<b>None/not at all</b>
1	Over the last week, how much has your child been itching and scratching?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2	Over the last week, how embarrassed or self conscious, upset or sad has your child been because of their skin?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3	Over the last week, how much has their skin affected your child's friendships?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4	Over the last week, how much has your child changed or worn special clothes/shoes because of their skin?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5	Over the last week, has your child's eczema interfered with playing, hobbies or going out?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6	Over the last week, has your child's eczema interfered with your child swimming or being involved in other sports?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7	<b>If in school time:</b> over the last week, how much did their skin affect your child's school work?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<b>If in holiday time:</b> over the last week, how much has their skin problem interfered with their enjoyment of the holiday?				
8	Over the last week, how much trouble has your child had because of their skin with other people calling them names, teasing, bullying, asking questions or avoiding them?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9	Over the last week, how much has your child's sleep been affected by their skin problem?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10	Over the last week, how much of a problem has the treatment for their skin been?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Children's Dermatology Quality of Life Index ©M.S. Lewis-Jones, A.Y. Finlay, May 1993

## Section Two: Steroid Medication

The following sets of questions are about your child's **steroid medication only**. If you are unsure as to which medication is the steroid, please ask a member of staff for help.

The following set of questions relate to your personal views about your child's medicine.

	<b>Please tick ONE box for each question.</b>	Strongly Agree	Agree	Uncertain	Disagree	Strongly Disagree
11	My child's health, at present, depends on this medicine	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12	Having to apply this medicine worries me	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13	My child's life would be impossible without this medicine	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14	I sometimes worry about long-term effects of this medicine	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15	Without this medicine my child would be very ill	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16	This medicine is a mystery to me	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17	My child's health in the future will depend on this medicine	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18	This medicine disrupts my child's life	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19	This medicine protects my child from becoming worse	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20	This medicine gives my child unpleasant side effects	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Adapted from Beliefs about Medicines Questionnaire (BMQ) ©RHome University of Brighton

The next set of questions relate to how regularly you use the steroid medication

	<b>Tick one box for each of the four questions below.</b>	Yes	No
21	Do you ever forget to use the medication?	<input type="checkbox"/>	<input type="checkbox"/>
22	Are you careless at times about using the medication?	<input type="checkbox"/>	<input type="checkbox"/>
23	When your child feels better, do you sometimes stop using the medication?	<input type="checkbox"/>	<input type="checkbox"/>
24	Sometimes if your child feels worse when you use the medication, do you stop using it?	<input type="checkbox"/>	<input type="checkbox"/>

Self-reported Medication-taking Scale. Morisky, D., Green, L., Levine, D. Concurrent and Predictive Validity of a Self-reported Measure of Medication Adherence. Medical Care, January 1986, Vol 24, No 1, 67-74

### Section Three: Emollient Medication e.g. moisturisers

The following sets of questions are about your child's **emollient/moisturiser medication only**. If you are unsure as to which medications are the emollients please ask a member of the pharmacy staff for help.

The following set of questions relate to your personal views about your child's medicine.

	<b>Please tick ONE box for each question.</b>	Strongly Agree	Agree	Uncertain	Disagree	Strongly Disagree
25	My child's health, at present, depends on this medicine	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
26	Having to apply this medicine worries me	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
27	My child's life would be impossible without this medicine	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
28	I sometimes worry about long-term effects of this medicine	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
29	Without this medicine my child would be very ill	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
30	This medicine is a mystery to me	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
31	My child's health in the future will depend on this medicine	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
32	This medicine disrupts my child's life	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
33	This medicine protects my child from becoming worse	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
34	This medicine gives my child unpleasant side effects	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Adapted from Beliefs about Medicines Questionnaire (BMQ) ©RHome University of Brighton

The next set of questions relate to how regularly you use the emollient medication

	<b>Tick one box for each of the four questions below.</b>	Yes	No
35	Do you ever forget to use the medication?	<input type="checkbox"/>	<input type="checkbox"/>
36	Are you careless at times about using the medication?	<input type="checkbox"/>	<input type="checkbox"/>
37	When your child feels better, do you sometimes stop using the medication?	<input type="checkbox"/>	<input type="checkbox"/>
38	Sometimes if your child feels worse when you use the medication, do you stop using it?	<input type="checkbox"/>	<input type="checkbox"/>

Self-reported Medication-taking Scale. Morisky, D., Green, L., Levine, D. Concurrent and Predictive Validity of a Self-reported Measure of Medication Adherence. Medical Care, January 1986, Vol 24, No 1, 67-74

## Section Four: Information about medicines

*How would you rate the information you have received about the following aspects of your medicine(s)?*

**Tick one box for each type of information.**

**If you use more than one medicine, please give your views about the information as a whole.**

	Type of Information	Amount of Information Received				
		Too much	About right	Too little	None	None needed
39	How to use the medicine.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
40	What the medicine is called.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
41	What the medicine is for.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
42	What it does.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
43	How it works.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
44	How long it will take to act.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
45	How you can tell if it is working.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
46	How long your child will need to be on the medicine.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
47	Whether the medicine has any unwanted effects (side-effects).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
48	What are the risks of your child getting side-effects.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
49	What you should do if your child experiences unwanted effects (side-effects).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
50	Whether the medicine will interfere with other medicines your child is prescribed.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
51	Whether the medicine will make your child feel drowsy.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
52	What you should do if you forget to apply the cream/ointment.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
53	How to get a further supply.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Satisfaction with Information about Medicines Scale (SIMS). ©RHome University of Brighton



### Section Five: Additional Comments

- 54 *If you have any concerns about your child's eczema medication or there is anything you wish to discuss with the pharmacist, please record below.*

### Section Six: Your child

- 55 What is your child's age in years?

- 56 What is your child's gender?

Male  Female

- 57 Is there a family history of eczema?

Yes  No

- 58 How many times has your child seen the GP/nurse in relation to their eczema, in the last three months?

**Thank you for taking the time to complete this questionnaire.**

# Appendix Seven

**Pharmacist LE<sub>d</sub> EcZema Management Support Service (PLEEZ). A Pilot Study.**

**Invitation to participate in a focus group.**

Following your participation in the PLEEZ trial service, we would like to know your thoughts on the service that you received from the pharmacy. This will involve you attending a focus group where you and other people who took part in the trial can discuss the trial with the researchers at UEA.

Please take the time to read the following information sheet which will explain more about the focus group, before you sign the consent form.

**Why have I been chosen?**

You have been chosen because you expressed an interest in taking part on the original consent form that you signed on behalf of your child.

**What happens if I agree to take part in the focus group?**

You will be invited to the School of Chemical Sciences and Pharmacy at the UEA to attend one of two focus groups. Even if you return the consent form, you may not be asked to attend the focus group; this depends on how many people agree to take part. There will be approximately five people in this group plus one researcher. The researcher will then ask the group questions to do with the trial. These could be anything from the way in which you were asked to join the study and layout and design of the questionnaire to the service and information you received from the pharmacist.

As a thank you for giving up your time to take part in this discussion, we will give you a voucher to the value of £20.

**What disadvantages are there?**

We do not anticipate any disadvantages to you participating in this focus group, apart from the time taken to complete the discussion.

**Who will have access to the information given by me?**

As part of the consent form, we will ask you to provide your address (so we can contact you) and the name of the pharmacy where you took part in the trial. This is so we can include at least one person from each pharmacy in the focus group. The focus group discussion will be tape-recorded and listened to by the research team at the UEA. Nobody in the pharmacy where you took part in the trial will have access to this information. The

information will be used to improve the design and structure of any further eczema trials that are developed.

**Confidentiality- will anybody be able to gain information about me from this focus group?**

The research team at UEA will maintain confidentiality when referring to the findings of the focus group. Any data that can identify you will **not** be published and nobody outside the research team will be able to access any information you give us.

**It is alright not to participate and you can withdraw from the focus group at any time without reason.**

*Thank You*

If you have any further questions about this project please do not hesitate to contact the UEA Medicines Management Team on 01603 593391. Alternatively, you can obtain independent advice from the following sources: Patient Advice and Liaison Service on 01603 289036

# Appendix Eight

**Pharmacist LEd EcZema Management Support Service (PLEEZ). A Pilot Study.**

**Focus Group Consent Form**

Study number     (Assigned by research team)

**If you wish to be involved, please initial each box and complete the details at the bottom of the form. Once completed, please return to the researcher that is looking after you in the envelope provided:-**

- |    |   |                          |
|----|---|--------------------------|
| 1. | I confirm that I have read and understand the information sheet dated Feb 2009 Version 2 for the above study and have had the opportunity to ask questions. | <input type="checkbox"/> |
| 2. | I understand that my participation is voluntary and that I am free to withdraw at any time.   | <input type="checkbox"/> |
| 3. | I confirm that my child participated in the PLEEZ trial and that I was the parent/guardian that provided information for the trial.                         | <input type="checkbox"/> |
| 4. | I am willing to allow the discussion within the focus group to be audio-taped for the purposes of improving the trial in the future                         | <input type="checkbox"/> |

.....  
 Name of participant                      Date                      Signature  
 (Your name)

**Address:** \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

**Postcode:** \_\_\_\_\_

**Telephone:** \_\_\_\_\_

**Name of pharmacy:** \_\_\_\_\_

# Appendix Nine

**Pharmacist Led Eczema Management Support Service (PLEEZ). A Pilot Study.**

**Data Collection Form**

Study number     (Assigned by research team)

This form is concerned with the content covered in the consultation (intervention patients only) and the types and amounts of the emollients and steroid creams prescribed to the patient.

Please give an estimate of the duration of the consultation (in minutes).

After discussion with the patient, how much time have they spent discussing their child's eczema with other health professionals (roughly and not counting the current consultation) (in minutes)?

**INITIAL DATA**

In the following tables please list the dates and quantities of emollient and steroid cream/ointment(s) dispensed in the three months preceding the trial. Please include bath additives in this table.

Emollient(s) dispensed	Date dispensed	Amount dispensed	Patient Preference

Steroid(s) dispensed	Date dispensed	Amount Dispensed	Patient preference



**DATA FROM THE TRIAL**

As above please list the emollient and steroid cream/ointment(s) and bath additives that were dispensed during the three months of the trial and if there has been a change from above would you please indicate whether this has been as a result of the pharmacist intervention. All the emollients listed are taken from the NHS Norfolk Skin Formulary.

Emollient(s) dispensed	Number of times dispensed	Amount dispensed on each occasion	Change due to pharmacist intervention
Zerobase			<input type="checkbox"/>
Cetraben Cream			<input type="checkbox"/>
Doublebase Gel			<input type="checkbox"/>
Hydromol Ointment			<input type="checkbox"/>
Emulsifying Ointment			<input type="checkbox"/>
White Soft Paraffin/Liquid Paraffin 50:50			<input type="checkbox"/>
Balneum Plus Cream			<input type="checkbox"/>
Eucerin Cream 10%			<input type="checkbox"/>
Eucerin Lotion 10%			<input type="checkbox"/>
Dermol Cream			<input type="checkbox"/>
Other:			
Other:			
Other:			
Other:			

Steroid(s) prescribed	Date dispensed	Amount dispensed.

For your information only  
(GP Notification form only)

For your consideration  
(GP Notification form only)

**ITEMS DISCUSSED WITH THE PATIENT**

- |                                       |                          |   |                          |
|---------------------------------------|--------------------------|---|--------------------------|
| Current topical eczema management     | <input type="checkbox"/> | Advice regarding future management strategies | <input type="checkbox"/> |
| Frequency and volume of emollient use | <input type="checkbox"/> | Lifestyle advice                              | <input type="checkbox"/> |
| Frequency and volume of steroid use   | <input type="checkbox"/> |   |                          |
| Technique of application              | <input type="checkbox"/> |   |                          |

The patient has been provided with emollient samples to try for preference

**SUGGESTIONS**

*Please tick all that apply.*

**Quantity**

The patient may benefit from an increase in the amount of emollient prescribed

**Patient Preference**

After trying a sample, the patient has expressed a preference for the emollient:

.....

The patient has expressed an interest in applying their emollient immediately before and after having a bath in preference to using bath additives

**Directions**

I have advised the patient to increase the frequency and/or volume of emollient used

Please record any other comments/suggestions in the box below.

*(Please attach this sheet to the GP Notification form)*

 *Appendix Two*



## National Research Ethics Service

### Hertfordshire REC

East of England REC Office No 3  
9th Floor, Terminus House  
The High  
Harlow  
Essex  
CM20 1XA

Telephone: 01279 418 439  
Facsimile: 01279 419 246

31 March 2009

Mr Michael Twigg  
PhD Student  
University of East Anglia  
Sch. of Chem. Sci. & Pharmacy  
University of East Anglia  
Norwich  
NR4 7TJ

Dear Mr Twigg

**Full title of study:** A randomised controlled trial of a Pharmacist LED EcZema management support service (PLEEZ). A pilot study.  
**REC reference number:** 09/H0311/45

The Research Ethics Committee reviewed the above application at the meeting held on 25 March 2009. Thank you for attending with Dr Bhattacharya to discuss the study.

#### Ethical opinion

At the meeting you informed the Committee of the following:

- a) This would be phase 2 of the research, which it was planned to follow-up with phase 3 that would be a randomised controlled study.
- b) The Numark Chemists were all independent pharmacies.
- c) Numark provide the pharmacies with a number of initiatives and they would be paying £10 per patient recruitment plus £20 per intervention. The university was involved to evaluate the study. The pharmacy might give the participants some free samples.
- d) The patients would be approached by a pharmacy team member whom they already knew to make them aware of the study; they would then be given the information to take away.
- e) The researchers would go into the GP practice and initially make an appointment with the Practice Manager, then possibly the practice nurse.

The Committee told you of an amendment that would need to be made to the consent form.

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

*This Research Ethics Committee is an advisory committee to East of England Strategic Health Authority  
The National Research Ethics Service (NRES) represents the NRES Directorate within  
the National Patient Safety Agency and Research Ethics Committees in England*

## Ethical review of research sites

The Committee agreed that all sites in this study should be exempt from site-specific assessment (SSA). There is no need to submit the Site-Specific Information Form to any Research Ethics Committee. The favourable opinion for the study applies to all sites involved in the research.

## Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission at NHS sites ("R&D approval") should be obtained from the relevant care organisation(s) in accordance with NHS research governance arrangements. Guidance on applying for NHS permission is available in the Integrated Research Application System or at <http://www.rdforum.nhs.uk>.

The amendment of the Consent Form to include the following point appropriately completed for this study:

"I understand that relevant sections of my medical notes and data collected during the study, may be looked at by individuals from [company name], from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records".

