

**ESTABLISHING AN EVIDENCE BASE FOR  
MEDICINES USE REVIEW:  
THE DEVELOPMENT AND EVALUATION OF  
METHODOLOGIES TO ASSESS THE IMPACT OF  
MEDICINES USE REVIEW IN PRACTICE**

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**“The man who has no imagination has no wings”**

**Muhammad Ali**

**This thesis is dedicated to my loving parents**

**Zahida Mohammad & Niaz Mohammad**

**My daughter**

**Nailah Mohammad**

**and to my Brothers:**

**Sajid Mohammad; Asad Mohammad and Amar Mohammad**

**You are my greatest teachers.**

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## **Abstract**

The aim of this thesis was to develop and evaluate methodologies to assess the impact of medicines use review (MUR), a new service introduced under the new Community Pharmacy Contract in April 2005.

A cohort study utilised a prospective active group of 120 patients recruited from 7 pharmacies across Kent with a retrospective control cohort matched for age, sex, GP practice and number of medicines. The primary outcome measure was a reduction in drug therapy problems (DTPs) with a 64% resolution observed in the active group compared to only 3% in the control group over the six month period of the study. The effect size was significant ( $p < 0.0001$ ) with an absolute risk reduction of 61% and a number needed to treat of 1.6. This means for every 16 DTPs receiving an intervention, 10 DTPs would be resolved over and above standard care at 6 months. There were no significant differences in secondary outcome measures (number of repeat medicines and use of health services) between the two groups.

A focus group of 6 patients not involved in the main study confirmed that MUR was well received by patients with overarching themes of awareness and trust. In addition a semi-structured questionnaire completed by 72 study participants confirmed that MUR was well received by patients.

Two further focus groups of 6 pharmacists (providers and non-providers of MUR) were also conducted which raised contrasting views regarding the New Pharmacy Contract but showed an overwhelming consensus between both groups that MUR was a beneficial service.

On the basis of these results, one can conclude that the hypothesis 'MUR will reduce drug therapy problems and will be well accepted by both patients and pharmacists' can be accepted. These findings make an original contribution to the literature and represent a significant contribution to the evidence base in support of MUR services.

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## **Chapter 1**

### **Introduction and Literature Review**

#### **1.1 General Introduction**

Medicines use review (MUR) was introduced under the new National Health Service (NHS) Community Pharmacy Contract in April 2005 (Department of Health, 2005). Accredited pharmacists working in approved premises may currently undertake 400 MURs per annum at £27 per review as of October 2007 which equates to £10,800 per contractor (Pharmaceutical Services Negotiating Committee, 2007a). This represents a significant annual income for this new patient centred clinical service. This chapter seeks to review the existing evidence base for patient centred clinical services, and to generate a hypothesis to test this new MUR service. Addressing this hypothesis will make a unique contribution to the literature and may help to establish an evidence base for MUR services.

#### **1.2 Recent Developments in Community Pharmacy**

In the UK before the formation of the National Health Service (NHS) in 1948, pharmacists used to manufacture and sell their own medicines and dispense private prescriptions (65 million prescriptions were dispensed in 1937). For people who could not afford to see a doctor, their local 'chemist' (pharmacist) was often the first port of call for advice on healthcare and provision of medicines. 'Chemists' were often referred to as the 'physicians of the poor'. The advice given to their patients was both informal and unpaid unless a related sale was made. With the introduction of the NHS in 1948, the pharmacists' workload greatly increased with 300 million prescriptions dispensed annually by 1960 rising to 659 million in 2000 (Nuffield 1986, Health and social information centre, 2005, Health statistics analysis unit,



2007, Information Services Division Scotland, 2007). This had its good and bad aspects. Good in the sense that pharmacists were happy with the growth of business turnover. Bad in the context of the relocation of their position from the medicines counter to an expanding dispensary as initially prescriptions needed to be manufactured by the pharmacist for individual patients. This resulted in the pharmacist spending most of their time in the 'back shop' and less time in public view.

During the 1950s and 60s the pharmaceutical industry started to produce bulk quantities of medicines as tablets and capsules and the need for the pharmacist to manufacture prescriptions to individual specifications diminished. Volumes of dispensing continued to grow throughout the seventies and eighties with repackaging of bulk medicines to individual prescription quantities becoming a pre-occupation of community pharmacy. This move of the community pharmacist from the medicine counter to the 'back shop' prompted criticism which questioned their future role.

**(Box 1.1)**

**Box 1.1: Statement made by Dr Gerard Vaughan at the British Pharmaceutical Conference in 1981.**

*“One knew there was a future for hospital pharmacists, one knew there was a future for industrial pharmacists, but one was not sure that one knew the future for the general practice [community] pharmacist”.*

This caused uproar in the community pharmacy sector. It fuelled ambitions to demonstrate that community pharmacists were an indispensable part of primary health care. An inquiry was established in 1983 by the Nuffield Foundation to

consider the future contribution of all the sectors of pharmacy. The committee's report, 'Pharmacy: A report to the Nuffield Foundation' was published in 1986. In general the tone of the report was very positive. (**Box 1.2**)

**Box 1.2: Statements from the Nuffield report 1986**

*'We believe that the pharmacy profession has a distinctive and indispensable contribution to make to health care that is capable of further development  
.....In our judgement, dispensing will continue to be an important part of the work done within community pharmacies, but both the extent and the nature of the pharmacist's active involvement in it will continue to change. The community pharmacist's future professional role should be seen in terms of greater collaboration with other health professionals, particularly GPs; and greater involvement with members of the public.'*

This report made 26 recommendations relating to community pharmacy. However, progress on these recommendations was slow such that six years after publication of the Nuffield report many of these recommendations reappeared in the joint report, 'Pharmaceutical Care: The Future For Community Pharmacy' (Department of health and Royal Pharmaceutical Society of Great Britain, 1992).

In terms of the original Nuffield recommendations, to date only six have not yet been introduced. Four of these relate to discharge of responsibility and accountability linked to the Royal Pharmaceutical Society of Great Britain's (RPSGB) 'interpretation' of the legal framework in relation to control and supervision. The final two relate to the number of and size of pharmacies (less in number but larger in

size) and, equivalence of dispensing services in rural settings. Such issues, particularly, 'control and supervision', are topics being widely debated at the present time as the RPSGB is undergoing restructuring to separate its regulatory and membership functions. **Box 1.3** highlights nine recommendations from Nuffield which feature in the new April 2005 Community Pharmacy Contract.

**Box 1.3: Recommendations made in 'Pharmacy: A report to the Nuffield Foundation' in 1986 which have been implemented by the new NHS Community Pharmacy Contract, April 2005**

**Number and recommendation:**

- 2 – Greater collaboration between health professionals - **MUR**
- 3 – Community pharmacist collaboration with GPs to reduce prescribing costs - **MUR**
- 4 – Advice on taking of medicines – **MUR**
- 9 – Change of remuneration structure - **MUR**
- 12 – Consultation areas - **MUR**
- 13 – Wider range of NHS services - **MUR**
- 15 – Information technology
- 18 – Pharmacists to decide which NHS services to offer
- 24 – Separate payments for other professional activities - **MUR**

Whilst the Nuffield enquiry was triggered by the adverse comments of the minister the resulting report was widely supported by the pharmacy profession but lacked an implementation plan. One may propose that the implementation plan came later in the form of the joint report on 'Pharmaceutical Care', which was produced by a working group comprised of representatives of the Department of Health (DOH) and the

RPSGB. Over the next decade both the DOH and the RPSGB worked together in the implementation phase. Of the 30 recommendations made in 1992, 16 were implemented by the end of 2004 with, a further 13 introduced as part of the new Community Pharmacy Contract in April 2005. Of these 13, 5 relate to the Medicines Use Review service (**Box 1.4**). Only one of the 30 recommendations (relating to emergency supply on the NHS) remains to be implemented to date.

**Box 1.4: Recommendations made in ‘Pharmaceutical Care: The Future For Community Pharmacy’ which have been implemented by the new NHS Community Pharmacy Contract, April 2005**

**Number and recommendation:**

- 1 – Repeat Dispensing
- 3 – Pharmacy referral forms – **MUR**
- 4 – Pharmaceutical consultations – **MUR**
- 8 – Patient Group Directions
- 9 – Compliance aids
- 11 – Therapeutic drug monitoring
- 13 – Disposal of medicines
- 14 – Accreditation by NHS for pharmacy premises – **MUR**
- 16 – Domiciliary services – **MUR**
- 17 – Domiciliary medicines management
- 23 – Diagnostic and screening services
- 27 – Sign posting
- 28 – Additional accreditation training - **MUR**

### **The new Community Pharmacy Contract, April 2005**

In April 2005 the national pharmacy contract changed across England and Wales. The contract now consists of three levels of service provision: Essential, Advanced and Enhanced services. 'Essential' and 'Advanced' are nationally funded, with 'Enhanced' consisting of locally commissioned services, which may vary according to each primary care trust depending on their needs and priorities set for their local population.

The 'Essential' tier of the contract consists of eight services: dispensing of medicines; repeat dispensing; promotion of healthy lifestyles; signposting; support of self care; disposal of unwanted medicines; support for disabilities and clinical governance.

The 'Advanced' tier of the contract consists of only one service: Medicines Use Review (MUR). To provide this service accreditation is required of both the pharmacist and their premises. MUR is an advanced service which has been commissioned nationally and represents the biggest change in the community pharmacy sector in the last 50 years. The aims of the MUR service are detailed in **Box 1.5** (Pharmaceutical Services Negotiating Committee, 2005a).

**Box 1.5: Aims of the MUR service**

To improve patient knowledge, concordance and use of medicines by:

- establishing the patient's actual use, understanding and experience of taking their medicines;
- identifying, discussing and resolving poor or ineffective use of their medicines;
- identifying side effects and drug interactions that may affect patient compliance;
- improving the clinical and cost effectiveness of prescribed medicines and reducing medicine wastage.

'Enhanced' services currently include: medicines management; minor ailments scheme; needle and syringe exchange; supervision of drug misusers; care homes services; rota-out of hours; smoking cessation and palliative care. There are also a number of pilots of future services such as weight management and Chlamydia screening.

Many of these 'Essential', 'Advanced' and 'Enhanced' services can be linked to specific recommendations of the report, 'Pharmaceutical Care: The Future For Pharmacy', as noted in **Box 1.6**.

**Box 1.6: Pharmaceutical care report recommendations linked to Essential, Advanced and Enhanced services**

**Essential Services**

- Recommendation 1 – Repeat Dispensing
- Recommendation 13 – Disposal of unwanted medicines
- Recommendation 27 - Signposting

**Advanced Services**

- Recommendation 3 – Referral forms
- Recommendation 4 – Pharmaceutical consultations
- Recommendation 14 – Accreditation by NHS for premises
- Recommendation 16 – Domiciliary services
- Recommendation 28 – Additional training

**Enhanced Services**

- Recommendation 8 – Patient Group Directions
- Recommendation 9 – Compliance aids
- Recommendation 11 – Therapeutic drug monitoring
- Recommendation 17 – Domiciliary medicines management scheme
- Recommendation 23 – Diagnostic and screening services

### 1.3 Pharmaceutical Care

The term, 'pharmaceutical care' was first introduced in 1975 by Mikeal et al (Box 1.7). In this definition it was viewed as a subset of medical care and not just provided by one health professional, but all taking responsibility for the patient's care. The conceptual model of medical care proposed by Donabedian consisting of structure, process and outcome was also adopted by Mikeal who proposed that the outcome of pharmaceutical care was to supply the right drug, at the right strength, by the correct route, to the right patient, at the right time (Mikeal et al., 1975).

#### Box 1.7: Original definition of pharmaceutical care (Mikeal et al., 1975)

*'The provision of any personal health service involving decision whether to use, the use and the evaluation of the use of drugs, including the range of services from prevention, diagnosis and treatment, to rehabilitation provided by physicians, dentists, nurses, pharmacists and other health personnel. Pharmaceutical care includes the complex personal relationships and organized arrangements through which these health services of a personal nature are made available to the population'*

Despite this early definition it was to take another twenty years for the Hepler and Strand definition to emerge, arguably the most recognised definition both nationally and internationally (Box 1.8). They recognised that pharmacists were caught up in their supply function and were not patient focused. Pharmacists needed to realise their worth. They stated that pharmaceutical practice had to restore what had been missing for years, which was a clear emphasis on the patient's welfare (Hepler and Strand, 1990).



**Box 1.8: Recognised pharmaceutical care definition (Hepler and Strand, 1990)**

*“The responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient’s quality of life”*

Hepler and Strand (1990) proposed that pharmacists wanted to move forward into the future and fulfil their responsibilities as health care professionals, but just lacked the opportunities to do so. The main barrier to this transition was the focus on supply of medicines and they suggested that the attention should not be made to supply but to that of preventable drug-related morbidity and mortality.

Hepler and Strand (1990) clearly highlighted that costs and impact on health services due to drug-related morbidity and mortality was a large problem which required action. Their definition of pharmaceutical care was clearly linked to specific patient outcomes. These were seen as cure of disease, elimination and or reduction of the patients symptoms, to stop or slow the disease process and to prevent a disease or symptoms.

Hepler and Strand (1990) described the pharmaceutical care process as encompassing all health professionals working together towards a greater patient outcome. This involved designing, implementing and monitoring a therapeutic plan. This was summarised as three major functions: identifying actual drug related problems; resolving actual drug related problems and preventing potential drug related problems. The most important factor in the whole process was that the pharmacist had to accept the responsibility for the patient if they truly wished to move forward.

Strand in parallel to her philosophical work with Hepler, was also working with Cipolle and colleagues on drug-related problems. She proposed that drug-related morbidity was preceded by drug-related problems and identified eight categories of these problems as can be seen in **Box 1.9**.

**Box 1.9: Categories of drug related problems (Strand et al., 1990)**

1. Needs pharmacotherapy but not receiving
2. Taking or receiving the wrong drug
3. Taking or receiving too little of correct drug
4. Taking or receiving too much of correct drug
5. Adverse drug reaction
6. Drug-drug or drug-food interaction
7. Not taking or receiving the drug prescribed
8. Taking or receiving a drug for which there is no valid medical indication

Strand and colleagues (Strand et al., 1992) outlined a nine step process to providing pharmaceutical care (**Box 1.10**).

**Box 1.10: Pharmaceutical care process (Strand et al., 1992)**

Step 1: Establish the pharmacist-patient relationship: Contact the patient and make commitment.

Step 2: Collect, synthesize, and interpret relevant information: Determine necessary patient, drug, and disease data – interpret as a pharmacist with the patient.

Step 3: List and rank the patient’s drug-related problems: Define and prioritize all actual and potential drug-related problems.

Step 4: Establish a desired pharmacotherapeutic outcome for each drug-related problem: For each problem needing resolution or prevention, determine with the patient the desired outcome – quantitative and measurable.

Step 5: Determine feasible pharmacotherapeutic alternatives: List those therapeutic modalities that could achieve the desired outcome in this patient.

Step 6: Choose the “best” pharmacotherapeutic solution and individualize the therapeutic regimen: With the patient, decide the best drug, dose, formulation, regimen, schedule, etc.

Step 7: Design a therapeutic drug-monitoring plan: Develop a plan to determine whether the desired therapeutic outcome has been achieved – plan must include monitoring for adverse effects.

Step 8: Implement the individualized regimen and monitoring plan: With the help of the patient and the healthcare professionals responsible for the patient, implement and document the decisions made.

Step 9: Follow up to measure success: Determine the pharmacist’s success on an individual patient basis and on a long-term basis.

The definition of pharmaceutical care was updated by Cipolle and colleagues (Cipolle et al., 1998) as stated in **Box 1.11**. This clearly elaborated that the responsibility and accountability of pharmaceutical care lay with the practitioner, an element which was absent in the previous definition.

**Box 1.11: Revised pharmaceutical care definition (Cipolle et al., 1998)**

*'Pharmaceutical care is a patient-centred practice in which the practitioner assumes responsibility for a patient's drug related needs and is held accountable for this commitment'*

Cipolle and colleagues also replaced 'Drug related problem' with 'Drug therapy problem' as defined in **Box 1.12**. Published with this DTP definition was a revised list of seven categories of DTPs (**Box 1.13**)

**Box 1.12: Definition of Drug Therapy Problem (Cipolle et al., 1998)**

*'A drug therapy problem is any undesirable event experienced by the patient that involves or is suspected to involve drug therapy and that actually or potentially interferes with a desired patient outcome.'*

**Box 1.13: Categories of drug therapy problems (Cipolle et al., 1998)**

1. Additional drug therapy
2. Unnecessary drug therapy
3. Wrong drug
4. Dosage too low
5. Adverse drug reactions
6. Dosage too high
7. Compliance

Three key elements of a Pharmaceutical care model may be delivered within the new MUR service (**Box 1.14**). For the first time in the UK, MUR services allow us to deliver an NHS funded pharmaceutical care model for the potential benefit of patients.

**Box 1.14: Pharmaceutical care model (incorporating MUR features)**

- Face to face consultation with patient (MUR interview)
- Documentation of drug therapy problems (Structured MUR documentation and action plan)
- Follow-up of outcomes (copy of action plan given to patient and General Practitioner)

This MUR service is the opportunity that Hepler and Strand theorised that pharmacists would need to fulfil their responsibilities. Pharmacists in England and Wales have now been given this opportunity. There is an urgent need to evaluate this

new MUR service to establish an evidence base. This evidence base may also be informed by the research literature on pharmaceutical care models.

## **1.4 Literature Review**

A review of prospective cohort studies and randomised controlled trials (RCTs) published in English was, conducted over a 15 year period (1990-2005) to identify the evidence base for pharmaceutical care since the seminal Hepler and Strand paper (Hepler and Strand, 1990). These were divided into disease specific and general models of pharmaceutical care. The studies were assessed firstly to establish if they described a pharmaceutical care model and secondly all such models were critically appraised to gauge the extent to which they contributed to the evidence base. To be included in this review a study was required to include three basic elements of a pharmaceutical care model: face to face consultations; documentation of a care plan; and patient follow-up. Studies were excluded if they did not include these three basic aspects in their design. Nursing and residential home settings were also excluded.

A total of 58 papers were selected for full appraisal (see chapter 2 for detailed methodology). All papers were reviewed to assess the quality of the methodology. Studies were then divided into disease specific and general models of pharmaceutical care.

Of the 58 papers reviewed, five studies claimed to provide pharmaceutical care but lacked a face to face consultation with the patient and therefore were excluded (Smith and Christensen, 1996, Cunningham et al., 1997, Smythe et al., 1998, Berringer et al., 1999, Godley et al., 2003). A further seven studies were excluded due to the highly specialist nature of the intervention and/or outcomes which were considered beyond

the MUR scope of practice and included: two studies in the palliative care setting (Diment and Evans, 1995, Needham et al., 2002), two studies of heart failure patients (Gattis et al., 1999, Sadik et al., 2005), a study of hypertension in renal transplant patients (Chisholm et al., 2002), a study in paediatric asthmatics (Stergachis 2002) and a study of patients with HIV (Foisy and Akai, 2004). Four papers were pharmaceutical care models but were excluded because the workup of each care plan took between one and four hours and was heavily orientated towards training of the practitioners and therefore lacked generalisability to current practice (Ho, 1994, Blain and Rappaport, 1996, Mclean et al 2003 and Saini et al 2004). A final paper on hyperlipideamia was excluded as it focused on processes of care rather than clinical outcome and was stopped early due to the finding of a significant difference in process measures between the two groups (Tsuyuki et al 2002).

Of the 41 remaining papers 18 related to disease specific models and 23 to general pharmaceutical care models.

### **1.4.1 Disease Specific Pharmaceutical care models**

#### **Diabetes**

Six of the published papers related to diabetes, a summary of each is provided in

#### **Table 1.1.**

The study by Veldhuizen-Scott et al, (1995) was notable because of the use of an RCT design. The forty-one participants were recruited from a regional diabetes centre, with fourteen control patients receiving a standard three day educational programme. The intervention patients were further divided into two groups, one of which received a standard programme and a group session with the pharmacists

whilst the other group received the standard programme plus a one to one with the pharmacist with telephone contact twice monthly for two months. The authors reported that both intervention groups achieved lower weekly average blood glucose scores than control together with improved perceptions and attitudes. However this study had several major limitations: the small sample size which was further reduced in power by having two intervention arms; the short duration of the study with only two months follow-up; the clinical outcome was based on self reported blood glucose with no methods adopted to reduce bias in reporting (HbA<sub>1c</sub> is gold standard but not possible because of short duration of follow-up). Finally even if all of these problems had been overcome, the three day educational programme severely limits the generalisability of the model.

An RCT by Jaber et al (1996) evaluated a pharmaceutical care model delivered in an outpatient clinic. Thirty-nine patients were followed-up for four months with a reduction of 2.3% HbA<sub>1c</sub> reported. A severe limitation of this study was the small number of patients attending a single outpatient clinic with broad exclusion criteria including non-compliance with clinic visits in the previous two years. In addition the high baseline HbA<sub>1c</sub> (11-12%) casts doubt on the clinical significance of the 2.3% reduction.

In contrast Clifford (2002) found no difference in HbA<sub>1c</sub> but started from a different baseline (8.4-8.5%) despite undertaking a well designed RCT of 73 patients attending a hospital out-patient clinic. This study was interesting in that it was a true pharmaceutical care model which recorded interventions and outcomes using six of the drug therapy problem categories (DTP) previously described by Strand et al



(1990). Limitations were few including the tight control of HbA<sub>1c</sub> at baseline and a lack of blinding of subject allocation to clinic staff which may have introduced bias.

Cranor and Christensen (2003) described the Asheville project, which was a community pharmacy based prospective cohort (before and after) study of a pharmaceutical care model of 85 patients followed up for 7 to 9 months. The authors claimed that the HbA<sub>1c</sub> had improved significantly from baseline ( $7.7\% \pm 2.2\%$  to  $6.9\% \pm 1.4\%$ ). Whilst the HbA<sub>1c</sub> change was statistically significant ( $p < 0.01$ ) its clinical significance is less certain given the relatively good control at entry to the study. In addition the before and after study design was undertaken between 1997 and 1999 which further limits the interpretation of these findings as clinical care of Type 2 diabetes changed dramatically over this period due to the publication of the UKPDS in 1998 (UKPDS 1998).

Cioffi et al (2004) conducted a prospective cohort study of pharmaceutical care provided at a predominantly male veteran affairs clinic with follow-up at 9 to 12 months. Patients met the pharmacist every 6-8 weeks for 30 minutes during this period. All outcome measures were positive with a significant 3.4% decrease in HbA<sub>1c</sub> observed ( $p < 0.001$ ). This was a well designed and conducted study which nevertheless had several limitations. Firstly the predominantly male fit population limits generalisability of the findings, secondly the intensive nature of the intervention may be unrealistic to achieve in practice and finally the study design itself had no control group therefore we cannot be sure that the observed effect was likely to be entirely due to the intervention. The latter is even more complicated by the lack of reporting of a time line for the intervention given that prior to the UKPDS

publication in 1998 type 2 diabetes was not so aggressively managed in terms of glycaemic control.

Clifford et al (2005) conducted a generally well designed RCT with a significant number of patients (180) followed-up over a twelve month period. Clinical outcomes were generally positive although HbA<sub>1c</sub> was reduced by only 0.5% in the intervention group compared with 0% in the control group, this also failed to meet their 10% target reduction (0.75%). Of more significance was the reduction in blood pressure of 14/5mmHg in the intervention group compared with 7/2mmHg in the control group. In reporting this study two things were not clear, firstly that allocation following randomisation was independent and secondly whether any form of blinding was used to minimise the risk of bias. This may have been a limitation of the reporting rather than the actual study. Generalisability of the findings are limited by the unusually restricted study entry criteria with the patients being of European or Anglo-celt ethnicity and being compliant in attending annual reviews for greater than five years.

**Table 1.1 – Summary of Diabetes pharmaceutical care models**

Study	Selection, recruitment and participants	Communication, interview techniques and interventions	Outcomes, results and author's conclusion	Limitations of study
Veldhuizen-Scott, (1995)	<ul style="list-style-type: none"> <li>▪ Inclusion criteria: Any patient attending the educational program at the regional diabetes centre (RDC) in America</li> <li>▪ RCT (Control - 14, Intervention group 1 -13, Intervention group 2 – 14)</li> <li>▪ 2 Type 1 diabetics, 39 Type 2 diabetics</li> <li>▪ 2 month follow-up</li> </ul>	<ul style="list-style-type: none"> <li>▪ Control – Standard 3 day RDC educational program</li> <li>▪ Intervention 1 - RDC education program, group session with pharmacist</li> <li>▪ Intervention 2 – RDC education program, one to one with pharmacist and telephone follow-up by pharmacist, twice monthly for two months</li> </ul>	<ul style="list-style-type: none"> <li>▪ <b>Outcomes</b></li> <li>▪ Clinical and patient knowledge, perceptions and attitudes</li> <li>▪ <b>Results</b></li> <li>▪ Intervention groups 1 and 2: achieved lower weekly average blood glucose values (<math>p \leq 0.05</math>)</li> <li>▪ No differences found in knowledge</li> <li>▪ Perceptions and attitudes were significantly improved in the intervention groups for: general (<math>p \leq 0.05</math>), medications (<math>p \leq 0.01</math>) compliance (<math>p \leq 0.05</math>), understanding of medicines (<math>p \leq 0.05</math>)</li> </ul> <p>No significant differences were found for counselling and pre-test, post-test questionnaires on general knowledge of diabetes between intervention group 1 and 2</p> <ul style="list-style-type: none"> <li>▪ <b>Author's conclusion</b></li> <li>▪ Involvement at the RDC was an efficient and effective mode for pharmacist intervention but would not necessarily reflect what might be accomplished in other pharmacy practice settings</li> </ul>	<ul style="list-style-type: none"> <li>▪ Short duration of study</li> <li>▪ Short follow-up</li> <li>▪ Small sample size</li> <li>▪ Self report of blood glucose measurements</li> <li>▪ 3 day education program – not practical</li> <li>▪ Did not use HbA1c</li> <li>▪ Not generalisable, set in a single RDC centre</li> </ul>

Table 1.1 continued. – Summary of Diabetes pharmaceutical care models continued.

Study	Selection, recruitment and participants	Communication, interview techniques and interventions	Outcomes, results and author's conclusion	Limitations of study
Jaber et al (1996)	<ul style="list-style-type: none"> <li>▪ Randomised controlled trial in a university affiliated medicine outpatient clinic in America</li> <li>▪ Inclusion criteria: Patients with type 2 diabetes currently attending the outpatient clinic.</li> <li>▪ 39 African American patients with Type 2 diabetes (17 intervention and 22 control)</li> <li>▪ Four month follow-up</li> </ul>	<ul style="list-style-type: none"> <li>▪ Control – two clinic visits, once for initial assessment and once for final exit visit</li> <li>▪ Intervention – Received pharmaceutical care – 1. Disease specific pharmacotherapeutic evaluation and dosage adjustments, 2. patient education, 3. training on recognition and treatment of hypo and hyperglycaemia, 4. medication counselling, 5. Diet and exercise plan, 6. self blood glucose monitoring of blood glucose (SBGM)</li> <li>▪ Four month follow-up</li> </ul>	<ul style="list-style-type: none"> <li>▪ <b>Outcomes</b> Clinical and humanistic</li> <li>▪ <b>Results</b> Reduction of HbA1c by 2.3 % intervention group (p=0.003). Blood pressure measurements did not differ significantly between or within groups. No significant changes in body weight, serum lipid measurements and renal function parameters were noted. There were no significant differences in quality of life measurements</li> <li>▪ <b>Good points</b> <ul style="list-style-type: none"> <li>- HbA1c used</li> <li>- Optimisation of therapy</li> </ul> </li> <li>▪ <b>Authors conclusions</b> The optimisation of oral hypoglycaemic regimens and patient education were the most likely reasons for decrease in HbA1c</li> </ul>	<ul style="list-style-type: none"> <li>▪ Broad exclusion criteria included no-compliance with clinic attendance over previous 2 years</li> <li>▪ Small sample size</li> <li>▪ High HbA1c at entry to study – <math>11.5 \pm 2.9</math> intervention and <math>12.2 \pm 3.5</math> in the control</li> </ul>

Table 1.1 continued. – Summary of Diabetes pharmaceutical care models continued.

Study	Selection, recruitment and participants	Communication, interview techniques and interventions	Outcomes, results and author's conclusion	Limitations of study
Clifford et al, (2002)	<ul style="list-style-type: none"> <li>▪ Randomised controlled trial in a hospital outpatient clinic in Australia</li> <li>▪ Inclusion criteria: Patients over 18 years with Type 1 or 2 diabetes and had one or more of the following               <ul style="list-style-type: none"> <li>- random blood glucose &gt;11 mmol/L</li> <li>- HbA1c &gt;8 %</li> <li>- Hypertension &gt;160/90 mmHg</li> <li>- Total serum cholesterol &gt;5.5mmol/L</li> <li>- &gt; 3 drugs</li> </ul> </li> <li>▪ RCT (Control - 25, Intervention - 48)</li> <li>▪ 6 month follow-up</li> </ul>	<ul style="list-style-type: none"> <li>▪ Control – Standard outpatient care, no contact with clinical pharmacist, completed QOL survey but not patient satisfaction survey</li> <li>▪ Intervention – patients attended appointments at six weekly intervals for six months with clinical pharmacist.</li> </ul>	<ul style="list-style-type: none"> <li>▪ <b>Outcomes</b> Clinical and humanistic</li> <li>▪ <b>Results</b> Mean HbA1c did not differ significantly between both groups. There were no significant differences between groups in the QOL survey. In the intervention group there was greater satisfaction with the pharmacist (p=0.007) and drug information (p = 0.036) from baseline to follow up.</li> </ul> <p>Thirty-nine drug therapy interventions were made and implemented</p> <ul style="list-style-type: none"> <li>▪ <b>Author's conclusion</b> Pharmaceutical care programs (PCPs) provide patients with valuable information and result in changes to drug therapy. However the six month PCP did not lead to an improvement in glycaemic control and further evaluation is needed</li> </ul>	<ul style="list-style-type: none"> <li>▪ HbA1c was already tightly controlled so a difference was unlikely in such a short period of 6 months</li> <li>▪ Staff and physicians knew of the control and intervention allocation, therefore potentially introducing bias</li> </ul>

Table 1.1 continued. – Summary of Diabetes pharmaceutical care models continued.

Study	Selection, recruitment and participants	Communication, interview techniques and interventions	Outcomes, results and author's conclusion	Limitations of study
Cranor and Christensen, (2003)	<ul style="list-style-type: none"> <li>▪ Prospective cohort study in twelve community pharmacies in America</li> <li>▪ Inclusion criteria: patients with diabetes from the two participating self-insured employers.</li> <li>▪ 85 patients, 38 in group 1 and 47 in group 2 combined later for a group analysis</li> <li>▪ 1<sup>st</sup> group recruited March 1997 – intervention group</li> <li>▪ 2<sup>nd</sup> group recruited in March 1999 – comparison group</li> <li>▪ Followed for 7-9 months</li> </ul>	<ul style="list-style-type: none"> <li>▪ Intervention – consultation with community pharmacist, offered to meet monthly with the pharmacist to monitor treatment goals and receive diabetes education, home glucose meter training and information about medication adherence. Pharmacists also performed physical assessments of patient's feet, skin, blood pressure and weight.</li> <li>▪ Baseline laboratory evaluations of HbA1c and serum lipid concentrations were collected and measured 1 to 3 months before the intervention began and at the first follow-up period</li> </ul>	<ul style="list-style-type: none"> <li>▪ <b>Outcomes</b> Clinical and humanistic</li> <li>▪ <b>Results</b> The authors reported that the HbA1c improved significantly in group 1 from a mean <math>\pm</math> SD of <math>7.7\% \pm 2.2\%</math> to <math>6.9\% \pm 1.4\%</math> at follow-up (<math>p &lt; 0.01</math>). With similar figures reported for group 2. No change in HRQOL</li> <li>▪ <b>Author's conclusion</b> Community pharmacists can provide effective cognitive services to help patients with diabetes improve clinical outcomes</li> </ul>	<ul style="list-style-type: none"> <li>▪ No control group – cannot assume the outcome is a result of intervention as patient care moves on over time</li> <li>▪ HbA1c measurement - no description given of how obtained as often between lab variation noted in this outcome measure, relevant here because of twelve pharmacy sites</li> <li>▪ Baseline HbA1c was 7.7% reduction to 6.9% unclear of clinical significance</li> <li>▪ Underpowered for health related quality of life outcome measure</li> <li>▪ A pre intervention period of one year is defined but only treatment costs data is provided.</li> </ul>

Table 1.1 continued. – Summary of Diabetes pharmaceutical care models continued.

Study	Selection, recruitment and participants	Communication, interview techniques and interventions	Outcomes, results and author's conclusion	Limitations of study
Cioffi et al (2004)	<ul style="list-style-type: none"> <li>▪ Prospective cohort study in a diabetes management clinic in America</li> <li>▪ Inclusion criteria: Veterans with type 2 diabetes treated with insulin or oral agents and had a HbA1c &gt;7%</li> <li>▪ 70 Veterans affairs patients</li> <li>▪ 9-12 month follow-up</li> </ul>	<ul style="list-style-type: none"> <li>▪ Intervention – patients met with pharmacist every 6-8 weeks for 30 minutes for at least 9-12 months. During the appointments they provided diabetes education, medication counselling, monitoring and management. Addition and alteration of current drug therapy was discussed with the patient's primary care provider.</li> </ul>	<ul style="list-style-type: none"> <li>▪ <b>Outcomes</b> Clinical</li> <li>▪ <b>Results</b> Reduction of HbA1c from 10.3%± 2.2% to 6.9%± 1.1%) p&lt;0.001, a 3.4% decrease. Secondary endpoints including 8mmHg drop in systolic (p&lt;0.001) and 4mmHg drop in diastolic (p&lt;0.001) blood pressure, drop of 20mg/dL total cholesterol (p&lt;0.001)</li> <li>▪ <b>Author's conclusion</b> This study showed clinical pharmacists could effectively care for patients with diabetes referred by their primary care provider because of poor glycaemic control.</li> </ul>	<ul style="list-style-type: none"> <li>▪ No control group – no comparison to standard care</li> <li>▪ Time line of study not reported – prior to 1998 type 2 diabetes not aggressively treated</li> <li>▪ Intensive intervention may not be reproducible in practice</li> <li>▪ Predominant male (68 years) population attending veteran clinic with baseline BP 133/74</li> </ul>

Table 1.1 continued. – Summary of Diabetes pharmaceutical care models

Study	Selection, recruitment and participants	Communication, interview techniques and interventions	Outcomes, results and author's conclusion	Limitations of study
Clifford et al, (2005)	<ul style="list-style-type: none"> <li>▪ Randomised controlled trial – Hospital - Prospective observational - 12 month in Australia</li> <li>▪ Clinical pharmacist in out-patient hospital setting in Australia</li> <li>▪ Inclusion criteria: Adults with type 2 diabetes taking at least one prescribed medication, attending an annual review between February and November 2001, southern European, Anglo-celt population</li> <li>▪ 180 patients (92 intervention, 88 control)</li> <li>▪ 6 and 12 month follow-up</li> </ul>	<ul style="list-style-type: none"> <li>▪ Control group: standard assessment, 6 and 12 month review (blood pressure, biochemical tests taken), lifestyle issues reinforced- data passed onto primary care physician.</li> <li>▪ Intervention group: assessed by clinical pharmacist at baseline, 6- weekly intervals by telephone, face to face meetings at 6 and 12 months, pharmaceutical care plans used, at baseline pt completed questionnaire, self-reported information on diet, exercise, home blood glucose monitoring, compliance with medication, leaflets given- treatment aims and all data passed onto primary care physician.</li> </ul>	<ul style="list-style-type: none"> <li>▪ <b>Outcomes</b> Clinical</li> <li>▪ <b>Results</b> There was a significant reduction in HbA<sub>1c</sub>, mean 0.5% reduction over 12 months (p=0.002), systolic blood pressure 14mmHg (p=0.024), diastolic blood pressure 5mmHg (p=0.043). There were no differences in any other parameter measured. There was no difference between both groups for number of medication changes except that ACE inhibitor or Angiotensin 2 antagonists were more frequently commenced in the PC group. There was also a greater increase in antihypertensive, lipid lowering and antiplatelet drug use in the PC group.</li> <li>▪ <b>Author's conclusion</b> Pharmacists contribution improved HbA<sub>1c</sub>, valuable component of community based multidisciplinary diabetes care</li> </ul>	<ul style="list-style-type: none"> <li>▪ Method of randomization not clear from reporting – describes consecutive allocation does not confirm independence of allocation.</li> <li>▪ Blinding not clear from reporting</li> <li>▪ Generalisability of the findings are limited by the unusually restricted study entry criteria with the patients being of southern European or Anglo-celt ethnicity and being compliant in attending annual reviews for greater than five years.</li> </ul>



## Hypertension

Six of the published papers related to hypertension, a summary of each is provided in **Table 1.2**.

Park et al (1996) reported an RCT of 53 patients in two community pharmacies with wide inclusion criteria. The authors reported a significant reduction in systolic blood pressure with no change in diastolic blood pressure. A limitation of the study was that it was not sufficiently powered to report on quality of life. This study generally used a good design (although method of allocation following randomisation was not clear) but was limited in the short duration of the follow-up and in the equipment chosen to measure blood pressure. In pharmacist intervention studies it is not possible to blind the actual pharmacist making the intervention, therefore it is important to select a verifiable monitoring technique to avoid the introduction of bias. In this case a mercurial sphygmomanometer did not meet these requirements.

Carter et al (1997) overcame the potential bias for pharmacist reporting of blood pressures by having blinded physicians undertake independent measurement for both active and control patients. This well designed RCT enrolled 51 patients to receive pharmaceutical care and reported a significant reduction of 11mmHg in systolic blood pressure. The study design overcame previous limitations, however the intensive follow-up (3 to 5 weeks) may be difficult to sustain in practice.

These findings are consistent with the study by Eriksson et al (1997) who also reported a significant reduction in systolic blood pressure (12 mmHg). This study was a controlled trial of eighty patients allocated to intervention and control group based on the day (Tuesday or Thursday) of attending a hospital outpatient clinic. However,

it did suffer limitations of previous studies in that there was no verification of blood pressure readings with only one reading being taken at each visit.

Garcao and Cabrita (2002) reported an even greater reduction in systolic blood pressure (23 mmHg) and unlike the previous studies also reported a significant reduction of 12 mmHg in diastolic blood pressure. This was a generally well designed community pharmacy based RCT of 82 patients with a six month follow-up. Although great care was taken over blood pressure measurements it was unfortunate that a digital sphygmomanometer was not used to eliminate potential bias. What was not clear from the reporting of the study was whether an intervention had occurred in the control group as the authors stated that control patients received traditional Portuguese pharmacy services including medication review. If control patients had received medication review, although from the excellent results obtained it seems unlikely, then this medication review must be different to that offered in the UK.

This reduction in diastolic blood pressure was also reported by Vivian et al (2002) in an RCT involving 53 patients with a six month follow-up. This study also reported a significant reduction in systolic blood pressure of 18 mmHg. The limitations were similar to previous studies regarding blood pressure measurement and non-blinding of physicians. However what was new about this study was that the pharmacist providing pharmaceutical care was also empowered to prescribe. Although it limits generalisability it is a useful addition to the evidence base given the recent changes in UK legislation regarding pharmacist prescribing.

Interestingly pharmaceutical care practice has also been evaluated in Thailand using an RCT design (Sookaneknun et al., 2004). Whilst the study design was robust with a

large sample size (235) it suffered several of the limitations previously discussed. The authors claimed to have demonstrated a significant reduction in blood pressure whilst in reality the differences between the two groups (5/2 mmHg) seems unlikely to be of clinical significance. It is notable that the control group demonstrated an 18 mmHg and 12 mmHg reduction in systolic and diastolic blood pressure respectively. This effect size has not been reported in previous control groups and may reflect a wash over effect between the two groups. Whilst the research pharmacist had no involvement in the control group, their regular presence for a minimum of three days a week within the community pharmacy may have altered standard care.

Table 1.2 – Summary of Hypertension pharmaceutical care models

Study	Selection, recruitment and participants	Communication, interview techniques and interventions	Outcomes, results and author's conclusion	Limitations of study
Park et al, (1996)	<ul style="list-style-type: none"> <li>▪ Randomised Controlled Trial conducted in two community pharmacies in America</li> <li>▪ Inclusion criteria: patients receiving antihypertensive medication or if BP was <math>\geq 140/90</math>mmHg</li> <li>▪ 53 patients completed study (27 intervention, 26 control)</li> <li>▪ 4 months follow-up</li> </ul>	<ul style="list-style-type: none"> <li>▪ Control group: received traditional pharmacy services, 1. screening for errors, 2. filling prescription orders, 3. limited patient education, 4. monitoring patient-volunteered adverse drug reactions</li> <li>▪ Intervention group: drug therapy monitoring,(recording of heart rate, blood pressure obtaining medication history, monitoring compliance, screening for drug interactions and adverse drug reactions) and patient education, on a total of four visits, each visit scheduled one month apart. All patient information was used to design a care plan</li> </ul>	<ul style="list-style-type: none"> <li>▪ <b>Outcomes</b> Clinical and humanistic</li> <li>▪ <b>Results</b> There was a significant reduction in blood pressure by the fourth visit. Mean systolic blood pressure decreased in intervention group by 12.3 mmHg from visit 1 to 4 (<math>p &lt; 0.05</math>) and rose by 0.7 mmHg in the control group. General health status did not change between groups</li> <li>▪ <b>Author's conclusion</b> Drug therapy monitoring and educational services provided by community pharmacists to hypertensive patients contributed to improved blood pressure control</li> </ul>	<ul style="list-style-type: none"> <li>▪ Method of randomization not clear from reporting – describes allocation at initial screening visit but does not confirm independence of allocation.</li> <li>▪ Short duration of follow-up may be insufficient to detect a reduction in compliance</li> <li>▪ Blood pressure measured by a mercurial sphygmomanometer with potential for bias in readings by pharmacist who were not blinded to patient allocation.</li> <li>▪ Insufficient power to measure secondary endpoint: Health status questionnaire.</li> </ul>

Table 1.2 continued – Summary of Hypertension pharmaceutical care models

Study	Selection, recruitment and participants	Communication, interview techniques and interventions	Outcomes, results and author's conclusion	Limitations of study
Carter et al, (1997)	<ul style="list-style-type: none"> <li>▪ Randomised Controlled Trial</li> <li>- 2 community pharmacists in one pharmacy located within a medical centre in a rural setting in America</li> <li>▪ Inclusion criteria: men and women of any racial group, over 18 years of age, with essential hypertension</li> <li>▪ 51 patients (25 intervention, 26 control)</li> <li>▪ 6 months follow-up</li> </ul>	<ul style="list-style-type: none"> <li>▪ Control group: blood pressure measured at baseline and at 6 months. Received traditional pharmacy services</li> <li>▪ Intervention group: blood pressure measured at baseline and at 6 months. Patients scheduled to obtain refills with pharmacist every 3-5 weeks. Blood pressure measured, questioned RE: ADRs and compliance with therapy. Understanding of drug regimen and lifestyle recommendations</li> </ul>	<ul style="list-style-type: none"> <li>▪ <b>Outcomes</b> Clinical and humanistic</li> <li>▪ <b>Results</b> There was a significant difference between baseline and 6 month follow-up in systolic blood pressure in the intervention group, <math>151 \pm 21</math> mmHg baseline, <math>140 \pm 14</math> follow-up mmHg (<math>p &lt; 0.001</math>). There was no change in blood pressures from baseline to follow-up for control patients.  Several QOL indicators improved significantly in the intervention group at 6 months (<math>p &lt; 0.05</math>). These included, physical functioning, physical role limitations and bodily pain. There were no significant changes in the control group.</li> <li>▪ <b>Good points</b> <ul style="list-style-type: none"> <li>- all efforts made to blind subjects and doctors</li> <li>- blood pressure measured independently by pharmacists and physicians</li> </ul> </li> <li>▪ <b>Author's conclusion</b> Clinical pharmacist can create significant improvements in blood pressure control when included as members of the primary care team</li> </ul>	<ul style="list-style-type: none"> <li>▪ See pharmacist every 3-5 weeks, labour intensive</li> <li>▪ Sample size calculated on the basis of a 5 mmHg reduction in blood pressure which was not achieved, actual was only 2 mmHg</li> </ul>

Table 1.2 continued – Summary of Hypertension pharmaceutical care models

Study	Selection, recruitment and participants	Communication, interview techniques and interventions	Outcomes, results and author's conclusion	Limitations of study
Erickson et al, (1997)	<ul style="list-style-type: none"> <li>▪ Cohort study prospective</li> <li>- Concurrent cohort design (Control vs Intervention)</li> <li>- Hospital outpatient clinic in America</li> <li>▪ Inclusion criteria:               <ul style="list-style-type: none"> <li>- control – patients diagnosed with hypertension at Tuesday clinics</li> <li>- intervention – patients diagnosed with hypertension at Thursday clinics</li> <li>- ≥18 years old, read and speak English, essential hypertension (≥140/90mmHg) and ≥1 hypertensive medication</li> </ul> </li> <li>▪ 80 patients (40 intervention, 40 control)</li> <li>▪ 5 months follow-up</li> </ul>	<ul style="list-style-type: none"> <li>▪ Systolic and diastolic blood pressures measured by the patient's physician at baseline and each subsequent clinic visit.</li> <li>▪ Control group: Care provided by physician only</li> <li>▪ Intervention group: Care provided by pharmacist - reviewing medical records, taking drug history, assessing presence of side effects, assessing patient specific drug issues, education about hypertension, lifestyle modifications, consulting with physicians RE potential and actual drug therapy problems (DTPs), counselling on new therapy</li> <li>▪ HRQOL both groups.</li> </ul>	<ul style="list-style-type: none"> <li>▪ <b>Outcomes</b> Clinical and humanistic</li> <li>▪ <b>Results</b> Significant decrease in systolic blood pressure in the intervention group from baseline(156 mmHg) to follow-up (144 mmHg) compared with the control (p=0.05)</li> <li>▪ No significant differences in HRQOL between groups. One domain (physical functioning) was significantly worse in the intervention group from baseline to follow-up (p=0.03)</li> <li>▪ 57 Drug therapy problems in the intervention group compared with 47 in the control</li> <li>▪ <b>Good points</b> Drug therapy problems assessed</li> <li>▪ <b>Author's conclusion</b> Pharmaceutical care contributed to improved blood pressure control in intervention patients</li> </ul>	<ul style="list-style-type: none"> <li>▪ Only one blood pressure reading taken per visit and mechanism of recording blood pressure not provided</li> <li>▪ No blinding, similar DTPs found in both groups, pharmacist recommendations may have influenced doctor interventions in the control group</li> </ul>

Table 1.2 continued – Summary of Hypertension pharmaceutical care models

Study	Selection, recruitment and participants	Communication, interview techniques and interventions	Outcomes, results and author's conclusion	Limitations of study
Garcao and Cabrita (2002)	<ul style="list-style-type: none"> <li>▪ Randomised controlled trial</li> <li>- One community pharmacy in rural Portuguese setting</li> <li>▪ Inclusion criteria: <ul style="list-style-type: none"> <li>▪ <math>\geq 1</math> hypertensive medication for more than 6 months, essential hypertension, receiving care from their physician and had their prescriptions from the study pharmacy</li> </ul> </li> <li>▪ 82 patients (41 intervention, 41 control)</li> <li>▪ 6 months follow-up</li> </ul>	<ul style="list-style-type: none"> <li>▪ Control group: traditional pharmacy services, brief counselling, medication review and monitoring of ADRs</li> <li>▪ Intervention group: Followed for 6 months, BP measured during monthly scheduled interviews, lifestyle modifications. During interview pharmacists obtained laboratory and body measurements. Lifestyle changes were recommended and recorded for patients with DTPs referred to physicians for reconsideration. In addition educational leaflets were given at the first visit.</li> </ul>	<ul style="list-style-type: none"> <li>▪ <b>Outcomes</b> Clinical</li> <li>▪ <b>Results</b> Significant decrease in BP in the intervention group from baseline to follow-up compared with the control (<math>p &lt; 0.001</math>)</li> <li>Significant decrease of Systolic BP (23.15mmHg) and Diastolic BP (12.34mmHg) in the intervention group from baseline to follow-up (<math>p = 0.0001</math>)</li> <li>29 actual DTPs, 5 potential. Actual DTPs - 5 related to need of drug therapy, 16 related to effectiveness, 8 drug related safety. Potential DTPs – related to high doses of thiazides and short acting nifedipine. At follow-up 24 out of 29 were resolved and 2 out of 5 potential DTPs were prevented</li> <li>▪ <b>Good points</b> <ul style="list-style-type: none"> <li>- Average of two BP results</li> <li>- BP measured at same time of day</li> <li>- Drug therapy problems measured</li> </ul> </li> <li>▪ <b>Author's conclusion</b> Applying pharmaceutical care to hypertensive patients in the rural setting can help BP control.</li> </ul>	<ul style="list-style-type: none"> <li>▪ Method of randomisation and allocation not described</li> <li>▪ Unsure if control group received an intervention as medication review is listed</li> <li>▪ Measurements of blood pressure conducted by sphygmomanometer which could not be verified</li> </ul>

Table 1.2 continued – Summary of Hypertension pharmaceutical care models

Study	Selection, recruitment and participants	Communication, interview techniques and interventions	Outcomes, results and author's conclusion	Limitations of study
Vivian (2002)	<ul style="list-style-type: none"> <li>▪ Randomised controlled trial</li> <li>- Veterans affairs medical centre in America</li> <li>- One pharmacist with prescribing authority</li> <li>▪ Inclusion criteria:               <ul style="list-style-type: none"> <li>- Stage 1,2 or 3 hypertension</li> <li>- ≥18 years old, confirmed diagnosis of essential hypertension (≥140/90mmHg)</li> </ul> </li> <li>▪ 53 patients completed study (26 intervention, 27 control)</li> <li>▪ 6 months follow-up</li> </ul>	<ul style="list-style-type: none"> <li>▪ Control group: traditional pharmacy services (brief counselling, dispensing services, review of drug profiles)</li> <li>▪ Intervention group: Patients scheduled monthly to meet with clinical pharmacist, pharmacist made drug therapy changes, drug counselling (side effects, lifestyle changes, assessment of compliance)</li> <li>▪ All patients had BP measured at baseline</li> </ul>	<ul style="list-style-type: none"> <li>▪ <b>Outcomes</b> Clinical and humanistic</li> <li>▪ <b>Results</b> Mean changes in SBP in intervention vs control were -18.4 mmHg vs -3.98 mmHg (p=0.01). Mean changes in DBP in intervention vs control were, -12.38 mmHg vs +2.54 mmHg (p=0.001)</li> <li>Non significant differences in compliance and patient satisfaction were found</li> <li>▪ <b>Good points</b> <ul style="list-style-type: none"> <li>- Pharmacist had prescribing authority to make changes to drug therapy</li> </ul> </li> <li>▪ <b>Author's conclusion</b> Pharmaceutical care provision to by a pharmacist improves blood pressure control</li> </ul>	<ul style="list-style-type: none"> <li>▪ Not generalisable, predominantly male population</li> <li>▪ Intervention group patients had significantly higher diastolic blood pressure (+12mmHg) than control (p=0.0012)</li> <li>▪ Physicians not blinded to intervention and control patients leading to potential for bias</li> <li>▪ No independent verification of blood pressure readings</li> </ul>



Table 1.2 continued – Summary of Hypertension pharmaceutical care models

Study	Selection, recruitment and participants	Communication, interview techniques and interventions	Outcomes, results and author's conclusion	Limitations of study
Sookaneknun et al (2004)	<ul style="list-style-type: none"> <li>▪ Randomised controlled trial</li> <li>- Community pharmacy in a city area and two primary care units in a rural area in Thailand</li> <li>▪ Inclusion criteria:               <ul style="list-style-type: none"> <li>- confirmed diagnosis of essential hypertension (<math>\geq 140/90\text{mmHg}</math>), diabetics (<math>\geq 130/85\text{mmHg}</math>)</li> </ul> </li> <li>▪ 235 patients (118 intervention, 117 control)</li> <li>▪ 6 months follow-up</li> </ul>	<ul style="list-style-type: none"> <li>▪ Control group: no research pharmacist involvement, received traditional services provided by pharmacy or primary care units. Blood pressure measured at baseline and follow-up</li> <li>▪ Intervention group: Patients monitored for six months, BP measured monthly, 30-50 minute face to face consultation (assessment of patient's understanding of medicines, counselling, assessment of adherence and lifestyle habits, reviewed adverse events due to drug-therapy problems. Drug-therapy problems identified, resolved and prevented</li> </ul>	<ul style="list-style-type: none"> <li>▪ <b>Outcomes</b> Clinical</li> <li>▪ <b>Results</b> The intervention group had a reduction in both SBP (23 mmHg) and DBP (14 mmHg) compared with control (18 mmHg and 12 mmHg).</li> <li>▪ <b>Good points</b> <ul style="list-style-type: none"> <li>- Large sample size</li> </ul> </li> <li>▪ <b>Author's conclusion</b> Hypertensive patients who received pharmaceutical care provided by a pharmacist achieved a significantly greater benefit in BP reduction and control.</li> </ul>	<ul style="list-style-type: none"> <li>▪ Details of pharmacist interventions not reported</li> <li>▪ Physicians not blinded to intervention and control patients leading to bias</li> <li>▪ Manual sphygmomanometer used with potential for bias in reporting</li> <li>▪ Authors multiple analysis of data likely to lead to statistically significant finding due to chance</li> <li>▪ Does not appear to be clinically significant difference in Bp between intervention and control groups due to size of effect seen in the control group itself. It is possible that research pharmacist influenced standard care provided to control patients</li> </ul>

## **Hyperlipidaemia**

Only one of the papers related to hyperlipidaemia a summary of which is provided in **Table 1.3**. Shibley and Pugh (1997) conducted a prospective cohort study involving twenty-five patients over a twelve month period. Whilst a strength of this study was the long period of follow-up, this actually became a limitation due to the lack of a control group to take into account of changes in practice over time. A major limitation of this study was the subjectivity of the inclusion criteria, which would have severely limited the generalisability of the study had its findings been clinically significant.

Table 1.3 – Summary of Hyperlipidaemia pharmaceutical care models

Study	Selection, recruitment and participants	Communication, interview techniques and interventions	Outcomes, results and author's conclusion	Limitations of study
Shibley and Pugh (1997)	<ul style="list-style-type: none"> <li>▪ Prospective cohort study</li> <li>- Two community pharmacies in America</li> <li>- Six community pharmacists</li> <li>▪ Inclusion criteria: <math>\geq 20</math> years; fasting lipid values above recommended NCEP guideline values: patient, pharmacist and physician belief that lipid lowering is indicated; and patient ability to return to the pharmacy for follow-up visits.</li> <li>▪ 25 patients (12 women, 13 control)</li> <li>▪ 12 months follow-up</li> </ul>	<ul style="list-style-type: none"> <li>▪ Control group: Patients acted as their own controls</li> <li>▪ Intervention group: each patient assessed and assisted in setting goals and priorities for therapy. Appointment schedule set, fasting lipid values measured at patient visits upon screening and at 6 and 12 months, patients educated and given lifestyle advice. Patients completed the SF-36 survey. Drug therapy recommendations were made to physician where appropriate. If patients were started on therapy, expected outcomes and adverse effects were discussed.</li> </ul>	<ul style="list-style-type: none"> <li>▪ <b>Outcomes</b> Clinical and humanistic</li> <li>▪ <b>Results</b> Both total cholesterol (-15 mg/dL) and LDL-cholesterol (-21 mg/dL) values were reduced (<math>p &lt; 0.02</math>) at 12 months compared with baseline values which were <math>241 \pm 48</math> and <math>167 \pm 48</math> mg/dL, respectively.</li> <li>▪ <b>Author's conclusion</b> This pharmaceutical care model was able to help patients improve outcomes.</li> </ul>	<ul style="list-style-type: none"> <li>▪ Small sample size</li> <li>▪ No control group therefore unable to say with certainty that changes observed over 12 months were directly due to the intervention.</li> <li>▪ Reduction in cholesterol unlikely to be clinically significant</li> <li>▪ Inclusion criteria subjective, including ability to return for follow-up visits, severely limiting generalisability of findings</li> </ul>

## **Asthma**

Five of the published papers related to asthma, a summary of each is provided in **Table 1.4**.

A prospective controlled trial of pharmaceutical care in asthma patients (Herborg 2001) included 665 participants with cluster allocation by pharmacy (n=31) and a 12 month follow-up period. No change in PEFR was reported within or between the control and intervention group. However, several other positive outcomes were reported such as symptom status and quality of life, however the generalisation of these findings is severely limited by the subjective nature of the inclusion and exclusion criteria and including the role of physicians who were unblinded when they screened lists of patients for potential inclusion to the study.

The study by Cordina (2001) over a twelve month period also reported no change in PEFR although positive improvements in quality of life and inhaler technique were reported. This multi-centred prospective RCT only recruited 152 patients (86 intervention) despite a large number of pharmacies (n=22) being involved in the study with only 119 patients (64 intervention) completing the study.

These findings are also reflected in another multi-centred study (Shulz et al., 2001) which recruited 242 patients across 48 pharmacies in Germany and showed no improvement in FEV<sub>1</sub> or PEFR at 12 months follow-up. The study design was a prospective controlled trial with many limitations not least of which, was the allocation of active and control pharmacies. Pharmacists were given the choice as to whether they wished to take part as either an active or control base, which not only

limits the generalisability of the findings but challenges the results as the control group will not represent standard care.

A further large multi-centred RCT conducted by Weinberger et al (2002) also failed to demonstrate a significant difference between the intervention and peak flow monitoring group. This study has many limitations, the most notable of which is that physicians were informed by letter which ‘stressed that the pharmacist would make no treatment decisions but may educate patients about their breathing problems and reinforce compliance with the physician’s prescribed treatment regimen’.

In contrast the study by Emmerton et al 2003 did set out to identify drug therapy problems, this prospective cohort study recruited 100 patients to five community pharmacies over a two year period. Given the length of the study the four month follow-up is inexplicable and severely limits the interpretation of data due to the seasonal nature of the condition. No difference in PEFr was demonstrated. The authors concluded that pharmacists are highly capable of implementing an asthma service with little evidence to support this assertion.

Table 1.4 – Summary of Asthma pharmaceutical care models

Study	Selection, recruitment and participants	Communication, interview techniques and interventions	Outcomes, results and author's conclusion	Limitations of study
Herborg et al (2001)	<ul style="list-style-type: none"> <li>▪ Prospective controlled trial</li> <li>- 31 community pharmacies throughout Denmark</li> <li>▪ Inclusion criteria: 16 to 60 years of age, moderate to severe asthma, using anti asthma drugs, speaking and reading Danish</li> <li>▪ 665 patients (334 intervention, 331 control)</li> <li>▪ 12 months follow-up</li> </ul>	<ul style="list-style-type: none"> <li>▪ Control group: dispensing, advice about medicines and answering of patients questions</li> <li>▪ Intervention group: patients visited their pharmacist once a month, recording of inhalation technique, PEFR and asthma symptoms, discussion of problems and solutions</li> <li>▪ Data collected at baseline, 6 and 12 months</li> </ul>	<ul style="list-style-type: none"> <li>▪ <b>Outcomes</b> Clinical and humanistic</li> <li>▪ <b>Results</b> There was no significant difference in PEFR within or between the intervention and control groups. There were significant differences between the intervention and control groups in Asthma symptoms status (<math>p=0.004</math>), Living with asthma questionnaire (<math>p&lt;0.001</math>), Knowledge of asthma and asthma medications (<math>p&lt;0.001</math>)</li> <li>▪ <b>Good Points</b> <ul style="list-style-type: none"> <li>- Randomised design</li> <li>- Large sample size</li> <li>- Measurement of drug therapy problems</li> </ul> </li> <li>▪ <b>Author's conclusion</b> Patient participation in this pharmaceutical care project was associated with improved outcomes of drug therapy, asthma symptom status and HRQOL.</li> </ul>	<ul style="list-style-type: none"> <li>▪ Patient report of PEFR and symptoms</li> <li>▪ Randomisation by pharmacy may limit generalisability</li> <li>▪ Assignment was not random and subjective based on pharmacist motivation</li> <li>▪ Physicians were not blinded to allocation and were told whether their patients were active or control before agreeing to take part.</li> <li>▪ Physicians participated in patient selection with lots of exclusions including mild asthma</li> <li>▪ Drug therapy problems not measured in control group</li> </ul>

Table 1.4 continued – Summary of Asthma pharmaceutical care models

Study	Selection, recruitment and participants	Communication, interview techniques and interventions	Outcomes, results and author's conclusion	Limitations of study
Cordina et al (2001)	<ul style="list-style-type: none"> <li>▪ Randomised controlled trial</li> <li>- 22 community pharmacies in Malta</li> <li>- Inclusion criteria: patients registered at the asthma clinic through recruitment sessions, <math>\geq 14</math> years old, asthma.</li> <li>▪ 119 patients completed the study(64 intervention, 55 control)</li> <li>▪ 12 months follow-up</li> </ul>	<ul style="list-style-type: none"> <li>▪ Control group: given prescribed drugs and informed of dosage regimen</li> <li>▪ Intervention group: patient education and patient monitoring. Patients supplied with peak flow meter to record daily readings in diary. Provided with patient profile included information on patient's best peak flow value, smoking history and other disease states, know drug allergies and prescribed drugs. Pharmacist reviewed patient's peak flow and compared to personal best and advised accordingly. Review of inhaler and PEF technique, suggested treatment changes were relayed to the patients physician</li> <li>▪ Data collected at baseline, 4, 8, and 12 months</li> </ul>	<ul style="list-style-type: none"> <li>▪ <b>Outcomes</b> Clinical and humanistic</li> <li>▪ <b>Results</b> No difference in PEFR was observed from baseline to follow-up in the intervention group. However at 12 months PEFR significantly decreased in the control group over the same period (<math>p=0.009</math>) Inhaler technique score – was significantly higher in the intervention group than in the control group (<math>p=0.021</math>) No significant differences in compliance Patients in the intervention group reported better quality of life than the control group At 12 months (<math>p=0.044</math>), satisfaction in both groups was positive.</li> <li>▪ <b>Good Points</b> <ul style="list-style-type: none"> <li>- Randomised design</li> </ul> </li> <li>▪ <b>Author's conclusion</b> This pharmaceutical care provision was well received by patients, despite the high level of participant dropout. Pharmacists need to become more proactive in terms of integrating themselves more fully into chronic disease management</li> </ul>	<ul style="list-style-type: none"> <li>▪ Patient report of PEFR, symptoms and compliance and hospitalisations</li> <li>▪ Randomisation by pharmacy</li> <li>▪ Large drop out rate of 20% in the intervention group</li> <li>▪ Small sample size for multi-centered study</li> </ul>

Table 1.4 continued – Summary of Asthma pharmaceutical care models

Study	Selection, recruitment and participants	Communication, interview techniques and interventions	Outcomes, results and author's conclusion	Limitations of study
Schulz et al (2001)	<ul style="list-style-type: none"> <li>▪ Prospective controlled trial</li> <li>- 48 community pharmacies in city of Hamburg, Germany (26 intervention and 22 control)</li> <li>- Inclusion criteria: asthma patients presenting at pharmacy</li> <li>▪ 242 patients (161 intervention, 81 control)</li> <li>▪ 12 months follow-up</li> </ul>	<ul style="list-style-type: none"> <li>▪ Control group: traditional care</li> <li>▪ Intervention group: Meetings scheduled at 6 week intervals (9 meetings in 12 months) assessment and correction of inhaler technique, detection and resolution of drug or health related problems in cooperation with patient and the physician. Instruction on how to use peak flow meter</li> <li>▪ Data collected at baseline, 6 and 12 months</li> <li>▪ All patients completed QOL questionnaires, self efficacy questionnaires and asthma knowledge questionnaire at baseline, 6 and 12 months</li> </ul>	<ul style="list-style-type: none"> <li>▪ <b>Outcomes</b> Clinical and humanistic</li> <li>▪ <b>Results</b> There was no significant changes in FEV1, dyspnoea rated by physician or patient, asthma severity rated by patient or physician, PEF measurements between the intervention and control groups Inhalation technique improved significantly in the intervention group (p=0.001) There were no significant differences in knowledge or self efficacy between the intervention and control groups.</li> <li>▪ <b>Good Points</b> <ul style="list-style-type: none"> <li>- Measurement of PEF in pharmacy</li> </ul> </li> <li>▪ <b>Author's conclusion</b> Based on study results, further research needed to assess long term outcomes and the pharmacoeconomical impact of pharmaceutical care programs.</li> </ul>	<ul style="list-style-type: none"> <li>▪ Randomisation by pharmacy</li> <li>▪ No specific inclusion exclusion criteria stated</li> <li>▪ Pharmacist opted whether to take part as intervention and control, hence motivated intervention pharmacist will be compared against pharmacists choosing to opt out rather than standard care</li> </ul>



Table 1.4 continued – Summary of Asthma pharmaceutical care models

Study	Selection, recruitment and participants	Communication, interview techniques and interventions	Outcomes, results and author's conclusion	Limitations of study
Weinberger et al (2002)	<ul style="list-style-type: none"> <li>▪ Randomised controlled trial</li> <li>- 36 community pharmacies Indianapolis, America</li> <li>- Inclusion criteria for the 3 study groups was that they obtained a prescription for methylxanthines, inhaled corticosteroids, inhaled or oral sympathomimetics, inhaled parasympathetic antagonists, or inhaled cromolyn sodium, reported with having active asthma or COPD as a problem, <math>\geq 18</math> years, received 70 or more of their medicines from one pharmacy, no significant impairment in vision, hearing or speech, not in a nursing home</li> <li>▪ 1113 patients(active 447, control PEFR group 363 and control 303)</li> <li>▪ 12 months follow-up</li> </ul>	<ul style="list-style-type: none"> <li>▪ Three groups:               <ul style="list-style-type: none"> <li>- Control: Usual pharmacy care and monthly telephone calls (no PEFR was asked for)</li> <li>- Control PEFR group: Received peak flow meter, instructions about its use and monthly call to illicit PEFR</li> <li>- Intervention group: patients received a peak flow meter, instruction about its use and monthly calls from research personnel to obtain current PEFR results, pharmacist had access to patient specific clinical data, training and customised patient education materials</li> </ul> </li> <li>▪ Data collected at baseline, 6 and 12 months</li> <li>▪ Face to face interviews at baseline, 6, and 12 months were conducted to assess primary and secondary outcomes. Monthly telephone interviews were conducted to illicit ED and hospital visits</li> </ul>	<ul style="list-style-type: none"> <li>▪ <b>Outcomes</b> Clinical and humanistic</li> <li>▪ <b>Results</b> No significant difference in PEFR between the intervention group and control PEFR group. The intervention group had significantly higher PEFRs than the control group (<math>p=0.02</math>) but not the Control PEFR group (<math>p=0.28</math>). There were no significant between group difference in medication compliance or HRQOL. The intervention group had significantly more breathing related ED visits than the control group(<math>p&lt;0.001</math>)</li> <li>▪ <b>Good Points</b> <ul style="list-style-type: none"> <li>- randomised design</li> </ul> </li> <li>▪ <b>Author's conclusion</b> Additional research is needed to determine whether other approaches using pharmaceutical care will improve patient outcomes</li> </ul>	<ul style="list-style-type: none"> <li>▪ Decision to include both asthma and COPD within a single study is deeply flawed as disease progression, guidelines for management and monitoring requirements are so different.</li> <li>▪ Self report of PEFR, ED and hospitalisations possible source of bias.</li> <li>▪ PEFR not appropriate for COPD patients. Spirometry should have been used</li> <li>▪ Nature of increased visits to hospital were not identified as being linked to the intervention</li> <li>▪ Focus was on reinforcement of compliance with existing drug treatment rather than optimization of therapy</li> </ul>

Table 1.4 continued – Summary of Asthma pharmaceutical care models

Study	Selection, recruitment and participants	Communication, interview techniques and interventions	Outcomes, results and author's conclusion	Limitations of study
Emmerton et al (2003)	<ul style="list-style-type: none"> <li>▪ Prospective cohort study</li> <li>- 5 community pharmacies in rural New Zealand</li> <li>- Inclusion criteria: Asthma patients, particularly those who were uncontrolled</li> <li>▪ 100 patients</li> <li>▪ 4 month follow-up</li> </ul>	<ul style="list-style-type: none"> <li>▪ Intervention group: Patient consultations, systematic assessment, care planning, patient education, recommendations, referrals, monitoring and follow-up.</li> <li>▪ Patients completed daily diaries for twice daily PEFRs and symptom assessment</li> <li>▪ QOL data using asthma quality of life questionnaire</li> <li>▪ Medication related problems were categorised for analysis.</li> </ul>	<ul style="list-style-type: none"> <li>▪ <b>Outcomes</b> Clinical, humanistic</li> <li>▪ <b>Results</b> There was no significant difference in PEFR was noted from baseline to follow-up. Average of 4.3 medication related problems were identified per patient. 285/431 problems (66%) were classed as compliance related, 83 (19.3%) medication choice or dose, choice of device (10.7%), ADRs or drug interactions, 11 (2.3%) other (1.4%). Within 6 months of consultation 70% of patients were estimated to have had between one quarter and three quarters of their medication related problems resolved</li> <li>▪ <b>Good Points</b> - Medication related problems identified</li> <li>▪ <b>Author's conclusion</b> Further research required to integrate this particular service into practice. This project showed that community pharmacists, with training and support are highly capable of implementing a specialist asthma management service.</li> </ul>	<ul style="list-style-type: none"> <li>▪ Non generalisable, convenience sample of pharmacies taken</li> <li>▪ Patients selected by the individual pharmacists</li> <li>▪ Short follow-up period</li> <li>▪ Patients used as their own controls does not take into account seasonal nature of condition</li> <li>▪ Patient self reported PEFR with no objective confirmation of result</li> </ul>

### **Summary of critical appraisal of disease specific pharmaceutical care models**

In terms of disease specific models we can conclude there is some evidence of the benefit of pharmaceutical care from well designed studies in the area of diabetes such as the prospective cohort study by Cioffi et al (2004) and the RCT by Clifford et al (2005). In hypertension the evidence of benefit appeared to be stronger with study design notable in several RCTs (Carter et al., 1997, Garcao and Cabrita., 2002 and Vivian et al., 2002). In the case of asthma and hyperlipidaemia from the papers reviewed an evidence base was not established partly due to severe limitations of the study design. These limitations include: subjectivity of inclusion criteria; lack of blinding of physicians; small sample size for multi-centred studies; patient self report of outcome measures; and lack of a control group for studies over twelve months.

#### **1.4.2 General models of pharmaceutical care**

This review focused on general models of pharmaceutical care which may best reflect the Medicines Use Review service model now incorporated in the NHS contract April 2005.

The remaining 23 papers(Lipton et al., 1992, Lobas et al., 1992, Jameson et al., 1995, Hanlon et al., 1996, Shalansky et al., 1996, Coleman et al., 1999, March et al., 1999, Mackie et al., 1999, Catellier et al., 2000, Ellis et al., 2000, Lowe et al., 2000, Bernsten et al., 2001, Coleman et al., 2001, Grymonpre et al., 2001, Jameson and VanNoord, 2001, Krska et al., 2001, Volume et al., 2001, Zermansky et al., 2001, Al-Rashed et al., 2002, Sellors et al., 2003, Taylor et al., 2003, Sorensen et al., 2004, Holland et al., 2005) covered general models of pharmaceutical care over a range of settings including: hospital inpatient; general practice; outpatient; community pharmacy; and domiciliary.

## **Hospital inpatient**

Two studies were undertaken in a hospital inpatient setting with individual summary data provided in **Table 1.5**.

In 1992 an RCT was conducted in a 450 bed community hospital (Lipton et al., 1992). The aim of the study was to assess the impact of clinical pharmacists' consultation on geriatric drug prescribing. The intervention and control groups were interviewed at intake for clinical and demographic data. The intervention consisted of clinical pharmacists reviewing hospital records. The pharmacist also conducted periodic consultations with the patients to discuss their medications and potential drug-therapy problems and consulted patients' physicians when problems or potential problems related to medications were detected. The pharmacists followed patients for 3 months post-discharge (1 week post discharge, 2 to 4 weeks post discharge, 2 month post discharge and at 3 months post discharge). Most of the post discharge consultations were provided by telephone or in the pharmacist's hospital based office. The clinical pharmacists made 1046 recommendations, 59% of recommendations were minor changes, such as taking medication with or after food. The remaining 41% of recommendations were focused on major problems, which included schedule (37%), appropriateness (less-than optimal medication/no indication) (25%), dosage (21%) and omitted-but-necessary therapies (17%). It was identified that 88% of study patients had one or more clinically significant drug problems and of these 22% had a potentially serious or life threatening problem. A standardised tool was developed to evaluate the appropriateness of prescribing and an improvement demonstrated in this in the intervention group compared with control.

This was a very robust well designed RCT with a significant number of patients and was one of the earliest papers to describe categories of drug therapy problems using categories defined by Strand et al (1990). A notable limitation of the study was its failure to report outcomes of these drug therapy problems instead the authors depended on a tool to describe the appropriateness of the overall drug therapy which limits comparison with other published studies.

Shalansky et al (1996) reported a prospective cohort study conducted in two 8 week phases, a control phase and then a pharmaceutical care (PC) phase. The primary outcome was number of DTPs identified and resolved per pharmacist shift. There were more problems identified and resolved in the PC phase (626 identified, 565 resolved) compared with the control phase (492 identified and 431 resolved). The difference between the two groups was significant.

There were a number of severe limitations with this study, the first being that the PC phase patients were chosen at the pharmacist's discretion, whereas the control phase patients were not. The PC phase patients had longer hospital stays and more drugs than control phase patients. DTPs (626) reported included a very large miscellaneous group (249) not included in Strand categories for the pharmaceutical care phase. This may have inflated the numbers of DTPs found.

Table 1.5 – Summary of hospital inpatient general pharmaceutical care models

Study	Selection, recruitment and participants	Communication, interview techniques and interventions	Outcomes, results and author's conclusion	Limitations of study
Lipton et al, (1992)	<ul style="list-style-type: none"> <li>▪ Randomised controlled trial - America</li> <li>▪ Inclusion criteria: 1) ≥ 65 years ,2) insurance coverage by medcare, 3) receipt or prescription of ≥ 3 medications for a chronic condition, 4) admitted to non-psychiatric ward, 5) residence within 35 miles of the study site, 6) English speaking, 7) mentally competent, 8) access to a telephone and 9) discharge to residences other than nursing homes.</li> <li>▪ 236 patients (Intervention group 123, Control group – 113)</li> <li>▪ 3 month follow-up</li> </ul>	<ul style="list-style-type: none"> <li>▪ Both groups interviewed at intake for clinical and sociodemographic data and were given booklets at hospital discharge to record information such as purpose, dosage schedule of medicines.</li> <li>▪ Control – Standard discharge</li> <li>▪ Intervention - Clinical pharmacist review of hospital records and drug regimen, to assess appropriateness of prescribing. Periodic consultations with patient to discuss medications and potential drug-therapy problems and consulted physicians when problems or potential problems related to medications were detected. Consultations occurred with patients, pre-discharge, 1 week post-discharge, 2-4 weeks post discharge, 2 months post discharge and 3 months post discharge</li> <li>▪ A panel consisting of the principal investigator, four physicians, two clinical pharmacists and a physician chairperson determined whether the problems found were clinically significant</li> </ul>	<ul style="list-style-type: none"> <li>▪ <b>Outcomes</b> Clinical</li> <li>▪ <b>Results</b> Out of 571 consultations with 121 patients and /or physicians, 1046 recommendations were made RE patient's drug regimens. The majority, 59%(617) were related to modifying drug regimens in minor ways (e.g. taking medications with or after food) or telling patients to talk to their physician RE a particular medication concern, 41%(432) were major prescribing problems such as: schedule(37%); appropriateness (25%); dosage(21%) and omitted but necessary therapy(17%)</li> <li>▪ 88% of patients had one or more clinically significant drug therapy problems, 22% had at least one potential life threatening problem</li> <li>▪ Intervention patients less likely to have prescribing problems (p=0.05). Intervention patient's drug regimens were more appropriate than control patients (p=0.01)</li> <li>▪ <b>Author's conclusion</b> Clinical pharmacists can significantly improve the appropriateness of prescribing practices for geriatric outpatients</li> </ul>	<ul style="list-style-type: none"> <li>▪ Intensive intervention consisting of 5 consultations in 3 months limits generalisability</li> <li>▪ Short follow-up, however limited may be relevant to hospital discharge</li> <li>▪ Number of problems resolved not stated</li> <li>▪ Developed a standardised tool to measure the appropriateness of the total drug regime which limits its value when comparing outcomes with other studies reporting different outcomes</li> </ul>

Table 1.5 continued – Summary of hospital inpatient general pharmaceutical care models

Study	Selection, recruitment and participants	Communication, interview techniques and interventions	Outcomes, results and author's conclusion	Limitations of study
Shalansky et al (1996)	<ul style="list-style-type: none"> <li>▪ Prospective cohort study (two 8 week phases, control and PC phase) in Canada</li> <li>▪ Inclusion criteria: Patients resident on two general medical wards at the time of the study</li> <li>▪ Follow-up conducted during the eight week PC phase.</li> </ul>	<ul style="list-style-type: none"> <li>▪ Control phase – drug or problem specific monitoring approach was used. Problems identified through review of medication profile, lab results and computer generated clinical investigation report (allergies, drug-drug interactions) or comments regarding potential problems identified by the dispensary pharmacist. Priority was given to problems found by this method, without specifically attempting to identify all drug-therapy problems in each patient seen.</li> <li>▪ Phases separated by four month period which pharmacists learned and practiced PC</li> <li>▪ PC phase – Patient specific approach was taken to identify and resolve all existing or potential DTPs in each patient seen in addition to all activities carried out in control phase. DTPs noted along with a brief description. The decision whether or not a DRP was resolved was made after the follow-up.</li> <li>▪ One hundred problems randomly selected from each phase for cost avoidance analysis</li> </ul>	<ul style="list-style-type: none"> <li>▪ <b>Outcomes</b> Clinical and cost</li> <li>▪ <b>Results</b> There were more problems identified and resolved in the PC phase (626 identified, 565 resolved) compared with the control phase (492 identified and 431 resolved). The number of problems identified per shift was significantly higher in the PC phase (<math>8.63 \pm 5.96</math> vs <math>6.75 \pm 5.25</math>, <math>p=0.04</math>) as was the no of problems resolved (<math>7.79 \pm 5.29</math> vs <math>5.92 \pm 4.74</math> <math>p=0.025</math>). Problems involving untreated indication were more common in the PC phase</li> </ul> <p>The identified DTPs had no effect on drug-related costs</p> <ul style="list-style-type: none"> <li>▪ <b>Good points</b> <ul style="list-style-type: none"> <li>- Number of DTPs resolved measured</li> <li>▪ <b>Authors conclusions</b> Despite caring for fewer patients during the PC phase, more DTPs can be identified and resolved. Further study is required to assess whether implementing PC will result in improved patient outcomes.</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>▪ Several weeks of practicing PC before actual study period</li> <li>▪ Selection of patients followed left to discretion of pharmacist</li> <li>▪ Short duration of follow-up</li> <li>▪ Not linked to actual patient outcomes</li> <li>▪ Pharmacists selected patients with larger numbers of drug during the PC phase</li> <li>▪ DTPs (626) included a very large miscellaneous group (249) not included in Strand categorical care pharmaceutical care phase.</li> </ul>

### **General practitioner and/or outpatient clinic studies**

Ten studies were reported in general practice and/or outpatient settings with a summary of each provided in **Table 1.6**.

Lobas (1992) reported a prospective cohort study conducted in a family practice clinic over a 14 month period. The aim of the study was to assess the effect of pharmaceutical care on medication cost and quality of care.

Two pharmacists provided pharmaceutical care for 184 patients and made a total of 360 recommendations to physicians in the clinic. Of these 297 were accepted and implemented. Data was only available for the outcome of 265 of the accepted recommendations, 213 led to improvement or resolution of a drug therapy problem. 23 resulted in no substantial change in patient status, 4 patients experienced a decline in health or therapy status and 25 recommendations involved monitoring. This study is limited as there was no control group. In addition subjective measures were used to determine improvements in clinical outcome.

In 1995 (Jameson et al., 1995) an RCT was conducted in a family health centre for 6 months. The aim of the study was to evaluate if a brief in-office pharmacotherapy consultation involving a clinical pharmacist, at risk patients, and treating physicians would be associated with improved outcomes including: decreased number of medications; decreased cost of medications; decreased number of doses per day; improvement in reported side effects score; and improvement in patient understanding and compliance with their medication regimens. The pharmacist evaluated the drug regimen for a number of drug-therapy problems. The pharmacist then met with the physician to discuss the findings. One month after the intervention



the pharmacist contacted the patient by phone to reinforce the treatment plan. Physicians were blinded to the research study taking place.