## Approved documents

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Supervisor CV		
Data Collection Form	3	01 February 2009
Participant Consent Form: Children's Assent	2	01 January 2009
Participant Consent Form: Parent	4	01 February 2009
Participant Information Sheet: Child	2	01 February 2009
Participant Information Sheet: Adult	4	01 February 2009
GP/Consultant Information Sheets	4	01 February 2009
Questionnaire: PLEEZ	5	01 March 2009
Summary/Synopsis	7	01 March 2009
Covering Letter		06 March 2009
Protocol	7	01 March 2009
Investigator CV		
Application		06 March 2009
Participant Consent Form: Focus Group	2	01 February 2009
Participant Information Sheet: Focus Group	2	01 February 2009
Compensation Arrangements		06 March 2009

This Research Ethics Committee is an advisory committee to East of England Strategic Health Authority  
*The National Research Ethics Service (NRES) represents the NRES Directorate within  
the National Patient Safety Agency and Research Ethics Committees in England*

### **Membership of the Committee**

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

### **Statement of compliance**

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

### **After ethical review**

Now that you have completed the application process please visit the National Research Ethics Website > After Review

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

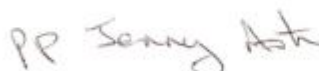
We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email [referencegroup@nres.npsa.nhs.uk](mailto:referencegroup@nres.npsa.nhs.uk).

09/H0311/45

**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project

Yours sincerely



**Dr Sunda Uthayakumar**  
**Vice Chair**

Email: [jenny.austin@eoe.nhs.uk](mailto:jenny.austin@eoe.nhs.uk)

Enclosures: List of names and professions of members who were present at the meeting and those who submitted written comments

"After ethical review – guidance for researchers" (SL-AR2)

This Research Ethics Committee is an advisory committee to East of England Strategic Health Authority  
The National Research Ethics Service (NRES) represents the NRES Directorate within  
the National Patient Safety Agency and Research Ethics Committees in England

 *Appendix Three*

East Norfolk and Waveney Research  
Governance Committee



Mr Michael Twigg  
University of East Anglia  
School of Pharmacy  
UEA  
Norwich  
Norfolk  
NR4 7TJ

Please reply to: Research Governance Committee Office  
Research and Development Department  
Level 3, East Block, Room 032  
Norfolk & Norwich University Hospitals NHS Foundation Trust

Colney Lane  
Norwich  
NR4 7UY  
Direct Dial: 01603 287408  
Internal: 3408  
Direct Fax: 01603 289800

e-mail: [rgoffice@nnuh.nhs.uk](mailto:rgoffice@nnuh.nhs.uk)  
Website: [www.norfolkhealthresearch.nhs.uk](http://www.norfolkhealthresearch.nhs.uk)

05 August 2009

Dear Mr Twigg

**Re: 2009IC01 A randomised controlled trial of a Pharmacist LEd EcZema management support service (PLEEZ). A pilot study.**

Thank you for submitting the above project to the East Norfolk and Waveney Research Governance Committee for approval. On behalf of the Committee I am pleased to inform you that your project has been given full approval and you may begin your research.

Please note that this approval applies to the following sites:

- NHS Norfolk

The following conditions are attached to this approval:

- Please inform the R&D Office at NHS Norfolk of any GP Practices which agree to participate in this study.

I have enclosed two copies of the Standard Terms and Conditions of Approval. Please sign and return one copy to the Research Governance office. Failure to return the standard terms and conditions may affect the conditions of approval.

**Please note, under the agreed standard terms and conditions of approval you must inform this Committee of any proposed changes to this study and to keep the Committee updated on progress.**

If you have any queries regarding this or any other project please contact Julie Dawson, Research Governance Administrator, at the above address. Please note, the reference number for this study is **2009IC01** and this should be quoted on all correspondence.

Yours sincerely

Dr Richard Reading  
Chair  
Consultant Paediatrician – NHS Norfolk

Enc



East Norfolk and Waveney Research  
Governance Committee



Mr Michael Twigg  
School of Chem. Sci. & Pharmacy  
University of East Anglia  
Norwich  
NR4 7TJ

16/11/2009

Please reply to: Research Governance Committee Office  
Research and Development Department  
Level 3, East Block, Room 032  
Norfolk & Norwich University Hospitals NHS Foundation Trust  
Colney Lane  
Norwich  
NR4 7UJ  
Direct Dial: 01603 287408  
Internal: 3408  
Direct Fax: 01603 289800  
e-mail: [rdoffice@nnuh.nhs.uk](mailto:rdoffice@nnuh.nhs.uk)  
Website: [www.norfolkhealthresearch.nhs.uk](http://www.norfolkhealthresearch.nhs.uk)

Dear Mr Michael Twigg

Re: **2009IC01 A randomised controlled trial of a Pharmacist LEd EcZema management support service (PLEEZ). A pilot study.**

Thank you for your correspondence dated November 2009 regarding Amendment 2 to the above study. It was noted that the amendment has already received a favourable opinion from the Hertfordshire Research Ethics Committee.

I am pleased to inform you that I have taken Chair's action to approve this amendment. Members of the Committee will be updated at the next Committee meeting.

The documents reviewed and approved are as follows;

- Letter to parents v3 (1/9/2009)
- Protocol v9 (1/9/2009)
- Notice of substantial amendment (non-CTIMPs) v2 (25/9/2009)
- HREC approval letter (5/10/2009)

If you have any queries regarding this study please contact Julie Dawson, Research Governance Administrator, at the above address. Please note, your reference number is **2009IC01** and this should be quoted on all correspondence. Please keep this Committee fully informed of any changes and / or progress in this study.

Yours sincerely

Dr Richard Reading  
Chair  
Consultant Paediatrician – NHS Norfolk

East Norfolk and Waveney Research  
Governance Committee



Please reply to: Research Governance Committee Office  
Research and Development Department  
Level 3, East Block, Room 032  
Norfolk & Norwich University Hospitals NHS Foundation Trust  
Colney Lane  
Norwich  
NR4 7UY  
Direct Dial: 01603 287806  
Internal: 3806  
Direct Fax: 01603 289800  
e-mail: [rgoffice@nnuh.nhs.uk](mailto:rgoffice@nnuh.nhs.uk)  
Website: [www.norfolkhealthresearch.nhs.uk](http://www.norfolkhealthresearch.nhs.uk)

Mr Michael Twigg  
University of East Anglia  
School of Pharmacy  
UEA, Norwich  
Norfolk  
NR4 7TJ

03 February 2010

Dear Mr Twigg

**Re: 2009IC01 A randomised controlled trial of a Pharmacist LEed EcZema management support service (PLEEZ). A pilot study.**

Thank you for your correspondence regarding amendment 3 to the above study. It was noted that the amendment has already received a favourable opinion from the Hertfordshire Research Ethics Committee.

I am pleased to inform you that I have taken Chair's action to approve this amendment. Members of the Committee will be updated at the next Committee meeting.

The approved documents are as follows;

- Questionnaire: Adult, version 1, dated 01 January 2010
- Participant Consent Form : Focus Group – Adult, version 1, dated 01 January 2010
- Participant Consent Form: Adult, version 1, dated 01 January 2010
- Participant Information Sheet: Adult, version 1, dated 01 January 2010
- Protocol, version 10, dated 01 January 2010
- Notice of Substantial Amendment Form, version 3, dated 12 January 2010

If you have any queries regarding this study please contact Claire Dawdry, Research Governance Administrator, at the above address. Please note, your reference number is **2009IC01** and this should be quoted on all correspondence. Please keep this Committee fully informed of any changes and / or progress in this study.

Yours sincerely

Dr Richard Reading  
Chair  
Consultant Paediatrician – NHS Norfolk

2009IC01

Mr Michael Twigg  
Research Pharmacist  
School of Pharmacy  
University of East Anglia  
Norwich  
NR4 7TJ

**Research & Development**  
NHS Norfolk  
Lakeside 400  
Old Chapel Way  
Broadland Business Park  
Thorpe St Andrew  
Norwich  
NR7 0WG

Tel: 01603 257283

Fax: 01603 257292

E-mail: [paul.mills@norfolk.nhs.uk](mailto:paul.mills@norfolk.nhs.uk)  
[www.norfolk.nhs.uk/research](http://www.norfolk.nhs.uk/research)

30<sup>th</sup> July 2010

Dear Mr Twigg

**Re: 2009IC01 A randomised controlled trial of a pharmacist Led Eczema management support service (PLEEZ). A pilot study.  
Amendment 4 (7<sup>th</sup> June 2010)**

Further to your submission of the above amendment this has now been reviewed for any research governance implications.

The following documents were reviewed:

- Notice of Amendment, Amendment 4, June 2010
- Protocol, Version 11, June 2010
- Information Sheet (Focus Group) Pharmacists, version 1, June 2010
- Consent Form (Focus Group) Pharmacist, version 1, June 2010 – see note below

Note

It is noted that the pharmacist focus group consent form refers to an information sheet dated January 2010, not June 2010 which is the version of the information sheet for the pharmacist focus groups. Please ensure this is corrected before use.

I am pleased to inform you on behalf of **NHS Norfolk** that we are able to accommodate the above amendment and have granted NHS permission for this amendment to be implemented within **NHS Norfolk**.

If you have any queries regarding this or any other project please contact Paul Mills, R&D Officer, at the above address. Please note, the reference number for this study is **2009IC01** and this should be quoted on all correspondence.

Yours sincerely



Jonathan Cook  
**Director of Corporate Services**  
**NHS Norfolk**

cc: Dr Alicia Meldrum, Research Contracts Manager, University of East Anglia (Sponsor Representative)  
File

Chair: Sheila Childerhouse  
Acting Chief Executive: David Stonehouse

Visit our website: [www.norfolk.nhs.uk](http://www.norfolk.nhs.uk)

 *Appendix Four*



## National Research Ethics Service

### Hertfordshire REC

East of England REC Office No 3  
9th Floor, Terminus House  
The High  
Harlow  
Essex  
CM20 1XA

Tel: 01279 418 439  
Fax: 01279 419 246

08 May 2009

Mr Michael Twigg  
PhD Student  
Sch. of Chem. Sci. & Pharmacy  
University of East Anglia  
Norwich  
NR4 7TJ

Dear Mr Twigg

**Study title:** A randomised controlled trial of a Pharmacist LED EcZema management support service (PLEEZ). A pilot study.  
**REC reference:** 09/H0311/45 (AM01)  
**Amendment number:** 1  
**Amendment date:** 15 April 2009

The above amendment was reviewed by the Sub-Committee in correspondence.

#### Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

#### Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Protocol	8	01 April 2009
Participant Information Sheet: Adult	5	01 April 2009
Data collection Form	4	01 April 2009
Notice of Substantial Amendment (non-CTIMPs)	1	15 April 2009
Covering Letter		15 April 2009

#### Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

This Research Ethics Committee is an advisory committee to East of England Strategic Health Authority  
The National Research Ethics Service (NRES) represents the NRES Directorate within  
the National Patient Safety Agency and Research Ethics Committees in England

**R&D approval**

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

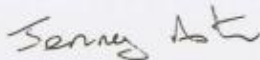
**Statement of compliance**

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

09/H0311/45:

Please quote this number on all correspondence

Yours sincerely



**Mrs Jenny Austin**  
**Committee Co-ordinator**

E-mail: [jenny.austin@eoe.nhs.uk](mailto:jenny.austin@eoe.nhs.uk)

Enclosures

List of names and professions of members who took part in the review

Copy to:

Dr Alicia Meldrum  
Research Contracts Manager  
REE Office  
University of East Anglia  
Norwich  
NR4 7TJ

 *Appendix Five*



## National Research Ethics Service

### Hertfordshire REC

East of England REC Office No 3  
9th Floor, Teminus House  
The High  
Harlow  
Essex  
CM20 1XA

Tel: 01279 418 439  
Fax: 01279 419 246

05 October 2009

Mr Michael Twigg  
Research Pharmacist  
School of Pharmacy  
University of East Anglia  
Norwich  
Norfolk  
NR4 7TJ

*Sent to  
Governance  
12/10/09*

Dear Mr Twigg

**Study title:** A randomised controlled trial of a Pharmacist LE<sup>d</sup> EcZema management support service (PLEEZ). A pilot study.  
**REC reference:** 09/H0311/45  
**Amendment number:** 2  
**Amendment date:** 25 September 2009

The above amendment was reviewed by the Sub-Committee in correspondence.

#### Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

#### Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Letter to Parents	3	01 September 2009
Protocol	9	01 September 2009
Notice of Substantial Amendment (non-CTIMPs)	2	25 September 2009
Covering Letter		25 September 2009

#### Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

This Research Ethics Committee is an advisory committee to East of England Strategic Health Authority  
The National Research Ethics Service (NRES) represents the NRES Directorate within  
the National Patient Safety Agency and Research Ethics Committees in England



### **R&D approval**

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

### **Statement of compliance**

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

09/H0311/45:

Please quote this number on all correspondence

Yours sincerely



**Mrs Jenny Austin**  
**Committee Co-ordinator**

E-mail: [jenny.austin@eoe.nhs.uk](mailto:jenny.austin@eoe.nhs.uk)

Enclosures: List of names and professions of members who took part in the review

Copy to: Dr Alicia Meldrum  
Research Contracts Manager  
REE Office  
University of East Anglia  
Norwich  
NR4 7TJ

 *Appendix Six*



## National Research Ethics Service

### Hertfordshire REC

East of England REC Office No 3  
9th Floor, Terminus House  
The High  
Harlow  
Essex  
CM20 1XA

Tel: 01279 418 439  
Fax: 01279 451 546

18 January 2010

Mr Michael Twigg  
Research Pharmacist  
School of Pharmacy  
University of East Anglia  
Norwich  
Norfolk  
NR4 7TJ

Dear Mr Twigg

**Study title:** A randomised controlled trial of a Pharmacist LE<sup>d</sup> EcZema management support service (PLEEZ). A pilot study.  
**REC reference:** 09/H0311/45 (AM03)  
**Amendment number:** 3  
**Amendment date:** 12 January 2010

The above amendment was reviewed by the Sub-Committee in correspondence.

#### Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

#### Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Questionnaire: Adult	1	01 January 2010
Participant Consent Form: Focus Group - Adult	1	01 January 2010
Participant Consent Form: Adult		01 January 2010
Participant Information Sheet: Focus Group - Adult	1	01 January 2010
Participant Information Sheet: Adult	1	01 January 2010
Protocol	10	01 January 2010
Notice of Substantial Amendment (non-CTIMPs)	3	12 January 2010
Covering Letter		11 January 2010

This Research Ethics Committee is an advisory committee to East of England Strategic Health Authority  
The National Research Ethics Service (NRES) represents the NRES Directorate within  
the National Patient Safety Agency and Research Ethics Committees in England

### Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

### R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

### Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

09/H0311/45:

Please quote this number on all correspondence

Yours sincerely



**Mrs Jenny Austin**  
Committee Co-ordinator

E-mail: [jenny.austin@eoe.nhs.uk](mailto:jenny.austin@eoe.nhs.uk)

Enclosures: List of names and professions of members who took part in the review

Copy to: Dr Alicia Meldrum  
Research Contracts Manager  
REE Office  
University of East Anglia  
Norwich  
NR4 7TJ

 *Appendix Seven*



## National Research Ethics Service

### Hertfordshire REC

East of England REC Office No 3  
9th Floor, Terminus House  
The High  
Harlow  
Essex  
CM20 1XA

Tel: 01279 418 439  
Fax: 01279 451 546

15 June 2010

Mr Michael Twigg  
Research Pharmacist  
School of Pharmacy  
University of East Anglia  
Norwich  
Norfolk  
NR4 7TJ

Dear Mr Twigg

**Study title:** A randomised controlled trial of a Pharmacist LE<sup>d</sup> EcZema management support service (PLEEZ). A pilot study.  
**REC reference:** 09/H0311/45 (AM04)  
**Protocol number:**  
**Amendment number:** 4  
**Amendment date:** 07 June 2010

The above amendment was reviewed by the Sub-Committee in correspondence.

#### Ethical opinion

Favourable Opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

#### Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Letter of invitation to participant	1	07 June 2010
Participant Consent Form	1	09 June 2010
Protocol	11	07 June 2010
Notice of Substantial Amendment (non-CTIMPs)	4	07 June 2010
Covering Letter		07 June 2010

#### Membership of the Committee

This Research Ethics Committee is an advisory committee to East of England Strategic Health Authority  
*The National Research Ethics Service (NRES) represents the NRES Directorate within  
the National Patient Safety Agency and Research Ethics Committees in England*

### **Membership of the Committee**

The members of the Committee who took part in the review are listed on the attached sheet.

### **R&D approval**

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

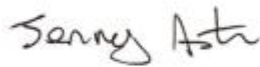
### **Statement of compliance**

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

09/H0311/45:

Please quote this number on all correspondence

Yours sincerely



**Mrs Jenny Austin**  
**Committee Co-ordinator**

E-mail: [jenny.austin@eoe.nhs.uk](mailto:jenny.austin@eoe.nhs.uk)

Enclosures: List of names and professions of members who took part in the review

Copy to: Dr Alicia Meldrum  
Research Contracts Manager  
REE Office  
University of East Anglia  
Norwich  
NR4 7TJ

 *Appendix Eight*



### **Invitation to participate in a focus group.**

Following your participation in the PLEEZ study, we would like to know your thoughts on the service. This will involve you attending a focus group where you and other pharmacists who took part in the trial can discuss any issues with the researchers at UEA.

Please take the time to read the following information sheet which will explain more about the focus group, before you sign the consent form.

#### **Why have I been chosen?**

You have been chosen because you provided the service as part of the PLEEZ pilot study.

#### **What happens if I agree to take part in the focus group?**

You will be invited to the School of Pharmacy at the UEA to attend a focus group. There will be approximately five to eight people in this group plus two researchers. The researcher will ask the group questions relating to the study including the following:

- General impression of the study
- Recruitment of participants
- Design and information contained within the questionnaire
- Reason(s) for poor uptake of the service
- Information and support received from the research team at UEA & Numark
- Identification of any benefit or service improvement needed

#### **What disadvantages are there?**

We do not anticipate any disadvantages to you participating in this focus group, apart from the time taken to complete the discussion.

#### **Who will have access to the information given by me?**

The focus group discussion will be tape-recorded and listened to by the research team at the UEA. This information will be stored securely and only the research team will have access to it. The information will be used to improve the design and structure of any further services developed.

**Confidentiality- will anybody be able to gain information about me from this focus group?**

The research team at UEA will maintain confidentiality when referring to the findings of the focus group. Any data that can identify you will **not** be published and nobody outside the research team will be able to access any information you give us.

**It is alright not to participate and you can withdraw from the focus group at any time without reason.**

*Thank You*

If you have any further questions about this project please do not hesitate to contact the UEA Medicines Management Team on 01603 593391.

Pharmacist LEd EcZema Management Support Service (PLEEZ). A Pilot Study.

Focus Group Consent Form

If you wish to be involved, please initial each box and complete the details at the bottom of the form. Once completed, please return to the researcher that is looking after you in the envelope provided:-

- 1. I confirm that I have read and understand the information sheet dated June 2010 Version 1 for the above study and have had the opportunity to ask questions.
2. I understand that my participation is voluntary and that I am free to withdraw at any time.
3. I confirm that I participated in the PLEEZ trial.
4. I am willing to allow the discussion within the focus group to be audio-taped for the purposes of improving the trial in the future
5. I understand that relevant sections of the data collected during the study may be looked at by individuals from regulatory authorities or from the NHS Trusts, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.

Five empty square boxes for initialing consent statements.

Name of participant (Your name) Date Signature

Address:
Postcode:
Telephone:

 *Appendix Nine*



An audit to determine the adherence  
to NICE guidance for prescribing in type  
2 diabetes in primary care.

Michael Twigg

Supervisor: Prof. David Wright

School of Pharmacy  
University of East Anglia  
Norwich

## 1.0 Introduction

In the United Kingdom there are approximately 2.1 million people with diabetes<sup>1</sup>. This is expected to rise over the next few years with the estimated number of people with the condition in 2020 expected to reach 3.2 million (5.9% prevalence). The majority of patients (85%) are diagnosed with type 2 diabetes which is largely controlled by oral medication. The total cost of oral anti-diabetic drugs issued in primary care to the National Health Service in the year to September 2008 was £161.3 million representing a 10% increase in the number of medicines prescribed<sup>2</sup>. Diabetes is a chronic condition that if not treated properly can lead to complications such as retinopathy, nephropathy and neuropathy which can further increase costs to the NHS. The total cost of type 2 diabetes to the NHS is estimated to be £1.3 billion with total costs to society estimated to be five times this figure<sup>2</sup>. Therefore, it is important that patients with type 2 diabetes receive the appropriate care to prevent them from developing complications as a result of their disease.

The National Institute of Health and Clinical Excellence has issued guidance on the management of type 2 diabetes including complications and co-morbid conditions such as hypertension and hyperlipidaemia. These guidance documents provide specific, evidence based and cost-effective treatment options for patients at various stages of the disease. It is important that these documents are adhered to by prescribers so that patients receive the best possible care and the NHS obtains the best possible value from the medicines that are prescribed. Currently in the UK, there is evidence examining the adherence to NICE guidance for conditions such as type 1 diabetes in children<sup>3</sup>, epilepsy in children<sup>4</sup>, head injuries<sup>5</sup>, the use of COX-2 NSAIDs<sup>6</sup> and various other conditions<sup>7</sup>. However, there appears to be none relating specifically to type 2 diabetes in primary care.

In the current economic climate, primary care trusts (PCTs) are looking to use budgets effectively and ensuring that prescribers are adhering to NICE guidance is one way of achieving this. As mentioned above, they provide the most cost-effective method of treating a disease and represent the best practise for prescribing. This type of monitoring of GP treatment and prescribing habits is already performed via the Quality and Outcomes framework (QOF). This framework defines targets that surgeries must achieve for each of their patients in reference to particular disease states. However, these QOF targets and NICE guidance do not correlate with each other.

This audit will look at whether prescribers in one primary care trust are following NICE guidance when it comes to the management of type 2 diabetes and whether it compares to the results generated by QOF.

Type II diabetes: Audit protocol, version 2, Aug 2010.

## **2.0 Aim**

### **2.1 Aim**

To determine the adherence to NICE guidance for prescribing in type 2 diabetes in primary care and compare it against the Quality and Outcomes Framework results from 2010.

## **3.0 Method**

### **3.1 Registration**

The study will be registered with NHS Norfolk and the University of East Anglia.

### **3.2 NICE guidance**

The following standards from NICE will be used for the audit:

Type 2 diabetes: The management of type 2 diabetes (CG87)<sup>8</sup>.

### **3.3 Data Collection**

Data will be collected on patients who have a registered diagnosis of type 2 diabetes and who are controlled by oral hypoglycaemic agents only. Data relating to patients who are controlled by insulin will not be collected and neither will data relating to patients who are largely controlled in secondary care. There will be no restriction relating to age or gender of patients placed on the data that is collected. Along with details of medication that a patient is taking and whether it is being prescribed according to NICE guidance, details regarding the therapeutic monitoring (type and frequency) of patients will also be collected.

### **3.4 Patient confidentiality**

No patient identifiable data will be collected

### **3.5 Study population**

The study population will be chosen from a number of local medical practices in the Norfolk PCT area.

### **3.6 Sampling strategy**

Patients will be chosen from an alphabetical diabetes register held at the practice using a random number generator.

#### **3.6.1 Inclusion criteria**

Type II diabetes: Audit protocol, version 2, Aug 2010.

- Patients with type 2 diabetes over the age of 18.
- Patients diagnosed in the previous five years

#### 3.6.2 Exclusion criteria

- Currently receiving insulin treatment
- Currently managed by secondary care

#### 3.7 Sample size

200 – 250 patients will be selected for the analysis in order to reduce to final confidence interval on the level of adherence to NICE guidance.

#### 3.8 Data analysis

Appropriate descriptive statistical analysis will be undertaken. QOF data will be taken from a PCT database by a Prescribing Advisor.



## References

1. The Health and Social Care Information Centre & The Yorkshire and Humber Public Health Observatory. Prescribing for diabetes in England - An update: 2002-2008. Vol ISBN: 978-1-84636-306-1; June 2009.
2. National Institute for Health and Clinical Excellence. National costing report: Type 2 diabetes: newer agents for blood glucose control (October 2009). London; October 2009.
3. Edge J, Swift P, Anderson W, Turner B. Diabetes services in the UK: fourth national survey; are we meeting NSF standards and NICE guidelines? *Arch Dis Child*. 2005;90(10):1005 - 1009.
4. Chinthapalli R, Serane V, Pill J, Millard D, Batten D, Chinthapalli V. Epilepsy clinic services, NICE guidelines and patient satisfaction - an audit. *Seizure*. 2008;17(7):611-616.
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7. Sheldon T, Cullum N, Dawson D, et al. What's the evidence that NICE guidance has been implemented? Results from a national evaluation using time series analysis, audit of patients' notes, and interviews. *BMJ*. 2004;329(7473):999.
8. National Institute of Health and Clinical Excellence. Type 2 diabetes: The management of type 2 diabetes (CG87). London; 2009.

 *Appendix Ten*

**Research & Development**

NHS Norfolk  
Lakeside 400  
Old Chapel Way  
Broadland Business Park  
Thorpe St Andrew  
Norwich  
NR7 0WG

**Michael Twigg**  
School of Pharmacy  
University of East Anglia  
Norwich  
NR4 7TJ

Tel: 01603 257283

Fax: 01603 257292

E-mail: paul.mills@norfolk.nhs.uk

11<sup>th</sup> January 2011

Dear Michael

**Re: 2010-13. An audit to determine the adherence to NICE guidance for prescribing in type 2 diabetes in primary care.**

Thank you for submitting the above project to NHS Norfolk for approval. Your project has undergone a risk assessment by the PCT and this letter confirms that approval has been given by **NHS Norfolk** for you to carry out this project.

The following conditions are attached as standard to all projects:

- Approval is given on the basis of the information supplied to the PCT at the time of application. This approval may become invalid if significant changes occur to the project such as to raise questions about the safety and/or its continued conduct.
- It is a condition of approval that a copy of the full proposal and this approval letter are supplied to each practice or department within NHS Norfolk at which this project will take place.
- You must abide with all relevant PCT policies when running this project, and must also ensure you follow Caldicott guidelines, data protection guidelines.
- The results of the project must be made available to NHS Norfolk at the end of the project.
- Any incidents or complaints in relation to this project must be reported to the PCT in line with PCT incident reporting and complaints procedures.
- NHS Norfolk reserves the right to monitor or audit all projects receiving approval from the PCT.

Please note that a log of all projects approved by the PCT is maintained by the Research & Development Office at NHS Norfolk.

Yours sincerely



Clare Symms  
**Research Governance Manager**  
**NHS Norfolk**

cc. David Wright, University of East Anglia



Chair: Sheila Childerhouse  
Chief Executive: Andrew Morgan

Visit our website: [www.norfolk.nhs.uk](http://www.norfolk.nhs.uk)

 *Appendix 11*





**■ ■ ■** *Appendix 12*



# Patients experience and opinions of the community pharmacist: A focus group study

PROTOCOL

Version 7

February 2011

Lead Researcher: Mr. Michael Twigg

Research Team: Dr Debi Bhattacharya

Dr. James Desborough

Dr. Fiona Poland

Prof. David Wright



## 1.0 Introduction

In the United Kingdom, the role of the community pharmacist is moving from dispensing medicines to the delivery of clinical services<sup>1</sup>. This means there is an increasing role for pharmacists in advising patients about their medical conditions and more importantly the medicines they are prescribed to treat these conditions. With the publication of the new Government White Paper: Equity and Excellence: liberating the NHS, pharmacies will now have to demonstrate to GP consortia that they can provide these services<sup>2</sup>. In a time when resources are scarce these services need to demonstrate quality and, more importantly, address the needs of the patient population. It is therefore of paramount importance that we determine what the public perceive as the role of the pharmacist and what services they would wish. Services can subsequently be designed with these attributes.

There has been limited research into the perception of community pharmacists by the general public. In a recent review, the consensus is that pharmacists are not seen as the primary source of information when it comes to health matters, however, patients do see a role for them in relation to advice in conjunction with medicines supply<sup>3</sup>. When patients are interviewed in relation to the pharmacist's role in a specific study they have participated in the reviews are mixed. Some perceive an educational benefit to the service the pharmacist was providing<sup>4</sup> while others prefer to see their own doctor about matters relating to their health and treatment<sup>5, 6</sup>. This seems to suggest that patients who have had different experiences of the pharmacist will view them in different ways.

People with long term conditions are the most regular visitors to a community pharmacy and it would therefore seem appropriate to capture their opinions. One such long term condition is type 2 diabetes; it requires input from many healthcare professionals. In the United Kingdom there are approximately 2.1 million people with diabetes.<sup>7</sup> This is expected to rise over the next few years with the estimated prevalence in 2020 expected to reach 5.9% (3.2 million people). The majority of patients (85%) are diagnosed with type 2 diabetes which is largely controlled by oral medication. The total cost of type 2 diabetes to the NHS is estimated to be £1.3 billion with total costs to society estimated to be five times this figure per annum.<sup>8</sup> Therefore, it is important that patients with type 2 diabetes receive the appropriate care to prevent them from developing complications as a result of their disease.