A total of 56 patients were recruited into the study, 27 intervention and 29 control patients. The number of drugs, number of doses, and the 6-month cost all decreased in the intervention group and increased in the control ( $p=0.004$ ,  $0.007$  and  $0.008$ , respectively). There was no difference in the side effect score and understanding and compliance outcomes. There were many limitations to this study including small sample size and clinical outcome measures which did not relate directly to quality of care.

In 1996, (Hanlon et al., 1996) an RCT was conducted in a Veterans Affairs Medical Centre. The target patient group were 65 years old or over and were receiving  $\geq 5$  medicines. Two hundred and eight patients were randomised into intervention and control groups using a computer generated scheme. The control group received usual care while the intervention group received usual care plus clinical pharmacist care. Clinical pharmacist's interventions were in accordance to the principles of pharmaceutical care. Clinical outcomes measured were: prescribing appropriateness with the Medication Appropriateness Index (MAI); adverse drug events; medication knowledge; and compliance. Humanistic outcomes measured were: Health Related Quality of Life (HRQOL) by using the SF-36 questionnaire; patient satisfaction; and physician receptivity to the process.

Overall closeout interviews were completed for 172 (88 intervention and 84 control) of the 208 patients. Using the MAI a 24% ( $P=0.0006$ ) and 6% ( $P=0.0002$ ) improvement was seen in the inappropriate prescribing category in the active and

control groups respectively. Written recommendations were implemented more frequently for the intervention group compared to the control (55.1% v 19.8%  $P < 0.001$ ). Implementation rates were higher for the intervention group compared to the control (55.8% v 18.9%,  $P < 0.001$ ). By closeout the percentage of inappropriate ratings had decreased in seven out of ten of the MAI dimensions, while increasing in five out of the ten dimensions in the control group. There were no between group differences in HRQOL at closeout ( $P = 0.99$ ). No significant differences were found in: patient knowledge; compliance; number of medications; or satisfaction from baseline to closeout. Physicians indicated they were highly satisfied with their interactions with their pharmacist.

This study is an improvement on the previous trials in terms of carrying out the pharmaceutical care and measuring outcomes, however there were still certain limitations. This study was conducted on predominantly male veterans therefore reducing the generalisability to the whole population. The MAI used only assesses the appropriateness of the medication being taken and has not itself been linked to actual clinical outcomes. The MAI also lacks the ability to measure patient compliance and adverse drug reactions (ADRs). Hence separate instruments need to be used for these factors.

Later in 1999 (Coleman et al., 1999) an RCT involving nine primary care physician practices with 24 months follow up was conducted. The purpose of the study was to determine whether the new model of providing chronic care clinics could improve outcomes of common geriatric syndromes (urinary incontinence, falls, depressive symptoms, high risk medications, functional impairment) in frail older adults. No significant differences were found in all outcome measures.

This study may not be reproducible as the inclusion criteria was based on 'high risk' as calculated using a complex computer based predictive index and described an extremely complex multi-professional intervention. There was no documentation of DTPs, only reinforcement of compliance and checks on patient knowledge. In addition it is not generalisable as it targeted 'high risk' frail elderly patients.

Mackie et al (1999) reported a large RCT of clinical medication review involving four pharmacists and sixteen GPs located in six GP practices in Glasgow. 1,677 patients aged greater than 20 years receiving four or more drugs participated with 96% followed up at  $10 \pm 2$  months. Both intervention and control patients received the same contact with a care plan and GP referral form completed but not actioned for the control group until follow-up at 6-12 months.

The referral rate was 83% overall in both groups. In the intervention group 2064 DTPs were identified ( $2.8 \pm 2$  per patient) vs 1825 ( $2.8 \pm 2$  per patient) for the control group. 81% of DTPs in the intervention group were resolved vs 30% in the control group. Two thirds of problems were clinical DTPs (cDTP) in each group with a reduction in cDTPs of 75% in the intervention vs 25% in the control. Clinical and cost-effectiveness was demonstrated with the model being well accepted by both GPs and patients.

The author's conclusions were supported by the data. Limitations were minor given the large number of patients and included: possible contamination between the two groups by GPs receiving intervention referrals which may have influence standard care given to controls; pharmacists interviewed both active and control and may have inadvertently influenced the control group behaviour such that they consulted the GP.

Both of these would not have reduced the results observed but actually may have improved control status over that reported such that the benefits observed in this study may have been greater than the difference reported.

Ellis et al (2000) reported the results of an RCT to determine the Impact of Managed Pharmaceutical care on Resource utilisation and Outcomes in Veterans affairs medical centres (IMPROVE). Patients were selected on the basis of their risk for experiencing drug-therapy problems. The total number of patients enrolled into the intervention and control groups was, 523 and 531 respectively.

This was a very large multi-centred (n=9) well designed RCT. However it had one major limitation in that DTPs were not identified for the control group therefore no comparison could be made and this was compounded by inflated reporting of drug therapy problems in the intervention group by the inclusion of medical education which accounted for a third of all DTPs reported.

In 2001 (Zermansky et al., 2001) an RCT was conducted in four general practices over a 12 month period. The primary outcome measure was the number of changes to repeat prescriptions between baseline and the end of the study. Sample size was calculated on the secondary outcome of cost of repeat drugs.

Patients were randomised to intervention and control groups by computer generated random numbers. The intervention group patients were invited to meet the pharmacist at the practice when their next review date was due, patients without a review date attended when it was convenient. During the consultation the pharmacist discussed each condition being treated and asked about relevant symptoms. In conditions where

monitoring was due the pharmacist directed the patient to the practice nurse or doctor. The pharmacist did not physically examine the patient but noted signs which were obvious. Patients with new clinical problems were referred to the doctor. Patients in the control group continued to receive standard care from their doctor.

One thousand one hundred and thirty-one patients completed the study. The mean number of changes was significantly different in the intervention group compared to the control (2.2 vs 1.9,  $p=0.02$ ). Number of drugs and costs rose in both groups, but the rise was significantly less in the intervention group ( $p=0.0001$ ). Limitations for this study included: the same clinical pharmacist conducted all the reviews for all patients which may limit the generalisability of the study; outcome measures were all process driven with no evidence of link to clinical care.

Jameson and VanNoord (2001) conducted an RCT in primary care for a period of six months to investigate the cost and adverse effect outcomes associated with a pharmacotherapy consultation. Patients were randomised by coin toss. Intervention group patients were scheduled for an appointment at the physician's office and control patients were not exposed to the intervention. All consultations were provided by the authors which, consisted of a 45 to 60 minute face to face interview.

A total of 124 intervention and 144 control patients completed the study. There were no significant differences in the changes in medical or drug costs between the intervention and control group. However there was a significant difference in the adverse effects and symptoms score between the intervention and control groups, with more patients improving in the intervention group ( $p=0.024$ ).

There were a number of limitations present in this study, one being no sample size calculation was conducted to assess the patient numbers required to show a significant difference in the primary outcome measure. In addition there was no evidence that the outcome measures chosen had any link to actual clinical outcomes. Finally the prolonged face to face interview of up to one hour is considered impractical to implement.

Grymonpre et al (2001) conducted an RCT based in a interdisciplinary health clinic. This study targeted patients over 65 years of age, taking two or more medications. Using computer generated random number lists 135 patients were randomised into either active or control groups. A detailed home medication history (HMH) was conducted by trained staff or volunteers. Drug-related issues were identified by the pharmacist and put in a letter to the physician. Recommendations were reviewed for appropriateness by the pharmacist consultant geriatrician before forwarding to the physician. The HMH on control patients was reviewed by a different pharmacist who answered any immediate concerns and referred clients to their usual pharmacist. Drug-related issues identified were categorised by a pharmacist and a nurse using a modified unvalidated Strand system. The symptom frequency or severity between the two interview times was used to determine whether drug-related issues had been resolved, partially resolved, not resolved or outcome unknown.

Outcomes measured were: drug related issues found and resolved; the use of prescribed and non-prescribed drugs; and the presence or absence of symptoms.

All 66 active patients had at least one drug-related issue and a mean of  $14.4 \pm 4$  potential or actual issues identified. Letters were sent regarding all 66 patients and a response was received regarding 35 (53%). Partial or complete resolution was noted

for 230 (29%) of the 794 pharmacist recommendations made. There was no impact on the number of prescription medications, adherence to therapy, knowledge and purpose of medication, cost of medication, and number of symptoms reported.

This study had multiple limitations as indicated in **Table 1.6**, the most significant of which was the contamination of the control group and the amended Strand classification system which included many irrelevant process issues which inflated the number of drug therapy problems per patient. This inflated number of drug therapy problems may also be due to the reliance on a 'home medical history instrument' which was reported to be validated with seventy percent reliability when used by lay volunteers.

Sellors et al (2003) reported an RCT conducted in 24 family practices for five months to assess whether a specially trained pharmacist could reduce the number of daily medication units taken by elderly patients, as well as costs and health care use and use of other health care resources. Patients allocated to the control group received usual care from their physician. Intervention patients had a structured medication assessment by the pharmacist. After the consultation the pharmacist wrote a letter to the physician that summarised the patient's medications, identified drug therapy problems and recommended actions to resolve such problems. The pharmacist then met with the physician to discuss the recommendations. The pharmacist and physician met again 3 months later to discuss progress in implementing the recommendations. Five months after the initial visit the pharmacist then met with the physician to determine which recommendations had been put in place.

431 patients in the intervention group and 458 in the control group completed the study. There was no statistically significant difference in: the number and cost of medications; health care use and costs; and health related quality of life. At least one drug therapy problem was identified by the pharmacists in 80% (344/431) of patients in the intervention group. The most common drug therapy problem identified was the need for drug therapy. Physicians implemented or attempted to implement 72% of these recommendations and found after 5 months that only 46% of recommendations were fully implemented.

There were a number of limitations with this study. Of particular note is the fact that the outcome measures reported on utilisation of services and number and cost of drugs prescribed are not sensitive enough to take account of extent of resolution of drug therapy problems. The control group were not interviewed by the pharmacist at base-line or follow-up therefore were unable to identify drug therapy problems making it impossible to undertake meaningful comparisons between the two groups.

Taylor et al (2003) conducted an RCT to determine the effect of pharmaceutical care on the prevention, detection and resolution of DTPs in high risk patients. The study was conducted at community based physicians offices. Patients were selected if they were 18 years or older, received care at clinics and were identified as being at high risk for medication-related adverse events (3 or more of a list of 6 risk factors). Patients in the intervention group received pharmacotherapeutic interventions by the pharmacist during scheduled face to face visits. The pharmacists were specifically trained to evaluate indication, effectiveness and dosage. Clinical outcomes measured were, hypertension (BP), diabetes (HbA<sub>1c</sub>), anticoagulation (INR) and dyslipidemia



and medication appropriateness (MAI). The humanistic outcomes measured were HRQOL and patient satisfaction. No economic outcomes were measured.

The authors reported that pharmaceutical care services had reduced inappropriate prescribing, enhanced disease management and improved medication compliance and knowledge. A strength of this study is that control patients were interviewed at baseline and follow-up with the potential to compare drug therapy problems between the two groups. A severe limitation is that the authors did not make such a comparison but instead used the MAI which only assesses the appropriateness of the medication being taken. Although the MAI instrument has been validated there has been no published evidence to link the MAI score to actual clinical outcomes. Patient sample size was too small to show any significant differences for the four selected chronic diseases analysed. The same patients were counted on multiple occasions and there was no standardisation of data collection and methods employed to reduce bias. For example the authors state that blood pressure readings were taken by different people on different occasions with different equipment each time. Nevertheless despite its limitations it did have a 12 months follow-up and the potential to report on clinical drug therapy problems had the authors chosen to compare the active and control groups.

Table 1.6 – Summary of General Practitioner and Outpatient clinic general pharmaceutical care models

Study	Selection, recruitment and participants	Communication, interview techniques and interventions	Outcomes, results and author's conclusion	Limitations of study
Lobas et al (1992)	<ul style="list-style-type: none"> <li>▪ Prospective cohort study in America</li> <li>▪ Inclusion criteria one or more of the following 1) <math>\geq 5</math> medications, 2) <math>\geq 12</math> doses per day, 3) medication regimen changed <math>\geq 4</math> times in the last year, 4) <math>\geq 3</math> disease states, 5) history of medication non-compliance, 6) drugs which require therapeutic monitoring, 7) physician request for a consultation and 8) request for pharmacist consultation by a nurse or the patient or 9) the presence of an already existing therapeutic problem, such as drug interaction or therapeutic duplication</li> <li>▪ 184 patients</li> <li>▪ 14 month follow-up</li> </ul>	<ul style="list-style-type: none"> <li>▪ Intervention – pharmacist interviewed target patients at designated appointment times and obtained a medical history. They educated and counselled the patient. After the interview the pharmacist consulted with the physician and made recommendations for therapy changes, and discussed the recommendations that had been presented to the patient.</li> <li>▪ To assess the pharmacist's effect on quality of care, the researchers classified the outcome of each accepted therapeutic intervention.</li> </ul>	<ul style="list-style-type: none"> <li>▪ <b>Outcomes</b> Clinical and cost avoidance, Quality of patient care</li> <li>▪ <b>Results</b> Therapy changes were recommended for 139 patients during 256 clinic visits. During the study period, 360 pharmacist recommendations were presented to physicians in the clinic. Of these 297 were accepted and implemented by physicians. During the study period an extrapolated annual decrease in \$19,076 in medication cost was attributed to pharmacist recommendations. When taking into account pharmacist salary and other costs led to a projected saving of \$362 because of decreased medication costs.</li> <li>Quality of patient care- Data was only available for the outcome of 265 of the accepted recommendations, 213 led to improvement or resolution of a drug therapy problem,<sup>23</sup> resulted in no substantial change in patient status, 4 patients experienced a decline in health or therapy status and 25 recommendations involved monitoring.</li> <li>▪ <b>Author's conclusion</b> This study demonstrated that the provision of comprehensive pharmaceutical care can reduce costs and improve quality of care</li> </ul>	<ul style="list-style-type: none"> <li>▪ No control group</li> <li>▪ Duration of follow-up varied for all patients from 1-14 months</li> <li>▪ Uncertainty of whether study was powered for primary outcome (DTPs)</li> </ul>

Table 1.6 continued – Summary of General Practitioner and Outpatient clinic general pharmaceutical care models

Study	Selection, recruitment and participants	Communication, interview techniques and interventions	Outcomes, results and author's conclusion	Limitations of study
Jameson et al, (1995)	<ul style="list-style-type: none"> <li>▪ Randomised controlled trial in America</li> <li>▪ Inclusion criteria were two or more of the following: 1) <math>\geq 5</math> medications, 2) <math>\geq 12</math> doses per day, 3) medication regimen changed <math>\geq 4</math> times in the last year, 4) <math>\geq 3</math> disease states, 5) history of medication non-compliance, 6) drugs which require therapeutic monitoring</li> <li>▪ 56 Patients (Intervention, 27, Control, 29)</li> <li>▪ 9-12 month follow-up</li> </ul>	<ul style="list-style-type: none"> <li>▪ Control – standard patient care</li> <li>▪ Intervention – each patient given a 45-60 minute pharmacotherapy consultation by the pharmacist. Goals were to simplify, improve the effectiveness and decrease adverse effects of the medication regimen. Secondary goal was to decrease cost if possible. Patients asked to bring all drugs with them, after performing a chart review, pharmacist conducted a medication history. Evaluated the regimen for drug-therapy problems. The pharmacist then met with physician to discuss problems. New regimen was developed and the pharmacist educated the patient on the changes. One month later the patient was telephone to reinforce treatment plan. Six months after the intervention the five outcomes were measured again</li> </ul>	<ul style="list-style-type: none"> <li>▪ <b>Outcomes</b> Clinical</li> <li>▪ <b>Results</b> The number of drugs, number of doses, and the 6-month cost all decreased in the intervention group and increased in the control (p=0.004, 0.007 and 0.008 respectively). There was no difference in two other measures: the score for side effects; and 'understanding and compliance'.</li> <li>▪ <b>Author's conclusion</b> This study shows the benefits of integration of the clinical pharmacist into the primary care setting, including improvement in costs and simplification of medication regimen with no reduction in quality of care.</li> </ul>	<ul style="list-style-type: none"> <li>▪ Small sample size resulting in an underpowered study.</li> <li>▪ Some physicians cared for both groups, may have had a wash over effect.</li> <li>▪ Outcome measures used did not relate to quality of care.</li> <li>▪ The only DTP included in the outcomes measures was measurement of score for side effects.</li> </ul>

Table 1.6 continued – Summary of General Practitioner and Outpatient clinic general pharmaceutical care models

Study	Selection, recruitment and participants	Communication, interview techniques and interventions	Outcomes, results and author's conclusion	Limitations of study
Hanlon et al, (1996)	<ul style="list-style-type: none"> <li>▪ Randomised controlled trial in America</li> <li>▪ Inclusion criteria: <math>\geq 65</math> years, <math>\geq 5</math> or more medicines and received primary care at the General Medical Centre.</li> <li>▪ 208 patients (Intervention 105, Control 103).</li> <li>▪ Follow-up 12 months.</li> </ul>	<ul style="list-style-type: none"> <li>▪ Control – usual care, which consisted of clinic nurse reviewing patient's current medications before their visit, the physician visit, and a clinic nurse reviewing with patients any medications that were modified after the visit. No contact with the clinical pharmacist. Written drug therapy recommendations for control patients prepared before randomisation, were not discussed or given to their primary physician but filed for review at the end of the study.</li> <li>▪ Intervention – usual and clinical pharmacist care - review of each patient's medical record and medication list, ascertained current medication use, identification of drug-therapy problems by meeting with patients and care givers and evaluation of patients medications by applying the MAI. Formulation and prioritisation of recommendations then feedback to the physician. After the visit the pharmacist educated the patient RE DTPs and any changes, also encouraged their compliance and gave written education materials.</li> <li>▪ HRQOL measured at baseline and 12 months with SF-36.</li> </ul>	<ul style="list-style-type: none"> <li>▪ <b>Outcomes</b> Clinical and humanistic</li> <li>▪ <b>Results</b> Overall closeout interviews were completed for 172(88 intervention and 84 control) of the 208 patients. Using the MAI a 24% improvement in prescribing score was seen at 3 months in the intervention group compared with 6 % in the control (P=0.0006). These were sustained at 12 months with the 28% improvement in the intervention compared with 5% in the control(P=0.0002) Written recommendations were implemented more frequently for the intervention group compared to the control (55% v 20 % P&lt;0.001). Implementation rates were higher for the intervention group compared to the control(56% v 19% P&lt;0.001).By closeout the percentage of inappropriate ratings had decreased in seven out of ten of the MAI dimensions, while increasing in five out of the ten dimensions in the control group. No observed between group differences where found in the SF-36 at closeout. There was also no significant change in compliance or knowledge, number of medications, or patient health care satisfaction.</li> <li>▪ <b>Author's conclusion</b> Clinical pharmacists providing PC for elderly patients can reduce inappropriate prescribing and possible adverse effects without affecting HRQOL.</li> </ul>	<ul style="list-style-type: none"> <li>▪ Not generalisable – population just men and delivered by just one pharmacist.</li> <li>▪ MAI validated in cohort of 10 elderly male veterans and difficult to compare outcomes to other studies.</li> <li>▪ MAI has not been linked to patient outcomes.</li> </ul>

Table 1.6 continued – Summary of General Practitioner and Outpatient clinic general pharmaceutical care models

Study	Selection, recruitment and participants	Communication, interview techniques and interventions	Outcomes, results and author's conclusion	Limitations of study
Coleman et al, (1999)	<ul style="list-style-type: none"> <li>▪ Randomised controlled trial – nine general practices in America</li> <li>▪ Inclusion criteria: Automated data regarding age, gender, presence in system wide registries for diabetes and heart disease, history of hospitalisation or more than six outpatient visits in the prior 12 months used to obtain a chronic disease score.</li> <li>▪ 169 patients (96 intervention, 73 control)</li> <li>▪ 24 month follow-up</li> </ul>	<ul style="list-style-type: none"> <li>▪ Control group: usual care from their physician</li> <li>▪ Intervention – Frail older patients were divided into cohorts of 6-8 patients who were then invited to participate in scheduled half day visits with their primary care team every 3-4 months. Specific components of these clinics included: 1)extended 30 minute visit to the patient's physician and team nurse dedicated to develop a shared treatment plan, 2) a session with the pharmacist which lasted 15 minutes, 3) a patient self management group session which lasted 45 minutes, led by a team nurse or social worker.4) The provision of health status assessment information to the practice team at the time of the visits</li> </ul>	<ul style="list-style-type: none"> <li>▪ <b>Outcomes</b> Clinical and humanistic</li> <li>▪ <b>Results</b> At 12 and 24 months there were no significant differences in outcomes of the selected geriatric syndromes was found with the exception of urinary incontinence. At 12 month control patients were significantly experiencing more urinary incontinence (<math>P=0.04</math>), by 24 months this difference was no longer present. No significant differences were found at 12 or 24 months in terms of depressive symptoms. There were no significant differences found in satisfaction at 12 and 24 months and during the 24 month period there was no differences in the SF-36, costs or utilisation rates of health care between the two groups.</li> <li>▪ <b>Author's conclusion</b> Improved outcomes for selected geriatric syndromes were not demonstrated. Findings suggest the need for developing greater system-wide support for managing geriatric syndromes in primary care</li> </ul>	<ul style="list-style-type: none"> <li>▪ Underpowered</li> <li>▪ Randomisation by practice and not patient</li> <li>▪ Not generalisable to the whole elderly population as targeted frail elderly</li> <li>▪ No documentation if problems found with patients medicines.</li> <li>▪ DTPs not documented or followed up</li> <li>▪ Complex inclusion criteria limits reproducibility of study</li> </ul>

Table 1.6 continued – Summary of General Practitioner and Outpatient clinic general pharmaceutical care models

Study	Selection, recruitment and participants	Communication, intervention techniques and interventions	Outcomes, results and author's conclusion	Limitations of study
Mackie et al (1999)	<ul style="list-style-type: none"> <li>▪ Randomised controlled trial in six randomly selected GP practices in Glasgow with randomisation by patient</li> <li>▪ Pharmaceutical care provided by four self-selecting community pharmacists</li> <li>▪ Inclusion criteria: <math>\geq 20</math> year <math>\geq 4</math> repeat medicines and not in care</li> <li>▪ 1677 patients (921 intervention, 877 (95%) completing study at 10<math>\pm</math>2 months, and 756 control with 726 (96%) completing the study at 10<math>\pm</math>2 months</li> <li>▪ Intention to treat analysis</li> </ul>	<ul style="list-style-type: none"> <li>▪ Intervention group: received clinical medication review, defined as 'a review of the patient, their chronic condition(s) and their repeat medicines during a consultation'. Semi-structured interview with pharmaceutical care plan and GP referral as appropriate. Pharmacists implemented agreed changes and then follow-up at 6-12 months.</li> <li>▪ Control group: Exact method repeated as for intervention except that Care plan was not actioned and GP referral written but stored until end of study. GP referral made (if still appropriate) at 6-12 month follow-up.</li> </ul>	<ul style="list-style-type: none"> <li>▪ <b>Outcomes</b> Clinical, Humanistic and Economic</li> <li>▪ <b>Results</b> Primary outcome: 81% reduction in DTPs in the intervention groups vs 30% in the control group. Figures for clinical DTPs were 75% resolution in the intervention vs 25% in the control. Secondary outcome measures: there was a reduction of 0.5 medicines in the intervention vs no change in the control – not considered clinically significant for patients with a mean of six drugs. With no difference in use of other health care services.</li> <li>▪ Of 1276 intervention referrals only 5% rejected by GP and 2% rejected by patients, considered major and significant finding. Patient satisfaction confirmed with 91% happy with changes made. There were 16 GPs with high expectations all of which confirmed met despite the high referral rate of 80%.</li> <li>▪ The cost per patient of £21 pounds was offset by savings in drug costs in £65 per patient per year. There were also indirect benefits of £500,000 due to changes in patterns of prescribing in the practices during the study period.</li> <li>▪ <b>Authors conclusion</b> First randomised controlled trial of medication review in primary care, clinical and cost-effectiveness was demonstrated in comparison to standard GP care. This service was well accepted by both patients and GP as reflected in high satisfaction expressed.</li> </ul>	<ul style="list-style-type: none"> <li>▪ Randomisation based on patient rather than practice, may have led to contamination such that difference between two groups is actually greater than observed.</li> <li>▪ Bias was kept to a minimum with generator and executor of assignment independent but pharmacists could not be blinded but may have influenced control patient during interview</li> <li>▪ DTPs 12% linked to compliance were based on self report (149 intervention vs 145 control)</li> <li>▪ Categorisation of DTPs, potential source of bias</li> <li>▪ 1677 patients but only represents 55% of eligible patients in the six practices, limits generalisability</li> <li>▪ Three pharmacists were perhaps atypical community pharmacists – leading edge practitioners</li> </ul>

**Table 1.6 continued – Summary of General Practitioner and Outpatient clinic general pharmaceutical care models**

Study	Selection, recruitment and participants	Communication, interview techniques and interventions	Outcomes, results and author's conclusion	Limitations of study
Ellis et al, (2000)	<ul style="list-style-type: none"> <li>▪ Randomised Controlled Trial – Multi centre</li> <li>▪ 9 Veterans Affairs Medical Centres in America</li> <li>▪ Inclusion criteria if participants met three or more of the following : 1) <math>\geq 5</math> medications, 2) <math>\geq 12</math> doses per day, 3) medication regimen changed <math>\geq 4</math> times in the last year, 4) <math>\geq 3</math> disease states, 5) history of medication non-compliance, 6) drugs which require therapeutic monitoring 7) Must have been a VAMC patient for at least 12 months 8) expected to receive care for the duration of the study 9) live reasonably close to the centre</li> <li>▪ 1054 patients (523 intervention, 531 control)</li> <li>▪ 12 months follow-up</li> </ul>	<ul style="list-style-type: none"> <li>▪ Control group: usual medical care receive care from their primary care clinic without any interventions</li> <li>▪ Intervention group: scheduled for drug assessments in addition to receive their usual medical care. Pharmacists responsible for making appropriate adjustments in patients drug regimens to improve care and disease control and identify and prevent drug-therapy problems. Pharmacists continued to follow patients and monitor response until predetermined outcome goals were achieved. Pharmacists determined the frequency of follow-up appointments. The protocol stated they should see patients at least 3 times : baseline, 6 months and 12 months</li> </ul>	<ul style="list-style-type: none"> <li>▪ <b>Outcomes</b> Clinical, humanistic, economic</li> <li>▪ <b>Results</b> Pharmacists documented 3048 interventions for DTPs, 2109(69%) of which were deemed to have been resolved. The top five problems were, patients who required medication education (996, 93.6% resolved), Needs a drug but not receiving it (487, 63% resolved), Not taking drug as prescribed(436, 54.6% resolved), taking too little of correct drug(346, 57.2% resolved) and experiencing adverse event (225, 58.2% resolved).</li> <li>There was no difference seen between groups in the satisfaction scores. Resource utilisation increased in both groups throughout the study. The mean increase in costs from year 1 to year 2 was \$1020 in the intervention group and \$1313 in the control group. There were no significant differences between groups for the costs of medications or hospitalisations. There was no significant difference in HRQOL from baseline to follow-up.</li> <li>▪ <b>Author's conclusion</b> The study describes an efficient method to document interventions made by pharmacists and may be a benchmark for the interventions that may be made.</li> </ul>	<ul style="list-style-type: none"> <li>▪ Predominantly male population – not generalisable</li> <li>▪ Medical education accounts for 1/3 of DTPs which may inflate reported rate of 3 per patient</li> <li>▪ The costs calculated were drawn from only one of the VAMC sites, when in actual fact there were nine which took part in the overall study.</li> </ul>

**Table 1.6 continued – Summary of General Practitioner and Outpatient clinic general pharmaceutical care models**

Study	Selection, recruitment and participants	Communication, interview techniques and interventions	Outcomes, results and author's conclusion	Limitations of study
Grymonpre et al (2001)	<ul style="list-style-type: none"> <li>▪ Randomised controlled trial in Canada – community health clinic</li> <li>▪ Inclusion criteria:               <ul style="list-style-type: none"> <li>- ≥65 years, non institutionalised, taking ≥2 prescribed or non prescribed medications and willing to provide signed informed consent</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>▪ Intervention group: A detailed medication history) was conducted by trained staff or volunteers. Drug related issues were identified by a pharmacist and peer reviewed by a consultant pharmacist geriatrician and put in a letter to the physician. The pharmacist then met with patients as required for follow-up to monitor specific therapeutic endpoints and to identify and resolve other issues as they arose. Drug-related issues identified were categorised by a pharmacist and a nurse with a modified Strand system. The symptom frequency or severity between the two interview times was used to determine whether drug-related issues had been resolved, partially resolved, not resolved or, “outcome unknown”.</li> </ul>	<ul style="list-style-type: none"> <li>▪ <b>Outcomes</b> Specific process measures</li> <li>▪ <b>Results</b> All 66 active patients had a mean of 14.4±4 potential or actual issues identified. Common issues included adverse drug reactions (197), need for prevention strategy (138) and improper storage of medication (76). Partial or complete resolution was noted for 230(29%) of the 794 pharmacist recommendations made. At follow-up a greater mean number of non-prescribed drugs were discontinued in the test group (<math>p&lt;0.04</math>) and the mean number of hoarded drugs decreased for both test and control groups (<math>P&lt;0.02</math>). There was no impact on the number of prescription medications, adherence to therapy, knowledge and purpose of medication, cost of medication, and number of symptoms reported. Physician satisfaction was not reported. There was no difference noted between groups at baseline in costs. They concluded that this PC model did not have a significant impact on outcome measures.</li> </ul>	<ul style="list-style-type: none"> <li>▪ Lack of reproducibility of medicine history at baseline and follow-up</li> <li>▪ HMM instrument used by lay volunteers with three hours training</li> <li>▪ Small sample size, study may have been underpowered to measure clinical outcomes</li> <li>▪ The amended Strand classification system clearly lost sensitivity as a mean of 14 drug therapy problems detected per patient.</li> </ul>
	<ul style="list-style-type: none"> <li>▪ 135 patients (69 intervention, 66 control)</li> <li>▪ 6 months follow-up</li> </ul>	<ul style="list-style-type: none"> <li>▪ Control group: A detailed history was taken by a different pharmacist who answered any immediate concerns and removed patients with life-threatening problems from the study. Six months after the intervention the detailed history was repeated by a blinded trained volunteer.</li> </ul>	<ul style="list-style-type: none"> <li>▪ <b>Author's conclusion</b> The pharmaceutical care model did not impact significantly on process outcome measures. Collaboration between physicians, patients and pharmacists will need to improve before the full benefits of Pharmaceutical care can be realised</li> </ul>	<ul style="list-style-type: none"> <li>▪ Pharmacist addressed immediate concerns of the control group – contamination</li> <li>▪ Authors conclusions not supported by the data as 94% of physicians agreed with at least one recommendation</li> </ul>



Table 1.6 continued – Summary of General Practitioner and Outpatient clinic general pharmaceutical care models

Study	Selection, recruitment and participants	Communication, interview techniques and interventions	Outcomes, results and author's conclusion	Limitations of study
Jameson and VanNoord, (2001)	<ul style="list-style-type: none"> <li>▪ Randomised controlled trial – Primary care in America</li> <li>▪ Inclusion criteria: - <math>\geq 50</math> total prescriptions filled in the preceding year. Primary care physician was participating, they were covered by one of the two Health Maintenance Organisations, and they had evidence of polypharmacy (<math>\geq 5</math> medicines).</li> <li>▪ 340 patients (179 intervention, 161 control)</li> <li>▪ 6 months follow-up</li> </ul>	<ul style="list-style-type: none"> <li>▪ Control group: followed without intervention</li> <li>▪ Intervention group: All consultations were provided by the authors, this consisted of a 45 to 60 minute face to face interview. The patients understanding of his or her medications, compliance, and disease state control was assessed. Drug-therapy problems were identified and the pharmacist met with the physician to discuss the findings and recommendations. The most appropriate course of action was decided by the physician. The pharmacist then met with the patient and explained any changes.</li> </ul>	<ul style="list-style-type: none"> <li>▪ <b>Outcomes</b> Clinical and humanistic</li> <li>▪ <b>Results</b> A total of 124 intervention and 144 control patients completed the study. There were no significant differences demonstrated in the changes in medical or drug costs between the intervention and control group. There was a significant difference in the adverse effects and symptoms score between the intervention and control groups, with more patients improving in the intervention group (<math>p=0.024</math>).</li> <li>▪ <b>Author's conclusion</b> Interpersonal relationship remains critical to the provision of pharmaceutical care. There are numerous difficulties in measuring the benefits of these interventions. Future studies should focus on patients with limited, specific problems or on interventions with narrow goals</li> </ul>	<ul style="list-style-type: none"> <li>▪ Used patient self report for data on if problems found were resolved or not.</li> <li>▪ Forty-five to sixty minute interview which is not generalisable to practice</li> <li>▪ Outcome measures are process driven apart from adverse effects and symptoms score, with no evidence of link to clinical outcomes</li> </ul>

Table 1.6 continued – Summary of General Practitioner and Outpatient clinic general pharmaceutical care models

Study	Selection, recruitment and participants	Communication, interview techniques and interventions	Outcomes, results and author's conclusion	Limitations of study
Zermansky et al, (2001)	<ul style="list-style-type: none"> <li>▪ Randomised Controlled Trial in the UK</li> <li>▪ Four general medical practices</li> <li>▪ Inclusion criteria: <math>\geq 65</math> years and <math>\geq 1</math> medicine</li> <li>▪ 1188 patients (608 intervention, 580 control)</li> <li>▪ 12 months follow-up</li> </ul>	<ul style="list-style-type: none"> <li>▪ Control group: normal care from their doctor, patients recalled for review of treatment by the general practitioner according to normal custom in the practice</li> <li>▪ Intervention group: clinical review by pharmacist, were invited to meet the pharmacist at the practice when their next review date was due, patients without a review date attended when it was convenient. During the consultation the pharmacist discussed each condition being treated and asked about relevant symptoms. In conditions where monitoring was due the pharmacist directed the patient to the practice nurse or doctor. The pharmacist did not physically examine the patient but noted signs which were obvious. Patients with new clinical problems were referred to the doctor.</li> </ul>	<ul style="list-style-type: none"> <li>▪ <b>Outcomes</b> Clinical</li> <li>▪ <b>Results</b> One thousand one hundred and thirty-one patients completed the study. The mean number of changes was significantly different in the intervention group compared to in the control (2.2 vs 1.9, <math>p=0.02</math>). Numbers and costs rose in both groups, but the rise was significantly less in the intervention group (<math>p=0.0001</math>). Seventy-five percent of patients had one or more changes made in the active group vs seventy-two percent in the control group</li> <li>▪ <b>Author's conclusion</b> A clinical pharmacist can conduct effective consultations with elderly patients in general practice to review drugs. Such review results in significant changes in patient's drugs and saves more than the cost of the intervention without affecting the workload of general practitioners.</li> </ul>	<ul style="list-style-type: none"> <li>▪ Only one pharmacist in four practices</li> <li>▪ Outcome measures were very process driven and no clinical outcomes were listed</li> <li>▪ The authors have assumed that intervention by pharmacist was positive if patient did not subsequently consult with GP</li> </ul>

Table 1.6 continued – Summary of General Practitioner and Outpatient clinic general pharmaceutical care models

Study	Selection, recruitment and participants	Communication, interview techniques and interventions	Outcomes, results and author's conclusion	Limitations of study
Sellors et al (2003)	<ul style="list-style-type: none"> <li>▪ Randomised controlled trial in family practices in Canada</li> <li>▪ Inclusion criteria: <math>\geq 65</math> years, <math>\geq 5</math> medications, seen by the physician within the last 12 months, had no evidence of cognitive impairment and could understand English</li> <li>▪ 889 patients - 70% completed the study (431 intervention, 458 control)</li> <li>▪ 5 months follow-up</li> </ul>	<ul style="list-style-type: none"> <li>▪ Control group: usual care from their physician.</li> <li>▪ Intervention group: structured medication assessment by the pharmacist, after the interview the pharmacist wrote a consultation letter to the physician that summarised the patient's medications, identified drug-therapy problems and recommended actions to resolve such problems.</li> <li>▪ The pharmacist then met with the physician to discuss the recommendations in the intervention group. The pharmacist and physician met again 3 months later to discuss progress in implementing recommendations. Five months after the initial visit the pharmacist then met with the physician to determine which recommendations had been put in place. One and three months after meeting with the physician, the pharmacist monitored each patient's drug therapy using a semi-structured telephone interview with the patient.</li> </ul>	<ul style="list-style-type: none"> <li>▪ <b>Outcomes</b> Clinical and humanistic</li> <li>▪ <b>Results</b> Four hundred and thirty one patients in the intervention group and 458 in the control group completed the study. At least one drug-therapy problem was identified by the pharmacists in 80% (344/431) of patients in the intervention group. The most common drug-related problem identified was need for drug therapy. After 5 months 46% of recommendations were fully implemented, 9.3% were partially implemented and 17% of recommendations were implemented but were not successful. There was no significant differences found in the number and cost of medications, health care use and cost or health related quality of life.</li> <li>▪ <b>Author's conclusion</b> Although no improvements were found, this study demonstrated the feasibility and acceptability of a collaborative relationship between family physicians and local, specially trained pharmacists</li> </ul>	<ul style="list-style-type: none"> <li>▪ Pharmacists did not interview control patients to determine drug-therapy problems at base-line or follow-up – no useful comparison therefore made between the two groups</li> <li>▪ Outcome measures actually used were very process driven given the very short follow-up</li> <li>▪ Most common drug therapy problem was need for drug therapy yet cost and number of medicines was an outcome measure, likely to have gone up in some patients and down in others. DTPs would have been a much more sensitive instrument</li> </ul>

Table 1.6 continued – Summary of General Practitioner and Outpatient clinic general pharmaceutical care models

Study	Selection, recruitment and participants	Communication, interview techniques and interventions	Outcomes, results and author's conclusion	Limitations of study
Taylor et al (2003)	<ul style="list-style-type: none"> <li>▪ Randomised controlled trial in community based physician offices in America</li> <li>▪ Inclusion criteria: <math>\geq 18</math> years and had been identified as at high risk for medication-related adverse events and had three or more of the following 1) <math>\geq 5</math> medications, 2) <math>\geq 12</math> doses per day, 3) medication regimen changed <math>\geq 4</math> times in the last year, 4) <math>\geq 3</math> disease states, 5) history of medication non-compliance, 6) drugs which require therapeutic monitoring)</li> <li>▪ 69 patients (33 intervention, 36 control)</li> <li>▪ 12 months follow-up</li> </ul>	<ul style="list-style-type: none"> <li>▪ Control group: Standard medical care - medical record review and patient interviews at baseline and one year later</li> <li>▪ Intervention group: standard medical care plus pharmaceutical care (pharmacotherapeutic interventions by pharmacist during regularly scheduled visits. Patient met with pharmacist for 20 minutes before seeing the physician. The pharmacist reviewed the medical record for medication-related problems, conducted a chart review to ensure information on drug therapy and allergies was accurately documented. Examined the medication history to determine compliance with and complications of medications. Provided an individualised patient education that included a brief review of the disease, important lifestyle modifications and basic drug information. Recommendations communicated through discussions of progress notes. Pharmacist also provided disease information during the follow-up visits and answered patient's questions.</li> </ul>	<ul style="list-style-type: none"> <li>▪ <b>Outcomes</b> Clinical – selected therapeutic areas</li> <li>▪ <b>Results</b> Hypertension – At 12 months the intervention group patients were significantly more likely than control patients to have targeted blood pressures (<math>p=0.001</math>). Diabetes – The percentage of patients meeting their HbA1c goals at 12 months was significantly higher in the intervention group compared with control (<math>p=0.001</math>). Dyslipidemia - the intervention group had a dramatic improvement in LDL cholesterol at 12 months (<math>p=0.001</math>), while the percentage in the control group actually declined. Prescribing appropriateness - The percentage of inappropriate medications decreased in all 10 MAI domains in the intervention group and increased in 5 domains in the control group. No severe medication misadventures were reported. Medication compliance scores improved in the intervention group but not in the control. Medication knowledge also improved in the intervention group. There were no significant difference in HRQOL</li> <li>▪ <b>Author's conclusion</b> Pharmaceutical care in a rural, community based setting appeared to reduce inappropriate prescribing, enhance disease management, and improve medication compliance and knowledge without adversely affecting HRQOL</li> </ul>	<ul style="list-style-type: none"> <li>▪ Small sample size and multiple counting of patients across the three clinical areas reported therefore difficult to interpret actual clinical significance although trend is observed for improvement</li> <li>▪ Clinical measures used were not standardized to reduce bias</li> <li>▪ MAI not linked to clinical outcomes in any study</li> <li>▪ Resolution of individual drug therapy problems was not documented</li> </ul>

### **Community pharmacy setting**

Four papers were located on general pharmaceutical care models in community pharmacy, each of these is summarised in **Table 1.7**.