There are a very many beliefs which may be held by patients with diabetes relating to their medication that a pharmaceutical intervention could potentially address. These beliefs can often lead to intentional non-adherence and the subsequent onset of complications with their associated

financial impact on the NHS. Patients are often worried about how they are going to fit all the medication around their current lifestyle and about side effects of the oral hypoglycaemic agents they have been prescribed<sup>9, 10</sup>. Most patients receive some form of education at diagnosis, usually provided by a diabetes nurse on a one-to-one basis to address these issues. *Lawton et al.* highlighted from their study that 4 years post-diagnosis many patients had unmet needs for education and information<sup>10</sup>. Therefore, we need to identify reasons why this is and if different patients see a role for the pharmacist in addressing this problem.

In relation to type 2 diabetes, there have been several studies that have ascertained the perceptions of patients regarding doctors and nurses and their treatment<sup>10, 11</sup>, however, patients have not been asked to comment on the pharmacist. GPs and nurses have also been asked for their views on the treatment of patients with type 2 diabetes and they mention nothing of pharmacy input into the management of these patients<sup>12</sup>.

The aim of this study is to build on this background research to ascertain the range of thoughts and experiences patients have about community pharmacy. We will use a series of focus groups to ascertain what sorts of patients use community pharmacy, their thoughts on what the pharmacist currently does and what sorts of roles they see the pharmacist taking on. The use of focus groups is now commonplace in the health sciences as researchers attempt to understand what it is that patients actually want from their health service. We will use the data to analyse the commonalities and discourses that occur within and between the groups to determine if there is a theme that emerges as to the role of the pharmacist in the healthcare team.

## **2.0 Aims & Objectives**

### **2.1 Aims**

To describe the relationship between a community pharmacist and patients with type 2 diabetes and where patients see the pharmacist having the greatest role in their healthcare in the future.

### **2.2 Objectives**

The objectives of the focus groups will be to understand:

- how diabetes affects their lives
- whether the disease has an effect on how often they see the community pharmacist
- when patients would deem it appropriate to see the pharmacist and what bearing their disease has on this decision
- the personal experiences of patients with the community pharmacist
- how patients see the role of the pharmacist developing.

### **3.0 Method**

#### **3.1 Participant recruitment**

Pharmacies in Norfolk will be identified with the help of the Local Pharmaceutical Committee (LPC) to ensure a spread across the county. The pharmacies will be provided with a supply of information sheets (appendix 2) and consent forms (appendix 3). They will be asked to supply every patient who presents with a prescription for an oral-antidiabetic medicine with an information sheet and consent form.

A researcher from the University of East Anglia will visit each pharmacy prior to the start of the study to ensure that the pharmacy staff are aware of the basic details in the event that a patient asks for more information than is contained in the information sheet. Having read the information sheet patients wishing to participate will indicate this by signing and returning the consent form to the research team in the pre-paid envelope supplied. The pharmacists will be asked to keep a list of the patients who they have supplied an information sheet to in order to keep track of those people who have been asked to participate. When the potential participant presents at the pharmacy the following month, the pharmacy staff will then be able to see if they have already received the information sheet and ask them if they have sent it back to the research team. If they have not, they could be provided with another information sheet and consent form.

We will be looking to recruit a number of different types of patients to the focus group in order to cover a broad range of opinions. Therefore as a part of the consent form, patients will be asked to provide their age, gender, length of time since diagnosis and the number of medicines they are currently prescribed.

#### **3.2 Sampling**

We will be using a 'grounded' approach to develop our sampling over the course of data collection. In the first focus group, we will use a wide range of participants of different gender, age and length of time since diagnosis. We currently have little idea about the factors that will affect how the focus group runs so in this first discussion, we will be looking to see if any one particular group needs to have a focus group on their own to obtain the best possible data from them and to ensure good management of the discussion.

Potential participants will be recruited into a pool subject to the following inclusion and exclusion criteria:

**Inclusion Criteria**

- Diagnosis of type II diabetes
- Aged 18 – 80

**Exclusion criteria**

- Unable to read or speak English
- Patients under the care of another person, e.g. carer or relative (i.e. not managing their own medication)

If this recruitment method is ineffective, after three months, we will approach a local diabetes support group to make contact with potential participants and ask the support group to send them a copy of the information sheet and consent form directly inviting them to participate in the study.

Once we have enough participants in the recruitment pool by whichever recruitment methods is successful, we will then allocate participants to the first focus group to reflect purposive sampling of a wide range of characteristics including age, sex and length of time since diagnosis. Discussion from this focus group will be transcribed and analysed as soon as possible so that further focus groups may be constituted following grounded theory principles as emerging theory needs to be tested. These might lead to more homogeneous focus groups, e.g. perhaps examining the experience of those more recently-diagnosed in one group and then those who have been living with the condition for several years, or perhaps groups consisting of older patients and then those consisting of younger patients. These would encourage different discussion of perhaps more specific types of shared experience.

**3.3 Sample recruitment**

We aim to recruit up to 32 participants to take part in the focus groups. We will recruit double this number to the participant pool from which we will sample to ensure that we have enough participants. This may involve receiving consent forms from potential participants who do not go forward to participate in the focus groups. These participants will be sent a letter thanking them for their time and informing them that they will not be required to take part. The potential for this occurrence will be clearly detailed in the patient information leaflet.

### **3.4 Focus group design**

The focus groups will consist of six to eight participants, each with two facilitators. There will be four focus groups in total. The topics discussed are likely to include the following areas:

- how diabetes affects their lives
- whether the illness has an effect on how often they see the community pharmacist
- when patients would deem it appropriate to see the pharmacist and what bearing their disease has on this decision
- the personal experiences of patients with the community pharmacist
- how patients see the role of the pharmacist developing
- areas of managing therapy where they may want help

These subjects are broad ranging as they are designed to stimulate conversation and debate between the participants. In turn, this will hopefully encourage the expression of true opinions regarding pharmacists and the care currently received. The group will be managed to encourage free discussion and to generate a wide range of ideas and opinions. Each focus group will last up to 90 minutes and refreshments will be provided to those taking part. Participants may also be provided with information about current research or ideas relating to pharmacists roles that have been published in relation to pharmacy services to determine their view on it. These materials will be developed with the research team and will be tested at the first focus group should they need to be used.

The role of the second facilitator will be to ensure that everyone is comfortable during the focus group, assist and advise any participants that wish to leave the focus group as well as taking notes. They will be responsible for making sure the recording equipment is working and that should anybody have any problems at the end of the focus group that they are given the appropriate direction on where to seek help. The facilitators will be a mix of researchers from the School of Pharmacy and the School of Allied Health Professionals all of whom have had training in conducting focus groups.

Once the first focus group has been conducted, the data will be analysed and subject to the outcome of any new information that was not previously identified, the design of the subsequent focus groups in terms of composition and discussion topics will be altered accordingly.

### **3.5 Data collection**

All focus groups will be recorded using two audio-recorders. A second researcher will be present to facilitate the running of the focus groups. The recordings will then be transcribed using software transcription service or manually by one of the researchers. A second researcher will then monitor the transcriptions to ensure they are accurate.

### **3.6 Data analysis**

Analysis will be emergent and concurrent so as to reflect elements of a grounded theory approach. The discussions will be fully transcribed and then coded in terms of units of meaning and elements of discourse to develop a thematic well-grounded analysis which can be used to contextualise understandings and values placed on aspects of care in relation to the flow of discussion and the characteristics of the participants displayed in the focus groups. To ensure the coding is trustworthy, it will be completed independently by two of the researchers and then compared for discrepancies.

Particular emphasis will be placed on identifying and conceptualising negative instances in the developed analysis to take account of the full range of variation. A comparative approach will also be adopted to compare individual and group narratives.

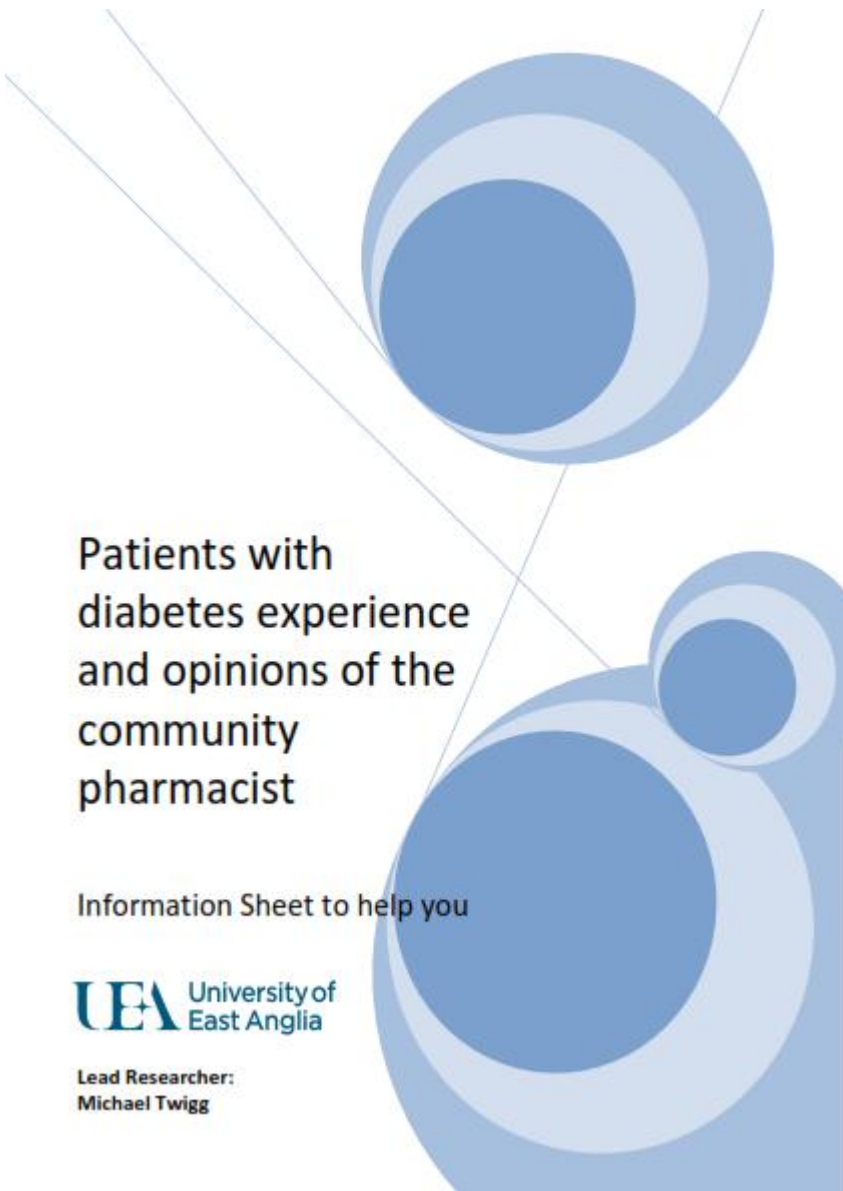
### **4.0 Further study**

The results from these focus groups will be used to design a service aimed at patients with a type II diabetes run by a pharmacist and more generally to inform researchers about the current thinking of patients with type II diabetes towards pharmacists and their role in healthcare.

## 5.0 References

1. Noyce PR. Providing patient care through community pharmacies in the UK: Policy, practice, and research. *Annals of Pharmacotherapy*. May 2007;41(5):861-868.
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6. Salter C, Holland R, Harvey I, Henwood K. "I haven't even phoned my doctor yet." The advice giving role of the pharmacist during consultations for medication review with patients aged 80 or more: qualitative discourse analysis. *BMJ*. 2007;334(7603):1101.
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11. Alazri MH, D Neal R, Heywood P, Leese B. Patients' experiences of continuity in the care of type 2 diabetes: a focus group study in primary care. *Br J Gen Pract*. Jul 2006;56(528):488-495.
12. Alazri MH, Heywood P, Neal RD, Leese B. UK GPs' and practice nurses' views of continuity of care for patients with type 2 diabetes. *Family Practice*. Apr 2007;24(2):128-137.



An abstract graphic consisting of several overlapping circles in various shades of blue. Two thin grey lines cross each other, forming an 'X' shape that passes through the center of the circles. The circles are arranged in a way that some are partially obscured by others, creating a sense of depth and movement.

## Patients with diabetes experience and opinions of the community pharmacist

Information Sheet to help you

**UEA** University of  
East Anglia

Lead Researcher:  
Michael Twigg

**What is the project about?**

- You are being invited to participate in a research project. Before you decide we would like you to understand why the research is being done and what it would involve for you. Please take your time to read this information sheet.
- This is a PhD student project funded by the UEA which is designed to collect the views of patients with type 2 diabetes about their experiences of community pharmacy. In this country the role of pharmacists is changing. We would like to know how you see the pharmacists' role developing in the future.
- We would also like to find out how diabetes affects your life, how often you visit the community pharmacy and when you think it would be appropriate to see a community pharmacist.

**Why have I been chosen?**

- The research team are interested in the views of patients who have type 2 diabetes. The pharmacy team have seen from your record that you take medication to treat this condition and therefore we would like to find out about your views in this study. Your pharmacist has been asked by the research team at UEA to find out whether you have received details on this study.

**What happens if I agree to take part?**

- We will ask you to complete the brief questionnaire which is on the back of the consent form. We will write to you to let you know if we also need you to take part in a small focus group with some other people who also live with type 2 diabetes.
- You are free to withdraw from the study at any time; it will not affect the service you receive from your local pharmacy.

**What is a focus group?**

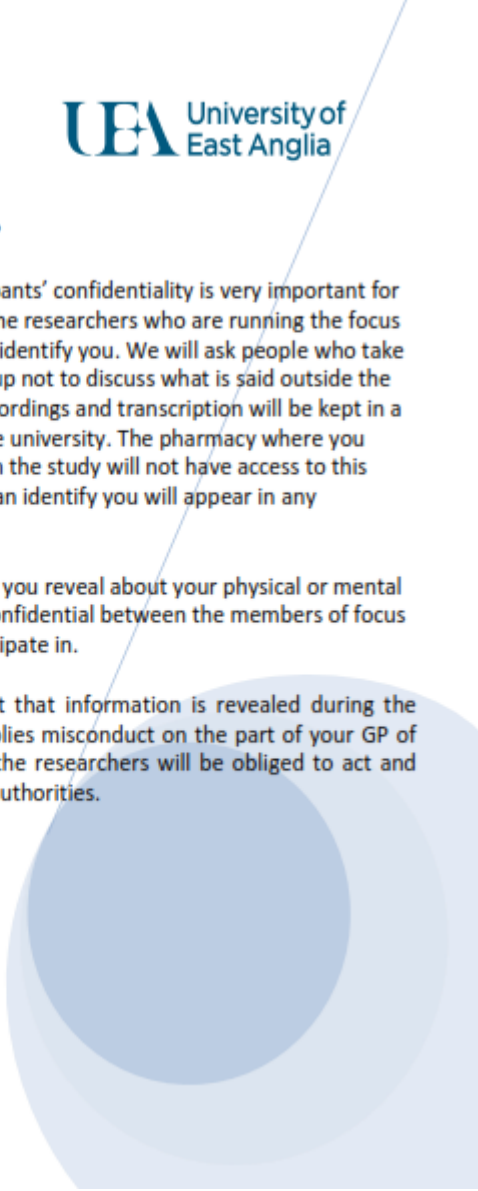
- A focus group is where six to eight people are brought together to have a discussion. This will involve having a chat with other people who have been diagnosed with type 2 diabetes. The focus group will last up to 90 minutes. It will take place at location near to where you live. The groups will be led by two researchers from the Schools of Pharmacy and Allied Health Professions.
- There will be free light refreshments provided and as a thank you for taking part we will give you a **£10 Marks & Spencer voucher** to spend as you wish.

- During the focus group the researcher will ask some questions. These will include:
  - How diabetes affects your life
  - When you usually see the pharmacist
  - Personal experiences of the community pharmacy
  - How you see the role of pharmacists developing
- The group will be supported to discuss these topics openly and honestly, and for everyone in the group to be able to speak freely and comfortably.
- All the groups will be voice-recorded so that we can listen and transcribe them after the session has finished.

**Can I join in a focus group discussion if I am a quiet person?**

- The researcher will try to ensure that everybody has an opportunity to speak if they wish to say something, as all opinions are important to us. However, you don't have to say anything if you don't want to.

**What about confidentiality?**

- Safeguarding participants' confidentiality is very important for this research. Only the researchers who are running the focus group will be able to identify you. We will ask people who take part in the focus group not to discuss what is said outside the focus group. The recordings and transcription will be kept in a secure location at the university. The pharmacy where you agreed to take part in the study will not have access to this data. Nothing that can identify you will appear in any published materials.
  - Any information that you reveal about your physical or mental health will be kept confidential between the members of focus group that you participate in.
  - In the unlikely event that information is revealed during the focus group that implies misconduct on the part of your GP or regular pharmacist, the researchers will be obliged to act and inform the relevant authorities.
- 

**Are there going to be any disadvantages to taking part?**

- The research team do not foresee any disadvantages to taking part in these focus groups. There will be a trained researcher available to help you if you feel the need to step out of the focus group at any point due to talking about sensitive matters.

**Complaints**

- Should you have any complaints about any aspect of this study then please call the academic supervisor: Prof. David Wright at the University of East Anglia on 01603 592042. Should the complaint not be satisfactorily resolved then contact the Patient Advice and Liaison Service (PALS) on 01603 289036.

If you have any further questions please call the lead researcher on the number overleaf.

**It is entirely your decision to take part in this research or not. If you decide not to take part or to leave the research it will not affect any services or treatment you may be receiving. You are also free to withdraw from the focus group at any time without reason.**

*Thank You*

**Lead Researcher: Michael Twigg**

PhD Student  
School of Pharmacy  
University of East Anglia  
Norwich  
NR4 7TJ  
Tel: 01603 593144  
E-mail: [m.twigg@uea.ac.uk](mailto:m.twigg@uea.ac.uk)

Version 7 February 2011



**Patients with diabetes experience and opinions  
of the community pharmacist**

**Focus Group Consent Form**

**If you wish to be involved, please initial each box and complete the details at the bottom of the form. Once completed, please return to the member of staff that is looking after you in the envelope provided:-**

1. I agree to participate in the above study to investigate my views about my community pharmacy.
2. I confirm that I have read and understand the information sheet dated February 2011 version 7 for the above focus group and have had the opportunity to ask questions.
3. I am willing to allow the discussion within the focus group to be audio-taped for the purposes of analysing the conversations that take place.
4. I agree to keep the information I hear in the focus group confidential at all times. I understand that everything I saw will be anonymised and will be kept securely at the UEA.

\_\_\_\_\_  
Name of participant

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

Address of participant: \_\_\_\_\_  
\_\_\_\_\_

Telephone number: \_\_\_\_\_

**Please turn over and complete the short questionnaire**



Please tick the relevant boxes:

**Age group**

20 – 40	<input type="checkbox"/>
41 – 50	<input type="checkbox"/>
51 – 60	<input type="checkbox"/>
61 – 70	<input type="checkbox"/>
71 – 80	<input type="checkbox"/>

**Gender**

Male	<input type="checkbox"/>
Female	<input type="checkbox"/>

**Length of time since diagnosis**

0 – 1 year	<input type="checkbox"/>
1 – 2 years	<input type="checkbox"/>
2 – 5 years	<input type="checkbox"/>
5+ years	<input type="checkbox"/>

**Number of medicines on your surgery repeat list**

Please return this consent form to the research team in the pre-paid envelope supplied. You do not need to put a stamp on the envelope.

**■ ■ ■** *Appendix 13*



**National Research Ethics Service**  
**Cambridgeshire 1 Research Ethics Committee**

Victoria House  
Capital Park  
Fulbourn  
Cambridge  
CB21 5XB

Telephone: 01223 597653  
Facsimile: 01223 597645

07 March 2011

Mr Michael J Twigg  
PhD Student  
School of Pharmacy  
University of East Anglia  
Norwich NR4 7TJ

Dear Mr Twigg

**Study Title:** Patient's experience and opinions of the community pharmacist: A focus group study  
**REC reference number:** 11/H0304/2

Thank you for your letter of 10 February 2011, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

**Confirmation of ethical opinion**

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

**Ethical review of research sites**

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

**Conditions of the favourable opinion**

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

For NHS research sites only, management permission for research ("R&D approval") should be obtained from the relevant care organisation(s) in accordance with NHS research governance arrangements. Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at <http://www.rdforum.nhs.uk>.

*Where the only involvement of the NHS organisation is as a Participant Identification Centre (PIC), management permission for research is not required but the R&D office should be*

notified of the study and agree to the organisation's involvement. Guidance on procedures for PICs is available in IRAS. Further advice should be sought from the R&D office where necessary.

Sponsors are not required to notify the Committee of approvals from host organisations.

**It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).**

#### Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	Version	Date
Protocol	Version 7	February 2011
Response to Request for Further Information from Michael Twigg		10 February 2011
Investigator CV Michael James Twigg		
Participant Consent Form	Version 6	February 2011
Letter to Pharmacist with attached 'asking' list		
Participant Information Sheet	Version 7	February 2011
Evidence of insurance or indemnity - Letter from UEA		02 December 2010
Evidence of insurance or indemnity - Zurich Municipal		16 September 2010
REC application	Submission Code 65380/171789/1/119	
Covering Letter		07 December 2010
CV for Dr Fiona Poland		
Academic supervisor CV - Dr David John Wright		

#### Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

#### After ethical review

Now that you have completed the application process please visit the National Research Ethics Service website > After Review

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

The attached document "*After ethical review – guidance for researchers*" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of

changes in reporting requirements or procedures.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email [referencegroup@nres.npsa.nhs.uk](mailto:referencegroup@nres.npsa.nhs.uk).

11/H0304/2

Please quote this number on all correspondence

With the Committee's best wishes for the success of this project

Yours sincerely



**Dr Daryl Rees**  
**Chair**

Email: [susan.davies@eoe.nhs.uk](mailto:susan.davies@eoe.nhs.uk)

Enclosures: "After ethical review – guidance for researchers"

Copy to: Mrs Sue Steel  
Research, Enterprise & Engagement  
UEA  
Norwich NR4 7TJ

Dr Paul Mills  
NHS Norfolk R&D  
Lakeside 400  
Old Chapel Way  
Thorpe  
Norwich NR7 0WG

 *Appendix 14*

Ref: 2010IC03

**Mr Michael Twigg**  
School of Pharmacy  
University of East Anglia  
Norwich  
NR4 7TJ

**Research & Development**  
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[www.norfolk.nhs.uk/research](http://www.norfolk.nhs.uk/research)

9 March 2011

Dear Mr Twigg

**Re: Project Ref 2010IC03. Patient's experience and opinions of the community pharmacist: A focus group study**  
**REC Number: 11/H0304/2**  
**Chief Investigator: Michael Twigg**  
**Sponsor: University of East Anglia**

Further to your submission of the above project to the R&D office at NHS Norfolk your project has now been reviewed and all the mandatory research governance checks for Participant Identification Centres<sup>1</sup> (PICs) have now been satisfied. I am therefore pleased to inform you on behalf of **NHS Norfolk** that that agreement was granted on **9<sup>th</sup> March 2010** for the following Participant Identification Centres to refer patients for this study:

- Pharmacies in NHS Norfolk

Please note that NHS Permission is granted on the basis of the information supplied in the research governance submission, if anything subsequently comes to light that would cast doubts upon, or alter in any material way, any information contained in the original application, or a later amendment application there may be implications for continued NHS Permission.

<sup>1</sup> Where potential participants will be identified through NHS organisations other than the research sites themselves, these organisations are termed "Participant Identification Centres" (PIC) IRAS Question Specific Guidance - Part C Version 2.2 dated April 2009



Chair: Sheila Childerhouse  
Chief Executive: Andrew Morgan

Visit our website: [www.norfolk.nhs.uk](http://www.norfolk.nhs.uk)

NHS Norfolk represents the Norfolk Primary Care Trust  
NHS Norfolk hosts the Research Management and Governance Services for NHS Norfolk, NHS Suffolk, NHS Great Yarmouth & Waveney and Norfolk Community Health & Care NHS Trust

Please note that the PCT does not indemnify the research site, the host organisation or the participants in relation to the conduct or management of the research; the responsibility for indemnity arrangements rests with the study Sponsor.

Permission is granted on the understanding that the study is conducted in accordance with the Research Governance Framework. I have enclosed two copies of the Standard Terms and Conditions of Approval for PICs. Please sign and return one copy to the R&D office at the above address. Failure to return the standard terms and conditions may result in agreement being revoked.

**Please note, under the agreed standard terms and conditions you must inform the R&D Office at NHS Norfolk of any proposed changes to this study, whether minor or substantial, and to keep the office updated on progress, particularly the contribution of the PICs in Norfolk & Suffolk to screening and recruitment.**

If you have any queries regarding this or any other project please contact Paul Mills, R&D Officer, at the above address. Please note, the reference number for this study is **2010IC03** and this should be quoted on all correspondence.

The following documents were reviewed:

Letter of Favourable Opinion from Cambridgeshire 1 REC, dated 7<sup>th</sup> March 2011

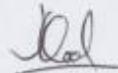
- Protocol, Version 7, February 2011
- Letter to Pharmacist\*
- Participant Information Sheet, Version 7, February 2011
- Participant Consent Form, Version 6, February 2011
- CV – Michael Twigg
- CV – Dr David Wright
- CV – Dr Fiona Poland
- Evidence of Insurance – Letter from UEA, 2<sup>nd</sup> December 2010
- Evidence of Insurance – Zurich Municipal, 16<sup>th</sup> June 2010
- Response to Request for Further Information, 10<sup>th</sup> February 2011

Other Documents Reviewed

- Signed R&D Form, Lock Code 65380/171803/14/54

**\*Note:** It is noted that, although the letter to pharmacist was labelled electronically as Version 1, February 2011, this wasn't detailed on the letter itself. It is recommended to add the version number and date to the letter.

Yours sincerely



Jonathan Cook  
Director of Corporate Services  
NHS Norfolk

cc: David Wright, Research Supervisor, University of East Anglia  
Sue Steel, Sponsor Representative, University of East Anglia  
File



**■ ■ ■** *Appendix 15*

# The diabetes drop-in clinic

A community pharmacy clinic for poorly controlled type 2 diabetes patients

November 2011

Version 2

**Michael Twigg**  
Principal Investigator

Dr Debi Bhattacharya

Dr James Desborough

Prof David Wright

NUMARK+

UEA University of  
East Anglia

## 1.0 Introduction

There are an estimated 17.5 million people diagnosed with a long term condition in the UK (Department of Health, 2005); 2.1 million with type 2 diabetes (The Health and Social Care Information Centre & The Yorkshire and Humber Public Health Observatory, June 2009). This figure is predicted to rise over the next few years with the estimated number of people with diabetes expected to reach 3.2 million (5.9% prevalence) by 2020. The majority of patients (85%) are diagnosed with type 2 diabetes which is largely controlled by oral medication.

The main clinical outcome used in type 2 diabetes is HbA<sub>1c</sub> which, according to national guidelines should be maintained below 7.5% (National Institute of Health and Clinical Excellence, 2009). However, recent figures from the NHS suggest that approximately only 60% of patients are achieving this target (The NHS Information Centre, 2011). In the UK, the National Institute for Health and Clinical Excellence (NICE), has published guidelines for the management of patients with type 2 diabetes (NICE, 2009). These guidelines provide treatment algorithms for prescribers and in recent research it has been shown this guidance is generally adhered to (Twigg, 2011).

The lack of patients achieving national targets for diabetes control may be due to non-adherence with evidence to suggest that 20-30% of patients with type 2 diabetes do not take their medication as directed and this may partially explain the difficulties many patients experience in hitting national targets (Schmittiel et al., 2008). Schectman *et al.* demonstrated that every 10% increase in adherence was associated with a 0.19% reduction in HbA<sub>1c</sub> levels (Schectman et al., 2002) and a lower HbA<sub>1c</sub> level has been demonstrated to lead to a reduction in the incidence of long term complications associated with diabetes (UK Prospective Diabetes Study (UKPDS) Group, 1998).

With the emphasis on both the prescribing of the correct medicines and the need for patients to adhere to their medicines, it seems logical that a pharmacist (the expert on medicines) should play some form of role in the care of patients with type 2 diabetes. The majority of patients with type 2 diabetes will be treated with medication dispensed by a community pharmacy in primary care. An average adult visits a community pharmacy 16 times per year with 86% of the population visiting at least once per year, 78% of those for health related reasons (Department of Health, 2008). This figure equates to over 47 million people visiting a community pharmacy at one point during the year and demonstrates the readiness with which the public use community pharmacy.

In the Government's Choosing Health through Pharmacy document published in 2005, community pharmacy is specifically targeted as a profession that can be used to improve the care of patients with long term conditions (Department of Health, 2005). Pharmacists are already engaged in providing adherence based interventions e.g. medicine use reviews and the new medicine service to patients with chronic conditions.

In research conducted by this research team, 25 patients with type 2 diabetes were asked about the views and experiences of the current and future role of the community pharmacist in one of four focus groups. The focus groups targeted all patients with type 2 diabetes that used a community pharmacy in Norfolk and asked them about their experiences of the service they received from the pharmacist. The groups were also given scenarios, based on real situations in a community pharmacy, on which they were asked to comment and provide feedback as to whether this was something they would be likely to engage with.