In 1999 a prospective cohort study was conducted in five community pharmacies in Australia to evaluate a medication management service (March et al., 1999). Evaluation measures included: the number of medication related problems identified and resolved by the pharmacists; acceptability of the service to consumers and medical practitioners; and assessment of the cost benefit of the service.

The study lasted 11 months and recruited 205 patients from the five pharmacies. This consisted of 50 male and 155 female participants. 26 patients were found to have no problems. In the remaining 179 patients a total of 526 drug therapy problems were identified: need for additional therapy (87); unnecessary drugs (40); wrong / inappropriate drug (30); wrong / inappropriate dose (78); adverse drug reaction (73); compliance (171); drugs out of date (21) and advice on lifestyle or general management issues (26). Two thirds of problems were managed by the pharmacist. The other third of problems involved direct contact with or referral to another health professional. There was an average of 3.4 consultations per patient, with an average duration of 38 minutes. An outcome was recorded for 432 problems and 75% of problems were deemed resolved. The average net saving per patient per year was reported as \$A40 to \$A311.

This study had a number of limitations, the most important of which was the absence of a control group for comparison over the 11 month period of the study. The authors

have assumed that all of the observed changes are due to the intervention rather than standard care.

A prospective cohort study evaluated the benefits of community pharmacist medication reviews (PHARMAssist programme) targeted to elderly patients (Catellier et al., 2000). A total of 121 patients completed the study at 12 months. The improvement in knowledge of medication purpose was statistically significant ( $p < 0.001$ ). There were no significant changes in adherence to medication or adverse drug reactions. The numbers of emergency room (ER) visits and hospital admissions did not decrease significantly although there was a decreasing trend.

There were severe limitations with this study. There was an absence of a control group for comparison over the 12 month period of the study therefore the observed trend of a decrease in ER visits and hospital admissions may have been due to seasonal variation within the 12 month cycle.

In 2001 a multicentre RCT was conducted in seven European countries (Bernsten et al., 2001). The aim of the study was to investigate the impact of a coordinated community pharmacy based pharmaceutical care program (PCP) for elderly patients on a range of health and economic outcomes. Pharmacies acted as the unit of randomisation. Pharmacists at the intervention sites were given training to provide pharmaceutical care. They actively assessed patients individually to identify actual and potential drug therapy problems, and formulated an intervention and monitoring plan if required. This 18 month study was completed in 5 out of the 7 countries with 45% of patients dropping out. The PCP implemented did not appear to have any effect on medication knowledge, usage of medicines or contact with GPs. The general

opinion of the PCP overall was that the intervention patients had a positive view, with 75% of patients reporting that it was better than the service received previously.

This study had some major flaws, patient contact was not necessarily made with all patients to identify the DTPs and those identified were not reported. There was a lack of robustness in the outcomes that were stated for example medicines changes and compliance were self reported leading to an enormous potential for bias. The patient numbers were underpowered for a multi-centred, multi-country study such as this therefore no conclusions can be drawn.

AN RCT with 13 months follow up was conducted in sixteen community pharmacies in Alberta, Canada (Volume et al., 2001). The aim of this study was to measure patient's adherence to therapy, expectations, satisfaction with pharmacy services and HRQOL after provision of pharmaceutical care. Once measured these factors were compared with those patients who received traditional pharmacy services. Eight pharmacies were randomised into each of the intervention and control groups. Intervention pharmacists provided pharmaceutical care and used the Pharmacist's Management of Drug therapy problems (PMDRP) instrument to summarise information collected during the patient interview and note information about patient follow up. Control pharmacies continued to provide usual care.

There was 159 intervention and 204 control patients recruited into the study. There were no significant differences detected in HRQOL in either group at the end of the study. The pharmacists documented 559 potential or actual drug therapy problems for 145 patients in the intervention group. The type, frequency, number resolved and number of outstanding problems were not reported.

This study had a number of severe limitations, the types of pharmacies and pharmacists may not have been representative of the whole population as they were potentially signing up for an extensive 16 month training programme. The number of DTPs identified included potential problems which may have over inflated the number reported. In addition 134 of the DTPs were linked to requirements for vaccination which may have further inflated overall DTPs reported. A major flaw in the study design was the failure to record DTPs in the control group at baseline and follow-up such that the 40% reduction in DTPs in the intervention group is not interpretable.



Table 1.7 – Summary of Community pharmacy general pharmaceutical care models

Study	Selection, recruitment and participants	Communication, interview techniques and interventions	Outcomes, results and author's conclusion	Limitations of study
March et al (1999)	<ul style="list-style-type: none"> <li>▪ Prospective cohort study in 5 community pharmacies in Australia</li> <li>▪ Inclusion criteria: <math>\geq 18</math> years, able to understand and consent to the service, and had one or more of the following : <math>\geq 3</math> medications, using a medication of low therapeutic index, confused about their medication, displaying possible drug-related adverse effects, living alone and solely responsible for their own medications, disabled and their disability might interfere with their ability to use medications effectively, recently or frequently admitted to hospital</li> <li>▪ 205 patients (55 male and 150 female)</li> <li>▪ 11 month follow-up</li> </ul>	<ul style="list-style-type: none"> <li>▪ Intervention group: an initial patient interview with the pharmacist, assessment of the patient's medication related issues, planning and implementation of interventions, patient follow-up and recording of the patient consultation on a common documentation proforma. Where identified problems could not be dealt with directly, the pharmacist would contact the patient's physician. Clinical pharmacists acted as mentors for the pharmacists involved and reviewed the case notes from the pharmacist/patient consultation and provided a critical review of any therapeutic issues that arose. They also helped pharmacists prepare comments to be relayed to the general practitioner.</li> </ul>	<ul style="list-style-type: none"> <li>▪ <b>Outcomes</b> Clinical, humanistic and economic</li> <li>▪ <b>Results</b> Twenty six patients were found to have no problems. In the remaining 179 patients a total of 526 medication related problems were identified: Need for additional therapy, 87; Unnecessary drugs, 40; Wrong/inappropriate drug, 30; Wrong/inappropriate dose, 78; Adverse drug reaction, 73; compliance, 171; Drugs out of date, 21 and advice on lifestyle or general management issues, 26 problems. Two thirds of problems were managed by the pharmacist. The other third of problems involved direct contact with or referral to another health professional. There was an average of 3.4 consultations per patient, with an average time of 38 minutes per consultation. An outcome was recorded for 432 problems (82%) and 75% of problems were deemed resolved. The average net saving per patient per year was \$A40 to \$A311.</li> <li>▪ <b>Author's conclusion</b> Pharmacists were able to apply the principles of pharmaceutical care to meet the need of at-risk consumers in the community.</li> </ul>	<ul style="list-style-type: none"> <li>▪ No control group – the model assumes all changes are due to the intervention rather than standard care, this is a major limitation of this study</li> <li>▪ Peer review of all patient encounters and recommendations limits generalisation</li> <li>▪ Several categories of problems are not DTPs for example lifestyle and compliance. Whilst non-compliance is a DTP, compliance issues are not.</li> <li>▪ Volunteer pharmacies also limits generalisation</li> <li>▪ Predominantly female population recruited limits application in practice</li> </ul>

Table 1.7 continued – Summary of Community pharmacy general pharmaceutical care models

Study	Selection, recruitment and participants	Communication, interview techniques and interventions	Outcomes, results and author's conclusion	Limitations of study
Catellier et al (2000)	<ul style="list-style-type: none"> <li>▪ Prospective cohort study in America</li> <li>▪ Inclusion criteria: income &lt; 140% of the federal poverty level, did not have private prescription coverage insurance and were not eligible for medicaid, which pays for prescriptions.</li> <li>▪ 127 patients</li> <li>▪ 12 months follow-up</li> </ul>	<p>Intervention: Patients were seen at PHARM Assist offices or in their homes every six months. Review sessions covered medication-related information, screening for drug interactions. A medication record was also created for the patient to be shared with other health care providers. Each client was asked to demonstrate administration techniques for medication inhalers, eye drops etc. If needed the pharmacist would model proper technique. Prescribers and pharmacists were contacted if any changes in medication were required.</p>	<ul style="list-style-type: none"> <li>▪ <b>Outcomes</b> Clinical and humanistic</li> <li>▪ <b>Results</b> The improvement in knowledge of medication purpose was statistically significant (<math>p &lt; 0.001</math>). There were no significant changes in adherence to medication or adverse drug reactions. The numbers of ER visits and hospital admissions did not decrease significantly although a decreasing trend was observed.</li> <li>▪ <b>Author's conclusion</b> The evaluation of this program shows a decrease in ER use and hospitalisations one year after enrolment</li> </ul>	<ul style="list-style-type: none"> <li>▪ No control group– the model assumes all changes are due to the intervention rather than standard care, this is a major limitation of this study</li> <li>▪ Only clinical outcome related to ADRs those reported are process</li> <li>▪ Self report of patient compliance, hospital visits, adverse medication effects, no control of bias</li> <li>▪ Author's conclusions not supported by the data, a trend was observed only over the period of the study. The lack of a control group makes it difficult to interpret this non-significant outcome.</li> </ul>

Table 1.7 continued – Summary of Community pharmacy general pharmaceutical care models

Study	Selection, recruitment and participants	Communication, interview techniques and interventions	Outcomes, results and author's conclusion	Limitations of study
Bernsten et al (2001)	<ul style="list-style-type: none"> <li>▪ Randomised controlled trial over seven European countries</li> <li>- Denmark</li> <li>- Germany</li> <li>- The Netherlands</li> <li>- Northern Ireland</li> <li>- Portugal</li> <li>- Republic of Ireland</li> <li>- Sweden</li> </ul> <ul style="list-style-type: none"> <li>▪ Inclusion criteria: <math>\geq 65</math> years, <math>\geq 4</math> medications and orientated with respect to self, time and place</li> </ul> <ul style="list-style-type: none"> <li>▪ 2450 patients (1290 intervention, 1164 control)</li> <li>▪ 18-24 months follow-up</li> </ul>	<ul style="list-style-type: none"> <li>▪ Control group: usual pharmacy care</li> <li>▪ Intervention group: actively assess patients individually and to identify actual and potential drug-therapy problems (DTPs) using a structured approach.</li> <li>▪ This 18 month study was completed in 5 out of the 7 countries, only 6 months of data was collected in the Republic of Ireland. In Portugal the study ended in 12 months instead of 18, in the Netherlands the study lasted for 24 months, data at 24 months being treated as 18 months data.</li> </ul>	<ul style="list-style-type: none"> <li>▪ <b>Outcomes</b> Clinical, humanistic, economic</li> <li>▪ <b>Results</b> Intervention patients agreed that they controlled their medical conditions better during the study. The Pharmaceutical Care Programme (PCP) implemented did not appear to have any effect on medication knowledge, usage of medicines or contact with GPs. In the pooled data there were no significant differences in the domains between the control and intervention patients over time for HRQOL. 75% of patients reported that PCP was better than the service received previously. Between group-analysis indicated that there were no significant differences between total costs for control and intervention patients.</li> <li>▪ <b>Author's conclusion</b> The results indicate that the pharmaceutical care program had some positive effects on humanistic health outcomes, but less impact than anticipated on drug therapy, knowledge and compliance with medication.</li> </ul>	<ul style="list-style-type: none"> <li>▪ Small sample size for a multi-centered, multi-country study</li> <li>▪ Possible bias as medicine changes and compliance were self reported.</li> <li>▪ Large dropouts - 45% dropout at 18 months</li> <li>▪ Lack of robust clinical outcome measures, DTPs not reported</li> <li>▪ Training of the pharmacists not consistent amongst countries</li> <li>▪ Countries health care systems not comparable</li> </ul>

Table 1.7 continued – Summary of Community pharmacy general pharmaceutical care models

Study	Selection, recruitment and participants	Communication, interview techniques and interventions	Outcomes, results and author's conclusion	Limitations of study
Volume et al (2001)	<ul style="list-style-type: none"> <li>▪ Randomised controlled trial in sixteen pharmacies in America (8 intervention and 8 control pharmacies).</li> <li>▪ Inclusion criteria: <math>\geq 65</math> years of age, <math>\geq 3</math> medications, able to complete telephone interviews, residing in Alberta for 12 of the 15 months, agreeable to receiving prescription medications only from the study pharmacy during the study period, willing to provide informed consent.</li> <li>▪ 363 patients (159 intervention, 204 control)</li> <li>▪ 12 months follow-up</li> </ul>	<ul style="list-style-type: none"> <li>▪ Control group: continued to receive standard care as they had before the study</li> <li>▪ Intervention group: 30-45 minute interviews using the Pharmacist's Management of Drug-therapy problems (PMDRP) instrument to summarise information collected during patient interview. DTPs identified were then ranked according to importance. Pharmacists then developed an initial subjective, objective assessment plan (SOAP) and follow-up SOAP for every intervention made.</li> </ul>	<ul style="list-style-type: none"> <li>▪ <b>Outcomes</b> Clinical and humanistic</li> <li>▪ <b>Results</b> 559 actual and potential DTPs identified, 39% of DTPs were actual and 60% potential and just over 1% were not labelled, average of 3.9<math>\pm</math>3.2 problems per patient. Need for flu and or pneumococcal vaccinations were a common DTP, making up 24% of all DTPs. At follow-up 40% of all 559 DTPs were resolved, controlled or improved according to the follow-up notes, 40% of all DTPs lacked any follow-up and the status of these DTPs could not be established</li> <li>▪ <b>Good Points</b> <ul style="list-style-type: none"> <li>- Randomised design</li> <li>- Measurement of drug therapy problems</li> </ul> </li> <li>▪ <b>Author's conclusion</b> Demonstrate that community pharmacists using a comprehensive and systemic approach to patient care can identify greater numbers of DTPs than previously reported in observational studies</li> </ul>	<ul style="list-style-type: none"> <li>▪ Potential Drug therapy problems measured, accounted for 60% may have inflated numbers of problems found</li> <li>▪ Pharmacists chose the patients may have introduced bias</li> <li>▪ Not generalisable, pharmacists in this study had an intensive training program (16 months)</li> <li>▪ Drug therapy problems not measured in the control group for comparison – 40% resolved or improved in the active group against x%? in control group, we cannot prove that the resolution was due to the intervention</li> <li>▪ 134 (24%) of all DTPs linked to requirement for vaccination, may explain authors conclusion.</li> </ul>

## **Domiciliary Setting**

Six papers were located on general pharmaceutical care models in community pharmacy, a summary of each are provided in **Table 1.8**.

Lowe et al (2000) reported an RCT conducted to determine whether a 'medicine review and education programme' influenced the compliance and knowledge of older people in a single general practice. Patients were randomly allocated to the intervention and control groups. In the intervention group at baseline their medication was rationalised in conjunction with the patient's doctor as appropriate. Control group patients were asked what medication they took and their understanding of the medicine explored with no attempt to rationalise therapy. 73 patients in the intervention group and 79 control patients completed the study. The mean compliance score for intervention patients was 91% and 80% in the control ( $p < 0.0001$ ). The overall change in knowledge over the three visits was highly significant between the intervention and control groups ( $p = 0.0001$ ).

There were a number of limitations in the study design. In the intervention group 47% of patients had a change to their medication, however the number of problems identified were not documented with no outcomes reported. The authors concluded that a 'medication review and education programme could be a practical and cost-effective method of helping older people manage their medicines'. Unfortunately no evidence was presented to support this conclusion. Firstly compliance rates were reported as 91% and 80% respectively in the intervention and control groups but no association was made between these compliance rates and clinical outcomes. Secondly knowledge was reported as 88% vs 70% respectively in the intervention and control groups and considered to be highly statistically significant. Once again no

evidence was provided to support a correlation between knowledge and improved clinical outcomes.

In 2001 a prospective cohort study was reported involving 100 patients from a single general practice to assess the impact of a domiciliary pharmaceutical care programme (Coleman et al., 2001). Patients were identified using computerised practice records. Each identified patient was enrolled into the domiciliary visiting programme, consisting of three visits, spaced at approximately three monthly intervals. Multidimensional questionnaires were used to underpin the patient interview and interventions made where appropriate. At the first visit patients were asked to present all medications they were taking and were interviewed using this questionnaire. Following the interview a number of notes were made including the formation of an action plan. The second visit was conducted after approximately three months, however some patients required more frequent visits. At the second visit a different questionnaire was used to assess any changes between the first and second visits. The third visit assessed the patient attitudes towards the visiting programme.

Of the 100 patients initially recruited, 160 issues were identified during the programme of visits. 19 patients required referral to their GP for a total of 49 problems, the most common of which were: severe risk of ADR (11); failure in health gain (9); and poor medicine concordance (9). This GP referral rate (19%) is surprisingly low considering the complex entry criteria (selected to target vulnerable elderly patients in need of domiciliary care) which suggests that the intervention was limited to ADRs and drug interactions rather than full range of DTPs expected from a pharmaceutical care model.

AN RCT of domiciliary pharmaceutical care was conducted for patients ( $\geq 65$  years old,  $\geq 4$  medications and  $\geq 2$  chronic conditions) registered with one of six general medical practices (Krska et al., 2001). Patients were randomly allocated to intervention or control group. All patients were interviewed at their homes about their use of and response to medication, and their use of health and social services. A pharmaceutical care plan was documented for each intervention patient, listing all potential and actual pharmaceutical care issues (PCIs), together with the desired output(s), action(s) planned to achieve the output(s) and any pharmacist outcomes of potential PCIs already resolved by the pharmacist. Copies of the plan were inserted into the patient's medical notes and a copy given to the doctor, who was asked to indicate their level of agreement with the PCI identified and the actions. The control group were similarly interviewed and PCIs identified, although no pharmaceutical care plan was implemented. Patients in both groups were followed up after 3 months, their use of medicines reassessed and new or pre-existing PCIs determined.

There was a number of severe limitations to this study. The follow-up of patients was short, only three months from baseline with no data provided on time from referral to implementation of agreed action. Pharmacists identified 2586 PCIs, 1380 in control patients (median 8, range 2-21) and 1206 in the intervention group (median 7, range 2-17). These figures appear vastly inflated and include potential pharmaceutical care issues, which has a broader definition from drug therapy problems and includes things such as, education required and administrative problems relating to out of date prescription lists which limits the generalisability of the study.

An RCT was conducted on two elderly care wards to determine if medication and information discharge summaries (MIDS), together with in-patient pharmaceutical

counselling backed up with a simple reminder card would help with the delivery of pharmaceutical care (Al-Rashed et al., 2002). Of the two elderly care wards, one was chosen randomly to recruit intervention patients and the other ward assigned control patients, the method of randomisation was not stated. Intervention group patients received pre-discharge counselling (approx 30 minutes per patient) by the clinical pharmacist. Normal discharge was provided to control patients which consisted of a nurse going through the patient's medication with them using a medicine reminder card. At discharge all intervention and control patients were given two envelopes, one to be given to their doctor and one to their pharmacist. The envelopes contained a feedback questionnaire to fill in and return. On discharge all patients were informed that the pharmacist would contact them to arrange a home visit. At the visit the pharmacist used a simple structured questionnaire to go through the patient's medication with them. If any discrepancies were found then the reason was obtained and another visit was arranged 3 months post discharge. This visit was the same as the first.

43 intervention and 40 control patients completed the study. A significant finding was the reduction in unplanned GP visits and hospital admissions. Unplanned GP visits were 19 in the intervention group vs 27 in the control group and readmissions were 5 in the intervention group and 13 in the control group, both of which were reported as significant ( $p < 0.05$ ). However there was no link made between these contacts and the use of health care services and overall clinical outcomes for example the increased admission rate might have been clinically appropriate and unrelated to medication problems identified at previous visit. We cannot assume that less visits mean better care. The small number of patients in the study would be unlikely to be powered sufficiently to make this determination.



Limitations of this study also include: there was no blinding of the intervention and control patients; the domiciliary visits were made to both sets of patients; the patients may have known the pharmacist was going to return in three months and may have just simply thrown medicines away or hidden them at the time of the pharmacists visit; and no power calculation is reported. In addition intervention and control patients used their own pharmacies, so there may have been some overlap in information given to both groups, due to the questionnaire given to both groups of patients to pass to their community pharmacist.

An RCT was conducted to examine the effectiveness of a multidisciplinary service model delivering medication review to patients in their homes (Sorensen et al., 2004). General practitioners were used as the unit of randomisation. Patients in the intervention group were subject to a home visit by a pharmacist. Home visits occurred approximately 2 weeks after enrolment. The visits identified any medication-related risk factors and other issues which needed to be addressed. The pharmacist who undertook the visit prepared a medication review report using interview data plus additional information provided by the doctor. The recommendations were then forwarded to the doctor and discussed at a multidisciplinary conference between the doctor, pharmacist and other members of the healthcare team. The doctor developed an action plan based on the conference. The patients were then followed up to monitor the outcomes of the action plan at least 6 weeks later. Control patients received normal care.

106 patients in the intervention group and 196 in the control group completed the study. In the intervention group an average of 5.5 problems were identified per

medication review. Of the actions implemented 212 (35%) recommendations were carried out successfully and resulted in a positive outcome. A negative outcome was recorded for only 11 (3.7%) enacted recommendations. Unfortunately equivalent figures for the control group were not reported. In addition the high drop out rate of GPs (44%) and patients (40%) in the intervention group is unexpected given the very short 6 week follow-up. From other studies we may predict that a certain percentage of problems would be resolved in the control group receiving standard care. However, in this study only 35% of problems were resolved in the intervention group a figure which is difficult to interpret.

An RCT was conducted to determine whether home based medication review by pharmacists affected hospital readmission rates among older people (Holland et al., 2005). Patients aged 80 years or older were recruited if admitted to hospital as an emergency admission. Patients were randomised to the intervention or control group. Pharmacists arranged home visits for intervention patients. They assessed patients ability to self medicate, measured drug adherence and completed a standardised visit form. Where appropriate, they educated the patient or carer and removed out of date drugs, reported possible adverse drug reactions or interactions to the general practitioner and requested a compliance aid from their local pharmacist. One follow-up visit occurred at six to eight weeks after recruitment to reinforce the original advice. The control group received usual care. The primary outcome measure was the total number of emergency admissions over six months. Secondary outcomes included deaths, admissions to residential homes and nursing homes, and self assessed quality of life.

A total of 178 emergency readmissions occurred in the control group and 234 in the intervention group ( $p = 0.009$ ). Fewer deaths occurred in the intervention group (49 vs 63). The authors concluded that the intervention was associated with a higher rate of hospital admissions. This study has cast a shadow over the benefits of medication review by pharmacists, however many aspects of the study design need to be addressed. Firstly it is titled, 'home based medication review' yet the pharmacists were limited to interventions to support compliance with the exception of adverse drug reactions and interactions. Secondly all other interventions focused on process issues linked to the taking of drug therapy such as education and compliance aids. Overall there was no opportunity to identify DTPs. In addition pharmacists had lists of drugs but no access to medical records for such a vulnerable group with a high risk of readmission. Whilst the study focused on hospital admissions as a surrogate outcome measure no attempt was made to link the interventions by the pharmacists to either a positive or negative outcome related to admission. Indeed admissions may have been beneficial as a trend for more deaths was observed in the control group which needs further exploration.

Table 1.8 – Summary of Domiciliary general pharmaceutical care models

Study	Selection, recruitment and participants	Communication, interview techniques and interventions	Outcomes, results and author's conclusion	Limitations of study
Lowe et al (2000)	<ul style="list-style-type: none"> <li>▪ Randomised controlled trial in one GP practice in Britain</li> <li>Inclusion criteria: <math>\geq 65</math> years old with <math>\geq 3</math> medications</li> <li>161 Patients (77 intervention, 84 control)</li> <li>2-3 months follow-up</li> </ul>	<ul style="list-style-type: none"> <li>▪ Control: Visit 1. – Home visit and patient interviewed about their medicines using a structured questionnaire. Asked the patients what medicines they actually took and their understanding of the purpose of each medicine, no further questions asked. Visit 2 – one month's supply of medication. Visit 3 – repeat questionnaire and tablet count</li> <li>▪ Intervention: three visits: Visit 1. – Home visit and patient interviewed about their medicines using a structured questionnaire. Asked the patients what medicines they actually took and their understanding of the purpose of each medicine, assessed patient's ability to read labels, open containers and use non-oral medications and devices. Rationalisation of medications as appropriate. Visit 2. Delivery of one month supply of medication to the patient. Other prescribed medication was removed with the patient's permission. Discussion of medication regimen with intervention patients and explained any changes. Information was summarised on a hand written drug reminder chart. Visit 3. – 3 weeks after visit 2 they were given a further one month supply of medication. Asked patients to describe the medicines they took and understanding of their purpose. A count taken of the number of tablets or capsules remaining from those medicines delivered at the previous visit</li> </ul>	<ul style="list-style-type: none"> <li>▪ <b>Outcomes</b> Knowledge and compliance rates</li> <li><b>Results</b> A change to medicines was made in 47% of the intervention group at visit 1. Mean medications taken in the intervention group was 4.1 which fell to 3.9 (<math>p=0.003</math>). Mean compliance score for intervention patients was 91.3% and control group 79.5%. At the first visit 58% intervention group patients correctly described the purpose of their medicine compared with 67% of control patients. At the third visit figures were 88% vs 70% respectively. The overall change in knowledge for both groups between the first and third visit was highly significant between the two groups (<math>p=0.0001</math>).</li> <li>▪ <b>Good Points</b> - Randomised design</li> <li>▪ <b>Author's conclusion</b> The study shows that medication review and patient education in the community can significantly improve patient knowledge of and compliance with medication in the short term</li> </ul>	<ul style="list-style-type: none"> <li>▪ The same person intervened and assessed outcome – potential source of bias</li> <li>▪ No evidence of clinical medication review, problems reported leading to 47% having change in medicines at visit 1, no comparator with control</li> <li>▪ Authors conclusion not supported as Medication Review and education judged to be single intervention when either one could have been responsible for observed effect</li> </ul>

**Table 1.8 continued – Summary of Domiciliary general pharmaceutical care models**

Study	Selection, recruitment and participants	Communication, interview techniques and interventions	Outcomes, results and author's conclusion	Limitations of study
Coleman et al (2001)	<ul style="list-style-type: none"> <li>▪ Prospective cohort study in a health centre pharmacy with patients from one GP practice (3 GPs) in the UK</li> <li>1) ≥65 years old with ≥ 5 medications</li> <li>2) ≤65 years old with ≥ 5 medications and also had one more of the following: a) disablement, sight impairment, caring for another patient, discharged from hospital during the previous 28 days, representing housebound or semi housebound status, specific diseases – diabetes mellitus, cardiovascular disease, COPD or asthma.</li> <li>3) ≥80 years old, taking three or more 'iatrogenic culprits' – repeat medicines associated with increased risk of ADRs, drug interactions.</li> </ul>	<ul style="list-style-type: none"> <li>▪ Intervention group: domiciliary visiting programme of three visits over six months. Visit 1: Structured questionnaire including demographics, medication management issues, level of physical and mental dependency and finally symptoms, side effects which may be related to medicine problem, concordance issues OTC medicines purchased, storage problems with medicines with the ninth and final section including an assessment of observed or potential ADRs or drug interactions. Visit two at 3 months using semi-structured questionnaire. Visit three was 30 questions to illicit their perception of service and health beliefs expressed during visit 1.</li> <li>▪ GP referral made if appropriate.</li> </ul>	<ul style="list-style-type: none"> <li>▪ <b>Outcomes</b> Clinical and humanistic</li> <li>▪ <b>Results</b> 74% completed all three visits, 160 interventions classified as: medication management issues (88); health beliefs and concordance (41); and therapeutic problems (31).</li> <li>19 patients required referral to the GP for a total of 49 problems, the most common of which were severe risk of ADR (11), failure in health gain (9), poor medicine concordance (9).</li> <li>Outcome of these interventions was not clear, they were reviewed by three GPs and three clinical pharmacists with limited agreement.</li> <li>▪ <b>Author's conclusion</b> This study demonstrated the feasibility of identifying candidates for domiciliary care from surgery records using carefully selected inclusion criteria. The visiting programme was well received by patients</li> </ul>	<p>No control group – limits generalisability</p> <p>Very complex recruitment criteria limits generalisability</p> <p>Study was not designed to test sensitivity and specificity of these criteria yet the authors claimed the study demonstrated feasibility of identifying these candidates from surgery records</p> <p>Very complex intervention at visit 1 with vast amounts of data being collected.</p> <p>Only 19% of patients required therapeutic intervention and referral to GP, this is surprisingly low considering the entry criteria suggests intervention limited to ADRs and drug interactions rather than full range of DTPs.</p>

Table 1.8 continued – Summary of Domiciliary general pharmaceutical care models

Study	Selection, recruitment and participants	Communication, interview techniques and interventions	Outcomes, results and author's conclusion	Limitations of study
Krska et al (2001)	<ul style="list-style-type: none"> <li>▪ Randomised controlled trial in six medical practices in Scotland</li> <li>▪ Inclusion criteria: ≥65 years old, regular request for ≥ 4 medicines via the computerised repeat prescribing system plus two chronic diseases</li> <li>▪ 332 patients (168 intervention, 164 control)</li> <li>▪ 3 months follow-up</li> </ul>	<ul style="list-style-type: none"> <li>▪ All patient interviewed in their own homes about their use and responses to medication and their use of health and social services and were asked to complete the SF-36 questionnaire</li> <li>▪ Control: similarly interviewed and Pharmaceutical Care Issues (PCIs) identified, although no pharmaceutical care plan was implemented. Patients were advised to consult any usual carers or health-care professionals in response to direct queries during the interview.</li> <li>▪ Intervention group: A pharmaceutical care plan was documented for each intervention patient. Copies of the plan were inserted into the patient's medical notes and a copy given to the doctor, who was asked to indicate their level of agreement with the PCI identified and the actions.</li> <li>▪ Patients in both groups followed-up after 3 months their use of medicines reassessed and new or pre-existing PCIs determined. Health and social services and SF-36 questionnaires were also administered.</li> </ul>	<ul style="list-style-type: none"> <li>▪ <b>Outcomes</b> Clinical and humanistic</li> <li>▪ <b>Results</b> Pharmacists identified 2586 PCIs, 1380 in control patients (median 8, range 2-21) and 1206 in the intervention group (median 7, range 2-17). Overall PCIs were associated most frequently with cardiovascular drugs. The number of PCIs resolved was significantly different in the intervention and control groups 950(79%) and 542 (39%) respectively, <math>p &lt; 0.0001</math>. There were no significant differences in the average monthly costs of prescribed medication per patient. There were no significant difference in HRQOL, hospital clinic attendance and use of social services.</li> <li>▪ <b>Author's conclusion</b> Pharmacist-led medication review has the capacity to identify and resolve pharmaceutical care issues.</li> </ul>	<ul style="list-style-type: none"> <li>▪ Short duration of follow-up – 3 months from baseline with no time given for actions to be implemented following GP referral.</li> <li>▪ Measured potential PCIs, which accounted for an extra 44% and 42% of problems being documented in the intervention and control groups respectively. These vastly inflated the numbers of problems found.</li> <li>▪ Control group patients were directed to other health care professionals which may have led to a higher resolution rate than would happen normally</li> <li>▪ Wash over effects of recommendations made in the intervention group, the GPs making same changes in the control</li> <li>▪ No attempt made to link PCIs to clinical outcomes</li> </ul>

Table 1.8 continued – Summary of Domiciliary general pharmaceutical care models

Study	Selection, recruitment and participants	Communication, interview techniques and interventions	Outcomes, results and author's conclusion	Limitations of study
Al-Rashed et al (2002)	<ul style="list-style-type: none"> <li>▪ Randomised controlled trial in a hospital in the UK</li> <li>▪ Predischarge counselling and domiciliary visit, 2-3 weeks and 3 months after discharge</li> </ul> <p>Inclusion criteria: <math>\geq 65</math> years old with <math>\geq 4</math> regular medications, were to be discharged to their own home and had an abbreviated mental score of greater than 7 out of 10.</p> <p>99 patients (45 intervention and 44 control)</p>	<ul style="list-style-type: none"> <li>▪ Control: normal discharge which consisted of a nurse going through the patient's discharge medication and explained that a new supply should be arranged within 14 days. They used a medicine reminder card and each prescribed drug when explaining the drugs and doses. They also went through the information in the MIDS</li> <li>▪ Intervention group: pre-discharge counselling by the clinical pharmacist (30 minutes per patient) patients received information about their medicines. Importance of compliance stressed. The pharmacist asked the patient appropriate questions to make sure they had understood.</li> <li>▪ At discharge all intervention and control patients were given two envelopes, one to be given to their doctor and one to their pharmacist. The envelopes contained a feedback questionnaire to fill and return. On discharge all patients were informed the pharmacist would contact them to arrange a home visit. At the visit the pharmacist used a simple structured questionnaire to go through the patient's medication with them. If any discrepancies were found then the reason was obtained. Another visit was arranged 3 months post discharge. This visit was the same as the first.</li> </ul>	<ul style="list-style-type: none"> <li>▪ <b>Outcomes</b> Knowledge, compliance, medicine stock and health care related events</li> <li>▪ <b>Results</b> 43 intervention and 40 control patients completed the study. The intervention group tended not to hoard drugs for more than 3 months between the two visits (<math>p &lt; 0.01</math>). There was a significant improvement in compliance for the intervention group (<math>p &lt; 0.001</math>). Unplanned visits to the GP were 19 in the intervention group vs 27 in the control group and readmissions were 5 in the intervention group and 13 in the control group, both of which were significant (<math>p &lt; 0.05</math>). There were no other statistically significant differences noted between the two groups.</li> <li>▪ <b>Author's conclusion</b> In-patient pharmaceutical counselling linked to a medication and information discharge summary and a medicine reminder card, contributed to better drug knowledge and compliance together with reduced unplanned visits to the doctor and readmissions.</li> </ul>	<ul style="list-style-type: none"> <li>▪ Short follow-up of intervention.</li> <li>▪ Measures used to determine extent of hoarding and compliance were dependent on patient's openness and engagement with process and may not reflect actual situation.</li> <li>▪ Authors conclude significant difference in unplanned visits to GP and readmission to hospital – study was not powered – sample size too small.</li> <li>▪ The control group was contaminated in that information was provided to them when they gave wrong answers during the domiciliary visit.</li> </ul>

Table 1.8 continued – Summary of Domiciliary general pharmaceutical care models

Study	Selection, recruitment and participants	Communication, interview techniques and interventions	Outcomes, results and author's conclusion	Limitations of study
Sorensen et al (2004)	<ul style="list-style-type: none"> <li>▪ Randomised controlled trial using GP practices and community pharmacies in Australia</li> </ul> <p>Inclusion criteria were one or more of the following 1) <math>\geq 5</math> medications, 2) <math>\geq 12</math> doses per day, 3) significant changes made to medication in the last 3 months 4) <math>\geq 3</math> disease states, 5) suspected by GP of medication non-compliance, 6) drugs which require therapeutic monitoring, 7) signs and symptom of possible medication-induced problems 8) inadequate response to treatment 9) admitted to hospital in the preceding 4 weeks or 10) at risk of managing their own medicines due to language difficulties, dexterity problems or impaired sight.</p> <ul style="list-style-type: none"> <li>▪ 631 patients (177 intervention, 223 control)</li> <li>▪ 6 week follow-up</li> </ul>	<ul style="list-style-type: none"> <li>▪ Control group: usual care</li> <li>▪ Intervention: subject to a home visit by a pharmacist. Home visits occurred approximately 2 weeks after enrolment. The visits identified any medication-related risk factors and other issues which needed to be addressed. The pharmacist who undertook the visit would then prepare a medication review report using the information provided by the doctor and from the home visit. The recommendations were then forwarded to the doctor and discussed at a multidisciplinary conference between the doctor, pharmacist and other members of the healthcare team. The doctor developed an action plan based on the conference. The patients were then followed up to monitor the outcomes of the action plan at least 6 weeks later.</li> <li>▪ SF-36 measured at baseline and at the end of the trial</li> </ul>	<ul style="list-style-type: none"> <li>▪ <b>Outcomes</b> Clinical, humanistic</li> <li>▪ <b>Results</b> In the intervention group an average of 5.5 problems were identified per medication review. Potential adverse drug event was the most commonly identified problem (16.9%), followed by sub optimal monitoring (16.3%). Most frequent recommendations were for monitoring and changes to prescribed medication. An average of 6.8 (range 1-17) recommendations were suggested in each review. The reviewing pharmacist sometimes suggested a number of recommendations for the same problem. More than half of the recommendations resulted in an action carried out either by the home visitor (6%) or by the GP (48.4%). Of the recommendations not implemented 29.3% were for laboratory tests, 10 recommendations were not implemented because of patient choice. Of the actions implemented 212 recommendations were carried out successfully and resulted in a positive outcome. A negative outcome was recorded for only 11 (3.7%) enacted recommendations. There were no significant differences in the SF-36 at baseline or follow-up between the two groups</li> <li>▪ <b>Author's conclusion</b> Even in the relatively short period of follow-up, there was some evidence of medication misadventure risk reduction and a trend towards positive patient outcomes.</li> </ul>	<ul style="list-style-type: none"> <li>▪ Short duration of follow-up (6 weeks)</li> <li>▪ Not all parts of the SF-36 questionnaire could be tested properly due to short time frame</li> <li>▪ High drop out rate of GPs (44%) and patients (40%) in the intervention group and 30% of GPs in the control group</li> <li>▪ 35% of problems resolved in intervention group following actions implemented with no comparator provided for control group receiving standard care</li> </ul>



**Table 1.8 continued – Summary of Domiciliary general pharmaceutical care models**

Study	Selection, recruitment and participants	Communication, interview techniques and interventions	Outcomes, results and author's conclusion	Limitations of study
Holland et al (2005)	<ul style="list-style-type: none"> <li>▪ Randomised controlled trial in the UK</li> <li>- Inclusion criteria:               <ul style="list-style-type: none"> <li>▪ ≥80 years old, admitted as an emergency, intended to be discharged to their own home or warden controlled accommodation, and prescribed two or more drugs on discharge</li> </ul> </li> <li>▪ 872 patients (437 intervention, 435 control)</li> <li>▪ 6 month follow-up</li> </ul>	<ul style="list-style-type: none"> <li>▪ Control group: received usual care</li> <li>▪ Intervention group: Pharmacists arranged home visits for intervention patients. They assessed patients ability to self medicate and drug adherence and completed a standardised visit form. Where appropriate, they educated the patient or carer and removed out of date drugs, reported possible adverse drug reactions or interactions to the general practitioner and requested a compliance aid from their local pharmacist.</li> <li>▪ One follow-up visit occurred at six to eight weeks after recruitment to reinforce the original advice.</li> </ul>	<ul style="list-style-type: none"> <li>▪ Outcomes               <ul style="list-style-type: none"> <li>▪ Clinical, humanistic</li> <li>▪ Results                   <ul style="list-style-type: none"> <li>▪ 429 patients in the intervention group, 362 received first visits. Visits lasted a mean of 61 minutes. Second visits were conducted for 297 patients and took a mean of 42 minutes. Visits generated a total of 933 recommendations to general practitioners (2.58/ visited patient), 120 of these referred to possible adverse drug reactions or interactions in 81 patients. Review pharmacists recommended compliance aids in 39 patients. Pharmacists felt that the visits were definitely or probably useful for 81 patients.</li> </ul> </li> </ul> </li> <li>▪ A total of 178 emergency readmissions occurred in the control group and 234 in the intervention group (p=0.009). Fewer deaths occurred in the intervention group (49 vs 63)</li> <li>▪ Quality of life scores decreased in both groups but the differences were not statistically significant.</li> <li>▪ Primary care data was analysed for 84 intervention patients and 81 control, GP carried out 204 home visits in the intervention group and 125 in the control group (p=0.002)               <ul style="list-style-type: none"> <li>▪ Author's conclusion                   <ul style="list-style-type: none"> <li>▪ Home based medication review for older people recently discharged from hospital increased, rather than decreased hospital admissions</li> </ul> </li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>▪ Non generalisable, frail elderly patients who had already been admitted to hospital via emergency</li> <li>▪ Enforced compliance of medications but did not rationalize therapy and identify all types of drug-therapy problems</li> <li>▪ Not a clinical medication review model – pharmacists had list of drugs but no access to medical records</li> <li>▪ Nature of admissions not reported, were they linked to the intervention – admissions may have been beneficial as a trend for more death occurred in the control group</li> </ul>

### **Summary of critical appraisal of general pharmaceutical care models**

Of the twenty-three general pharmaceutical care models reviewed, fifteen can be dismissed due to limitations of the methodology; Small sample size  $\leq 100$  patients (Jameson et al., 1995; Al-Rashed et al., 2002; Taylor et al., 2003); Short follow-up of  $\leq 3$  months (Lipton et al., 1992; Shalansky et al., 1996, Lowe et al., 2000; Krska et al., 2001; Sorensen et al., 2004); Lack of control group (Lobas et al., 1992; March et al., 1999; Catellier et al., 2000; Coleman et al 2001) and failure to identify equivalent outcome measures in control group (Ellis et al., 2000; Volume et al., 2001; Sellors et al., 2003). Of the 8 remaining well designed studies 3 failed to show any benefit (Coleman et al., 1999 and Bernsten et al., 2001; Grymonpre et al., 2001).

Of the five remaining studies, two of the studies were limited to a narrow range of DTPs related to ADRs and interactions (Jameson & VanNoord., 2001; Holland et al., 2005). Whilst Jameson and VanNoord demonstrated significant benefit, Holland et al (2005) demonstrated an increase in emergency readmissions in the intervention group without linking this to a positive or negative outcome. This intervention described a limited pharmaceutical care model.

Of the three remaining general pharmaceutical care studies direct comparison of findings is difficult due to inconsistency in the reporting of the outcome measures.

Hanlon et al (1996) used a Medicines Appropriateness Index (MAI) which has not been validated to establish a link to clinical outcomes. In addition the MAI lacks the ability to measure adverse drug reactions (ADRs) and drug interactions. Similarly a well designed study by Zermansky et al (2001) reported positive outcomes but is equally difficult to interpret as it focused on process outcomes such as number of

drugs, drug changes and costs with no attempt to link these measures to clinical outcomes.

Nevertheless the Hanlon study was a well designed study which informed the study design of Mackie et al (1999). In contrast Mackie et al (1999) adopted an amended Strand classification system (Strand et al., 1990) which increased the number of categories from 8 to 12 and reported the extent of resolution of DTPs from baseline to follow-up. This well designed study which demonstrated positive outcomes was limited by the partial validation of this classification system by the three research pharmacists who coded approximately 4000 DTPs (Mackie, 2002). No attempt was made to test the validity and reliability in a wider pharmacist population.

## **1.5 Conclusion**

Medicines Use Review (MUR) was introduced within the new NHS community pharmacy contract in April 2005 providing pharmacists in England and Wales with the opportunity to deliver a pharmaceutical care model in line with the principles proposed by Hepler and Strand (1990). This MUR model permits the pharmacist to select the patient from wide inclusion criteria: receiving  $\geq 1$  medicine; and regularly attending the pharmacy for the preceding three months. There is an urgent need to evaluate this new MUR service to establish an evidence base.

This chapter has reviewed the research literature on pharmaceutical care models from January 1990 to April 2005 and concluded that further evidence is required and that any model should include a robust DTP classification system to enable meta-analysis to be undertaken in the longer term to establish an evidence base for MUR in the UK.

## **Hypothesis**

The hypothesis to be tested is that Medicines Use Review will reduce drug therapy problems and will be well accepted by both pharmacists and patients. This thesis has employed both quantitative and qualitative methodologies to address this hypothesis.

## Chapter 2

### General Materials and Methods

#### 2.1 Introduction

This chapter provides an overview of the general materials and methods employed to conduct this original enquiry. Firstly it is important to define what is meant by research (**Box 2.1**).

##### **Box 2.1: Definition of research (Bowling 2002)**

*'Research is the systematic and rigorous process of enquiry which aims to describe phenomena and to develop and test explanatory concepts and theories, in order to contribute to scientific body of knowledge'*

In this particular case it may be more appropriate to use the narrower definition of health services research (**Box 2.2**).

##### **Box 2.2: Definition of health services research (Bowling 2002)**

*'Health services research is concerned with the relationship between the provision, effectiveness and efficient use of health services and health needs of the population'*

## **Hypothesis**

Medicines Use Review (MUR) is a health care intervention introduced in the new community pharmacy contract in England and Wales in April 2005. The hypothesis to be tested is that Medicines Use Review will reduce drug therapy problems and will be well accepted by both pharmacists and patients. This thesis has employed both quantitative and qualitative methodologies to address this hypothesis.

## **2.2 Methods employed within individual chapters**

### **Chapter 1**

A systematic literature search of four databases (MEDLINE, CINAHL, IPA and Cochrane) was conducted using the search terms: Cohort studies; Drug-related problems; Drug therapy problems; Medication related problems; Pharmaceutical care; Pharmaceutical care model; RCT; Randomised controlled trial; and studies. These terms were all combined to search each database so as to achieve the maximum number of 'hits' of potentially relevant literature. Search results are provided in **Appendix 1**.

The searches were limited to: the period 1<sup>st</sup> January 1990 to 1<sup>st</sup> April 2005; English language; and human studies. All abstracts were then reviewed and inclusion based upon the confirmation of the following core elements of a pharmaceutical care model: face to face interaction between patient and pharmacist; an intervention designed to optimise drug therapy; documentation and referral as appropriate and follow-up to measure actual outcomes of the intervention.

Following screening of abstracts a total of 50 papers were found from the four databases. A manual search of reference lists within selected papers was also

conducted to check for any articles missed in the original database search. In this way a further eight papers were found giving a total of 58 papers for critical appraisal. The results of the critical appraisal form the basis of the discussion in chapter 1 and inform the study design and detailed methodology used throughout this thesis. Any literature published after April 2005 was not included in chapter 1 as it did not inform the method, instead the literature review was updated and used to inform the discussions sections of all subsequent chapters as appropriate.

### **Chapter 3**

In the main study the primary outcome measure was the number of drug therapy problems from baseline to follow-up in the active and control groups. Therefore one needed to consistently code the drug therapy problems hence the classification system required to be tested for reliability and validity. Where reliability 'refers to the reproducibility and consistency of the instrument' and validity 'is an assessment of whether an instrument measures what it aims to measure' (Bowling 2002).

#### **Measurement of Reliability**

Reliability was assessed using inter-rater, test-retest reliability and a measure of internal consistency, in this case Cronbach's Alpha.

Inter-rater reliability was assessed using Fleiss's kappa ( $\kappa$ ) coefficient (Fleiss 1981). This was used to assess the extent to which the results obtained by two or more raters (pharmacists) agreed. Cohen's kappa ( $\kappa$ ) coefficient (Cohen 1968) was not used as this method only takes into account the agreement between two raters. Fleiss suggested a kappa result of less than 0.40 indicates poor agreement, 0.40-0.59 is fair

agreement, 0.60-0.74 is good agreement and 0.75-1.00 is excellent agreement. (Fleiss 1981)

Test-retest reliability was assessed using percentage agreement of responses over time. This is a test of the stability of the instrument over time, which is not expected to change. The instrument was subjected to test-retest one calendar month after initial exposure.

Internal consistency produces an estimate of reliability based on all possible correlations between all the items within the instrument. It provides an estimate of internal consistency. There is no agreed minimum acceptable standard for instrument reliability although it has been suggested that 0.70 and above may be considered an acceptable level for internal consistency (Nunnally 1978). Internal consistency was measured using Cronbach's alpha (Cronbach 1951).

### **Measurement of Validity**

Three aspects were considered: face; content; and criterion validity.

Face validity is a subjective assessment of the presentation and the relevance of the instrument: does the instrument appear to be relevant, reasonable, unambiguous and clear? (Bowling 2002)

Content validity is more systematic than face validity. It refers to judgements (usually made by a panel) about the extent to which the content of the instrument appears to logically examine and comprehensively include, in a balanced way, the full scope of the characteristic or domain it is intended to measure. (Bowling 2002)



Criterion validity estimates the correlations of the measure with another criterion measure, which is accepted as valid ('gold standard'). In this case there was no 'gold standard' measure for classifying and identifying drug therapy problems (Bowling 2002).

#### **Chapter 4 (main study)**

In this chapter a matched cohort study design was used to test the hypothesis. Two cohorts were recruited, a prospective cohort who received the intervention (active) and a matched retrospective cohort who served as a control group. Due to the dynamic environment of primary care a prospective randomised controlled trial (RCT) would have been the favoured study design as it allows the study of two cohorts of patients receiving 'standard' care where the only difference between the two groups is the intervention itself. Advantages and disadvantages of RCT study designs are provided in **Box 2.3**. It was originally intended to use an RCT study design however in April 2005 the New Pharmacy Contract resulted in MUR becoming 'standard care'. This gave rise to two potential problems, firstly the ethics of withholding standard care and secondly contamination which may result from controls being invited to have an MUR during the study period.

This withholding of 'standard care' may have been considered to be a breach of the RPSGB code of ethics. For example this may have occurred if a patient in the control group had several drug therapy problems identified as part of a MUR and the protocol required the referral to be withheld in order to evaluate the impact of MUR on the active group only. A RCT study design has been adopted many times in the evaluation of medication review and pharmaceutical care models (chapter 1) and the

approach considered ethical because ‘the intervention’ was not standard care and patients in the control group continued to have full access to their regular pharmacist and doctor. The key ethical issues in these studies were that no ‘standard’ services were withheld and there was no evidence that ‘the intervention’ was better than ‘standard care’ which is why the studies were being undertaken.

**Box 2.3: Advantages and disadvantages of RCT design (Centre for Evidence Based Medicine 2008)**

**Advantages**

- Most rigorous way of determining whether a cause-effect relation exists between treatment and outcome
- Unbiased distribution of confounders
- Blinding more likely
- Randomisation facilitates statistical analysis

**Disadvantages**

- Expensive: time and money
- Volunteer bias
- Ethically problematic at times

The active group were a prospective cohort of patients  $\geq 18$  years, invited to have a MUR in line with the new Pharmacy Contract at participating pharmacies during the period of the study. The control cohort were then retrospectively recruited from the same GP practices matched to active patients by age, gender and number of repeat medicines. They received a MUR at the time of recruitment into the study and all drug therapy problems assessed for likelihood of presence at baseline.

The MUR involved a semi-structured interview, recorded using the national documentation template with an action plan forming the GP referral where appropriate. Outcomes were determined using quantitative methods (reduction in drug therapy problems, changes to number of repeat medicines, changes to primary care consultations and hospital admissions). All active and control patients received an MUR intervention. Some advantages and disadvantages of cohort studies are provided in **Box 2.4**.

**Box 2.4: Advantages and Disadvantages of cohort study design (Centre for Evidence Based Medicine 2008)****Advantages**

- Ethically safe
- Subjects can be matched
- Can establish timing and directionality of events
- Eligibility criteria and outcome assessments can be standardised
- Administratively easier and cheaper than a randomised controlled trial

**Disadvantages**

- Controls may be difficult to identify
- Exposure may be linked to a hidden confounder
- Blinding is difficult
- Randomisation not present
- For rare disease, large sample sizes or long follow-up necessary

A prospective design was not possible for the control cohort because they could not be practically excluded from MUR services as the new national contract allowed an intervention MUR at the time a prescription is presented in any pharmacy. A disadvantage of the retrospective control cohort is that it relied on patient recall and or routine clinical data recorded in medical case notes. The result was that the baseline number of drug therapy problems may have been under reported in the control group. For ethical reasons all control patient referrals were passed to the GP as appropriate.

## **Chapter 5 and 6**

These two chapters employed qualitative methodology including three focus groups and a semi structured questionnaire, with the latter administered by post and telephone.

### **Focus group methodology**

The focus groups reported in chapter 5 include two groups of pharmacists, those actively providing MUR services and those who were not providing MUR services at the time of the focus group discussions. The focus group reported in chapter 6 included a cohort of patients who had received MUR services as part of routine care rather than as participants of the prospective cohort study. This group were chosen to obtain patient's views of the actual MUR service which may have been distorted by information provided to patients in order to obtain informed consent in line with ethics committee permission for those participating in the main study.

Focus groups are unstructured interviews with small groups. A moderator guides the interview while the group discusses the topics that the moderator raises. Typically there are six to eight participants all with a similar background, the moderator is an experienced professional who works with a predetermined set of discussion topics. The groups tend to last between one and two hours depending on the type of discussion. The advantage of this type of approach is that it uses group dynamics to stimulate discussion, gain insights and generate ideas, which they would find more difficult in face to face interviews (Bowling 2002). Disadvantages include potential for: domination of an individual participant within the group; leading/misdirection by

the moderator; 'Hawthorn effect' of being observed; and lack of participation of individuals due to characteristics of group composition.

Bias was reduced by having a moderator and two or three observers to note down times participants spoke and to note the tone and body language of participants. Misdirection/leading by the moderator was minimised by pre-setting the topic guide for discussion and further ensured by digitally recording and transcribing all proceedings.

The group composition is important and has to be carefully balanced in relation to the characteristics of respondents to prevent the participants from feeling socially constrained. One additional source of bias is data analysis. This was minimised by subjecting the transcript to independent content analysis.

### **Semi-structured questionnaire**

A semi-structured questionnaire was administered to patients participating in the main study and is reported in chapter 6.

This method was chosen for two reasons. Firstly to minimise additional burden on this group and secondly it was felt that a focus group would not be as helpful as this group had taken part in a research project as opposed to receiving an MUR service as part of standard care.

A semi-structured questionnaire was drafted and tested for face and content validity by the research team (AWM, CAM and SC). The semi-structured questionnaire was posted with a letter stating that patients would be telephoned within two weeks. Patients had the option of having the questionnaire administered by telephone interview by an independent researcher (FS) or by posting the questionnaire in the

prepaid envelope provided, alternatively they could indicate on the form that they did not wish to take part any further. No reminders were sent.

## **Chapter 7**

This chapter provides an overview of the thesis and brings the literature review up to date where relevant from April 2005 to December 2007.

### **2.3 Data collection and coding**

All data were collected and entered onto computer with the following software used to store and analyse the data: Microsoft office professional 2003 (Word, Access, Excel); SPSS version 15; Graph Pad InStat Version 3.05 and Endnote 8 Reference Manager.

The process of data coding and entry was controlled and validated as recommended by Bowling (2002). The quality assurance of this process is described in detail within each of the individual chapters 3-6.

### **2.4 Statistical analysis**

Mean and median values were used to describe parametric and non-parametric data. Fleiss Kappa coefficient, Cronbach's alpha and percentage agreement were used as described in chapter 3. The sample size for the cohort study was calculated using a nomogram (Altman, 1992) as described in chapter 4. The chi squared test was used to compare categorical data. It was planned to use an intention to treat analysis but this was not necessary as no patients were lost to follow-up. The effect size was calculated as 'relative risk' (RR) and the measure of its precision expressed as confidence intervals (95% CI). The difference in outcomes between the proportions

receiving the active and control interventions was calculated as ‘absolute risk reduction’ (ARR). Finally the ‘number needed to treat’ (NNT) was calculated by inverting the ARR as this provides an estimate of the number of patients needed to be treated with the intervention to achieve a desired outcome over a specified period of time.

## **2.5 Pharmacists recruited to the main study**

The eight participating pharmacists in the main study were recruited following a letter of invitation sent to all 15 pharmacies accredited by the nine PCTs across Kent in September 2005. It should be noted that there were 286 pharmacies at that time therefore the 15(5%) accredited pharmacies reflected the slow uptake nationally in the first six months of introduction of this new service. Detailed descriptions of participating pharmacists are as follows.

### **Pharmacist one**

Pharmacist one is male, 60 years of age and has always worked in the community sector of pharmacy. Qualifying in 1967 he has been working as a community pharmacist for approximately 40 years and now works for a large multiple in Kent. This pharmacist practices regular Continuing Professional Development (CPD), attends local branch meetings and attends all relevant training evenings for his further development.



**Pharmacist two**

Pharmacist two is male, 41 years of age and has also worked only in the community sector of pharmacy. Qualifying in 1987 he has been working as a community pharmacist for approximately 20 years. He works for a supermarket pharmacy in Kent. This pharmacist also participates in regular CPD.

**Pharmacist three**

Pharmacist three is male, 37 years of age and has worked in the hospital and community sectors of pharmacy. Qualifying in 1995 he is currently a locum pharmacist for a large multiple in Kent. This pharmacist participates in regular CPD and has a particular interest in clinical pharmacy.

**Pharmacist four**

Pharmacist four is female, 38 years of age and has only worked in the community sector of pharmacy. Qualifying in 1991 she has been working as a community pharmacist for approximately 16 years. She has completed a post graduate diploma in community clinical pharmacy and spends half her time providing professional services to a large medical practice. She also undertakes regular CPD.

**Pharmacist five**

Pharmacist five is female, 30 years of age and has only worked in the community sector of pharmacy. Qualifying in 2000 she has been working as a community pharmacist for approximately 7 years. She regularly teaches students in her pharmacy and at the company head office. She participates in CPD regularly and is constantly trying to improve what she knows.

### **Pharmacist six**

Pharmacist six is female, 45 years of age and has worked in the community and hospital sectors of pharmacy. She was a pharmacy manager for a large multiple for 10 years and recently opened her own pharmacy business in the Kent area. Her CPD includes regular training evenings and research conferences.

### **Pharmacist seven**

Pharmacist seven is female, 46 years of age and has worked in both the community and hospital sectors of pharmacy. Qualifying in 1981 she worked in the hospital sector for a total of six years before buying her own pharmacy which she has been running since that time. She participates in regular CPD including attending regular branch meetings.

### **Pharmacist eight**

Pharmacist eight is female, 49 years of age and has worked in the community, hospital and industrial sectors of pharmacy. She has been qualified for approximately 25 years and is currently working for a large community multiple in the Kent area. She also regularly participates in CPD.

## **2.6 Other personnel and organisations involved in the study**

### **Validation of DTP classification system**

Twelve pharmacists participated in the pilot study with a further 26 pharmacists completing the validation of the DTP classification system. Details of recruitment of pharmacists to the validation of the classification system are provided in chapter 3.

### **Main study**

After recruitment of the eight pharmacists to the main study they were asked to nominate their local general medical practice. All nominated practices were posted details of the study and a meeting arranged with the practice manager and GPs to discuss their potential participation in this study. GPs were given full details about the study and provided with the opportunity to ask questions. In order to participate each practice was asked to confirm that they would allow access to all consenting patient's medical case notes and access to wider records to allow identification of matched controls for invitation to participate in the study. A total of 35 practices (65 GPs) were recruited across Kent.

### **Focus Groups**

Chapter 5 describes two focus groups. The first focus group consisted of six pharmacists who were participating in providing MUR services. Of these three participated in the main study described in chapter 4. The second group of six pharmacists were not participating in MUR services but agreed to take part in a focus group. These were a self-selected group following postal invitation to all pharmacists not currently providing MUR services. And finally a convenient sample of five patients from one pharmacy participated in a focus group as described in chapter 6.

An independent senior lecturer (CD) from Medway School of pharmacy, experienced in moderation of focus groups and two final year MPharm students (OO, SAN) facilitated all three focus groups. The researcher (AWM) observed all proceedings but did not take part. In addition the two students (OO, SAN) undertook data collection, transcription and analysis. The transcripts were independently analysed by two members of the research team (AWM, CAM).

### **Academic supervision and ethical approval**

Academic supervision was provided by a professor of pharmacy (CAM) with experience of clinical medication review and a senior lecturer (SC) from Medway School of pharmacy. Ethical approval was granted by West Kent Local NHS ethics committee in August 2005 (main study), amended in July 2007 (patient satisfaction questionnaire) and August 2007 (patient focus group). Documentation to support this is reproduced in **Appendix 2**.

## Chapter 3

# Validation of a Hierarchical Drug Therapy Problem Classification System

### 3.1 Introduction

In the main study (chapter 4) the primary outcome measure was the extent of resolution of drug therapy problems (DTPs) identified in a cohort of patients in receipt of medicines use review (MUR) services compared to a matched cohort of patients receiving standard care. Where a DTP exists *'when a patient experiences or is likely to experience either a disease or symptom having an actual or suspected relationship with drug therapy'* (Strand et al., 1990). To measure DTPs accurately we needed a consistent and reliable method to help the researchers classify individual DTPs following identification by the community pharmacist participants.

Cipolle et al (1998) defined a DTP as *'any undesirable event experienced by the patient that involves or is suspected to involve drug therapy and that actually or potentially interferes with a desired patient outcome.'* The authors also proposed seven categories of DTPs as listed in **Box 3.1**:

#### **Box 3.1: Drug therapy problem categories (Cipolle et al., 1998)**

1. Additional drug therapy
2. Unnecessary drug therapy
3. Wrong drug
4. Dosage too low
5. Adverse drug reactions
6. Dosage too high
7. Compliance

However, the authors have never published any validation to support the use of these categories including both internal and external validity. A major limitation of this definition of DTPs is that one may interpret that the patient has to actually experience an 'undesirable event' before a DTP may be identified, it was not the intention of the original paper by Strand et al (1990) which further states *'that the use of the term problem in the phrase drug related (therapy) problem is used to denote a drug related event amenable to detection, treatment or more appropriately, prevention and should not be interpreted in the common usage where it vaguely communicates the idea that something (puzzle, paradox, perplexity) is wrong here.....Practitioners frequently perceive that there are an infinite number of DRPs. However, we concluded that such perceptions are largely the result of unstructured observations and experience.'*

Van mil et al (2004) reviewed the literature and identified a number of methods used to classify DTPs based on the original classification of Strand et al (1990) updated by Cipolle et al (1998) including: The ASHP Classification (1996); Krska et al (2002); Mackie (2002); PI-Doc<sup>®</sup> (Schaefer, 2002); Second Granada Consensus (2002); Westerlund and Melander (2002) and PCNE v5 (2003).

The ASHP system (1996) described 13 categories of drug related problems (DRPs) where a DRP was defined as *'an event or circumstance involving medication therapy that actually or potentially interferes with an optimum outcome for a specific patient'* (ASHP, 1993). This system included categories such as *'lack of understanding of medication'* and *'problems arising from the financial impact of therapy'* in addition to *'failure of the patient to adhere to the regimen'* and is therefore likely to inflate the

number of DRPs identified. In addition there has been no published validation of this system.

Krska et al (2002) described 'pharmaceutical care issues' (PCIs) which were defined as, '*an element of a pharmaceutical care need which is addressed by the pharmacist*'. 18 categories of PCIs were described including five which were prefixed with the word, '*potential*', for example, '*potential adverse drug reaction*' which was separately categorised from, '*suspected adverse drug reaction*'. In addition categories such as '*need for education*' and '*cost issues*' together with separate categories for, '*actual compliance issue*' and '*potential compliance issue*' result in exaggerated numbers of PCIs being reported. This exaggeration was confirmed by the authors reporting a median of 7-8 (range 2-21) PCIs per patient with the authors concluding that further work is needed to assess the reliability, precision and usefulness of this classification system (Krska et al., 2002). In the context of the current study a focus on clinical DTPs this classification is not helpful.

Mackie (2002) adapted the Strand et al (1990) classification and refined the term to clinical DTP (cDTP) whilst recognising that administrative DTPs such as, '*repeat prescription record inaccurate*' may lead to a cDTP in the future. The author defined a DTP as existing in line with Strand's criteria such that a cDTP exists '*when a patient experiences or is likely to experience either a disease or symptom having an actual or suspected relationship with drug therapy*'. Mackie developed the classification by arranging the DTPs into a hierarchical system under three headings, '*appropriateness, safety and effectiveness*'. The seven DTP categories described by Cipolle et al (1998) were assigned to these three headings with five additional categories added including, '*no indication apparent*' under appropriateness,

*'clinically significant drug-interaction'* and *'contra-indication'* under safety and *'ineffective therapy'* and *'ineffective formulation/delivery'* under effectiveness. In addition a final category of *'miscellaneous'* was created. A basic validation was undertaken by two independent researchers coding a sample of 50 patients with one or more DTPs which refined the original Strand list to ensure consistency and reliability a further 50 patients with one or more DTPs were identified and independently coded by two pharmacists with 98% agreement.

In 2002 the development of a Problem intervention documentation (PI-Doc<sup>®</sup>) system in Germany was reported (Schaefer., 2002), which consisted of six main categories.

This system was a modified Strand system with under and over dosage categories combined and the omission of the *'indication but no drug'* category. The author concluded that validation should be completed before the coding system is recommended for further use. No such validation has been reported.

The Second Granada Consensus (2002) modified Strand's system (1990) by reducing the categories to six. However, similar to Mackie (2002) they grouped the categories into three supra-categories of *'necessity'*, *'effectiveness'* and *'safety'*. This group revised the definition of DTP to *'DTPs are health problems, understood as negative clinical outcomes, resulting from pharmacotherapy, that for different causes, either do not accomplish therapy objectives or produce undesirable effects'*. A limitation of this classification system is that it represents a consensus and has not been validated in practice.

In 2002 a DRP classification system was developed (Westurlund, 2002) which consisted of 13 categories of DTPs which included four of the original Strand (1990)



Chapter 3: Validation of a Hierarchical Drug Therapy Problem Classification System with an additional nine categories added. Several were identical to those added by Mackie (2002) within the three supra-categories: Safety, the author also added '*contraindication*' and '*drug-drug interaction*'; '*appropriateness*' the author added, '*uncertainty about aim of drug*' which Mackie called '*no indication apparent*' and finally effectiveness the author added '*therapy failure*' and '*difficulty swallowing tablet/capsule*', '*other problem of administration/handling*' and '*other dosage problem*' where Mackie reported these four DTPs under the two categories, '*ineffective therapy*' and '*ineffective formulation/delivery*' finally Westerlund added '*other*' where Mackie added '*Miscellaneous*'. The most notable omissions by Westerlund's DTP categories are: '*untreated indication*'; '*inappropriate choice of therapy*'; '*admitted non-compliance*' and '*monitoring required*'. Westerlund did not recommend a hierarchical system using supra-categories as suggested by Mackie (2002) and although Van mil et al (2004) indicates that his categories have been validated it has not been published in English and is therefore not available for further review.

Version 5 of the PCNE (2003) classification system defines a DRP as '*an event or circumstance involving drug therapy that actually or potentially interferes with desired health outcomes*'. The major difference between this and other classifications described is that the PCNE system separates the problem from its cause. The structure of this classification system is that each domain has a sub-domain with more detailed description of the DRP. Various versions have been validated by having 20 cases classified by pharmacists in a number of different countries followed by a new version based on consensus of the researchers, it has not been possible to obtain a published paper in order to appraise the method of validation. Of the review published by Van Mil (2004) the lead author of the PCNE classification system, he

himself states in relation to version 4 that, *“there are still some inconsistencies originating from it’s usability in practice that need to be further addressed. Due to the complex nature of many DRPs occurring in practice and the fact that they have a cause as well as a consequence, it is very difficult to develop a system that allows a consistent classification based on one choice only. Therefore, an additional set of rules for classification is needed for cases that are ambiguous.”*

With so many versions of the original Strand classification (1990) it is not surprising that studies are unable to report results consistently in order that meta-analysis is undertaken to strengthen the evidence base for delivery of pharmaceutical care. In order to address the primary outcome measure there is a clear need to validate a system to ensure consistent and reliable classification of DTPs.

Van mil et al (2004) proposed that an optimal classification system should be one which leads the user to one choice of coding, be based on clear definitions, should be validated and easy to use for research and clinical practice, should be structured in a hierarchical manner and should focus on the process of pharmaceutical care and be based on definitions that takes the outcomes of pharmacotherapy into account. The hierarchical system by Mackie (2002) is the nearest to the optimal classification system however, it has only been validated by research pharmacists and requires further work to establish it’s validity and reliability in clinical practice.

## **3.2 Aim**

To further refine and validate the hierarchical classification system by Mackie (2002) which was based on the original non-hierarchical Strand classification (1990) in order to consistently and reliably report on DTPs (the primary outcome measure) for the main study.

## **3.3 Objectives**

1. To pilot the DTP hierarchical classification system following face and content validity to test the classification system with a volunteer group of pharmacists using a sample of anonymised data derived from patients participating in the main study.
2. To validate the DTP hierarchical classification system for the main study by refining and retesting the system for reliability and validity in a cohort of community pharmacists.

## **3.4 Pilot of the hierarchical DTP classification system**

### **3.4.1 Pilot test of Version 1 for face and content validity**

#### **Method**

The hierarchical classification system (Mackie et al, 1999 and 2005.: Mackie, 2002) has been established for coding DTPs in clinical medication review in the UK. This DTP classification system consists of a hierarchical structure of 13 categories of DTP under the three supra-categories of Appropriateness, Safety and Effectiveness as detailed in **Box 3.2**. It should be noted that there is no hierarchy within the three categories with the most suitable descriptor chosen to classify the DTP.

**Box 3.2: Hierarchical classification system for DTPs (Mackie, 2002)**

<p><b>1. Appropriateness</b></p> <ul style="list-style-type: none"><li>• Unnecessary therapy</li><li>• No indication apparent</li><li>• Untreated indication</li></ul> <p><b>2. Safety</b></p> <ul style="list-style-type: none"><li>• Adverse drug reaction</li><li>• Clinically significant drug interaction</li><li>• Contra-indication</li></ul> <p><b>3. Effectiveness</b></p> <ul style="list-style-type: none"><li>• Ineffective therapy</li><li>• Inappropriate choice of therapy</li><li>• Inappropriate formulation/delivery</li><li>• Inappropriate dose/dosing schedule</li><li>• Admitted non-compliance</li><li>• Monitoring required</li><li>• Miscellaneous</li></ul>
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These 13 categories of DTPs together with definitions and criteria to confirm presence of DTPs were tabulated and a flow chart designed to help the volunteer pharmacists code DTPs. In the process we removed the category '*miscellaneous*' and combined the two categories '*Inappropriate formulation/delivery*' and '*Inappropriate dose/dosing schedule*'. Version 1 of the table and flow chart containing eleven categories is provided in **Appendix 3**.

Version 1 of the table and flow chart were then tested for face and content validity by the research team (AWM, CAM and SC). Face validity is an assessment of whether a measure appears to measure the concept it is intended to measure. It refers to the researcher's subjective assessments of the presentation and relevance of the coding system. Content validity refers to the extent to which the research team judged the

content of the coding system to identify and articulate, in a balanced way, the full scope of the DTPs.

## **Results**

In the initial stages of testing the criteria were iterated to reduce subjectivity in interpretation. Where possible these criteria referred to standard definitions for example, drug interaction was only confirmed if criterion met was identified as potentially hazardous in the BNF. The flow chart was also modified as it was felt that it would be too complicated and time consuming to use in practice. Version 2 of the resulting table and flow chart are provided in **Appendix 4**.

## **Discussion**

A minor change to the table was to incorporate guidance on the use of the hierarchical system which had caused some confusion. Major changes were made to the flow chart which appeared complex with Version 2 much simplified from the original chart.

### **3.4.2 Pilot test of Version 2 of the DTP classification system**

#### **Method**

Once the system had been validated for face and content validity, eleven DTPs were extracted from MUR documentation from patients participating in the main study to ensure that one DTP existed for each of the eleven categories. The DTPs extracted from the MUR documentation (AM) were independently checked (CAM) to ensure the DTPs were accurately described.

The pilot validation was conducted with a convenient sample of academic, community and pre-registration pharmacists and as such the participants all had

varying experience in community pharmacy. A case study approach was not taken as it was felt that this may adversely affect the results of the validation due to varying degrees of clinical experience of the pharmacists which may have influenced the coding. The aim was to test whether pharmacists could classify DTPs rather than identify DTPs at this stage.

The eleven DTPs were anonymised and presented on MUR documentation (single page action plan) in random order for the pharmacists to code. Each action plan contained only one DTP which corresponded to one specific DTP code from the classification system. These action plans are reproduced in **Appendix 5**.

Once the action plans had been coded, all sheets were returned to the researcher (AM) for coding to ensure a valid test-retest could be carried out later. This process was repeated after 4 weeks. The eleven action plans were coded (to match individual pre and post tests) and posted to the community and pre-registration pharmacists to return in a prepaid envelope. A reminder email was sent after one week with a follow up phone call after two weeks for non-respondents. The academic members of staff were also given the same coded action plans with an envelope for return to the researcher. Data was entered into Microsoft Excel and exported to SPSS for windows version 15. A number of measures for reliability were used: Fleiss kappa coefficient ( $\kappa$ ) for inter-rater reliability; Cronbach's alpha ( $\alpha$ ) for internal consistency and percentage agreement for measuring test-retest reliability. Data was rechecked after one month to ensure correct data entry and all calculations and analysis were repeated.

Inter-rater reliability was measured using Fleiss's unweighted Kappa coefficient ( $\kappa$ ) (Fleiss, 1981). The Fleiss Kappa coefficient takes into account agreement between

multiple raters. Fleiss suggested a kappa result of less than 0.40 indicates poor agreement, 0.40-0.59 is fair agreement, 0.60-0.74 is good agreement and 0.75-1.00 is excellent agreement.

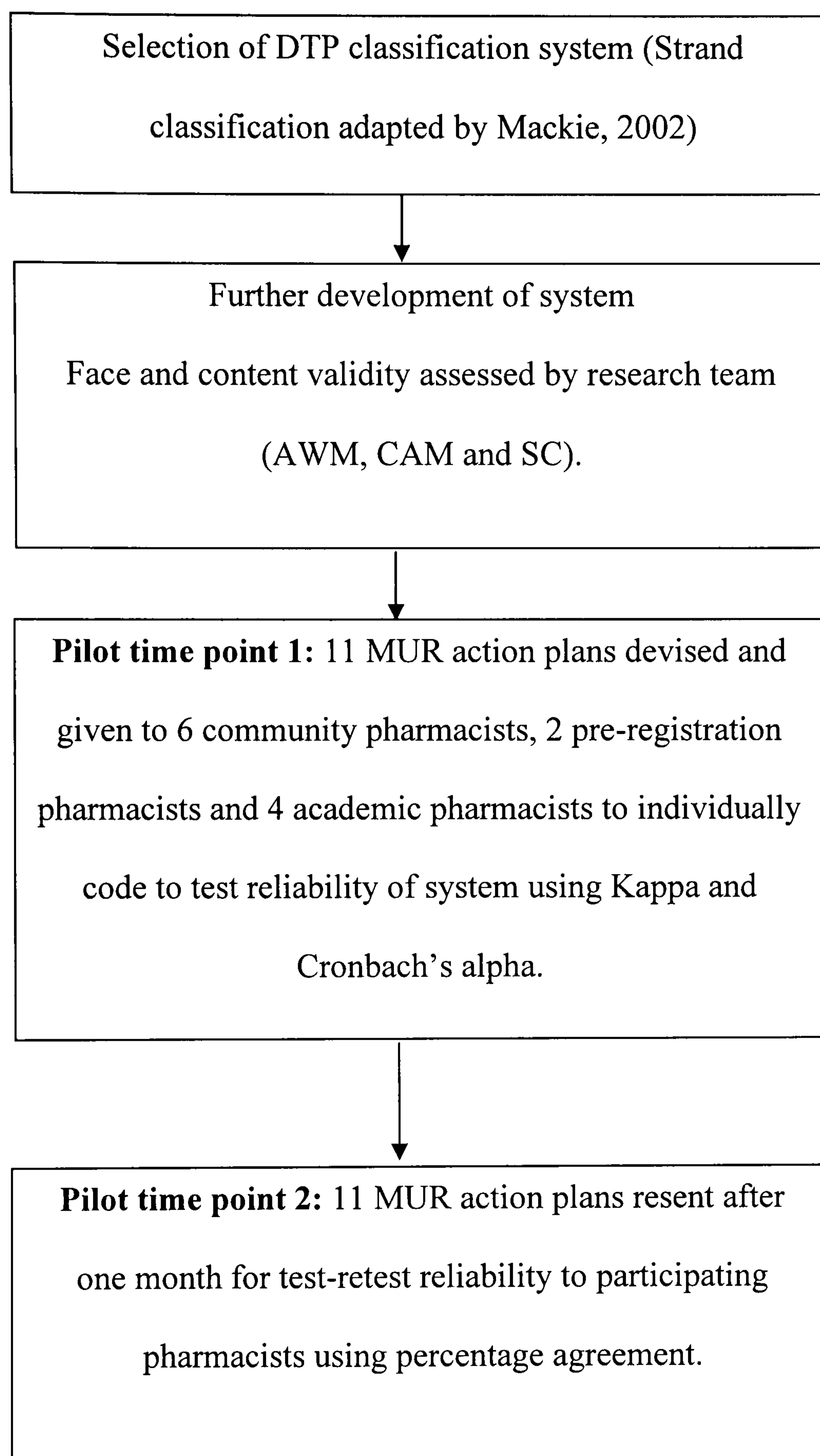
Internal Consistency was measured using Cronbach's alpha ( $\alpha$ ). This produces an estimate of reliability based on all the possible correlations between all the items within the scale. It is based on the average correlation among the items and the number of items in the instrument. A value of  $>0.50$  is recognised as a good indicator of internal consistency (Bowling 2002). The data was entered into SPSS for Windows version 15 and the alpha value calculated.

Test-retest reliability was assessed by comparing the number of pharmacists (%) agreeing with each category from baseline to one month follow up. A paired t-test was conducted to ascertain if there was any significant difference in the categorisation of the DTPs between the two time periods.

## **Results**

The eleven action plans were given to 12 pharmacists in total consisting of 6 community pharmacists, 2 pre-registration pharmacists and 4 academics at Medway School of Pharmacy. The community and pre-registration pharmacists were approached whilst attending a study day with the academic pharmacists approached at the same time period. **Figure 3.1** provide a summary of the pilot validation process.

**Figure 3.1: Summary of pilot validation process**



Measure of inter-rater reliability at baseline and one month follow up is provided in **Tables 3.1** and **3.2** respectively. Fleiss's Kappa coefficient ( $\kappa$ ) (Fleiss, 1981) was found to be 0.67 at baseline reducing to 0.64 at follow up which is considered to be good agreement when within the range 0.60-0.74.



**Table 3.1: Measure of Inter-rater reliability using Kappa ( $\kappa$ ) at 95% confidence and percentage agreement at baseline**

<b>Code</b>	<b>Drug Therapy Problem</b>	<b>Kappa (<math>\kappa</math>) 95% CI</b>	<b>Agreement (%)</b>
A1	No indication Apparent	0.70	75
A2	Unnecessary Therapy	0.75	100
A3	Untreated indication	0.81	92
S1	Adverse Drug Reaction	0.14	25
S2	Drug Interaction	0.78	100
S3	Contraindication	0.35	50
E1	Ineffective Therapy	0.73	100
E2	Inappropriate choice of therapy	0.40	58
E3	Inappropriate formulation/ dose/ delivery of therapy	0.66	92
E4	Admitted non-compliance	0.53	67
E5	Monitoring Indicated	0.90	92
<b>Overall Kappa (<math>\kappa</math>)</b>		<b>0.67</b>	

**Table 3.2: Measure of Inter-rater reliability using Kappa ( $\kappa$ ) at 95% confidence and percentage agreement at one month follow-up**

<b>Code</b>	<b>Drug Therapy Problem</b>	<b>Kappa (<math>\kappa</math>) 95% CI</b>	<b>Agreement (%)</b>
A1	No indication Apparent	0.80	83
A2	Unnecessary Therapy	0.46	75
A3	Untreated indication	0.77	100
S1	Adverse Drug Reaction	0.30	58
S2	Drug Interaction	0.85	100
S3	Contraindication	0.61	67
E1	Ineffective Therapy	0.66	83
E2	Inappropriate choice of therapy	0.27	42
E3	Inappropriate formulation/ dose/ delivery of therapy	0.63	100
E4	Admitted non-compliance	0.42	50
E5	Monitoring Indicated	0.91	100
<b>Overall Kappa (<math>\kappa</math>)</b>		<b>0.64</b>	

Following entry of all data into SPSS for Windows Version 15 a value of 0.987 was obtained for alpha. This showed excellent internal consistency of the coding system taking into account all of the possible correlations (>0.50 is considered good).

The number of pharmacists agreeing and percentage agreement with each category from baseline to one month follow up is provided in **Table 3.3**. A paired t-test revealed a p-value of 0.89 which demonstrates that there was no significant difference in coding between the two periods therefore demonstrating high test retest reliability of the system.