Overall, patients largely welcome the advances in the pharmacist's role and they recognise that pharmacists have a role in information provision to patients who are poorly controlled or those who do not have a good relationship with their medical practice (data on file). They saw the pharmacist as a healthcare professional that is easy to access and a good source of knowledge of side effects, how to take medicines and interactions with over-the counter medicines. Some patients view the pharmacist as more informed and with more time to devote to them than their general practitioner or nurse at the medical practice. However, patients also acknowledge that the environment of the pharmacy is not always conducive to good patient-pharmacist privacy when discussing medical problems.

The scenarios that were used during the focus groups are described below:

1. You enter a community pharmacy to collect your prescription and you are given it by the counter assistant, who asks your address and then you leave the pharmacy.
2. As scenario 1, except once a year the pharmacist asks you for a chat about your medicines in the private consultation area (real-life MUR situation)
3. As scenario 1, except if you are identified by the medical practice as poorly controlled you are referred to the pharmacy for a series of consultations with the pharmacist over a period of months to try and understand and rectify the lack of control of your diabetes (taken from research conducted by *Krass et al.* that demonstrated this type of intervention has positive impacts on clinical indicators for type 2 diabetes (Krass et al., 2007, Krass et al., 2011)).

After discussion, participants in all the focus groups identified that scenario 1 occurred the most often and that some of the participants had experienced something like scenario 2 in their community pharmacy. However, of those that had experienced scenario 2, many did not find the consultation useful as they were either well controlled, had a good relationship with the medical practice or did not have any unmet needs for information. These same patients did identify that this kind of service may be useful to patients who were uncontrolled as the pharmacist may be able to help them achieve targets for clinical tests.

In terms of scenario 3, participants in the focus groups did not acknowledge the need for such a defined service, as they highlighted it may not be feasible for a pharmacist to perform such a service in terms of time and workload but also from a patient preference angle. However, they did highlight the benefits of prescriber referral into any service in community pharmacy. Referral from the medical practice to the pharmacist with the doctor then acting upon advice from the pharmacist was seen as an approach that would be welcomed by patients whilst not undermining the overall control the doctor has over patient care.

One of the greatest advantages that pharmacy has over the other professions is its access and convenience and participants in the focus groups thought that this strong point of community pharmacy should be utilised in any future advances to the profession. Participants liked to be able to drop-in and have a "chat" with the pharmacist about their condition or medication, sometime just to make sure they are doing the right thing. Elsewhere in the literature patients have demonstrated that they want to manage their condition but may need help and support to overcome problems that occur with self management (Minet et al., 2011). A pharmacist may be the appropriate healthcare professional for this.

From our own focus group research it is clear that patients want an easy to access and convenient place where they can ask a qualified healthcare professional questions about their condition and medicines to treat that condition in a professional environment without the need to make an appointment with the medical practice. Following the MRC framework for complex interventions (Medical Research Council, 2008) and the published definition of feasibility (Arañ et al., 2010) this feasibility study will determine if pharmacists can conduct a drop-in clinic for patients with poorly controlled type 2 diabetes and if it is acceptable to patients.

## **2.0 Aims and Objectives**

### **2.1 Aims**

To determine whether a pharmacy diabetes drop-in clinic is feasible and acceptable to patients with poorly controlled diabetes.

### **2.2 Objectives**

To assess:

- the feasibility of a community pharmacy drop-in clinic for poorly controlled diabetes patients
- whether poorly controlled patients engage with the service
- the acceptability of the service to patients and pharmacists
- the characteristics of patients accessing the service and identify their needs
- changes in perception and the way the pharmacist is used after visiting the drop-in clinic
- if there is an effect on the questionnaire measures from baseline to follow-up
- if the questionnaires are useful to capture the necessary data and whether the pharmacists thought they were useful to inform the consultation

### **3.0 Method**

#### **3.1 Ethical Review**

This study will be submitted to an NHS Research Ethics Committee for approval and to the relevant NHS R&D committee of the local primary care trust.

#### **3.2 Study Design**

The diabetes pharmacy drop in clinic will be specifically targeted at patients who are poorly controlled. The clinic will be conducted in four pharmacies with the regular pharmacist in the private consultation room.

#### **3.3 Practice and pharmacy recruitment**

In conjunction with the local primary care trust, the researchers will identify potential independent community pharmacies where the study can be conducted. Once these sites have been identified, the researchers will approach both the pharmacy and the medical practice and arrange meetings to discuss the project and seek consent to participate in the study.

#### **3.4 Pharmacist training**

Pharmacists will be asked to complete the CPPE Diabetes Management training package and have read the NICE guidance for the management of type 2 diabetes before they attend a study evening at the University. The pharmacists will be paid to complete this training.

The pharmacists will also attend a study evening at the university to receive information regarding the study and undertake a brief training session in consultation techniques. This will not be assessed, instead will be used to ensure the pharmacists are aware of the needs of the patients and the need to make their advice to the participants positive. Detailed excerpts from the focus group study will be used to highlight real concerns that patients may have and how they felt they should be dealt with.

#### **3.5 Participant identification**

The medical practice will be asked to identify poorly controlled patients subject to the following criteria:

- Confirmed diagnosis of type 2 diabetes

- Poorly controlled (HbA<sub>1c</sub> > 7.5% (58 mmol/mol) and/or blood pressure >140/80mmHg and/or total cholesterol >4 mmol/L for more than two consecutive measurements
- Aged > 18 years

Once these patients have been identified the researcher will provide the medical practice with pre-filled envelopes enclosing a letter from the practice partners and a leaflet advertising the service. The practice will be asked to mail these envelopes to the patients identified. The researcher will have no access to medical records for this process. This process will happen twice during the course of the period of the study, the second as a reminder of the service. Medical staff at the practice will also be encouraged to refer patients to the service if they are experiencing difficulties when they attend for regular appointments.

The patient will also have the opportunity to visit the pharmacy outside of the clinic times but will be informed that they may have to wait a short while to see the pharmacist.

### 3.6 Participant recruitment and consent

The leaflet advertising the service will contain a consent section on the back that the patient will be asked to bring along to the clinic. Should the patient forget, they will be asked to complete a consent form before the consultation can commence. The consent/data collection form will be attached to the information sheet. The pharmacist or pharmacy staff will be available to assist the patient complete the consent form and subsequent questionnaires should they need any help. Once the patient has consented, the consent/data collection form can be detached from the information leaflet so that the patient can keep that section and the pharmacist can keep the consent form. The **participant**, researcher and medical practice will also be given copies of the consent form should they require it.

### 3.7 The drop-in clinic

Before the consultation has started, the patient will be given time to read and ask questions about the information leaflet. If they are happy with the information contained in the leaflet, they will be asked to sign the consent form. The patient will then be asked to complete a short questionnaire containing three validated questionnaires: the Beliefs about Medicines Questionnaire (BMQ) (Horne et al., 1999), the Satisfaction with Information about Medicines questionnaire (SIMS) (Horne et al., 2001) and Morisky measure of adherence (Morisky et al., 1986). Data will also be collected on how many times and why they have used the community pharmacy over the preceding three months.



These will help define the type of patient accessing the service and nature of problems experienced with their medicines or condition. Once the participant has completed these, the pharmacist will start the consultation. The content of all the consultations will be negotiated between the pharmacist and the patient based on the needs of the patient and the responses to the questionnaire. This could include questions relating to their disease, lifestyle and diet or medicines.

If necessary, the pharmacist will call the prescriber and they will discuss any potential changes that the pharmacist thinks will be beneficial to the patient. This may include:

- Dose titration
- Prescribing of an alternative medicine due to adherence issues or side effects
- Prescribing of an alternative formulation

The prescriber is under no obligation to follow the recommendations and any changes that require prescription changes that are agreed by the participant, pharmacist and prescriber will be arranged by the pharmacist in conjunction with the practice staff.

### 3.8 Follow-up data collection

Once the consultation is finished, the patient will be asked to complete a feedback form, which will contain questions regarding the conduct of the pharmacist, the surroundings in which the consultation occurred and whether they felt the consultation was beneficial. The patient will be asked to deposit the completed anonymous questionnaire into a box in the pharmacy before they leave. At the end of the questionnaire, there will be an option for patients to include their telephone number so that should any aspects of their answers need clarification, the research team may contact them. It will be made clear on the questionnaire that by giving their telephone number they are consenting to the research team calling them for clarification.

The pharmacist will collect information from the consultation such as age, gender, postcode and the types of information asked by the patient during the consultation. After the consultation, the pharmacist will call the medical practice to obtain the following information required to complete the reverse of the consent form:

- Most recent HbA<sub>1c</sub>, blood pressure and total cholesterol results

- Number of medicines prescribed
- Length of time since diagnosis

The data collection side of the consent form will contain the patient number and a photocopy containing only the patient number will be given to the researcher. The pharmacist will also document the content of the consultation using the pharmacy data collection form. This will also contain only a patient number and will be given to the researcher after the consultation has been completed.

Three months after the consultation, the patient will be asked to complete a repeat of the baseline questionnaire. This will be sent to their address by the researcher. The questionnaire will contain only the patient number and will be returned in a pre-paid envelope to the University. The researcher will keep track of which patients are due to receive a questionnaire and if they have returned it. If they do not return the questionnaire within two weeks, they will be sent a follow-up.

All data collection forms and questionnaires will contain a patient number, assigned at the beginning of the consultation, so that they can be matched up to the pharmacy by the researcher at the UEA and to maintain patient confidentiality. Only the pharmacist, medical practice and researcher will know that they are participating in a research study. The consent form will reflect the need for the researcher to have the patient's contact details.

### 3.9 Funding

The medical practice will be paid a set fee for participating in the evaluation. The pharmacy will receive free locum support from the lead researcher on the day of the clinic and will be paid per patient that attends the drop-in clinic to a maximum of 40 between the four pharmacies.

### 3.10 Pharmacist interviews

The pharmacists will be interviewed to determine their views on the drop-in clinic, patient interaction and the study design. They will be asked to comment on the following areas to inform the design for a pilot study

- **The service**
  - What was your general impression of the service?
    - Did you have enough time to prepare for the service?

- What did you think of the delivery and content of the consultations?
  - How do you think the service benefitted:
    - Patients?
    - Relationship with the medical practice?
    - You personally?
  - What impact do you think the pharmacy environment has on this kind of service?
  - How has your practice changed as a result of providing the service?
- **The research**
  - What are your thoughts about the research design?
    - What was your impression of the targeting of patients for this study?
    - What did you think of the conduct of the research and the research team?
    - What did you think of the paperwork for the study?
    - What did you think about liaising with the medical practice?
    - Do you think the data collected for the study was appropriate?

Other questions will be asked where necessary to clarify remarks made to the researcher. These interviews will be held at a convenient location and time for the pharmacists and will be audio-recorded and transcribed verbatim. They will be analysed using framework analysis with reference to the original questions.

### 3.11 Data analysis

All demographic and clinical data from the participants will be analysed using descriptive statistics. Each section of the questionnaires will be assigned a score according to the respective validated tool and will then be analysed using descriptive statistics. Although not a powered study, appropriate parametric and non-parametric statistical tests will be used to determine any difference between the questionnaire responses at baseline and follow-up and any correlation between questionnaire data and participant demographics.

The free-type sections of the questionnaires and the pharmacist interviews will be transcribed and coded by the researcher and themes will be developed using a framework approach. A second researcher will also undertake the analysis of this data to ensure nothing important has been missed.

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University of East Anglia

**Michael Twigg MRPharmS**

**School of Pharmacy**  
University of East Anglia  
Norwich NR4 7TJ

Email: [m.twigg@uea.ac.uk](mailto:m.twigg@uea.ac.uk)

Tel: 01603 591956

Pharmacy Address

[Date]

Dear [pharmacist's name]

Re: Diabetes drop-in clinic

Thank you for agreeing to participate in the diabetes drop in clinic that is being run as part of my PhD. This feasibility study is aimed at identifying whether pharmacists are able to conduct a diabetes drop in clinic and what kind of information they are requesting.

The drop-in clinic will be advertised via a direct mail-out to all patient registered with the local medical practice that are poorly-controlled for their diabetes. During the clinic, patients will need to complete the consent form and initial questionnaire before the consultation can begin. After the consultation, we would like patients to complete the feedback questionnaire and data to be collected from their medical notes regarding blood glucose and blood pressure results. A follow-up questionnaire will be sent to them three months later. You will be responsible for obtaining consent after an adequate opportunity to ask questions has been given, the pre-questionnaire and the feedback questionnaire and obtaining the data from the medical practice. The research team will be responsible for collecting this data from you and sending out the follow-up questionnaire three months later.

During the evaluation period, we will be available to provide additional locum support free of charge for the duration of each clinic.

As part of the service, you will need to complete the most recent CPPE training pack for type 2 diabetes. You will be paid £250 once you have completed this. You will then be paid an additional £10 per patient up to a maximum of 40 patients between the four participating pharmacies. This will be calculated at the end of the evaluation period.

At the end of the service we would like to collect your views about the service and this will involve a short interview conducted at a location and time convenient to you.

Once again, thank you for agreeing to participate in this study. If you have any further questions please do not hesitate to contact me.

Yours sincerely,

Michael Twigg



University of East Anglia

**Michael Twigg MRPharmS**

**School of Pharmacy**  
University of East Anglia  
Norwich NR4 7TJ

Email: [m.twigg@uea.ac.uk](mailto:m.twigg@uea.ac.uk)

Tel: 01603 591966

Practice address

[Date]

Dear [practice manager's name]

Re: Diabetes drop-in clinic

Thank you for agreeing to support my trial of a diabetes drop in clinic that is being run as part of my PhD. This feasibility study is aimed at identifying whether this service is worthwhile for patients and pharmacists.

During the clinic, patients will need to complete the consent form and initial questionnaire before the consultation can begin. They are then free to discuss anything they wish with the pharmacist. After the consultation, we would like patients to complete the feedback questionnaire and data to be collected from their medical notes regarding blood glucose and blood pressure results. A follow-up questionnaire will be given to them three months later. The questionnaires will only be available in English and will need to be answered in English.

As part of the service and to attract interest, we would like to mail patients who are poorly controlled with information about the clinic. I will provide you with a set of pre-filled stamped envelopes containing a letter and information leaflet. All you need to do is attach an address sticker for those patients identified and then post the letters on behalf of the research team. We hope to send these leaflets out twice during the study, the second as a reminder. We anticipate the number of patients involved in the mail out will be in the region of [number range calculated from QOF data for each practice] for your practice.

Once patient have attended the clinic we need to collect some basic data about them in order to evaluate the service. This data will be restricted to recent HbA<sub>1c</sub>, blood pressure and lipid results, number of medicines the patient is prescribed and the length of time since diagnosis. The pharmacist conducting the clinic will call the medical practice and request this data immediately after the consultation has been completed.