**Table 3.3 Comparison of DTPs identified from baseline to one month follow up**

<b>Code</b>	<b>Drug Therapy Problem</b>	<b>No. of pharmacists Baseline</b>	<b>No. of pharmacists Follow up</b>
A1	No indication Apparent	9	10
A2	Unnecessary Therapy	12	9
A3	Untreated indication	11	12
S1	Adverse Drug Reaction	3	7
S2	Drug Interaction	12	12
S3	Contraindication	6	8
E1	Ineffective Therapy	12	10
E2	Inappropriate choice of therapy	7	5
E3	Inappropriate formulation/ dose/ delivery of therapy	11	12
E4	Admitted non-compliance	8	6
E5	Monitoring Indicated	11	12
<b>p value</b>		<b>0.89</b>	

### 3.4.3 Development of Version 3 of the DTP classification system

Comparison of scoring results in **Tables 3.1** and **3.2** showed lower scores for the supra-category safety with score for ADR with 0.14 at baseline rising to 0.3 at follow-up and score for contraindication of 0.35 at baseline rising to 0.61 at follow up. A kappa result of less than 0.40 indicates poor agreement. A review of the individual action plans indicated that these DTP categories may have been selected due to the narrative provided by the individual pharmacist to express the problem

identified at the time of the MUR. The three categories within the supra-category '*safety*' were left unchanged.

On reflection it was thought that the category '*inappropriate formulation /dose /dosing schedule/delivery of therapy*' was too large and should be split into two categories, '*unsuitable formulation/drug delivery*' and '*inappropriate dose/dosing schedule*' which is back to the original number of 12 categories proposed by Mackie (2002).

In addition the only other poor result was found in the supra-category '*effectiveness*' with a score of 0.40 for '*inappropriate choice of therapy*' reducing to 0.27 at follow up. On reflection the placement of this category under the supra-category '*effectiveness*' rather than the supra-category '*appropriateness*' was confusing and difficult to defend. To address this it was decided to transfer the category: '*inappropriate choice of therapy*' and to move '*inappropriate dose/dosing schedule*' to the '*appropriateness*' supra-category resulting in a total of five categories in this section.

The supra-category '*effectiveness*' was left with four categories following the removal of one category and the splitting of the second category as described above.

Finally it was felt necessary to change the hierarchy of the supra-categories following expansion of the '*appropriateness*' category such that the hierarchy would be '*safety*' > '*appropriateness*' > '*effectiveness*'. For example if a drug was contra-indicated this would be picked up under '*safety*' in the first instance rather than '*inappropriate choice of therapy*' which would have made the '*contraindication*' category redundant had the hierarchical order not been reversed.

The research team (AM, CAM and SC) also considered feedback from participants which resulted in some simplification of the wording used to describe the DTP to avoid ambiguity. *'No indication apparent'* was changed to *'no indication for therapy'*, *'unnecessary therapy'* was changed to *'duplication of therapy'* and *'untreated indication'* was changed to *'additional drug therapy required'*.

Finally the three researchers (AWM, CAM and SC) repeated face and content validity as described in section 3.4.1 with Version 3 of the DTP classification system reproduced in **Appendix 6**. In summary the DTP classification system has 12 categories arranged in three supra-categories in a hierarchical order of *'safety'* first then *'appropriateness'* then *'effectiveness'* with some minor changes to the wording used to describe the DTP category to remove any ambiguity.

### **3.5 Validation of Version 3 of the DTP hierarchical classification system**

A limitation of the pilot was that pharmacists were given a narrative describing the DTPs which in the case of ADRs and contra-indications led to the selection of the wrong category and a Kappa score of less than 0.4 for reliability. In contrast the opposite is also true that those who correctly allocated the DTP category may have been influenced by the narrative describing the DTPs. In this way the narrative itself may have led to significant bias in the assignation of category of DTP. The research team therefore decided to minimise this bias by validating the DTP classification using case studies in which no DTPs had been previously identified. Whilst a concern was that the Kappa correlation may drop due to the variability in clinical skills across the cohort of pharmacist this was felt to more realistically reflect MURs as they would be delivered in practice. In this context it was decided to test the revised DTP

Chapter 3: Validation of a Hierarchical Drug Therapy Problem Classification System classification system on a cohort of community pharmacists who had qualified for MUR.

The validation of the DTP classification system consisted of two parts: Firstly there was a need to confirm (at cohort and individual level) that DTPs could be correctly identified from case studies and that this was reproducible over time. Secondly one needed to ensure validity and reliability of the DTP classification system. Where validity refers to 'an assessment of whether the instrument measures what it intends to measure' and reliability refers to 'the reproducibility and the consistency of the instrument' (Bowling, 2002).

### **3.5.1 Identification of DTPs**

#### **Method**

Four clinical case studies based, on problems reflective of actual practice were drafted by the research team (AWM, CAM and SC) and finalised following face and content validity. A database of 9000 pharmacists who had gained accreditation to perform MURs was accessed for the validation. A random sample of 400 pharmacists was selected from this database by random number generation using Microsoft Excel. These 400 pharmacists were sent a validation pack explaining the purpose of the study, a table and flow chart, four case studies together with instructions on how to identify and code DTPs. They had to use the information given to find three DTPs per case, which in total covered all DTPs within the classification system. A second set of identical cases was sent out after one calendar month to determine test-retest reliability of the classification system. The individual pharmacists had to return both mailings and had to have identified at least eight DTPs at baseline to be included in

the validation of the DTP classification system (phase 2). A copy of the validation pack including all four case studies is provided in **Appendix 7**.

Each case had three clinical drug therapy problems to identify and consisted of:

- A brief description of the patient including age and smoking status
- Past medical history
- Current problems
- Current medicines with dosage regimen
- Recent monitoring results covering the last 6 months
- Additional information if relevant to the DTP to be identified.

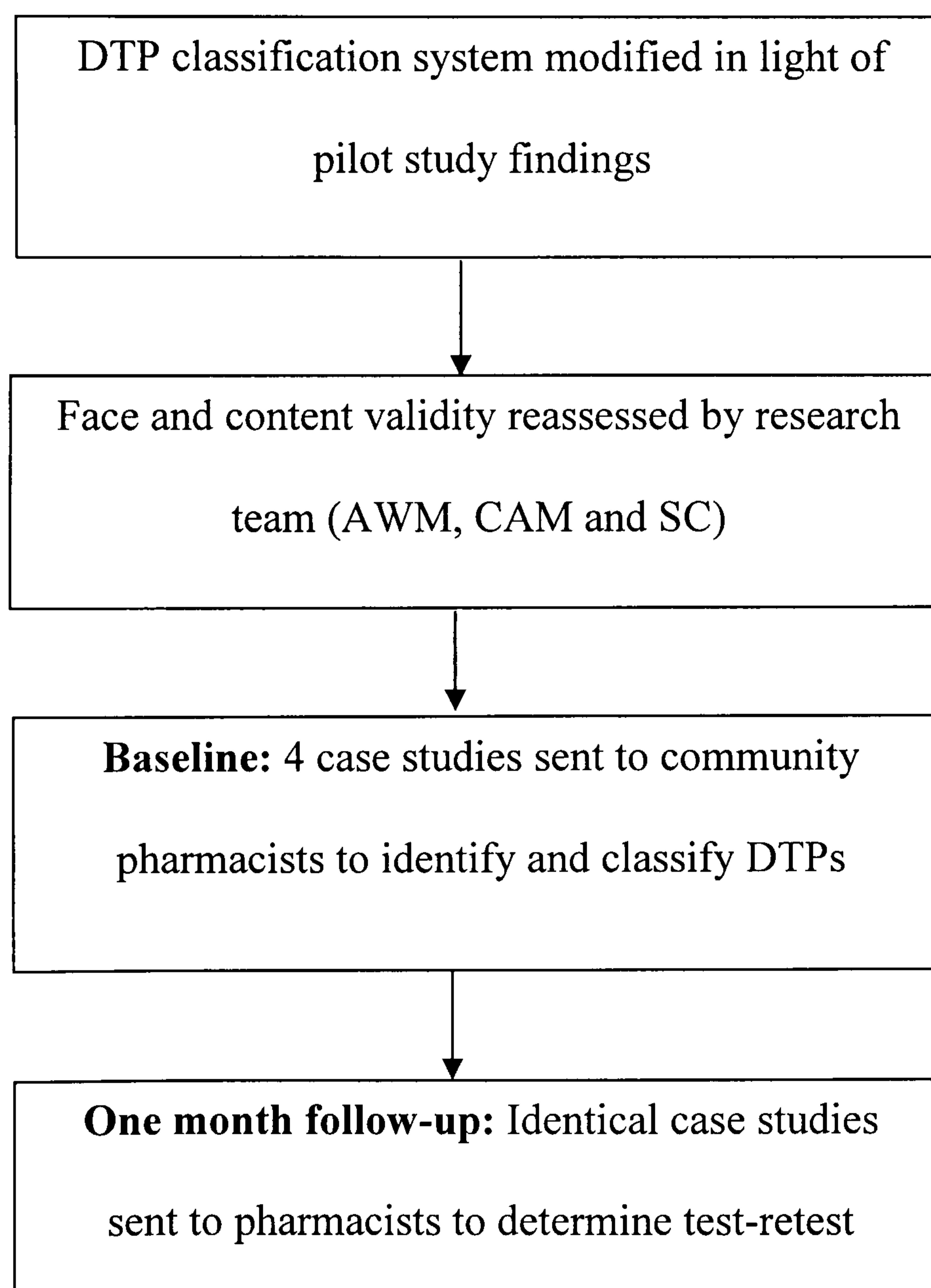
The pharmacist was requested to identify the DTPs and complete a preformatted response sheet. If a DTP was identified that could not easily be classified they were asked to describe the DTP in the free text box and leave as ‘unclassified’ to avoid guessing. The expected answers to the case studies are provided in **Appendix 8**.

In this phase the number of DTPs identified by the cohort of pharmacists was required to be assessed, both to identify any difficulties identifying particular DTPs and to undertake test-retest reliability from baseline to follow-up. The former was then assessed at individual pharmacist level by estimating the repeatability of the individual pharmacist scores by calculating the British Standards Institution repeatability co-efficient (Petrie and Sabin, 2006) which equals 2 x Standard deviation (2SD) of the difference found between the two scores. Where repeatability is demonstrated when these values are plotted and 95% of the differences found in pharmacist scores lie between the mean of observed differences  $(d) \pm 2SD$ .

## Results

The initial response for the study was very low, with only ten pharmacists out of 400 responding (2.5%). A repeat mailing was sent out to the remaining 390 pharmacists one month later. From this second mailing an additional twenty-one pharmacists responded giving a total of 31 pharmacists agreeing to take part in the study which reflects a response rate of only 7.75%. **Figure 3.2** provides a summary of the steps involved in the validation of DTP hierarchical classification system.

**Figure 3.2: Summary of validation of DTP hierarchical classification system**



All responses were reviewed by the researcher (AWM) and the DTP classification code and number of DTPs identified entered on an Excel spreadsheet. If pharmacists



failed to identify the correct DTP this was not counted. From the 31 initial responses, only 26 returned both sets of cases. Results for these 26 pharmacists are provided in **Table 3.4** and **Table 3.5** corresponding to baseline and one month follow up data respectively.

**Table 3.4 Number of DTPs correctly identified at baseline**

<b>Category of Drug Therapy Problem (DTP)</b>	<b>Number of pharmacists (n= 26)</b>	<b>% DTPs correctly identified</b>
<b>Safety</b>		
Adverse Drug Reaction	24	92
Drug interaction	21	81
Contraindication	19	73
<b>Appropriateness</b>		
No indication for therapy	18	69
Inappropriate choice of therapy	22	85
Duplication of therapy	19	73
Inappropriate dose/dosing schedule	20	77
Additional drug therapy required	13	50
<b>Effectiveness</b>		
Ineffective therapy	25	96
Unsuitable formulation/ drug delivery	20	77
Non Compliance	24	92
Monitoring indicated	9	35

**Table 3.5 Number of DTPs correctly identified at one month follow up**

<b>Category of Drug Therapy Problem (DTP)</b>	<b>Number of pharmacists (n= 26)</b>	<b>% DTPs correctly identified</b>
<b>Safety</b>		
Adverse Drug Reaction	24	92
Drug interaction	25	96
Contraindication	19	73
<b>Appropriateness</b>		
No indication for therapy	17	65
Inappropriate choice of therapy	18	69
Duplication of therapy	14	54
Inappropriate dose/dosing schedule	22	85
Additional drug therapy required	13	50
<b>Effectiveness</b>		
Ineffective therapy	26	100
Unsuitable formulation/ drug delivery	21	81
Non Compliance	20	77
Monitoring indicated	10	38

From **Table 3.4** it can be seen that at baseline pharmacists had difficulty identifying DTPs in the categories '*Additional drug therapy required*' (50%) and '*Monitoring indicated*' (35%). These difficulties persisted at follow-up with 50% and 38% reported respectively as detailed in **Table 3.5**. In addition the percentage of '*duplication of therapy*' dropped from 73% at baseline to 54% at follow-up.

A paired t-test was used to compare the values obtained for identification of individual categories of DTPs from baseline to one month follow-up for the cohort. There was no statistically significant (p-value= 0.61) difference found demonstrating that the cohort of pharmacists were able to consistently identify DTPs over a period of one month. One can conclude that the system was reliable for the consistent identification of number of DTPs over time for this cohort.

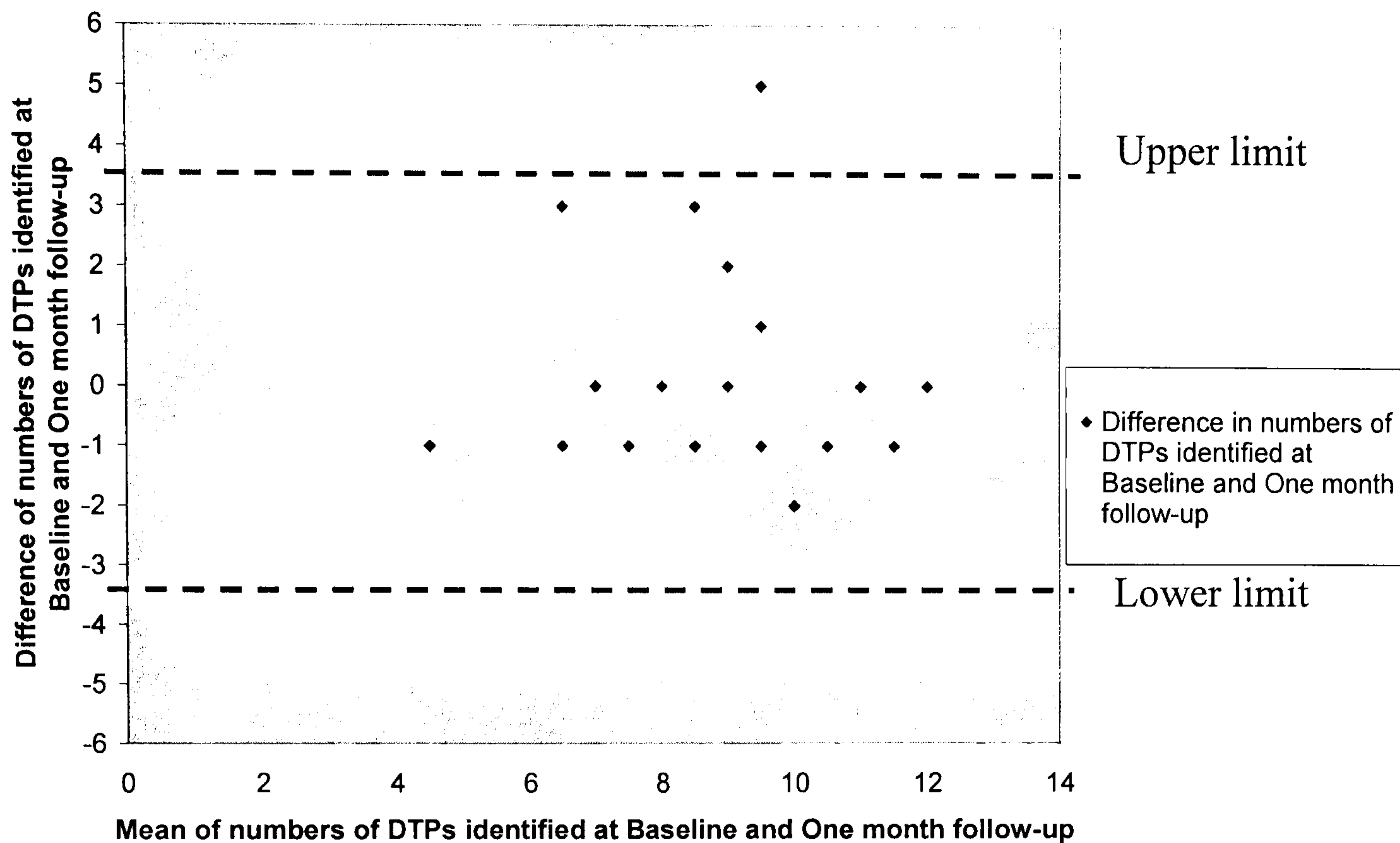
The mean number of DTPs identified per pharmacist was  $9 \pm 1.9$  out of a maximum score of 12. The pharmacists' individual scores from baseline to follow-up are provided in **Table 3.6**.

**Table 3.6 Number of DTPs identified at baseline and one month follow up by individual pharmacist**

<b>Pharmacist Code</b>	<b>Number of DTPs identified at Baseline</b>	<b>Number of DTPs identified at one month follow-up</b>	<b>Difference</b>
316	8	8	0
473	9	11	-2
809	9	9	0
818	12	12	0
946	11	12	-1
969	9	10	-1
1202	8	9	-1
1296	8	5	3
1497	7	7	0
1513	9	9	0
1589	10	7	3
1867	4	5	-1
1906	7	8	-1
1938	6	7	-1
1947	11	11	0
2063	10	11	-1
2077	10	9	1
2933	10	11	-1
3435	10	7	3
3644	11	12	-1
3719	9	9	0
3805	8	8	0
3835	12	7	5
3977	9	9	0
4612	10	8	2
5155	7	8	-1

From **Table 3.6** it can be noted that a third of pharmacists had no difference in scores with others showing a range of differences from -2 to +5. This is better represented diagrammatically as illustrated in **Figure 3.3**.

**Figure 3.3: Difference in the numbers of DTPs identified plotted against mean score from baseline to one month follow-up**



**Figure 3.3** shows that the majority of scores were between the upper and lower limits ( $0.19 \pm 3.34$ ) with only one notable outlier. This demonstrates confidence that individual pharmacists can consistently identify a number of DTPs over time.

### Discussion

During the pilot phase of the validation of Version 2 concerns were raised about the narrative used to describe the pre-identified DTPs and the influence that this may have on the subsequent classification. In this section previous methodological problems were overcome and bias reduced by giving pharmacist's case studies to code without prior identification of the DTPs. This was achieved with a mean number of  $9 \pm 1.9$  DTPs correctly identified out of a maximum of 12. Cohort test-retest reliability was confirmed ( $p = 0.61$ ). In addition repeatability at the level of the

individual pharmacist was demonstrated by calculation of the British standards institution repeatability coefficient.

Whilst reliability and repeatability of identification of DTPs was demonstrated it was evident that pharmacists consistently failed to identify two of the twelve DTPs from the four case studies provided. This may have been a limitation of the information provided in the validation pack.

### **3.5.2 Evaluation of Version 3 of the DTP classification system for consistency and reproducibility (Reliability)**

Version 3 of the DTP classification system was required to be tested to ensure its validity, consistency and reproducibility in practice. Face and content validity has been described previously in section 3.4.3. This section focuses on its reliability and is a measure of the reproducibility and consistency of the DTP classification system.

#### **Method**

To be included in this phase of the study the pharmacists had to correctly identify  $\geq 8$  DTPs out of a maximum of 12 within section 3.5.1. To have included lower numbers of DTPs would have invalidated the analysis as there had to be agreement in the first place in order for one to test reliability.

Fleiss' Kappa coefficient ( $\kappa$ ) was calculated to determine inter-rater reliability with Cronbach's alpha ( $\alpha$ ) used as a measure of internal consistency of the system. These were calculated using SPSS for Windows Version 15. Fleiss suggested a kappa result of less than 0.40 indicates poor agreement, 0.40-0.59 is fair agreement, 0.60-0.74 is good agreement and 0.75-1.00 is excellent agreement. A Cronbach's alpha value of

>0.50 is recognised as a good indicator of internal consistency. Percentage agreement was used to measure test-retest reliability from baseline to follow-up.

## **Results**

Twenty one of the twenty-six pharmacists successfully identified  $\geq 8$  DTPs out of a maximum of 12 and were therefore included in this analysis. **Table 3.7** and **3.8** provide details of the kappa values for each DTP category together with percentage agreement across all pharmacists from baseline to follow-up.

**Table 3.7: Measure of Inter-rater reliability using Kappa ( $\kappa$ ) at 95% confidence with percentage agreement at baseline**

<b>Category of Drug Therapy Problem (DTP)</b>	<b>Kappa (<math>\kappa</math>)</b>	<b>% agreement</b>
<b>Safety</b>		
Adverse Drug Reaction	0.70	86
Drug interaction	0.63	71
Contraindication	0.54	76
<b>Appropriateness</b>		
No indication for therapy	0.55	71
Inappropriate choice of therapy	0.10	24
Duplication of therapy	0.58	62
Inappropriate dose/dosing schedule	0.58	81
Additional drug therapy required	0.19	33
<b>Effectiveness</b>		
Ineffective therapy	0.68	76
Unsuitable formulation/ drug delivery	0.73	76
Non Compliance	0.95	95
Monitoring indicated	0.24	33
<b>Overall Kappa (<math>\kappa</math>)</b>	<b>0.51</b>	



**Table 3.8: Measure of Inter-rater reliability using Kappa ( $\kappa$ ) at 95% confidence with percentage agreement at one month follow-up**

Category of Drug Therapy Problem (DTP)	Kappa ( $\kappa$ )	% agreement
<b>Safety</b>		
Adverse Drug Reaction	0.79	81
Drug interaction	0.61	76
Contraindication	0.45	62
<b>Appropriateness</b>		
No indication for therapy	0.52	67
Inappropriate choice of therapy	0.03	10
Duplication of therapy	0.48	62
Inappropriate dose/dosing schedule	0.59	86
Additional drug therapy required	0.23	29
<b>Effectiveness</b>		
Ineffective therapy	0.79	81
Unsuitable formulation/ drug delivery	0.79	81
Non Compliance	0.79	81
Monitoring indicated	0.27	48
<b>Overall Kappa (<math>\kappa</math>)</b>	<b>0.48</b>	

From **Table 3.7** and **3.8** Fleiss' Kappa coefficient was 0.51 and 0.48 respectively which corresponds to fair agreement (0.40-0.59) as suggested by Fleiss .

Using SPSS for Windows Version 15 the value for Cronbach's alpha obtained at the baseline was 0.956 and at one month follow-up was 0.949. This demonstrates good internal consistency as a Cronbach's alpha value of  $>0.50$  is recognised as good.

**Table 3.9: Measure of test-retest reliability using correct category of DTP at baseline and one month follow-up**

<b>Category of Drug Therapy Problem (DTP)</b>	<b>DTP correct at Baseline</b>	<b>DTP correct at follow-up</b>
<b>Safety</b>		
Adverse Drug Reaction	18	17
Drug interaction	15	16
Contraindication	16	13
<b>Appropriateness</b>		
No indication for therapy	15	14
Inappropriate choice of therapy	5	2
Duplication of therapy	13	11
Inappropriate dose/dosing schedule	17	18
Additional drug therapy required	7	6
<b>Effectiveness</b>		
Ineffective therapy	15	17
Unsuitable formulation/ drug delivery	16	17
Non Compliance	20	17
Monitoring indicated	7	9

The number of correctly categorised DTPs at baseline and one month follow-up were compared using a paired t-test and a p value of 0.317 obtained demonstrating that there was no statistical difference observed between baseline and follow-up further demonstrating that the classification system was reliable.

### **3.5.3 Pharmacist views on Version 3 of the DTP classification system**

#### **Method**

The research team wanted to provide an opportunity for pharmacists to comment on the DTP classification system. Due to pressures on time and resources it was decided to keep this brief as there was a risk that it may be a deterrent to pharmacists completing the follow-up at one month (response rate for first phase was 7.75% after second mailing). The five questions posed were subject to face and content validity. These questions were enclosed with the second mailing of the validation pack with a request to return the completed form with the four cases to be submitted at one month follow-up.

#### **Results**

Six pharmacists out of the twenty-six who returned the second validation pack also submitted a completed feedback form. The questions and responses are detailed below.

**Q1. Did the classification system help you to identify drug therapy problems, you many not have otherwise been able to identify without it?**

All six pharmacists answered “yes” with only one comment:

*“Helped to provide a focus on how to look at problems”*

**Q2. What are the positive features of the coding system?**

*“Flow chart helps to prioritize when there is more than one problem with a drug – it would be easy to be sidetracked with a “red herring” of e.g. non-compliance”*

*“it provides a concise guide to what to look out for”*

*“very useful tool which provides a systematic approach for identifying DTPs”*

*“Easier to identify and classify issues”*

*“it is a helpful summary of problems to lookout for when doing MURs – A good reminder sheet”*

**Q3. What are the negative features of the coding system**

*‘would sometimes feel the need to use two codes’*

*‘found it difficult to restrict my comments to a simple code’*

*‘it works on a hierarchical system, in practice there are often multiple issues that need to be addressed and although they may not hold the same importance, they need to be noted and dealt with’*

*‘somewhat overlapping in some parts’*

**Q4. Can you suggest changes or improvements that would make it more useful in practice?**

Only two pharmacists suggested improvements, however these did not relate to the DTP classification system but to the DTP coding sheets provided for research purposes only. For completeness these are reproduced below:

*'Larger boxes providing space to enlarge on reasons for coding and for suggesting changes to medication'.*

*'I think it's useful to have a one line comment following the identification code to help the reader to understand the reason behind the code'.*

**Q5. Any other comments**

Only one pharmacist commented that the system may be too time consuming to use in practice as it already takes fifteen to twenty minutes to conduct an MUR with an additional ten minutes for the paperwork.

**3.6 Discussion and conclusion**

The aim of this chapter was to refine and validate the hierarchical classification system by Mackie (2002) which was based on the original non-hierarchical Strand classification (Strand et al., 1990) in order to consistently and reliably report on DTPs which was the primary outcome measure for the main study.

This was achieved with Version 3 of the DTP classification system tested for validity and reliability. The response rate from the pharmacists was very low at only 7.75%. However, only a small sample size was required for determining inter-rater reliability (Fliess Kappa Coefficient showed fair agreement) and for measuring internal consistency (Cronbach's alpha was 0.956 at baseline and 0.95 at follow-up).

Pharmacist feedback (6 out of 26 responded) was generally positive with no suggestions for improvement of the DTP classification system. A few comments related to problems linked to difficulties in choosing a single code to describe the DTP and perhaps reflect the individuals need for training in the use of the hierarchical system. In contrast positive comments were made about the hierarchical system in making it easy to identify and classify DTPs.

This validation of a hierarchical DTP classification system had several limitations, mostly of a minor nature. Firstly the pilot required pharmacists to code DTPs that were already identified for them in narrative form and although it produced very high validity and reliability there was doubt about pharmacists being able to use this system in practice. This was overcome in the main study by providing four case studies which reflected the full range of DTPs and required the individual pharmacists to identify up to 12 DTPs. However, the disadvantage of asking the pharmacists to identify and categorise the DTPs was that the response rate was low with only 31 out of 400 (7.75%) responding after one postal reminder.

Van mil et al (2004) proposed that an optimal classification system should be one which leads the user to one choice of coding, be based on clear definitions, should be validated and easy to use for research and clinical practice, should be structured in a hierarchical manner and should focus on the process of pharmaceutical care and be based on definitions that takes the outcomes of pharmacotherapy into account. The hierarchical system by Mackie (2002) is the nearest to the optimal classification system however, it had only been validated by research pharmacists with the authors suggesting that further work was required to establish it's validity and reliability in clinical practice. This chapter describes an extensive validation process resulting in

Version 3 of this hierarchical DTP classification system. Whilst this Version still has limitations (as discussed above) it has advantages over other published DTP based classification systems and is therefore the system of choice within this thesis to determine the primary outcome measure for the main study.

## **Chapter 4**

### **A Matched Cohort Study to Evaluate Medicines Use Review Services: consisting of a prospective cohort (active) who received the intervention matched with a retrospective cohort (control)**

#### **4.1 Introduction**

Medicines Use Review (MUR) is a health care intervention introduced in the new Community Pharmacy National Health Service (NHS) Contract in England and Wales in April 2005. The hypothesis to be tested in this thesis is that ‘Medicines Use Review will reduce drug therapy problems and will be well accepted by both pharmacists and patients’. In this chapter a matched cohort study design was used to test the first part of this hypothesis with pharmacists and patients views reported in chapters 5 and 6.

The aims of MUR services are to improve patient knowledge, concordance and use of medicines by: establishing the patient’s actual use, understanding and experience of taking their medicines; identifying, discussing and resolving poor or ineffective use of their medicines; identifying side effects and drug interactions that may affect patient compliance; and improving the clinical and cost effectiveness of prescribed medicines and reducing medicine wastage (PSNC, 2005a).

MUR services are supported by a national documentation system which facilitates a face to face consultation between patient and pharmacist to establish the patient’s use for both prescribed and non-prescribed medicines. This system also facilitates care planning and includes a national GP referral form which is called an ‘action plan’. A



copy of this 'action plan' is given to both the patient and their General Practitioner (GP) with the original retained by the pharmacist in order to follow-up outcomes which may be dependant on actions from the GP, patient and / or the pharmacist. MUR services therefore meet the three basic elements of a pharmaceutical care model: face to face consultation; documentation of a care plan; and patient follow-up (Chapter 1).

To offer this service pharmacists and pharmacies need to be accredited. Pharmacists are accredited by meeting nationally agreed competencies with formal assessment offered by a number of Higher Education Institutions. Pharmacies are accredited by local Primary Care Trusts (PCT) to ensure adequate facilities exist to carry out the MUR whilst assuring privacy for the patient.

There are two opportunities to access NHS MUR services, these are referred to as annual and intervention MURs. Annual MURs can be offered to patients who are taking one or more repeat medicines and have been regularly attending a particular pharmacy for three months. Annual MURs may be conducted no more than once per year. Intervention MURs can be offered at any time a NHS prescription is presented that requires an intervention in the judgement of the pharmacist. The requirement for the patient to have regularly attended the pharmacy for three months does not apply to intervention MURs. The intervention must be over and above what the pharmacist would usually do when dispensing a prescription. The pharmacist will not qualify for an MUR service fee if they only deal with the intervention itself. The intervention must trigger the offer of a full MUR to qualify for payment under this NHS service. The MUR process and documentation are identical irrespective of whether patients

Chapter 4: A Matched Cohort Study to Evaluate Medicines Use Review Services are recruited through annual or intervention MUR following the presentation of a NHS prescription.

MUR services provide an opportunity for pharmacists in England and Wales to deliver a pharmaceutical care model in line with the principle proposed by Hepler and Strand (1990). There is an urgent need to evaluate this new MUR service to establish an evidence base for MUR in the UK. Chapter 1 reviewed the research literature on pharmaceutical care models and concluded that further evidence is required and that such research should include a robust Drug Therapy Problem (DTP) classification system to enable meta-analysis to be undertaken in the longer term. Chapter 2 described the rationale for the selection of the matched cohort study design. In chapter 3 the validation of a hierarchical DTP classification system was described and is now employed in this chapter to evaluate whether MUR services are effective in reducing DTPs.

## **4.2 Method**

### **4.2.1 Hypothesis and study design**

To test the hypothesis ‘Medicines Use Review will reduce drug therapy problems’ a matched cohort study design was chosen. Two cohorts of patients were recruited: a prospective cohort who received MUR services (active); and a matched retrospective cohort, who served as a control group.

#### **4.2.2 Definition of drug therapy problem**

The definition of drug therapy problem used was that of Cipolle et al (1998):

*' A drug therapy problem is any undesirable event experienced by the patient that involves or is suspected to involve drug therapy and that actually or potentially interferes with a desired patient outcome. '*

Interpretation of this definition has been discussed previously in Chapter 3 with reference to the original paper by Strand et al (1990) making clear that the definition included prevention. Strand et al (1990) gave further guidance such that a DTP exists *'when a patient experiences or is likely to experience either a disease or symptom having an actual or suspected relationship with drug therapy'*. Mackie (2002) referred to this as a clinical DTP (cDTP) and excluded administrative DTPs (aDTPs) such as *'repeat prescription record inaccurate'* and *'generic or therapeutic substitution on the basis of cost'* from the hierarchical DTP classification system which was validated in chapter 3. The rationale for exclusion of aDTPs was that they did not meet Strand's (1990) criteria for a DTP to exist whilst recognising that aDTPs may lead to a cDTP at some time in the future. In this thesis a DTP is equivalent to a cDTP as described by Mackie (2002) and refers to any problem that meets the Strand criteria whilst excluding aDTPs. This is an important point as many studies falsely inflate DTPs by use of a broad definition which incorporates many potential problems which are difficult to confirm or refute at follow-up.

#### **4.2.3 Primary outcome measure**

The primary outcome measure was a reduction in the number of DTPs from baseline to 6 month follow-up. In the active group, patients received an MUR at both baseline and 6 month follow-up which together with information from the case notes, was

Chapter 4: A Matched Cohort Study to Evaluate Medicines Use Review Services used to confirm the presence or absence of DTPs. In the control group, patients received only one MUR on inclusion to the study with the presence of DTPs at baseline (minus 6 months) estimated from MUR interview data supplemented by retrospective review of case notes.

#### **4.2.4 Secondary outcome measures**

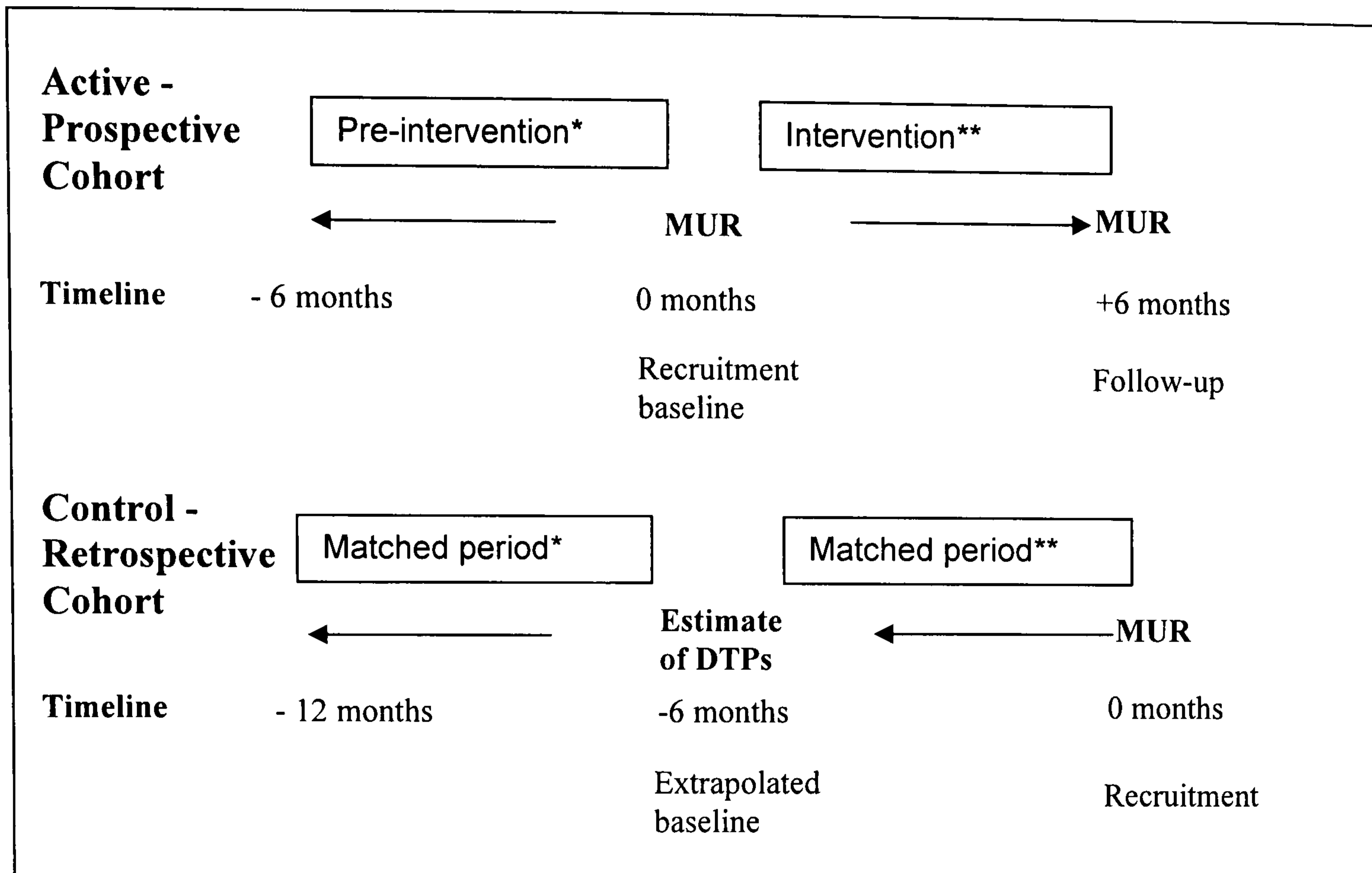
##### **Number of repeat medicines at baseline and follow-up**

During the MUR, all prescribed and purchased medicines were recorded on the standard documentation. The researchers (AWM and CAM) counted only the repeat medicines that were listed during the MUR, if any uncertainty existed about the status of a particular medicine this was confirmed with reference to patient's medical records. In this way all repeat medicines at baseline MUR and follow-up MUR were calculated for the active group. Due to the study design equivalent information was not available for the control group and no attempt was made to estimate this data.

##### **Primary care consultations, hospital consultations and admissions**

Secondary outcome measures also included changes in the use of other services including: primary care consultations; hospital consultations; and hospital admissions. All secondary outcome measures were obtained from information in the case notes and surgery held computer records. The changes in use of other services were measured from baseline to follow-up and compared with an equivalent period pre the intervention. The time line for the active group compared the period 0 to 6 months (intervention period) with -6 to 0 months (pre-intervention period). The equivalent period for the control group was -6 to 0 and -12 to -6 respectively which ran in parallel with the active group as the baseline differed by 6 months. This is illustrated in **Figure 4.1**.

**Figure 4.1: Timeline for measurement of outcomes**



#### 4.2.5 Sample size required to test the hypothesis

The primary outcome measure was a reduction in the number of DTPs from baseline to 6 month follow-up. A previous RCT of clinical medication review (Mackie et al., 1999) showed a 75% reduction in DTPs in the active group compared with a 25% reduction in the control. Overall this demonstrated a net 50% reduction in DTPs however, this study was performed under ideal conditions within a general practice setting using full time experienced clinical pharmacists with access to patient medical records. Although practitioners have to be accredited to provide MUR services they have no access to patient's medical records therefore in this thesis a lower target of 25% net reduction in DTPs between the two groups was set from baseline to 6 month follow up.

The study was designed with a high probability of detecting this difference. The power was set at 95% with a 1% ( $\alpha = 0.01$ ) significance level and the standardised difference was estimated as 0.55 using the following formula:

$P_1$  estimate = 0.9 from previous work (Mackie, 2002)

$P_2$  estimate = 0.675 (25% reduction in DTPs)

$$\text{Standardised difference} = \frac{P_1 - P_2}{\sqrt{P(1-P)}} \quad \text{where } P = \frac{P_1 + P_2}{2}$$

A nomogram (Altman, 1992) was then used for calculating that a sample size of 240 patients was needed with 120 required in each group (active and control).

#### **4.2.6 Recruitment of study participants**

##### **Recruitment of pharmacists**

All pharmacists accredited to provide MUR services who were working in accredited community pharmacy premises within the Kent region were invited by letter to participate in the study. Only one reminder letter was sent. At the time of recruitment to the study (September 2005) there were nine PCTs in Kent all of whom, were contacted by letter and asked to provide a list of accredited pharmacists and premises. The only exclusion criteria were failure to recruit at least one of their nominated general practices.

##### **Recruitment of general practitioners**

Once the pharmacists were recruited they were asked to nominate any number of local general practices whom they were likely to deal with for MUR services. In this way a convenient sample of general practitioners were recruited following nomination. Information on the study was sent by post to the practice manager and was followed up by a telephone call and an offer to visit the practice at their next

available scheduled meeting. The researcher (AWM) visited these nominated practices to provide additional information and obtain agreement (verbal) from individual practitioners to access medical records as appropriate. The only exclusion criteria was that if any single GP did not agree to participate then that group practice was excluded from the study.

### **Recruitment of prospective cohort of active patients**

Once agreement was obtained from pharmacists and nominated practices, the pharmacists recruited patients according to the inclusion and exclusion criteria detailed in **Box 4.1**.

#### **Box 4.1 Patient inclusion and exclusion criteria**

**Inclusion criteria:** consenting patients  $\geq 18$  years of age who had received an MUR from a participating pharmacist; and were registered with one of the participating general practices.

**Exclusion criteria:** Unable to give informed consent either due to cognitive impairment or severe mental health problems as confirmed by GP; together with those resident within residential or nursing homes.

Inclusion and exclusion criteria were kept to a minimum to reduce selection bias and improve generalisability of the findings. Pharmacists provided all eligible patients with a research pack (letter of invitation, information, consent form and researcher contact details for further information) at the time of their MUR. The patient was given the option of taking the pack home to read, or they could read the information in the pharmacy. The participating pharmacists were fully briefed on the study and were able to answer many of the patient's questions. The patients then either signed the consent form in the pharmacy or returned it in the prepaid envelope supplied. This pack is reproduced in **Appendix 9**.

The written information contained within the pack reassured patients that they were free to decide to take part in the study and that refusal to participate would not affect their future care. In addition, consenting patients were informed that they were free to withdraw from the study at any time in accordance with ethics committee approval (Chapter 2).

Once consent was obtained, the researcher (AWM) contacted each patient within two weeks to confirm inclusion in the study and explain that they would be contacted again at 6 months in accordance with the study protocol.

#### **Recruitment of retrospective cohort of control patients**

At the six month follow-up MUR for the active patients, a cohort of control patients were then identified and individually matched for practice, age, gender, and number of repeat medicines. Control patients were excluded if their case notes confirmed that they had previously had an MUR. Following identification the appropriate participating pharmacist contacted the potential control patient and invited them for an annual MUR. At the time of the MUR, control patients were consented in the same manner as the active patients with a modified research pack which is reproduced in **Appendix 10**. Consenting patients received an MUR at point of entry to the study with retrospective data derived from the case notes by the researcher (AWM) and used to establish baseline at minus 6 months.

#### **4.2.7 The intervention: Medicines Use Review at baseline**

Patients and GPs were blinded to active and control allocation. It was not possible to blind the pharmacists providing the service or the researchers analysing the data due to the nature of the intervention within the study design.



### **Invitation to receive MUR services**

Criteria for inclusion in MUR services had been described previously with the pharmacist free to select any patient receiving  $\geq 1$  medicine. To receive this service under the NHS patients have to consent (verbal) to take part and agree that a copy of the documentation can be provided to their GP. A copy of this national documentation is provided in **Appendix 11**.

### **The MUR interview and completion of documentation**

After obtaining patient consent, the pharmacist noted basic patient demographics, the reason for the review (annual or intervention MUR) and what the patient would like to gain (if anything) from the review, the location of the interview and the name of the pharmacist conducting the review.

The standard documentation for MUR services takes the format of a semi-structured interview with data collected under the following headings: basic health data (previous adverse drug reactions, known allergies and sensitivities, medical history and monitoring as described by the patient); prescribed medicines and instructed dosage regime; dosage actually taken by the patient; patient's knowledge of medicine use; patient self reported compliance and suitability of treatment; if the medicine was working and if any side effects were present.

It was considered good practice to include purchased and prescribed medicines and to group them for particular conditions. Each group of prescribed medicines was discussed across all the headings before moving on to review the next group. This method was advised to participating pharmacists to facilitate discussion to avoid the

interview being perceived as an interrogation of the patient. The pharmacist either filled in the MUR documentation manually or electronically.

### **Development of the MUR action plan**

The MUR action plan had the following columns: 'medicines use issue' (DTPs); 'priority' (high, medium and low); 'proposed action'; 'action by'; and 'outcome (if known)'.

All DTPs were recorded by the pharmacist with the proposed action for implementation by the named person (patient, pharmacist, GP, nurse or other health care professional). The DTPs and proposed actions were described in the pharmacists own words with no attempt made to categorise the DTPs at this stage. Any urgent DTPs requiring attention were detailed on the action plan and phoned through to the GP straight away. For non urgent DTPs copies of the MUR documentation including the action plan were given to the patient and sent to the GP. The master of the documentation was stored at the pharmacy and a copy made available to the researcher (AWM).

All active patients received an MUR at baseline with control patients receiving an MUR at + 6 months, the latter was timed to coincide with the follow-up MUR for the active patients.

#### **4.2.8 Follow-up MUR at six months**

Only the active patients received a follow-up MUR six months after the baseline MUR had been conducted. The follow-up MUR repeated the steps described in 4.2.7.

#### **4.2.9 Identification and classification of DTPs**

##### **Active cohort at baseline and follow-up**

The researchers (AWM and CAM) coded the DTPs identified and described by the pharmacist on the MUR documentation system. All DTPs were classified according to the hierarchical DTP classification system (Version 3) described and validated in Chapter 3. A random sample of 40% of patients, were independently coded on a second occasion 3 months apart to determine consistency of the coding over time. Outcomes of the DTPs identified at baseline were determined by review of the follow-up MUR interview data together with patient information extracted from GP held patient records.

##### **Control cohort at entry to study and estimated baseline (- 6months)**

All control patients received an MUR at the time of the active patient follow-up MUR with all DTPs identified and categorised as described in 4.2.9. However, information from case notes was required to estimate the number and categories of DTPs at a point six months earlier to determine baseline DTPs in the control group

#### **4.2.10 Data handling and statistical analysis**

Patients, GPs and pharmacists were all coded to ensure confidentiality. All coded data was entered by the researcher (AWM) onto computer with the following software used to store and analyse data: Microsoft office professional 2003 (Word, Access and Excel); SPSS (version 15); and Graph pad Instat (version 3.05). Random samples of 10% of the data sets were checked for reliability of coding and data entry by an independent researcher (CAM) every 3 months during the coding period.

Mean ( $\pm$ SD) and median values were used to describe parametric and non-parametric continuous data respectively. Continuous variables were compared within or between groups using the paired sample t-test or independent sample t-test as appropriate. A chi-squared test was used to compare categorical data such as DTPs at baseline and at 6 months follow-up between the active and the control groups. A two tailed p value of less than 0.05 was regarded as statistically significant.

‘Relative risk’ (RR) was used to calculate the effect size and the confidence interval (95% CI) calculated as a measure of its precision. The ‘absolute risk reduction’ (ARR) was calculated, to reflect the difference in outcomes between the proportions receiving the intervention (active) and standard care (control). The ‘number needed to treat’(NNT) is the inverse of ARR and was calculated to provide an estimate of the number of patients needed to be treated with the intervention rather than standard care, in order to avoid a DTP over a set period of time (Altman, 1992).

#### **4.2.11 Retrospective peer review to assess risk**

Retrospective peer review of MUR documentation by the researchers was undertaken to identify problems that the pharmacist had failed to identify and actions that the pharmacist had proposed which were considered unnecessary. In addition peer reviewers examined patient medical records to identify any cases of potential harm resulting from pharmacist recommendations. Peer review was undertaken by the researchers (AWM and CAM) but as it was retrospective in nature it did not impact on the study results.

## **4.3 Results**

### **4.3.1 Recruitment of study participants**

#### **Recruitment of pharmacists**

In September 2005 all nine PCTs in the Kent region were asked to provide lists of pharmacists accredited to provide MUR services in accredited pharmacies in Kent. Only 15 (5%) of pharmacies within Kent were accredited at that time. Letters of invitation were sent to all 15 pharmacies with 8 (53%) actually recruited to the main study. More detailed information on the participating pharmacists is provided in Chapter 2.

#### **Recruitment of general practitioners**

The eight pharmacists who were recruited to the main study nominated 35 GP practices who all agreed to take part representing a total of 65 general practitioners across the Kent region. No practices were excluded as all GPs willingly participated in the project following a briefing from the researcher (AWM).

#### **Recruitment of patients**

Recruitment to the main study took place between October 2005 and May 2007. All active patients received a Medicines Use Review (MUR) between October 2005 and September 2006. Control patients received their MURs between August 2006 and May 2007. A summary of patient participation in the active group by age, sex and GP practice is provided in **Table 4.1**.

**Table 4.1 Summary of active patient participation by age, sex and practice**

Practice Code	Age & Sex												Total		
	18-29		30-50		51-60		61-70		71-80		>80		Total (%)		
	M	F	M	F	M	F	M	F	M	F	M	F	M	F	Total
A	0	0	3	0	1	3	7	6	4	5	1	2	16	16	32
B	0	0	0	1	1	1	7	9	2	1	3	1	13	13	26
C	0	0	0	0	0	2	3	2	6	2	1	0	10	6	16
D	0	0	0	3	0	0	3	3	1	1	0	1	4	8	12
E	0	0	1	1	2	1	1	1	3	0	0	0	7	3	10
F	0	0	1	1	1	0	0	1	1	0	0	2	3	4	7
G	0	0	0	0	0	1	3	1	0	0	0	1	3	3	6
H	0	0	0	0	0	0	0	1	1	1	0	0	1	2	3
I	0	0	0	0	1	0	0	0	0	1	1	0	2	1	3
J	0	0	0	1	0	0	1	0	0	0	0	0	1	1	2
K	0	0	0	0	0	0	1	0	0	0	0	1	1	1	2
L	0	0	0	0	0	0	0	0	0	1	0	0	0	1	1
<b>Total</b>	<b>0</b>	<b>0</b>	<b>5</b>	<b>7</b>	<b>6</b>	<b>8</b>	<b>26</b>	<b>24</b>	<b>18</b>	<b>12</b>	<b>6</b>	<b>8</b>	<b>61</b>	<b>59</b>	<b>120</b>
													<b>(51)</b>	<b>(49)</b>	<b>(100)</b>

From **Table 4.1** it can be seen that all active patients who participated in the study were registered with GPs in one of twelve participating practices (coded A-L) despite recruiting 35 practices at the outset. In addition 80% of patients were recruited from only five practices (coded A-E).

A summary of patient participation by age, sex and pharmacist is provided in **Table 4.2**. Although all 8 volunteer pharmacists went on to recruit patients, 68% of active patients were recruited by three of the eight pharmacists.

**Table 4.2 Summary of active patient participation by age, sex and pharmacist**

Pharmacist Code	Age & Sex												Total		
	18-29		30-50		51-60		61-70		71-80		>80		Total (%)		
	M	F	M	F	M	F	M	F	M	F	M	F	M	F	Total
1	0	0	3	0	1	5	10	8	10	8	3	2	27	23	50
2	0	0	0	0	0	1	3	2	1	1	0	1	4	5	9
3	0	0	0	1	1	0	2	0	0	1	0	1	3	3	6
4	0	0	0	1	1	0	4	9	2	1	2	0	9	11	20
5	0	0	0	3	0	0	3	3	1	1	0	1	4	8	12
6	0	0	1	1	2	1	1	1	3	0	0	0	7	3	10
7	0	0	1	1	1	0	0	1	1	0	0	2	3	4	7
8	0	0	0	0	0	1	3	0	0	0	1	1	4	2	6
<b>Total</b>	<b>0</b>	<b>0</b>	<b>5</b>	<b>7</b>	<b>6</b>	<b>8</b>	<b>26</b>	<b>24</b>	<b>18</b>	<b>12</b>	<b>6</b>	<b>8</b>	<b>61</b> <b>(51)</b>	<b>59</b> <b>(49)</b>	<b>120</b>

#### 4.3.2 Demographics and clinical characteristics of active and control cohorts

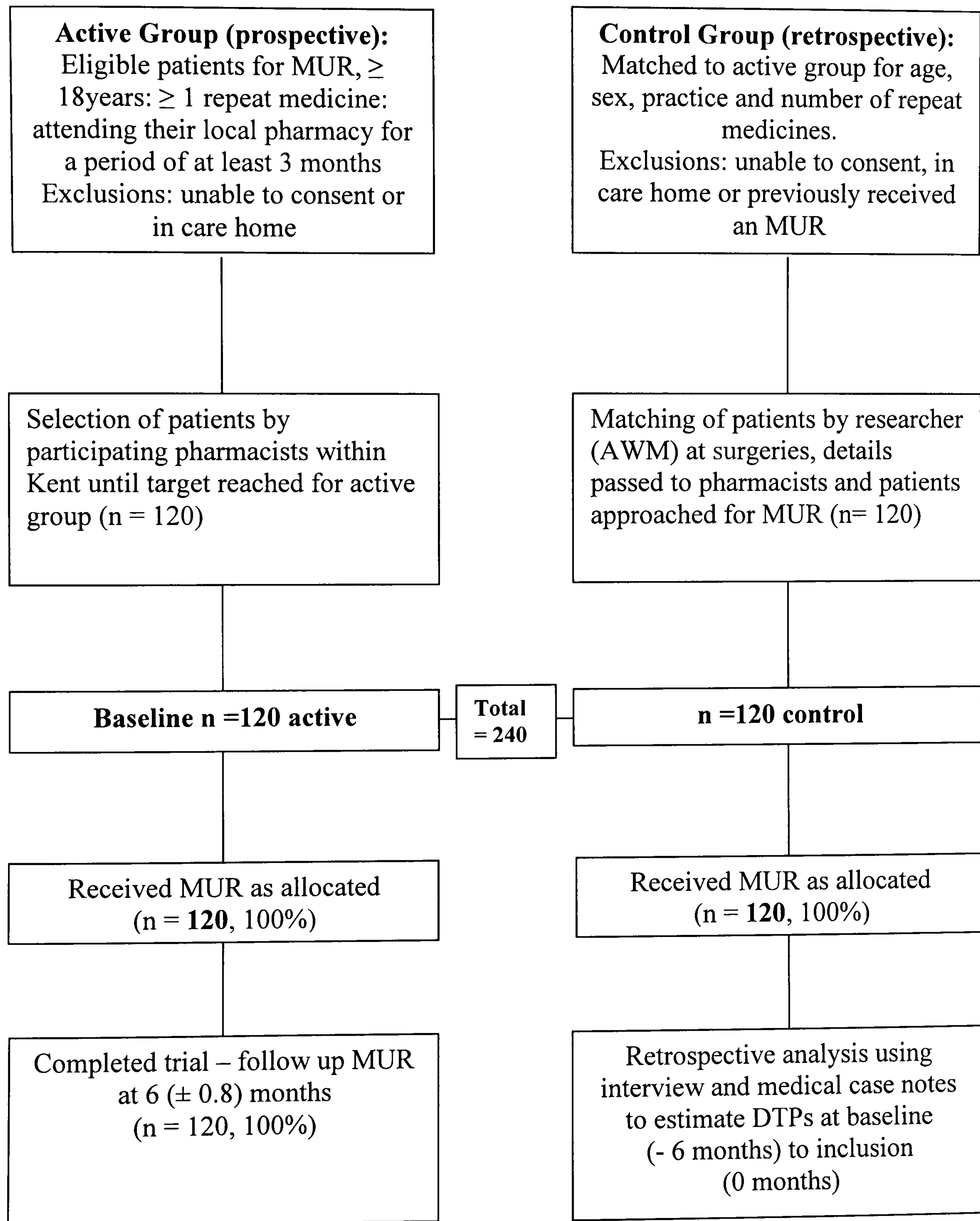
The mean age for each cohort was 67 ( $\pm 11$ ) years, with approximately 50% male in each group. Demographic and clinical characteristics were summarised and are provided in **Table 4.3**. From this it can be seen that the two cohorts were well matched for age, gender, number of medical conditions and number of medicines on repeat.

**Table 4.3: Demographic and clinical characteristics of participants**

Participants	Active (n = 120)	Control (n = 120)
No of Males	61	61
Mean Age $\pm$ St Dev	67 $\pm$ 11 yrs	67 $\pm$ 11 yrs
Total number of repeat medicines reviewed	742	783
Number of medicines on repeat mean $\pm$ St Dev	6.2 $\pm$ 2.6	6.5 $\pm$ 2.8
Number of medical conditions, mean $\pm$ St Dev	2.9 $\pm$ 1.3	2.9 $\pm$ 1.2

A total of 240 patients were recruited into the study, no patients were lost to follow-up. The flow of participants throughout the study can be seen in **Figure 4.2**.

**Figure 4.2: Flow chart of participants throughout the study**



From **Table 4.4** it can be seen that a total of 693 medical conditions were recorded for the two groups.



**Table 4.4: Medical conditions of active and control patients**

Medical Condition	Active (120 patients)		Control(120 patients)	
	Prevalence	Rate/100 patients	Prevalence	Rate/100 patients
Hypertension	87	73	85	71
Hyperlipidemia	58	48	63	53
Type 2 Diabetes	36	30	28	23
Osteoarthritis	26	22	31	26
Angina/IHD/Post MI	20	17	26	22
Asthma	14	12	9	8
TIA/ Stroke	12	10	4	3
Thyroid	12	10	16	13
COPD	12	10	14	12
GORD	12	10	12	10
Benign Prostatic Hypertrophy	10	8	10	8
Atrial Fibrillation	7	6	14	12
Depression	7	6	6	5
Osteoporosis	6	5	7	6
Hysterectomy	5	4	0	0
PUD	4	3	1	1
Heart Failure	4	3	4	3
Epilepsy	2	2	1	1
Type 1 Diabetes	2	2	2	2
Diverticulitis	2	2	4	3
Cervical Spondylitis	2	2	0	0
Dyspepsia	2	2	2	2
Migraine	1	1	2	2
Rheumatoid Arthritis	1	1	2	2
IBS (Chron's & UC)	0	0	6	5
Total	344	-	349	-

Overall patients were well matched for conditions across the two groups despite the fact that the two groups had only been matched at recruitment for age, gender,

number of medications and practice. It is noticeable that only 5 medical conditions account for two thirds of all history recorded. When undertaking MUR, pharmacists are reliant on taking a good patient history as they have no access to case notes. It is interesting to note that researcher (AWM and CAM) review of the case notes found the accuracy in medical history taking was 91% with only 60 conditions being added following case note review.

**Table 4.5** provides details by BNF chapter of 1,512 medicines which were reviewed comprising 742 and 783 in the active and control group respectively.

**Table 4.5: BNF chapter and number of medicines reviewed**

<b>BNF Chapter</b>	<b>Active (%)</b>	<b>Control (%)</b>
Chapter 2 – CV	387 (52)	380 (49)
Chapter 6 – Endocrine System	81 (11)	80 (10)
Chapter 4 – CNS	72 (10)	89 (11)
Chapter 3 – Respiratory	67 (9)	64 (8)
Chapter 1 – GI	49 (7)	57 (7)
Chapter 10 – Musculoskeletal and joint diseases	25 (3)	23 (3)
Chapter 9 – Nutrition and Blood	18 (2)	20 (3)
Chapter 7 – Obstetrics, gynaecology, UTIs	13 (2)	12 (2)
Chapter 11- Eye	13 (2)	15 (2)
Chapter 13- Skin	7 (1)	24 (3)
Chapter 5 – Infections	5 (1)	10 (1)
Chapter 12 – Ear, Nose and oropharynx	4 (1)	6 (1)
Chapter 8 – Malignant disease and immunosuppression	1 (0)	3 (0)
<b>Total</b>	<b>742 (100)</b>	<b>783(100)</b>

In addition to **Table 4.5** there were 62 OTC medicines reviewed during the MUR with 27 patients in the Active group reporting that they were taking one or more OTC medications compared with 22 patients in the control group.

### **4.3.3 Baseline Medicines Use Review data**

Of the 120 active patients 97 (81%) received an annual MUR with the remaining 23 patients receiving an intervention MUR linked to a prescription being presented. In contrast all 120 control patients were invited for an annual MUR following identification for matched data for the active group. Very few patients had expectations of the review recorded on the actual MUR forms with those that were completed referring to requirements for information about medicines and/ or conditions. All 120 baseline interviews for the active group were conducted in the community pharmacy, with the equivalent figure for the control of 116 (97%) with only four being conducted by telephone. There were no urgent MUR action referral sheets that needed an immediate response from the GP. Documentation was submitted to the GP via a variety of methods including phone, fax and electronic transmission.

### **Self report of previous history of ADRs and Allergies**

In the active group there were 7 ADRs and 12 allergies reported; equivalent figures for the control group were 27 and 22 respectively.

### **Patient's knowledge of medicines demonstrated during MUR**

Patients demonstrated good knowledge of what each medicine was for with correct knowledge of medicines confirmed for 696 (90%) medicines in the active group and 726 (90%) in the control group.

**Self reported compliance**

Patients were asked to indicate their level of compliance from a range of options including: always; frequent; seldom; and never. Medicines that were prescribed ‘as required’ were excluded from this report. Self reported compliance rates are provided in **Table 4.6**. It should be noted that no attempt was made to measure actual patient compliance.

**Table 4.6: Self reported compliance noted during MUR**

<b>Compliance</b>	<b>Active (%)</b>	<b>Control (%)</b>
Always	623 (92)	627 (90)
Frequent	24 (4)	37 (5)
Seldom	17 (2)	15 (2)
Never	13 (2)	22(3)
<b>Total</b>	<b>677 (100)</b>	<b>701 (100)</b>

During the MUR, 92% of patients reported being always compliant with their medications in the active group compared to 90% in the control, with the remaining 8% admitting non compliance or varying degrees in the active group compared to 10% in the control group.

**Suitability of treatment as assessed during patient interview**

The pharmacist judged the formulation to be inappropriate for 7% (54) of medicines reviewed in the active group with an equivalent figure of 5% (41) in the control group. In addition the pharmacists attributed side effects to current drug therapy for 7% (58) of medicines in the active group and 4% (36) of medicines in the control group.

#### 4.3.4 Referral rate for patients with one or more problems at baseline

Action plans were written and referrals made to the GP for 93% (112) of active patients compared to 79% (95) of control patients. Pharmacists were free to propose any action they felt appropriate to resolve the problem identified including a prompt for the ‘GP to review’. A wide range of proposed actions were made and are summarised in **Table 4.7**.

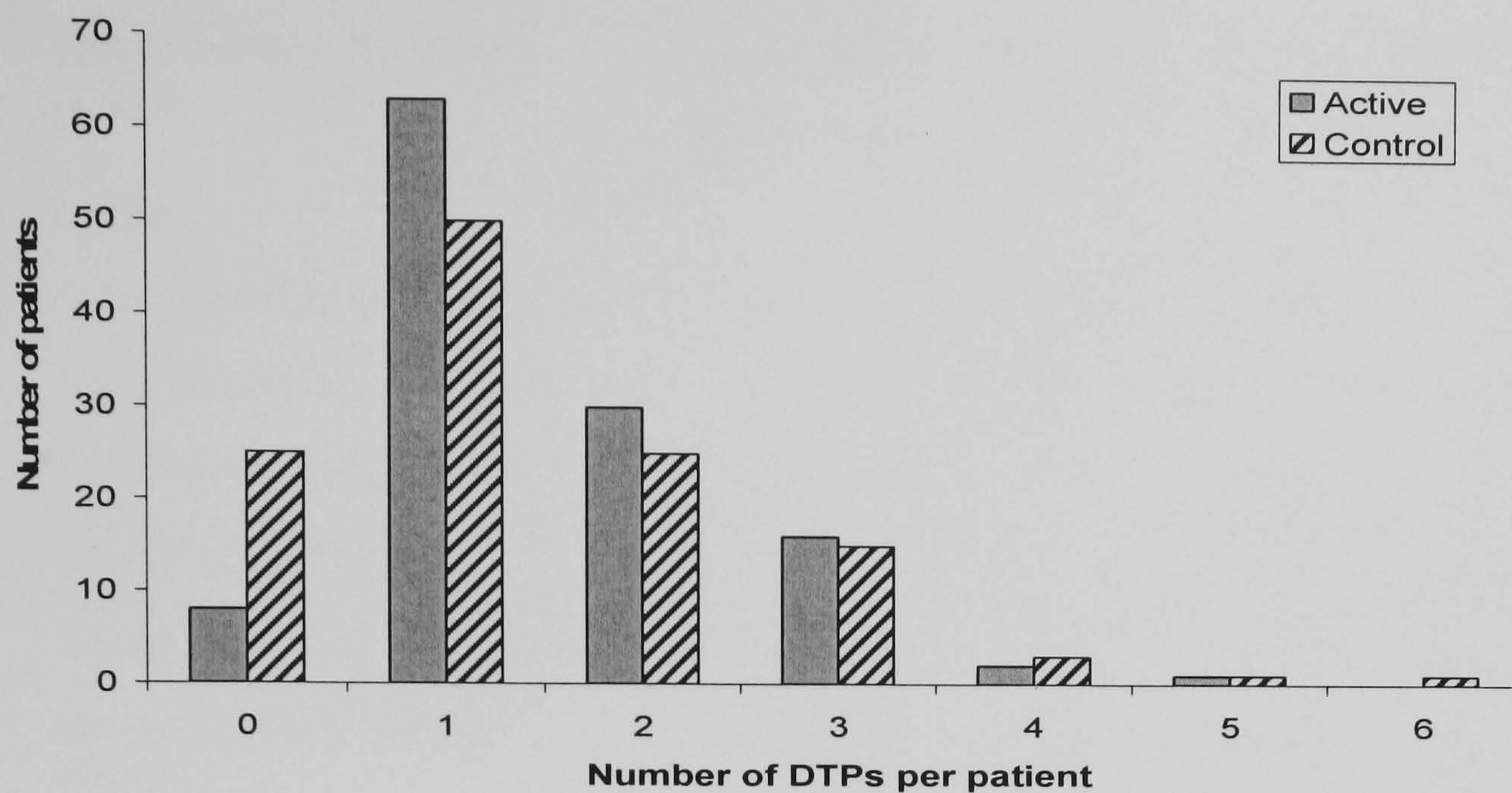
**Table 4.7: Proposed action recommended to the GP on referral**

<b>Action</b>	<b>Active (%)</b>	<b>Control (%)</b>
GP to review	39 (21)	10 (6)
Change dose/directions	31 (17)	19 (11)
Monitoring required	30 (16)	9 (5)
Initiate Therapy	28 (15)	46 (27)
Change drug to new BNF subsection	23 (13)	35 (21)
Counselling required	12 (7)	14 (8)
Change drug and/or formulation within same BNF subsection	10 (5)	10 (6)
Stop Drug	9 (5)	22 (13)
Other	2 (1)	1(1)
Confirm Indication	0 (0)	2 (1)
<b>Total</b>	<b>184 (100)</b>	<b>168 (100)</b>

#### 4.3.5 Number of Drug Therapy Problems identified at baseline

The mean ( $\pm$ SD) value per patient was found to be 1.5 ( $\pm$  0.9) and 1.4 ( $\pm$ 1.1) in the active and control groups respectively. The range of DTPs per patient is illustrated in

**Figure 4.3**

**Figure 4.3: Number of DTPs per patient at baseline**

#### 4.3.6 Categories of DTPs at baseline

The researchers (AWM and CAM) categorised all DTPs using the hierarchical classification system validated in chapter 3. Individual figures for the active and control group are provided in **Table 4.8**.

A random sample of 48 patients was independently coded on a second occasion 3 months apart to determine consistency of the coding over time. In total 72 DTPs were coded in this manner with 100% consistency confirmed. DTP categories remained unchanged as reported.

**Table 4.8: Categories of DTPs at baseline**

<b>Drug Therapy Problems (DTPs)</b>	<b>Active DTPs 120 patients</b>	<b>Rate/100 Patients</b>	<b>Control DTPs 120 patients</b>	<b>Rate/100 Patients</b>
<b>Safety</b>				
Adverse Drug Reaction	42	35	28	23
Drug Interaction	2	2	3	3
Contraindication	0	0	0	0
<b>Appropriateness</b>				
No indication for therapy	16	13	21	18
Inappropriate Choice of therapy	15	13	20	17
Duplication of therapy	0	0	2	2
Inappropriate dose/ dosing schedule	18	15	17	14
Additional drug therapy required	25	21	44	37
<b>Effectiveness</b>				
Ineffective Therapy	31	26	12	10
Unsuitable drug formulation/delivery	5	4	6	5
Non-compliance	15	13	11	9
Monitoring indicated	15	13	4	3

**Supra-categories of DTP**

Overall 352 DTPs were identified across both groups. The hierarchical coding system identified DTPs in the order of ‘safety’, ‘appropriateness’ and ‘effectiveness’. DTPs classified under the supra-category ‘safety’ accounted for 75 (21%) DTPs with 44 in the active group compared to 31 in the control group. Examples of ‘safety’ DTPs are provided in **Table 4.9**.

DTPs classified under the supra-category ‘appropriateness’ accounted for 178 (51%) DTPs with 74 in the active group compared to 104 in the control group. Examples of ‘appropriateness’ DTPs are provided in **Table 4.10**.

DTPs classified under the supra-category ‘effectiveness’ accounted for 99 (28%) DTPs with 66 in the active group compared to 33 in the control group. Examples of ‘effectiveness’ DTPs are provided in **Table 4.11**.

**Table 4.9: Examples of DTPs in the supra category ‘Safety’**

Category of cDTP	Example (Patient number)
<b>Safety</b>	
Adverse Drug Reaction	ADR with Felodipine causing ankle oedema (115)
	ADR with ACE inhibitor, causing dry cough (47)
	ADR with bendroflumethiazide 2.5mg, patient still experiencing diuresis (64)
Drug Interaction	ACE inhibitor and potassium sparing diuretic , NB actual confirmed potassium was noted as high, 5.5mmol/L (62)
	Fluoxetine decreases the effect of Epilim by lowering anticonvulsant threshold, patient has increased frequency of seizures (28)
Contraindication	None noted

**Table 4.10: Examples of DTPs in the supra category ‘Appropriateness’**

Category of cDTP	Example (Patient number)
<b>Appropriateness</b>	
No indication for therapy	Patient has been on Lansoprazole 30mg without indication and reports no GI symptoms (117)
	Tamsulosin 400mcg caps, patient has no history or symptoms to indicate prostate problems(78)
	Bumetanide prescribed with calcium channel blocker for ankle oedema (102)
	Beta Blocker being used for blood pressure with no co-morbidity to support 1 <sup>st</sup> line use (106)
Duplication of therapy	None noted
Inappropriate dose/dosing schedule	Review antihistamine, risk of side effects with high dosage of chlorpheniramine, taking 8 daily (59)
	Dose of bendroflumethiazide 5mg for blood pressure, no additional hypertensive benefit above 2.5mg dose, just increased incidence of side effects (76)
Additional drug therapy required	Beta blocker needed for cardioprotection in IHD(100)
	Antiplatelet agent with diabetes, start aspirin 75mg daily (132)



**Table 4.11: Examples of DTPs in the supra category ‘Effectiveness’**

<b>Category of DTP</b>	<b>Example (Patient number)</b>
<b>Effectiveness</b>	
Ineffective Therapy	Ineffective therapy for hypertension patient has blood pressure of 192/89 mmHg on beta blocker and ACE inhibitor (120) Ineffective/insufficient therapy. Patient is very concerned with her poor blood glucose control, HbA1c is 8.8% on Gliclazide 80mg , one tablet twice a day (48)
Unsuitable drug formulation/delivery	Inappropriate formulation salbutamol MDI, technique poor, give autohaler to improve drug penetration (118) Patient using syringes with Mixtard 30 penfill, change to either vials or give pen (43)
Non-compliance	Patient stopped Co-dydramol due to constipation (60) Patient has not been taking beta-blocker for IHD has agreed to restart (58)

**DTPs linked to BNF chapter for active and control group**

DTPs linked to the top 5 BNF chapters for the active and control groups are displayed in **Tables 4.12** and **4.13** below. Cardiovascular drugs accounted for approximately half of all medicines reviewed and over half of all associated DTPs.

**Table 4.12: Top 5 BNF Chapters of medicines reviewed and associated DTPs for the active group**

<b>BNF (chapter)</b>	<b>Medicines reviewed (%)</b>	<b>Medicines associated with DTPs (%)</b>
Chapter 2 – Cardiovascular	387 (50)	111 (53)
Chapter 4 – CNS	72 (9)	22 (11)
Chapter 6 – Endocrine System	81 (10)	20 (10)
Chapter 3 – Respiratory	67 (9)	18 (9)
Chapter 10 – Musculoskeletal	25 (3)	13 (6)
Other	145 (19)	24 (11)
<b>Total</b>	<b>777 (100)</b>	<b>208 (100)</b>

**Table 4.13: Top 5 BNF Chapters of medicines reviewed and associated DTPs for the control group**

<b>BNF (chapter)</b>	<b>Medicines reviewed (%)</b>	<b>Medicines associated with DTPs</b>
Chapter 2 – Cardiovascular	380 (47)	120 (59)
Chapter 6 – Endocrine System	80 (10)	22 (11)
Chapter 1 – Gastrointestinal	57 (7)	20 (10)
Chapter 3 – Respiratory	64 (8)	14 (7)
Chapter 4 – CNS	89 (11)	14 (7)
Other	140 (17)	15 (7)
<b>Total</b>	<b>810 (100)</b>	<b>205 (25)</b>

#### **4.3.7 Primary outcome measure**

The primary outcome measure was to demonstrate a reduction in DTPs from baseline to follow-up. Planned follow-up for the active group occurred between April 2006 and March 2007. Time from baseline to follow-up was 6 ( $\pm$  0.8) months for the Active group. The time periods for the control group were equivalent as previously described.

#### **Changes in number of Drug Therapy problems from baseline to follow-up**

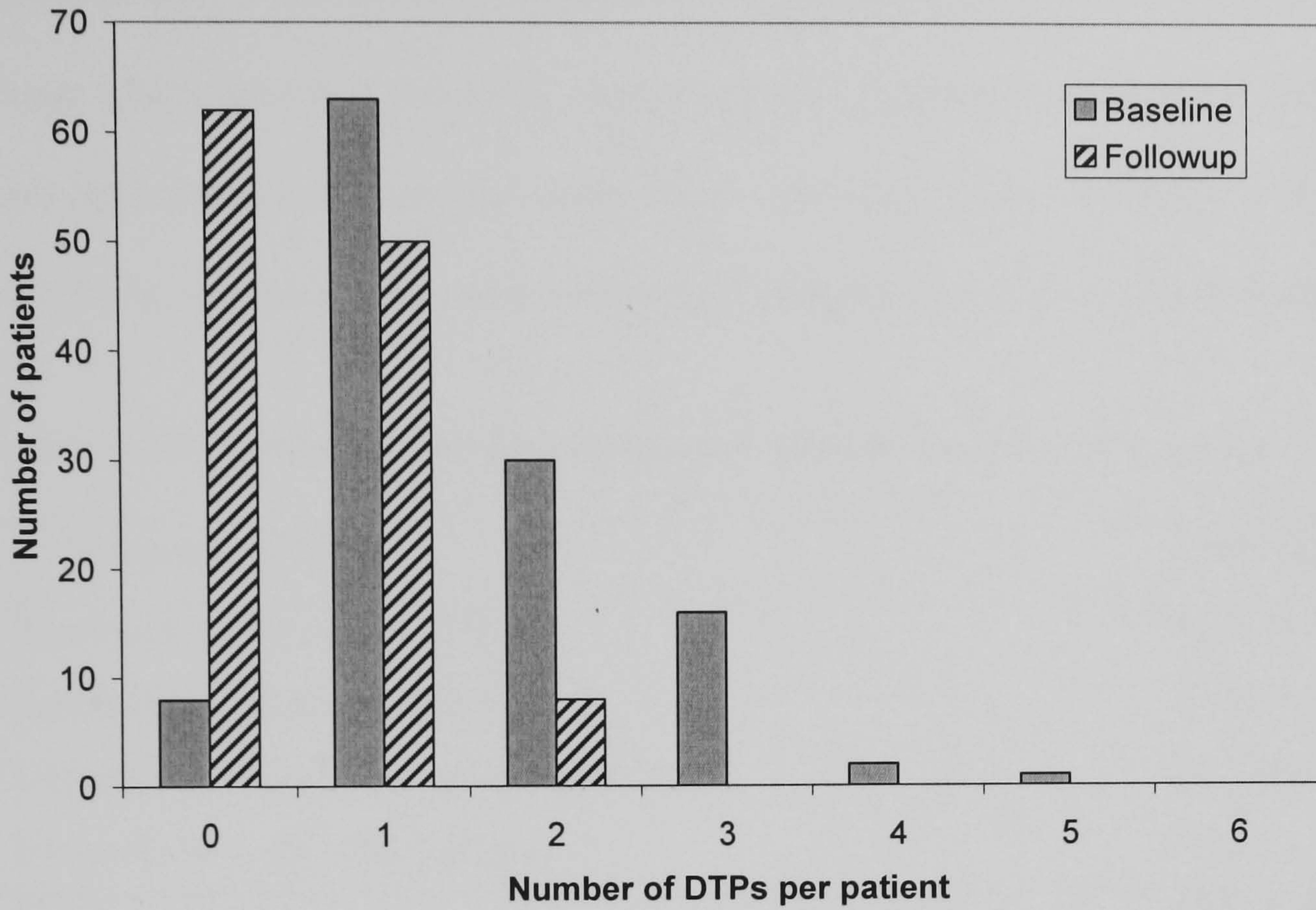
Of the 352 DTPs identified at baseline, 123 (35%) were resolved at follow-up overall. In the active group, the number resolved were 118 (64%) with only 5 (3%) resolved in the control group. The mean ( $\pm$  SD) number of DTPs per patient at baseline and follow-up are provided in **Table 4.14** for both groups.

**Table 4.14: Mean DTPs at baseline and follow-up**

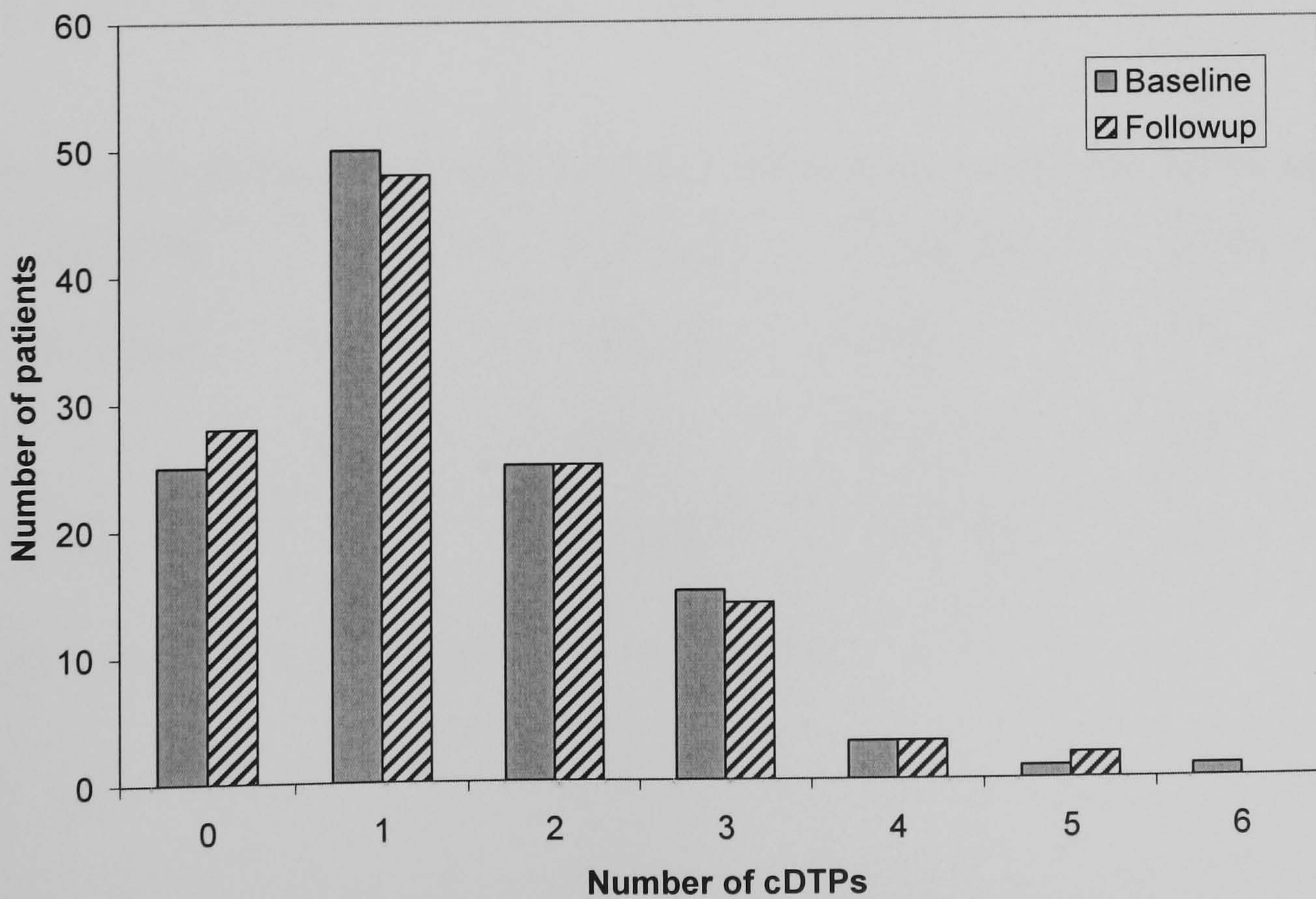
<b>Group</b>	<b>Mean (<math>\pm</math> SD) DTPs Baseline</b>	<b>Mean (<math>\pm</math> SD) DTPs Follow-up</b>
Active	1.5 ( $\pm$ 0.9)	0.6 ( $\pm$ 0.6)
Control	1.4 ( $\pm$ 1.1)	1.36 ( $\pm$ 1.1)

The range of DTPs per patient is illustrated in **Figures 4.4** and **4.5** for the active and control group respectively. From **Figure 4.4** it can be seen that there is a distinct shift to the left for the follow-up DTPs with over 60 patients having no DTPs. In contrast **Figure 4.5** shows minor change from baseline to follow-up.