As a thank you for agreeing to participate and helping us evaluate the study, we will pay you £250 at the end of the evaluation period. We will also cover the mailing costs.

Once again, thank you for agreeing to participate in this study. If you have any further questions please do not hesitate to contact me.

Yours sincerely,

Michael Twigg

[Date]

Dear Sir/Madam,

**Re: Diabetes drop-in clinic at [insert name] pharmacy.**

As a patient with type 2 diabetes we would like to draw your attention to a new service that is being offered at [insert name] pharmacy as part of a PhD research project being conducted by the University of East Anglia. The pharmacist has been trained to answer any concerns you may have including:

- Type 2 diabetes and how it affects your life
- Why you need to take the medicines you have been prescribed
- Benefits and risks of taking medicines
- How your medicines work
- How to help you take your medicines
- Side effects of your medicines

You may find it useful to speak to the pharmacist about your condition or your medicines and they may be able to help if you are having problems. As part of the service the pharmacist will ask you to complete some questionnaires and will ask your permission to obtain some clinical data from the medical practice.

The clinics are only operating for a period of eight weeks and are being evaluated by the School of Pharmacy at the UEA. If you use the service, as part of the evaluation the research team will need to collect some information about you. This will help describe the patients who are using the service.

This service is completely free and there is no need to book an appointment. For full details of the service please read the enclosed information leaflet, it also details the times of the clinics.

If the pharmacist feels a change to your medicines would be beneficial then they will inform the practice and the doctor will decide what course of action to take. This service will not affect the care you receive from the doctors or nurses at this practice.

We encourage you to use the service, so that the research team can evaluate whether pharmacists have a role in the care of patients with type 2 diabetes. We do not consider this service to be a necessary part of your treatment, however, you may find it useful. Participation in the study is not a condition of use of the service.

Yours faithfully,

[Practice manager]

[Date]

Dear Sir/Madam,

**Re: Diabetes drop-in clinic at [insert name] pharmacy.**

If you have already attended this service, please ignore this letter. If you have not attended the service, please continue to read on.

As a patient with type 2 diabetes we would like to draw your attention to a new service that is being offered at [insert name] pharmacy as part of a PhD research project being conducted by the University of East Anglia. The pharmacist has been trained to answer any concerns you may have including:

- Type 2 diabetes and how it affects your life
- Why you need to take the medicines you have been prescribed
- Benefits and risks of taking medicines
- How your medicines work
- How to help you take your medicines
- Side effects of your medicines

You may find it useful to speak to the pharmacist about your condition or your medicines and they may be able to help if you are having problems. As part of the service the pharmacist will ask you to complete some questionnaires and will ask your permission to obtain some clinical data from the medical practice.

The clinics are only operating for a period of eight weeks and are being evaluated by the School of Pharmacy at the University of East Anglia. If you use the service, as part of the evaluation the research team will need to collect some information about you. This will help describe the patients who are using the service.

This service is completely free and there is no need to book an appointment. For full details of the service please read the enclosed information leaflet, it also details the times of the clinics.

If the pharmacist feels a change to your medicines would be beneficial then they will inform the practice and the doctor will decide what course of action to take. This service will not affect the care you receive from the doctors or nurses at this practice.

We encourage you to use the service, so that the research team can evaluate whether pharmacists have a role in the care of patients with type 2 diabetes. We do not consider this service to be a necessary part of your treatment, however, you may find it useful. Participation in the study is not a condition of use of the service.

Yours faithfully,

[Practice manager]



The Pharmacy Diabetes Drop-In clinic

## Do you have Type 2 diabetes?

[Insert name] pharmacy is offering a new service for patients with type 2 diabetes. This **FREE** drop in clinic will give you the chance to talk about your condition with the pharmacist and problems you may have in the consultation room without the need for an appointment.



- Having problems with taking your medicines?
- Are you having side effects with your medicines?
- Are you concerned about your blood glucose levels?
- Do you have questions about your diet and lifestyle?

Then come and have a conversation with the pharmacist, who may be able to help you tackle some of those problems you may have been wondering about

This service is a pilot service run in conjunction with the University of East Anglia and Numark Pharmacies

### The drop-in clinic

The drop-in clinic is there for patients with type 2 diabetes who may wish to talk about their condition, medicines and how it affects their life in a consultation room with a pharmacist.

The pharmacist may be able to help you with problems you may have been experiencing with your medication or lifestyle.

The consultation will last as long as you feel is necessary for you to get answers to your questions.

**See the back of this leaflet for clinic times in your local pharmacy**



### Evaluating the service

This is a new service being offered by your local pharmacy for a period of eight weeks **only**. The service has been set up as part of a PhD project at the School of Pharmacy at the University of East Anglia.

As this is a new service, we would like to see who is using it and what sort of problems the pharmacists are being asked about.

If you agree to take part in the evaluation, we will need to collect some information from you before and after you have spoken to the pharmacist. This will involve asking you some questions and obtaining some recent test results from your doctor's surgery.

**You only need to sign the consent form if you are taking part in the evaluation**

## No appointment needed

Just drop in and the pharmacist will be able to see you there and then

If you are happy with everything in this information sheet then please sign the consent form overleaf.

---

This section is for completion by the medical practice/pharmacy

Patient number:

Gender:

Male

Female

Age:

Postcode:

Most recent HbA<sub>1c</sub> result (% or mmol/mol):

Most recent BP result (mmHg):

Most recent TC result (mmol/L):

Number of medicines prescribed:

Years since diagnosis:

## A few Questions

This is the information we will be requesting from the medical practice.

# Free

This service is totally free for all patients with type 2 diabetes

## Questionnaires

Before the consultation, the pharmacist will ask you to complete a short questionnaire. This will help guide the consultation and provide details for the evaluation of the service. At the end of the consultation we will ask you to complete a short questionnaire about the service you received from the pharmacist.

Three months after your visit to the clinic the pharmacist will give you another questionnaire to complete. This is the same as the first one and should be sent back to the research team at UEA.

## Confidentiality

Your details will be kept confidential. The research team will have access to all your data but only once you have consented to them having it. The pharmacists are acting as researchers for this project and will also have access to all the data in the study.

## Withdrawing consent

If you wish to withdraw consent at any time please inform the pharmacist and no more details will be taken from you. If you lose the ability to take part during the study all data already collected will still be used for the analysis.

## What sort of details will the doctor's surgery be providing?

Your recent blood glucose, blood pressure, cholesterol results and the number of medicines on your medical record will be requested from your surgery. The research team need these to evaluate the service properly. The surgery will receive a copy of your consent form.

## Are there any disadvantages to attending the clinic?

We do not foresee any disadvantages to taking part in this service and it will not affect the care you currently receive from your GP and practice nurse.

## [INSERT NAME] PHARMACY

Address

Date 1

Date 5

Time 1

Time 5

Date 2

Date 6

Time 2

Time 6

Date 3

Date 7

Time 3

Time 7

Date 4

Date 8

Time 4

Time 8

**The service will run from [date] to [date]**

Remember no need to book an appointment, just call in and see what the pharmacist can do for you.

At busy times, a small wait may be necessary

If you cannot make any of the times above, feel free to call in and see the pharmacist at any time and he/she may be able to see you straight away. Participation in the research study is not a condition of use of the service.

The pharmacist is bound by their ethics to inform the relevant authorities e.g. GP or primary care trust of any relevant safety information such as drug interactions or improper care.

# Clinic dates

## Consent Form

So that we can evaluate the service properly and to indicate you have read the information sheet please initial the boxes below and complete the information at the bottom.

I have read and understood the information leaflet and state that I am not participating in any other research study at this time.	
<b>I agree to the research team at the UEA, the pharmacist and medical practice receiving a copy of the consent form and for the pharmacist to contact the medical practice to obtain data for the study.</b>	
I understand that my participation is voluntary and that I am free to withdraw at any time.	
<b>I consent to the researcher using anonymised quotes from the questionnaire in the report produced at the end of the study.</b>	
<b>I have had an opportunity to ask questions of the pharmacist about this study before I consent to participate.</b>	
<b>I agree to the disclosure, to the relevant authorities, of relevant safety information such as drug interactions or improper care.</b>	
I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from the primary care trust or from regulatory authorities, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.	

\_\_\_\_\_  
Name

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Date of birth

Address \_\_\_\_\_  
\_\_\_\_\_

**Thank you for helping us to evaluate this service**

If you have any questions please ask the pharmacist or call Michael Twigg (PhD student) at the UEA on 01603 591996. If you have a complaint, please call Prof David Wright (PhD supervisor) on 01603 592042.

Patient information, consent and data collection v3; Nov 2011 FINAL

# The Pharmacy Diabetes Drop-in Clinic Questionnaire

## Guidance on completing this questionnaire

- This questionnaire is designed to take less than 5 minutes to complete and is completely anonymous
- Please tick one box **only** in response to each question unless requested to do so otherwise
- Please complete **all** sections in the questionnaire to the best of your knowledge
- If you have any questions or don't understand a question please ask the pharmacy team



Patient Number :

Date:

## Section 1: Beliefs about your medicines

The following set of questions relate to your personal views about your medicines.

Please tick ONE box for each question	Strongly agree	Agree	Uncertain	Disagree	Strongly disagree
My health, at present, depends on my medicines	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Having to take medicines worries me	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
My life would be impossible without these medicines	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I sometimes worry about the long term side effects of my medicines	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Without my medicines I would be very ill	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
My medicines are a mystery to me	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
My health in the future will depend on my medicines	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
My medicines disrupt my life	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
My medicines protect me from becoming worse	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I sometimes worry about becoming too dependent on my medicines	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Adapted from the Beliefs about medicines questionnaire ©RHome University of Brighton

## Section 2: How often you remember to take your medicines

The next set of questions relate to how regularly you take your medication

Tick one box for each of the four questions below.

	Yes	No
Do you ever forget to use the medication?	<input type="checkbox"/>	<input type="checkbox"/>
Are you careless at times about using the medication?	<input type="checkbox"/>	<input type="checkbox"/>
When you feel better, do you sometimes stop using the medication?	<input type="checkbox"/>	<input type="checkbox"/>
Sometimes if you feel worse when you use the medication, do you stop using it?	<input type="checkbox"/>	<input type="checkbox"/>

Self-reported Medication-taking Scale. Morisky, D., Green, L., Levine, D. Concurrent and Predictive Validity of a Self-reported Measure of Medication Adherence. Medical Care, January 1986, Vol 24, No 1, 67-74



### Section 3: Information received about medicines

How would you rate the information you have received about the following aspects of your medicine(s)?

Tick one box for each type of information. If you use more than one medicine, please give your views about the information as a whole.

Type of Information	Amount of Information Received				
	Too much	About right	Too little	None	None needed
What your medicine is called.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
What your medicine is for.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
What it does.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
How it works.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
How long it will take to act.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
How you can tell if it is working.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
How long you will need to be on the medicine.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
How to use the medicine.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
How to get a further supply.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Whether the medicine has any unwanted effects (side-effects).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
What are the risks of you getting side-effects.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
What you should do if you experience unwanted effects (side-effects).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Whether you can drink alcohol whilst taking this medicine	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Whether the medicine will interfere with other medicines you are prescribed.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Whether the medicine will make you feel drowsy.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Whether the medication will affect you sex life	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
What you should do if you forget to take a dose	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Satisfaction with Information about Medicines Scale (SIMS). ©RHome University of Brighton

#### Section 4: How you use the community pharmacy

Not counting today, in the past three months how many times have you visited the community pharmacy?

Not counting today, in the past three months how many times have you spoken to the pharmacist?

If you have spoken to the pharmacist in the past three months what have you spoken about?

- Your condition e.g. prognosis, the effect diabetes has on the body
- Your medication e.g. side effects, formulation, alternatives
- Over-the-counter medication
- Lifestyle advice
- Dietary advice
- Diagnosis and advice regarding other medical conditions
- Diagnosis and advice regarding minor ailments
- Prescriptions and supply of medicines e.g. prescription collection service

#### Section 5: Any other comments

If you have any other comments about your condition, the medicines you are prescribed for it or the pharmacy and how you use it please write in this box.

**Thank you for completing this questionnaire**

# The Pharmacy Diabetes Drop-in Clinic Feedback Questionnaire

## Guidance on completing this questionnaire

- This questionnaire is designed to take less than 5 minutes to complete and is completely anonymous
- Please circle one answer **only** in response to each question unless requested to do so otherwise
- The information you give will be used to improve the service for next time
- If you have any questions or don't understand a question please ask the pharmacy team.



Patient Number :

Date:

## Section 1: The diabetes drop-in clinic

1. What was your general impression of the service you received today?  
Very good  Good  Average  Poor  Very poor
2. How much do you think attending the drop in clinic will help you manage your diabetes?  
A lot  Some help  A small amount  No help
3. Would this service make you more or less likely to consult a pharmacist in future about other conditions?  
More likely  About the same  Less likely  Not sure
4. What did you think about the length of time for the consultation?  
Too long  About right  Too short
- |   | Yes                      | No                       | Not sure                 |
|---|--------------------------|--------------------------|--------------------------|
| 5. Did you find it useful to speak to the pharmacist about your condition?  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 6. Were you satisfied with the information you received during the consultation?  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 7. Did you feel the information given was at a level that you could understand?   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 8. Do you think this service, or a service like it, could be useful for other patients with diabetes or other conditions? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 9. Would you use this service again?  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 10. Would you recommend this service to other patients with type 2 diabetes?  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

PTO

## Section 2: The research project

11. What did you think of the invitation and leaflet telling you about the diabetes clinic?
- Very good       Good       Average       Poor       Very poor
12. Did you think that a direct leaflet was the best way to inform you of the clinic?
- Yes       No       Not sure
13. In terms of length, what did you think of the first questionnaire?
- Too long       About right       Too short
14. In terms of content, do you think the first questionnaire asked the right questions for you?
- Yes       No       Not sure
15. Do you think the pharmacy was the right place for this type of clinic?
- Yes       No       Not sure
16. Do you think the pharmacist is the right person to conduct this type of clinic?
- Yes       No       Not sure

## Section 3: Any other comments

17. What did you think of the pharmacist conducting this type of service?

18. What did you think of the way the pharmacist answered your questions and gave you information?

19. Are there any areas you wanted to discuss but felt you couldn't?

If yes, were there any particular reasons why you felt you couldn't discuss those with the pharmacist?

20. Finally, what were your impressions of the consultation room and the pharmacy environment?

21. Please use this box for any extra comments you may have about the service or the research.

For some of the answers you have given the research team may need to contact you to clarify what you mean so that we can make further changes to the study for next time.

If you are happy for the research team to do this, please complete your name and telephone number below. By completing these details you are consenting to the lead researcher contacting you by telephone. You are under no obligation to complete this section if you do not wish to.

Name: \_\_\_\_\_

Telephone number: \_\_\_\_\_

**Thank you for taking the time to complete this questionnaire**

### **Telephone script for clarification of feedback questionnaires**

Michael: Hello, my name is Michael Twigg, I am the lead researcher for the diabetes drop-in clinic study that is being evaluated by the School of Pharmacy at the UEA... Can I just confirm your address please? Are you still happy to answer some questions about the responses you gave on the feedback questionnaire? [If no, politely say thank you and that you will take no more of their time and hang up; if yes, continue]

Examples of questions that may be used:

- Could you please explain more about the pharmacist conducting this type of service?
- Could you please explain more about the way the pharmacist answered your questions?
- Could you please explain more about not being able to discuss certain things with the pharmacist? Are there any reasons for this?
- Finally, could you please explain more about the consultation room and the pharmacy environment?

Michael: Thank you for those answers that has really helped us to evaluate the service properly. Is there anything else you would like to ask about the study before I hang up? Ok, Goodbye.

**Pharmacy data collection form for the diabetes drop-in clinic**

Pharmacy number (entered by pharmacist)		
Patient number (entered by pharmacist)		
How long did you spend with the patient		Minutes
Information requested at the drop-in clinic	<b>Specifically requested by patient</b>	<b>Discussed</b>
Diabetes – the disease	<input type="checkbox"/>	<input type="checkbox"/>
Diabetes – prognosis and complications	<input type="checkbox"/>	<input type="checkbox"/>
Diabetes - effect on lifestyle	<input type="checkbox"/>	<input type="checkbox"/>
Lifestyle – diet and nutrition	<input type="checkbox"/>	<input type="checkbox"/>
Lifestyle – smoking	<input type="checkbox"/>	<input type="checkbox"/>
Lifestyle – physical activity	<input type="checkbox"/>	<input type="checkbox"/>
Lifestyle – alcohol	<input type="checkbox"/>	<input type="checkbox"/>
Lifestyle – sexual health	<input type="checkbox"/>	<input type="checkbox"/>
Lifestyle – weight management	<input type="checkbox"/>	<input type="checkbox"/>
Medicines – indications	<input type="checkbox"/>	<input type="checkbox"/>
Medicines – side effects	<input type="checkbox"/>	<input type="checkbox"/>
Medicines – formulation	<input type="checkbox"/>	<input type="checkbox"/>
Medicines – alternatives	<input type="checkbox"/>	<input type="checkbox"/>
Medicines – mode of action	<input type="checkbox"/>	<input type="checkbox"/>
Medicines – dosage instructions	<input type="checkbox"/>	<input type="checkbox"/>

Please list other information **requested by the patient** in the box below:



Please list other information **discussed during the consultation** in the box below:

Please list any alterations for this patient the pharmacy will make as a result of this consultation:

Please list any amendments requested for this patient from the medical practice:

**Please keep this safe until the researcher collects it at the end of the evaluation period.**

The diabetes drop-in clinic: a community pharmacy clinic for poorly controlled type 2 diabetes patients

**Invitation to participate in semi-structured interview**

Following your participation in the diabetes drop-in clinic, we would like to know your thoughts on the service. This will involve answering some questions in an interview format where you can discuss any issues with the researcher from the UEA. The interview will happen at a mutually convenient time and place.

Please take the time to read the following information sheet which will explain more about the interview, before you sign the consent form.

**Why have I been chosen?**

You have been chosen because you provided diabetes drop-in clinic in your pharmacy.

**What happens if I agree to take part in the interview?**

A researcher will visit you at a mutually convenient time and location to record your thoughts about the service. The interview will be audio-recorded by the researcher and should last no longer than one hour. The researcher will ask you questions relating to the study including the following:

- **The service**
  - What was your general impression of the service?
    - Did you have enough time to prepare for the service?
    - What did you think of the delivery and content of the consultations?
  - How do you think the service benefitted:
    - Patients?
    - Relationship with the medical practice?
    - You personally?
  - What impact do you think the pharmacy environment has on this kind of service?
  - How has your practice changed as a result of providing the service?

- **The research**

- What are your thoughts about the research design?
  - What was your impression of the targeting of patients for this study?
  - What did you think of the conduct of the research and the research team?
  - What did you think of the paperwork for the study?
  - What did you think about liaising with the medical practice?
  - Do you think the data collected for the study was appropriate?

**What disadvantages are there?**

We do not anticipate any disadvantages to you participating in this interview, apart from the time taken to complete the discussion.

**Who will have access to the information given by me?**

The interview will be tape-recorded and listened to by the research team at the UEA. This information will be stored securely and only the research team will have access to it. The information will be used to improve the design and structure of any further services developed.

**Confidentiality- will anybody be able to gain information about me from this focus group?**

The research team at UEA will maintain confidentiality when referring to the findings of the interview. Any data that can identify you will **not** be published and nobody outside the research team will be able to access any information you give us.

**It is alright not to participate and you can withdraw from the interview at any time without reason.**

*Thank You*

If you have any further questions about this project please do not hesitate to contact the UEA Medicines Management Team on 01603 593391.



**■ ■ ■** *Appendix 16*



**National Research Ethics Service**  
**NRES Committee East of England - Essex**

East of England Rec Office 1  
Victoria House  
Capital Park  
Fulbourn  
Cambridge  
CB21 5XB

Telephone: 01223 597893  
Facsimile: 01223 597645

24 November 2011

Mr Michael Twigg  
School of Pharmacy  
University of East Anglia  
Norwich  
NR4 7TJ

Dear Mr Twigg

**Study title:** The diabetes drop-in clinic: A community pharmacy clinic for poorly controlled type 2 diabetes patients  
**REC reference:** 11/EE/0494

Thank you for your email responding to the Proportionate Review Sub-Committee's request for changes to the documentation for the above study.

The revised documentation has been reviewed and approved by the sub-committee.

**Confirmation of ethical opinion**

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised.

**Ethical review of research sites**

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

**Conditions of the favourable opinion**

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

*Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.*

*Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at <http://www.rdforum.nhs.uk>.*

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations.

**It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).**

**You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. Confirmation should also be provided to host organisations together with relevant documentation.**

#### Approved documents

The documents reviewed and approved by the Committee are:

Document	Version	Date
Covering Letter		07 November 2011
Evidence of insurance or indemnity		28 June 2011
Investigator CV		
Letter from Sponsor		04 November 2011
Other: CV Prof D J Wright		
Other: Telephone Script	1.0	01 October 2011
Other: Pharmacy Data Collection Form	1.0	01 October 2011
Other: Patient Information, Consent and Data Collection	2.0	18 November 2011
Other: Letter to Practices	2.0	18 November 2011
Other: Letter to Patients	2.0	18 November 2011
Other: Letter to patients (second mailing)	2.0	30 October 2011
Other: Letter to Pharmacists	2.0	18 November 2011
Participant Consent Form: Diabetes Pharmacist Consent Form	1.0	01 October 2011
Participant Information Sheet: Diabetes Pharmacist Interview PIS	1.0	01 October 2011
Protocol	2.0	18 November 2011
Questionnaire: Feedback Questionnaire	1.0	01 November 2011
Questionnaire: Pharmacy Diabetes drop-in Clinic	1.0	01 November 2011
REC application	3.4	07 November 2011
Response to Request for Further Information		18 November 2011

#### Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

#### After ethical review

##### Reporting requirements

This Research Ethics Committee is an advisory committee to East of England Strategic Health Authority  
*The National Research Ethics Service (NRES) represents the NRES Directorate within the National Patient Safety Agency and Research Ethics Committees in England*

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

#### Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

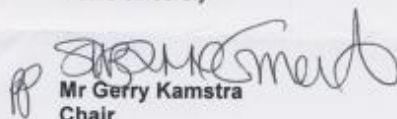
Further information is available at National Research Ethics Service website > After Review

**11/EE/0494**

**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project

Yours sincerely

  
**Mr Gerry Kamstra**  
**Chair**

Email: [suzanne.emerton@eoe.nhs.uk](mailto:suzanne.emerton@eoe.nhs.uk)

Enclosures: "After ethical review – guidance for researchers"

Copy to: Mrs Sue Steel  
Research and Enterprise Services  
UEA  
Norwich  
NR4 7TJ

Prof David Wright  
School of Pharmacy  
University of East Anglia  
Norwich  
NR4 7TJ





## Health Research Authority

### NRES Committee East of England - Essex

East of England Rec Office 1  
Victoria House  
Capital Park  
Fulbourn  
Cambridge  
CB21 5XB

Tel: 01223 597693  
Fax: 01223 597645

03 January 2012

Mr Michael Twigg  
School of Pharmacy  
University of East Anglia  
Norwich  
NR4 7TJ

Dear Mr Twigg

**Study title:** The diabetes drop-in clinic: A community pharmacy clinic for poorly controlled type 2 diabetes patients  
**REC reference:** 11/EE/0494  
**Amendment number:** NOSA 1  
**Amendment date:** 30 November 2011

The above amendment was reviewed by the Sub-Committee in correspondence.

#### Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

#### Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Pharmacist information sheet	2.0	30 November 2011
Letter to patients (second mailing)	3.0	30 November 2011
Letter to patients	3.0	30 November 2011
Patient Information, consent and data collection	3.0	30 November 2011
Notice of Substantial Amendment (non-CTIMPs)	NOSA 1	30 November 2011
Covering Letter		01 December 2011

#### Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

#### R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

**Statement of compliance**

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

11/EE/0494:

Please quote this number on all correspondence

Yours sincerely

  
pp Dr Alan Lamont  
Chair

E-mail: [suzanne.emerton@eoe.nhs.uk](mailto:suzanne.emerton@eoe.nhs.uk)

Enclosures: List of names and professions of members who took part in the review

Copy to: Mrs Sue Steel  
Research and Enterprise Services  
UEA  
Norwich  
NR4 7TJ

Prof David Wright  
School of Pharmacy  
University of East Anglia  
Norwich  
NR4 7TJ

**■ ■ ■** *Appendix 17*



Ref: 2011IC01

**Michael Twigg**  
School of Pharmacy  
University of East Anglia  
Norwich  
NR4 7TJ

**Norfolk and Waveney**

**Research & Development**  
NHS Norfolk  
Lakeside 400  
Old Chapel Way  
Broadland Business Park  
Thorpe St Andrew  
Norwich  
NR7 0WG

Tel: 01603 257283

Fax: 01603 257292

E-mail: [paul.mills@norfolk.nhs.uk](mailto:paul.mills@norfolk.nhs.uk)  
[www.norfolk.nhs.uk/research](http://www.norfolk.nhs.uk/research)

2 December 2011

Dear Michael,

**Re: 2011IC01. The diabetes drop-in clinic: A community pharmacy clinic for poorly controlled type 2 diabetes patients**

**REC Number:** 11/EE/0494

**Chief Investigator:** Michael Twigg, University of East Anglia

**Sponsor:** University of East Anglia

Further to your submission of the above project to the R&D office at NHS Norfolk your project has now been reviewed and all the mandatory research governance checks have been satisfied. I am therefore pleased to inform you on behalf of **NHS Norfolk** that NHS permission (R&D approval) was granted on **2<sup>nd</sup> December 2011** for your study to take place at the following sites:

- Pharmacies and GP Practices, NHS Norfolk

Please note that NHS Permission is granted on the basis of the information supplied in the application form, protocol and supporting documentation, if anything subsequently comes to light that would cast doubts upon, or alter in any material way, any information contained in the original application, or a later amendment application there may be implications for continued NHS Permission.

Please note the following conditions of approval.

- Thank you for providing the R&D office with a copy of Substantial Amendment 1. Please supply a copy of the Letter of Favourable Opinion for this amendment to the NHS Norfolk R&D office when received.
- Please provide the NHS Norfolk R&D Office with details of all participating GP practices within NHS Norfolk on an ongoing basis

Please note it is your responsibility to ensure that these conditions are disseminated to all parties involved in this project.

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NHS Norfolk and Waveney represents Norfolk Primary Care Trust and Great Yarmouth and Waveney Primary Care Trust

Chair: Sheila Childerhouse  
Chief Executive: Andrew Morgan



[www.norfolk.nhs.uk](http://www.norfolk.nhs.uk)  
[www.gywpct.nhs.uk](http://www.gywpct.nhs.uk)

NHS Norfolk hosts the Research Management and Governance Services for NHS Norfolk, NHS Suffolk, NHS Great Yarmouth & Waveney and Norfolk Community Health & Care NHS Trust

You may now begin your study at the above sites.

Permission is granted on the understanding that the study is conducted in accordance with the Research Governance Framework. I have enclosed two copies of the Standard Terms and Conditions of Approval. Please sign and return one copy to the R&D office at the above address. Failure to return the standard terms and conditions may result in NHS permission being revoked.

**Please note, under the agreed standard terms and conditions you must inform the R&D Office at NHS Norfolk of any proposed changes to this study, whether minor or substantial, and to keep the Committee updated on progress. Please note also, if you wish to extend approval to any sites other than those listed above you must apply for this through the relevant R&D office.**

If you have any queries regarding this or any other project please contact Paul Mills, R&D Officer, at the above address. Please note, the reference number for this study is **2011IC01** and this should be quoted on all correspondence.

The following documents were reviewed:

Letter of favourable Opinion from NRES Committee East of England – Essex

- Protocol, Version 2, November 2011
- Letter to Practices, Version 2, November 2011
- Letter to Pharmacists, Version 2, November 2011
- Participant Consent Form – Pharmacist Interview, Version 1, October 2011
- Questionnaire – Drop In Clinic, Version 1, November 2011
- Questionnaire – Feedback, Version 1, November 2011
- Pharmacy Data Collection Form, Version 1, October 2011
- Telephone Script, Version 1, October 2011
- Response to REC Request for Further Information, 18<sup>th</sup> November 2011
- Investigator CV – Michael Twigg
- Investigator CV – Prof. David Wright
- Letter from Sponsor, 4<sup>th</sup> November 2011
- Evidence of Insurance/Indemnity, 28<sup>th</sup> June 2011

Substantial Amendment 1

- Notice of Substantial Amendment 1, 1<sup>st</sup> December 2011
- Covering Email, 1<sup>st</sup> December 2011
- Patient Information, Consent and Data Collection, Version 3, November 2011
- Letter to Patients, Version 3, November 2011
- Letter to Patients (Second Mailing), Version 3, November 2011
- Participant Information Sheet – Pharmacist Interview, Version 2, November 2011

Other Documents Reviewed

- Fully Signed R&D Form, Lock Code 93719/264887/14/987
- Signed SSI Form, Lock Code 93719/263682/6/976/133221/227532

Yours sincerely



Dr Jenny Harries  
Joint Director of Public Health  
NHS Norfolk & Norfolk County Council

cc: Prof. David Wright, University of East Anglia, Supervisor  
Sue Steel, University of East Anglia, Sponsor Representative  
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