**Figure 4.4: Number of DTPs per patient from baseline MUR to follow up MUR (6± 0.8 months) in the active group**



**Figure 4.5: Number of DTPs per patient from baseline (Estimated) to inclusion (MUR) in the control group**



**Outcomes of DTPs in the active group in relation to proposed actions**

At follow-up the researchers (AWM, CAM) recorded whether the DTP had been resolved due to action recommended by the pharmacists or by alternative action. In cases where the DTP remained unresolved two categories were used: unresolved – proposed action not taken; and unresolved – all other causes. A summary of outcomes of DTP in relation to proposed actions by the pharmacist is provided in **Table 4.15**.

**Table 4.15: Outcomes linked to proposed actions for the active group**

<b>Outcome of DTPs</b>	<b>Active (%)</b>
Resolved due to action taken	96 (52)
Resolved by alternative action	22 (12)
Unresolved – proposed action not taken	56 (30)
Unresolved – all other causes	10 (6)
<b>Total</b>	<b>184 (100)</b>

**Statistical analysis of primary outcome measure**

A Chi-squared test was used to compare DTPs resolved from baseline to follow-up between the two groups. The data is presented in **Table 4.16** and suggests that the hypothesis should be accepted ( $\chi^2 = 144.4$  ;  $p < 0.0001$ ).

**Table 4.16: Comparison of reduction in DTPs from baseline to follow-up**

<b>All DTPs</b>		<b>Active(%)</b>	<b>Control(%)</b>	<b>Total</b>
Resolved	Yes	118(64)	5(3)	123
	No	66(36)	163(97)	229
<b>Total</b>		<b>184(100)</b>	<b>168 (100)</b>	<b>352</b>

**( $\chi^2 = 144.4$ , df 1,  $p < 0.0001$ , RR = 21 [9 to 51])**

The effect size is represented by the relative risk (RR), which was found to be 21 (9 to 51) for DTPs. The absolute risk reduction (ARR) was calculated as 61% and the number needed to treat (NNT) was calculated as 8. This means for every 8 DTPs receiving an intervention, a DTP is avoided over a period of 6 ( $\pm 0.8$ ) months.

The chi-squared test assumes that all DTPs are independent which may not be the case. Although all DTPs were only coded once and therefore may be considered independent, in practice co-morbidity is often linked for example patients with diabetes often have related cardiovascular problems resulting in multiple DTPs. However, patients themselves are independent therefore the analysis was repeated, based on patients having one or more DTPs at follow-up. In this way a Chi-squared test was used to compare the number of patients with one or more DTPs from baseline to follow-up between the two groups. The data is presented in **Table 4.17**. The result was statistically significant ( $\chi^2 = 55.3$ ;  $p < 0.0001$ ) with an absolute risk reduction (ARR) of 46% giving the number needed to treat (NNT) as 2.2. This means that for every 22 patients receiving the intervention 10 patients will have no DTPs at 6 ( $\pm 0.8$ ) months.

**Table 4.17: Comparison of patients with one or more DTPs**

<b>DTPs</b>	<b>Active (%)</b>	<b>Control (%)</b>	<b>Total</b>
Yes	58(52)	93(98)	151
No	54(48)	2(2)	56
Total	112(100)	95(100)	207

( $\chi^2 = 55.3$ , df 1,  $p < 0.0001$ , RR = 23 [5 to 91])

### 4.3.8 Secondary Outcome measures

#### Number of repeat medicines at baseline and follow up

This outcome measure was only available for the active group. The total number of repeat medicines at baseline and follow-up were 742 and 769 respectively with mean ( $\pm$  SD) values provided in **Table 4.18**. This difference was not found to be statistically significant.

**Table 4.18: Repeat medicines at baseline and follow-up**

Variable	Active
Initial number of medicines mean $\pm$ SD	6.2 $\pm$ 2.6
Final number of medicines mean $\pm$ SD	6.4 $\pm$ 2.8

#### Primary care consultations, hospital consultations and admissions

From the case notes, details of all consultations, for the prospective active group, were extracted for a period of 6 months prior to the intervention date and compared with the equivalent period immediately after the intervention. For the retrospective control group who received the intervention at month 0, equivalent data was collected for the matched periods from -12 to -6 months and -6 months to 0. Results are provided in **Table 4.19**. There was found to be no significant difference in health care resources use from baseline to follow-up for: the active group ( $p= 0.51$ ); the control group ( $p= 0.95$ ); and between groups ( $p= 0.67$ ).

**Table 4.19: Use of health care resources during the study period**

Variable	Active (n=120)		Control (n=120)	
	Pre-intervention	Post-intervention	Pre-intervention	Post-intervention
<b>Primary care visits</b>				
- GP or Nurse	395	390	404	416
- Out of hours	15	12	35	33
<b>Hospital visits</b>				
- Out patient	83	95	93	96
- Accident and emergency	8	14	14	9
<b>Hospital admissions</b>	11	12	18	11

Although the results were not statistically significant, a trend was observed for an increase in A & E visits in the active group compared to a decrease in the control. Further investigation revealed that the reason for these visits was unrelated to the MUR service and was accounted for by minor trauma.

#### **4.3.9 Retrospective peer review to assess risk**

##### **Review of active patients MUR documentation without access to case notes**

At the end of the study, the two researchers (AWM, CAM) reviewed all 120 active patients and highlighted an additional 61 (33%) DTPs which the participating pharmacists had not recorded on the MUR documentation. This review only took into account what was recorded and did not make any reference to patient's case notes so as to reflect the actual situation that pharmacists are in when they undertake an MUR. In contrast only one DTP was deemed to be inappropriate following peer review. **Table 4.20** provides an overview of the DTPs which would have been added in the Active group if the reviews had actually been peer reviewed by a clinical pharmacist before submission to the patient's GP. It should be noted that since no reference was



made to the case notes, it is difficult to confirm whether the DTPs suggested by the reviewers were appropriate or would put the patient at risk.

**Table 4.20 Categories of DTPs added by peer review for the active group**

<b>Drug Therapy Problems (DTPs)</b>	<b>Added</b>	<b>Deleted</b>
<b>Safety</b>		
Adverse Drug Reaction	0	1
Drug Interaction	1	0
Contraindication	2	0
<b>Appropriateness</b>		
No indication for therapy	18	0
Inappropriate Choice of therapy	6	0
Duplication of therapy	1	0
Inappropriate dose/ dosing schedule	4	0
Additional drug therapy required	24	0
<b>Effectiveness</b>		
Ineffective Therapy	1	0
Non-compliance	1	0
Monitoring indicated	1	0
<b>Total</b>	<b>61</b>	<b>1</b>

**Review of active patients MUR documentation with access to case notes**

All pharmacists' recommendations were reviewed by the researchers (AWM and CAM) in conjunction with the patient's medical case notes to assess if there was any recommendation which would have been considered as potentially hazardous.

A review of all 120 active patient's documentation revealed only 1 out of 184 recommendations which was considered to be hazardous. A case summary of this is provided in **Box 4.2**.

**Box 4.2 Case summary of potentially hazardous recommendation**

<b>Patient code 46</b>	Male, age 76 years
<b>Current drug therapy:</b>	Candesartan 16mg tablets, one daily Amiodarone 100mg tablets, one daily Simvastatin 40mg tablets, one at night Furosemide 40mg tablets, one daily Warfarin tablets, as directed
<b>Interview on 1<sup>st</sup> of February 2006:</b>	The pharmacist recommended that this patient be initiated on low dose Aspirin 75mg daily.
<b>On further examination of the medical notes the following was revealed</b>	
<b>Relevant medical notes:</b>	Aspirin and Clopidogrel contraindicated
<b>Monitoring:</b>	BP 140/70 February 2006 Cholesterol 5.9 mmol/l, February 2006
<b>Peer review comment:</b>	The pharmacist had not recorded medical history or allergies for this patient and the recommendation was considered hazardous.
<b>Actual outcome:</b>	This recommendation was not initiated by the patient's GP, so the patient was unharmed.

**Failure to identify problems during MUR considered potentially hazardous**

Of the 61 DTPs identified by peer review and omitted from the pharmacist recommendations for the active patients, only 2 were considered high risk and

included one patient taking a beta blocker, with a medical history of asthma (patient 120) and another in which the patient was taking diltiazem which is contra-indicated in heart failure (patient 84). A case summary is provided in **Boxes 4.3** and **4.4** respectively.

**Box 4.3 Case summary for DTP considered to be hazardous by peer review due to pharmacist failing to record and refer problem to GP**

<b>Patient code 84</b>	Male, age 84 years
<b>Relevant medical history:</b>	Heart Failure Atrial Fibrillation Hypothyroidism
<b>Current drug therapy:</b>	Levothyroxine 25mcg tablets, one at lunch Bumetanide 1mg tablets, two in the morning Carvedilol 3.125mg tablets, two daily Simvastatin 40mg tablets, one at night Aspirin EC 75mg tablets, two in the morning Diltiazem XL 300mg capsules, one daily Lisinopril 20mg tablets, one at night
<b>Interview on 12<sup>th</sup> of June 2006:</b>	The pharmacist recommended that this patient be switched from Aspirin EC to Aspirin 75mg dispersible.
<b>On further examination of the medical notes the following was revealed</b>	
<b>Monitoring:</b>	BP 125/79 July 2006 Cholesterol 3.1 mmol/l, September 2006
It also appears this patient's heart failure is worsening, no dosage adjustments have been made.	
<b>Peer review comment:</b> Pharmacist failed to record that there is a contraindication with Diltiazem in heart failure and a potentially hazardous drug interaction with Carvedilol noted in the BNF.	
<b>Actual outcome:</b> Referred to the GP when noted by peer review at end of study	

**Box 4.4: Case summary for DTP considered to be hazardous by peer review due to pharmacist failing to record and refer problem to GP**

<b>Patient code 120</b>	Female, age 75 years
<b>Relevant medical history:</b>	Asthma Hypertension Gout Osteoarthritis
<b>Current drug therapy:</b>	Salbutamol MD inhaler, two puffs PRN Paracetamol 500mg tablets, 2 TID Atenolol 25mg tablets, one in the morning Enalapril 5mg tablets, one in the morning Allopurinol 100mg tablets, two daily Amitriptylline 10mg tablets, two at night Arthrotec 75mg tablets, one twice a day
<b>Interview on 27<sup>th</sup> of February 2006:</b>	The pharmacist recorded that an asthma review was needed because the patient's peak flow was low.
<b>Outcome of referral:</b>	Inhaler type changed to 'Easi-breathe'
<b>On further examination of the medical notes the following was revealed</b>	
<b>Monitoring:</b>	BP 180/90 February 2006 Peak Flow 280L/min May 2006
<b>Peer review comment:</b>	Pharmacist did not record that beta-blockers are contraindicated in Asthma (BNF).
<b>Actual outcome:</b>	Referred to the GP when noted by peer review at end of study

#### 4.3.10 Post study revision of estimated resolution of DTPs in the control group

A previous study (Mackie et al., 1999) in a general practice setting reported clinical DTP resolution of 75% in the active versus 25% in the control group. A more closely related study (Mackie et al., 2005) in a community pharmacy setting reported clinical DTP resolution of 61% in the active group versus 21% in the control group. The figures for the present study suggest clinical DTP resolution of 64% in the active group versus 3% in the control. This 3% may be due to limitations of the study design, in particular the difficulties in determining the presence of DTPs at -6 months for the retrospective control cohort. Hence it was decided to repeat the analysis using a figure of 21% for resolution of DTPs in the control group.

#### Statistical analysis of primary outcome measure with revised estimate for control cohort

A Chi-squared test was used to compare DTPs resolved from baseline to follow-up between the two groups. The data is presented in **Table 4.21** and suggests that the hypothesis may be accepted using a revised estimate of 21% resolution of DTPs in the control group due to standard care ( $\chi^2 = 67$ ;  $p < 0.0001$ ).

**Table 4.21: Comparison of reduction in DTPs from baseline to follow-up with revised estimate for control cohort**

All DTPs		Active (%)	Control (%)	Total
Resolved	Yes	118 (64)	35 (21)	153
	No	66 (36)	133 (79)	199
Total		184 (100)	168 (100)	352

( $\chi^2 = 67$ , df 1,  $p < 0.0001$ , RR = 3.1 [2.3 to 4.2])

The effect size is represented by the relative risk (RR), which was found to be 3.1 (2.3 to 4.2) for DTPs. The absolute risk reduction (ARR) was calculated as 43% and the number needed to treat (NNT) was calculated as 2.3. This means for every 23 DTPs receiving an intervention, 10 DTPs would be avoided over a period of 6 ( $\pm 0.8$ ) months using a revised estimate of 21% for resolution of DTPs in the control group due to standard care.

#### **4.4 Discussion**

Medicines Use Review is a health care intervention introduced in the new NHS community pharmacy contract in England and Wales in April 2005. There was an urgent need to evaluate this new service in order to establish an evidence base. In this chapter, a matched cohort study design was selected to test the quantitative aspect of the hypothesis that ‘Medicines Use Review will reduce drug therapy problems and will be well accepted by both pharmacists and patients’. Qualitative methodology was adopted to ascertain practitioner and patient’s views which are reported separately in chapters 5 and 6.

A drug therapy problem was defined by Cipolle et al (1998) as: *‘any undesirable event experienced by the patient that involves or is suspected to involve drug therapy and that actually or potentially interferes with a desired patient outcome.’* In addition, a DTP was deemed to exist *‘when a patient experiences or is likely to experience either a disease or symptom having an actual or suspected relationship with drug therapy’* (Strand et al., 1990).

Evaluation of the primary outcome measure demonstrated a significant reduction in drug therapy problems in the active group compared to the control over the six month

period of the study. The primary outcome measure was a reduction in drug therapy problems with a 64% resolution in the active group compared to only 3% in the control group. Mean number of drug therapy problems was found to be 1.5 ( $\pm$  0.9) for the active group and 1.4 ( $\pm$  1.1) for the control group at baseline. This reduced to 0.6 ( $\pm$  0.6) and 1.36 ( $\pm$  1.1) at follow-up for the active and control group respectively. This effect size is significant ( $p < 0.0001$ ) suggesting that the hypothesis can be accepted. However, the effect size on the control group of only 3% is lower than that reported for previous studies (Mackie et al., 1999, Mackie et al., 2005). Hence the results were reanalysed using a revised estimate of 21% for resolution of DTPs in the control group due to standard care. The effect size remained significant ( $p < 0.0001$ ) with an absolute risk reduction of 43% and number needed to treat of 2.3, this means for every 23 DTPs receiving an intervention, 10 DTPs would be avoided over a period of 6 ( $\pm$  0.8) months over and above standard care.

There were no changes in the secondary outcome measures which included number of repeat medicines and use of health care services. The number of medicines at baseline and follow-up remained at a mean of 6 ( $\pm$  3) indicating that drug therapy problems were resolved without a significant increase in repeat prescribing. This is reassuring but should not be interpreted as patients not having had changes made to drug therapy. 38% of proposed actions in the active group suggested a change to medicines (28%, starting medicines; changing medicines both within (10%) and out with (23%) BNF chapters and 9%, proposing stopping drugs) with 64% of these changes successfully implemented.

In terms of use of health care services, no significant differences were noted in primary care visits, secondary care visits and hospital admissions between the two

groups. This may be considered a very positive outcome in that MUR is a new model of care such that if patients needed reassurance regarding changes made by the pharmacist this may have contributed to an increase in consultation rates. This was not observed.

Two hundred and forty patients were recruited to the study with 120 patients in each group. Remarkably all 240 patients completed the study after 6 ( $\pm 0.8$ ) months which may be a reflection on the criteria for access to annual MUR services (81% of active study participants received an annual MUR) which required patients to be known to the pharmacy for at least 3 months. The entry criteria to the study itself were deliberately kept wide ( $\geq 18$  years and registered with a participating GP practice) to improve generalisability of the findings. This rate is comparable to the 80% of patients with chronic diseases reported to regularly attend the same pharmacy (Royal Pharmaceutical Society of Great Britain, 1996) and bodes well for the future of MUR services. It should be noted that these patients did not receive a standard MUR service but received an enhanced level of information linked to their recruitment to a research study, the impact of which is unknown.

Although these results appear to be outstanding for a new service their generalisability is limited by the low number of pharmacists accredited to provide MUR services at the outset of this study in September 2005. In the Kent region at this time, only 15 (5%) out of 286 pharmacies were accredited to provide MUR services with the 8 participating pharmacists being recruited from this rather select group. However, this level of uptake was typical of the national picture following the introduction of the new Pharmacy Contract in April 2005. The majority of pharmacies at that time prioritised meeting the extensive requirements for the



Chapter 4: A Matched Cohort Study to Evaluate Medicines Use Review Services essential services (level 1) by October 2005 (PSNC, 2005) before moving on to provide advanced services (level 2). In this case our 8 pharmacists may be considered to be early adopters of new services.

What was extraordinary was that all 35 GP practices (including 65 GPs) who were nominated by these 8 pharmacists agreed to participate in the research. This high recruitment rate (100%) may be a reflection on the pre existing good relationships between the GPs and the pharmacists who nominated them. Although many were nominated, only 12 GP practices actually participated in the study due to pharmacists selecting patients from a narrow range of practices for the actual MUR.

The demographics of patients who participated were well matched between the two groups, with a mean age of 67 ( $\pm 11$ ) years, receiving multiple repeat medicines with approximately 3 medical conditions per patient. What appears to be unusual is the high rate of participation of males who accounted for approximately half of all participants in both groups. This may reflect the accessibility and acceptability of a pharmacy based MUR service by this group of patients which has important implications for public health. In 2001, Banks highlighted the fact that men often worry about health but feel unable to seek help until it is often too late such that the NHS will remain 'a no man's land' until changes are made to health policies to improve access to alternative services such as NHS direct online and walk in centres. This study suggests that MUR services may improve this accessibility.

MUR services require the pharmacist to take a medical history from the patient, an activity that hospital pharmacists have much experience of. However, it is new to community pharmacists and may have presented a challenge to participants. In this

Chapter 4: A Matched Cohort Study to Evaluate Medicines Use Review Services study, pharmacists correctly recorded 91% (603) of medical conditions with only 60 being added by the researchers following case note review. In addition patient's knowledge of medicines use was found to be 90% in both groups. This is reassuring to note as both an accurate medical history and information on medicines use is required to be recorded if pharmacists are going to deliver pharmaceutical care through MUR services. In contrast, the recent amendment to the MUR documentation system (Version 2, December 2007) has removed all reference to patient history, allergies and monitoring leaving only current medicines use which raises concerns in relation to the development of MUR as a clinical service (PSNC, 2007).

It is notable that cardiovascular conditions accounted for 55% of all medical conditions in both groups and consequently approximately 50% of all medicines reviewed at the MUR. Not surprisingly cardiovascular drugs were associated with drug therapy problems in 53% and 59% of active and control patients respectively. One of the criticisms of MUR services is that pharmacists are allowed to select any patient on  $\geq 1$  medicines (if known to the pharmacy as described previously) with PCTs able to advise but not dictate which patient groups should be targeted. On the basis of this study, it would appear advisable to target patients receiving multiple medicines and in particular cardiovascular medicines. Further research is required to evaluate the cost effectiveness of this approach.

A major limitation of previous studies (Hanlon et al., 1996, Westerlund et al., 1999, Zermansky et al., 2001, Grymonpre et al., 2001, Taylor et al., 2003) has been the lack of the use of a hierarchical system to categorise DTPs. This was overcome with the validation of an amended system as described in chapter 3. Of particular note was the distribution of drug therapy problems across the three supra categories with safety

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accounting for 21% of all problems, appropriateness 51% of all problems and effectiveness only 28% of all problems. If we consider the categories represented within each of these groups, we would anticipate that pharmacists would be confident to report DTPs under safety which includes adverse drug reactions, drug interactions and contraindications. In addition we would anticipate pharmacists being able to identify DTPs under the supra category effectiveness which includes non-compliance, monitoring, ineffective therapy and unsuitable drug, formulation /delivery. What was perhaps unexpected was that more than half of the DTPs identified related to appropriateness of therapy which was traditionally the domain of the GP. Where appropriateness includes categories such as: no indication for therapy; inappropriate choice of therapy; inappropriate dose / dosing schedule; and additional drug therapy required.

One of the potential risks of MUR is that pharmacists may make inappropriate referrals to GPs based on patient history without access to case notes. Peer review of case notes for all 120 active patients identified only one such patient; this was linked to the recommendation to start low dose aspirin which was contraindicated but unknown to both the patient and the pharmacist. However the MUR system proved effective in this case as the GP, who had access to the case notes, rejected the recommendation. It should be noted that aspirin can be purchased over the counter and therefore the patient could have been exposed to this risk irrespective of whether or not they had access to an MUR service. Indeed a study of drug related hospital admissions by Pirmohamed et al (2004) identified that aspirin was the most common drug associated with hospital admissions, accounting for 18% of all admissions over the six month period of the study. In conclusion, the MUR service was effective and

did not expose the patient to unnecessary risk due to an action being implemented following the recommendation of a pharmacist without access to case notes.

An interesting observation was that two patients were considered to be exposed to potential hazard not due to the action of the pharmacist but due to the inaction of the pharmacist who failed to record significant DTPs. What is unknown is whether the pharmacist identified these problems and dismissed them following discussion with the patient. Both of these cases involved potentially hazardous drug interactions and contraindications which could have been picked up by the most basic pharmacy patient medication record (PMR) software, so it seems incredible that they were missed. It may be possible that the patient may have been on the combination and had attended the pharmacy regularly. In which case the pharmacist may have already contacted the GP to discuss this in the past and may have been told that the patient was being monitored by the GP or a hospital based consultant. What is concerning is that there was no written record of this possible interaction in the patient's case notes, which has legal and ethical implications. Further research is required into this area as this study was not designed nor powered to assess risks associated with inaction on the part of the pharmacist.

There were several limitations to this study; some of these have been discussed previously such as generalisability linked to the 'early adopter' pharmacists who volunteered to take part within 6 months of the service being introduced in September 2005. However, the results were consistent with the East London community pharmacy based clinical medication review (Mackie et al., 2005) which reported 61% resolution of DTPs in the active group compared to the 64% resolved in this study.

A randomised controlled trial would have been the favoured design as it would have allowed the study of two cohorts of patients randomised to receiving 'standard' care and the intervention. It was originally intended to use an RCT study design, however in April 2005, the New Pharmacy Contract resulted in the MUR service becoming 'standard care'. This gave rise to two potential problems; firstly, the ethics of withholding standard care and secondly, contamination which may have resulted from controls being invited to have an MUR during the study period. This withholding of 'standard care' may have been considered to be a breach of the RPSGB code of ethics. For example, this may have occurred if a patient in the control group had several drug therapy problems identified as part of a MUR and the protocol required the referral to be withheld in order to evaluate the impact of MUR on the active group only. As a randomised controlled design could not be carried out a prospective cohort study with a matched control was undertaken instead.

The main difference between an RCT and a cohort study is that allocation of individuals is not by chance. In this case, patients were selected by the participating pharmacists, which could give rise to selection bias. However, this reflects the actual conditions of MUR which together with the minimal exclusion criteria and a matching of cohorts strengthens the internal validity of the study. One of the main criticisms of RCT designs is that they are too highly controlled and not likely to reflect current practice, this was overcome with the current cohort study design. (Rochon et al., 2005).

## Summary

This matched cohort study has demonstrated clinical effectiveness of MUR services. It overcame limitations of previous work in several ways. The sample size was sufficiently powered to test the study hypothesis and the setting was representative of community pharmacy premises. A particular strength of the current study was the prospective cohort design for the active group. However, a limitation was the reliance on a retrospective matched control possibly resulting in a low estimation for resolution of DTPs in this group. This was overcome by using a revised estimate based on two well designed RCTs previously reported.

A prospective cohort of 120 patients receiving a medicines use review service had two thirds of DTPs resolved over the six month study period with no significant changes to number of repeat medicines and use of other health care services. This compares to an estimate of one fifth of DTPs resolved due to standard care from published literature. These findings have implications for practice and the potential to make a significant contribution to the evidence base for MUR services within the UK. However, for any new service to be adopted, it must not only be effective but must be well received by patients and pharmacists. Qualitative methodology has been adopted to address this aspect and is reported in Chapter 5 and 6.

## Chapter 5

### Pharmacists' Views of Medicines Use Review Services

#### 5.1 Introduction

Chapter 4 described a study testing the first part of the hypothesis 'Medicines Use Review will reduce drug therapy problems and will be well accepted by both pharmacists and patients'. This new service was radical in that it empowered the pharmacist to invite patients to receive pharmaceutical care, without their doctor's consent, and to provide copies of the action plan directly to the patient and their doctor. This chapter adopts qualitative methodology to explore views of pharmacists currently providing MUR services.

Blenkinsopp et al (2007) reported slow uptake of MUR services nationally citing barriers to service provision such as pharmacist workload and lack of resources. This impact of increasing workloads and role expansion was further investigated by Gidman et al (2007), who reported that although community pharmacists enjoyed their new roles, high pressure working environments had become common and were likely to have a negative impact on both pharmacists and the services they provide. Latif and Boardman (2008) undertook a study in May 2006, exploring the attitudes of community pharmacist towards MUR and recently reported that they were generally positive towards this new service perceiving that it was beneficial to both pharmacists and patients. They highlighted that MUR had been slow to become established in practice even although a number of pharmacists were accredited shortly after its introduction.

From the outset of the new contract this service was allocated £39 million for the period April 2005 to March 2006. Of this £39 million only £3.4 million was actually claimed that year. In 2006/2007 only £13.5 million was claimed which confirms the slow uptake previously reported (Blenkinsopp et al., 2007; Latif and Boardman, 2008). This is a matter of great concern and the reasons for non participation need to be explored. To address this concern this chapter also explores the views of pharmacists not currently providing MUR services.

## **5.2 Aim**

To obtain views on MUR services from two groups of community pharmacists: those who are delivering MUR services and those who are not.

## **5.3 Focus Group Methodology**

Two independent focus groups of pharmacists were held; one including providers of the MUR service with a second group of non providers of MUR services. Focus group methodology was employed for this study as it allows a more in depth discussion about topics raised than would be possible using one to one interviews. Advantages and disadvantages of focus groups have been discussed previously in Chapter 2.

### **5.3.1 Recruitment of participants**

#### **MUR service providers**

1. A formal request was made to Medway Primary Care Trust (PCT) to obtain details of pharmacies in Medway who were delivering MUR services.



2. Letters of invitation to participate in the focus group were sent out to all 14 pharmacies listed as providing MUR services in Medway, which represented 33% of pharmacies in the area.
3. Included in the information pack was a consent form and self-exclusion form for those who did not wish to participate. Pharmacists were asked to return the appropriate form following which a telephone call was made, one week later by the research assistant (OO), to those who consented to participate in the focus group. Participants were asked to confirm suitability of possible dates at that time.
4. Once 6 to 8 participants had confirmed a particular date, the meeting was fixed. A final letter confirming the time, date and venue for the focus group was posted to participating pharmacists.

#### **Non providers of MUR services**

1. A formal request was made to Medway Primary Care Trust (PCT) to obtain details of pharmacies in Medway who were not providing MUR services.
2. Letters of invitation to participate in the focus group were sent out to all 28 pharmacies listed as not providing MUR services in Medway, which represented 67% of pharmacies in the area.
3. A similar methodology was adopted for recruiting providers of MUR services (steps 3 and 4 above).

### **5.3.2 Topic guide and group facilitation**

A topic guide to facilitate discussion for both groups, was researched and designed by a research assistant (OO) and agreed with the independent pharmacist facilitator (CD). Each group overlapped in certain topics in addition to the group specific topics. A copy of both topic guides can be found in **Appendix 12**.

### **5.3.3 Participant observation and data recording**

The two meetings were digitally recorded and participants were assigned a number so as to facilitate coding and analysis of the resulting transcript. The time at which each participant spoke was recorded by a research assistant (SNA) and body language noted by a second research assistant (OO). The researcher (AWM) observed all proceedings but did not take part.

### **5.3.4 Organisational issues**

The two focus groups were held at Medway School of Pharmacy on separate evenings with each scheduled to last approximately one hour. Dinner was provided to all participants before the focus groups were conducted as many participants came directly from work.

### **5.3.5 Data coding and analysis**

In each case the digital recordings were transcribed by the research assistant (OO) and independently checked by researcher (AWM). The confirmed transcripts were subjected to content analysis with key themes and concepts representing ideas, opinions and attitudes identified by repeated reading of the transcripts and subsequently categorised by the researcher (AWM). The data were independently analysed by a second researcher (CAM) and the final themes, concepts and categories

agreed separately for each group. Each theme and concept was illustrated by quotes from participants.

## **5.4 Results of focus group discussions of MUR service providers**

A letter of invitation was sent to 14 out of 42 pharmacies in Medway PCT listed as providing the MUR service. Six pharmacists out of 14 agreed to participate in the group. The focus group was held at the Medway School of Pharmacy in November 2007 and was moderated by an independent pharmacist facilitator (CD). The meeting lasted approximately 1 hour.

### **5.4.1 Pharmacists views of the New Community Pharmacy Contract April 2005**

The tone of the meeting was very positive towards the 'New Pharmacy Contract', with the new range of services supported as an excellent idea. The views expressed highlighted three themes: resources, change and workload.

*"I'm really quite happy with the new contract.... our pharmacy was getting really stale, I was getting fed up with that supply situation.....why did I bother to do a degree for what we are doing now? So from that point of view....it's great!"*

[Focus group 1 – Participating - Pharmacist 3]

#### **Resources**

Even though the group were positive towards the new contract a key theme which emerged was the lack of resources to provide services. These resources included: facilities; time; money; adequate training of staff; and in some cases the training of the pharmacist.

*"The worst point as far as I'm concerned is like I practise in a shop that is nearly 100 years old..... the problem is there is no space"*

[Focus group 1 – Participating, Pharmacist 4]

*“It’s very much a question of time constraint.....there’s not the finance to allow for extra staff.....we need to have locum cover while doing MURs”*  
[Focus Group 1 – Participating, Pharmacist 3]

*“there’s not wide enough support, you know either in the training of the pharmacist themselves or training of the staff”*  
[Focus Group 1 – Participating, Pharmacist 5]

## **Change**

One pharmacist was concerned that the new contract was trying to achieve too many things too quickly and expressed doubts about the need for the types of services now offered.

*“its like a vision of where they would like to see pharmacy at, but a lot of these services like MUR....there is no actual demand for these things”*  
[Focus Group 1 – Participating, Pharmacist 2]

## **Workload**

There was a consensus that the new contract brought with it, large increases in workload.

*“I mean my dispensing volumes have vastly increased.....I’m doing everything going, I’m doing some MURs, I do EHC and minor ailments, a whole gammat of things..... I go home every night absolutely whacked out!”*  
[Focus Group 1- Participating, Pharmacist 3]

### 5.4.2 Provision of annual and intervention MURs

Two key themes which emerged were awareness and relationships

#### Awareness

Pharmacists expressed that lack of awareness about this new pharmacy service made it difficult for them to convince patients to undertake MURs.

*“it’s really hard to convince the patient about having a chat”*  
[Focus Group 1 – Participating, Pharmacist 5]

*“the wording is very important....because a lot of people are looking at you like, what? What do you want to talk to me about? I say no worries, I just wanna have a chat with you, it wont take too long”*  
[Focus Group 1 – Participating, Pharmacist 2]

This awareness deficiency also extended to the patient’s doctor.

*“like it’s a bit of a problem with pharmacists doing MURs and doctors not accepting that”*  
[Focus Group 1 – Participating, Pharmacist 1]

One pharmacist suggested it was the PCTs responsibility to address the awareness issue with GPs.

*“they are telling us that we should actually go see the GPs and say we are doing them but I feel it’s not our job you know .I think the local PCT should actually go in and say, yes, pharmacists are doing them”*  
[Focus Group 1 – Participating, Pharmacist 1]

Pharmacists were very clear on the difference between the two types of MUR.

*“bendroflumethiazide 5mg being used for blood pressure I would put that down as an intervention MUR and send it off on that basis”*  
[Focus Group 1 – Participating, Pharmacist 4]

*"I will say intervention is basically like say the interaction of two drugs then you would make an intervention..... that leads towards MUR"*

[Focus Group 1 – Participating, Pharmacist 5]

*"it's the compliance of the patient that underpins MUR, that they are using their drugs properly"*

[Focus Group 1 – Participating, Pharmacist 6]

## **Relationships**

The theme of relationships also emerged, mainly relationships between the patient and their GP and the pharmacist's working relationship with the GP. Pharmacists expressed the view that patients did not want to affect their relationship with their GP by undermining their authority.

*"they don't want you to tell the doctor what they're experiencing because they're frightened.....they'll say, " this lady's been my doctor for about 25 years and she's such a nice lady and I don't want to hurt her feelings""*

[Focus Group 1 – Participating, Pharmacist 4]

In some cases the pharmacists expressed the view that some patients did not want their doctor to know they had undertaken an MUR.

*"they say, well as long as it doesn't get further than here"*

[Focus Group 1 – Participating, Pharmacist 4]

Others felt GPs may have been apprehensive due to the nature of the national documentation, which would lead to an audit trail.

*"I think they're a bit worried that they've got notes from us and its gone into the patients notes.....you feel they are actually frightened that somebody else is checking on them"*

[Focus Group 1 – Participating, Pharmacist 1]

With the overwhelming feeling was that doctors did not like having their authority challenged by the pharmacist.

*"...the reception I get from them like, who are you to interfere with what we're doing"*

[Focus Group 1 – Participating, Pharmacist 4]

*"I've got one like that as well , which means I tend to do less MURs for them...but like you know that they're going to totally ignore them so what's the point?"*

[Focus Group 1 – Participating, Pharmacist 3]

In contrast some pharmacists perceived that GPs seemed to accept intervention MURs more readily.

*"I do a lot of interventions...I tend to think the doctors are more receptive when your telling them, look I think you have made a mistake..... if I send an MUR to them , they'll say ok but I mean they're more receptive when its an intervention"*

[Focus Group 1 – Participating, Pharmacist 6]

### **5.4.3 MUR service engagement**

The time taken to start providing the service ranged from 9 to 18 months. With number of MURs carried out per week ranging from one to five. From the views expressed, two themes emerged pressure and satisfaction

*"I think it's taken about a year and a half"*

[Focus Group 1- Participating, Pharmacist 1]

*"I think it's about 9 months as well"*

[Focus Group 1- Participating, Pharmacist 3]

*“About a year probably”*

[Focus Group 1- Participating, Pharmacist 2]

## **Pressure**

When prompted, the key drivers to providing the service were; if self-employed, financial pressure and if employed by a multiple, pressure from employers to deliver set targets.

*“ you begin to realise the amount of revenue that your getting from your prescription turnover is getting less and less because of claw backs and various things, you have to you know get on with other means to get your funds”*

[Focus Group 1 – Participating, Pharmacist 4]

*“with the global fund I’ve got to do it, cos of from this pot it will go into that pot and that pot”*

[Focus Group 1 – Participating, Pharmacist 1]

*“the big multiples ....they recognise how much revenue they can get from that....i’d guessed many of them see it as the direction to go to get a large chunk of revenue and I’d guessed the bottom line is that it’s a business whatever”*

[Focus Group 1 – Participating, Pharmacist 2]

*“they give you a target.....and ask you what have you done with your target....not even on a weekly basis but on a daily basis, what have you done ?.....they have constant check on you”*

[Focus Group 1 – Participating, Pharmacist 5]

In contrast one, pharmacist delivered the service with his own self-satisfaction as the key driver, but his employer (multiple) offered incentives for its pharmacists to undertake MUR.



## Satisfaction

*“this is gonna sound awful but self satisfaction really.....I wasn't pressurised into doing it, it's self motivation which is unusual for me”*

[Focus Group 1 – Participating, Pharmacist 3]

*“we do get a bonus for actually doing them, we get paid for each one we do, which is a carrot rather than a stick”*

[Focus Group 1 – Participating, Pharmacist 3]

### 5.4.4 Challenges to MUR service provision

Key themes re-emerging were: resources, awareness and relationships.

#### Resources

The overwhelming factor which was expressed was the time taken to provide services and having to fulfil all the other responsibilities.

*“time and time it's totally the major restraint”*

[Focus Group 1 – Participating, Pharmacist 3]

*“not forgetting the fact.....if you're a pharmacy owner you're not just a pharmacist there your like a shop keeper as well..... your like everything in one you know and that's very difficult”*

[Focus Group 1 – Participating, Pharmacist 4]

#### Awareness

When asked what barriers they perceived prevented them from providing the services, the theme of awareness of both patients and GPs re-emerged.

*“I would say the patient awareness about the value of MUR is also a challenge.....like people they just don't know what an MUR constitutes.....when you approach the patient and try to convince them, they say, “what is MUR?”, my doctor doing this already”*  
[Focus Group 1 – Participating, Pharmacist 5]

Some pharmacists suggested ways in which these barriers could be overcome.

*“a lot of the time I say this doesn't replace what the doctor does it just compliments it”*  
[Focus Group 1 – Participating, Pharmacist 3]

*“I did visit the surgeries....there's a certain amount of antagonism, you know, I think what it needs to be it's like MUR awareness in GPs”*  
[Focus Group 1 – Participating, Pharmacist 1]

Some suggested it was the pharmacist's role to change patient perception.

*“doing MURs will get patients to realise that perhaps we do have more knowledge on medications.....I think it's basically down to us to change public perception of what pharmacy is all about”*  
[Focus Group 1 – Participating, Pharmacist 3]

## **Relationships**

Again pharmacists expressed the view that GPs did not like their authority to be challenged

*“they feel like your treading on their toes”*  
[Focus Group 1 – Participating, Pharmacist 4]

### **5.4.5 Time spent on MUR**

The amount of MURs carried out weekly ranged from one to five per week. Two themes were expressed: resources and influence on the dispensing process.

#### **Resources**

Pharmacists explained they simply did not have enough time and staffing and avoided some patients with a large number of items on prescription as the MUR would take too long.

*“I’ve just done the script with someone who’s got six, seven, eight items and I feel yeah this is someone I could talk to, do an MUR but then I look around and I see about four, five people before me and I’m like oh no not this time...I’ll let that one go.”*

[Focus Group 1 – Participating, Pharmacist 2]

*“if you dedicate your time to MURs you don’t have time for anything else”*

[Focus Group 1 – Participating, Pharmacist 4]

The paperwork was seen as a potential factor in the number of MURs carried out.

*“when your thinking to do an MUR then your thinking....the documentation you have to fill in everything you know and then you forget about it.”*

[Focus Group 1 – Participating, Pharmacist 5]

#### **Influence on the dispensing process**

Pharmacists perceived that undertaking MURs had impacted on the dispensing process such that they took more time to clinically review prescriptions. All pharmacists reached a consensus on the importance of this aspect.

*“You do look at the prescription more closely.....a year ago I wouldn't look at a prescription and think ok..... you do look at it more”*

[Focus Group 1 – Participating, Pharmacist 1]

#### **5.4.6 Other service provision**

Pharmacists felt other services such as the minor ailment scheme was far easier to provide than the MUR service and was well received. Two themes expressed were resources and acceptability.

#### **Resources**

Pharmacists perceived the minor ailment scheme and other enhanced services to use less resources and save the GPs time and money.

*“you see if a minor ailment came in you can actually delegate it to one member of staff to hand the form out and go through it with the customer and all you've got to do is just check and you know it's dead easy, hold the MUR have ten minor ailments instead”*

[Focus Group 1 – Participating, Pharmacist 1]

*“I mean a lot of the time they're pressurised and pushed with the amount of people coming in, they refer them to you, you give them the stuff, there's no hassle, no worry, nothing, the patients happy and it doesn't come out of their (GP) pocket.”*

[Focus Group 1 – Participating, Pharmacist 4]

#### **Acceptability**

Pharmacists expressed that other services were easier to establish as they were well accepted by both patients and their GPs.

*“say compare to the other services you know like minor ailments and things, it also reduces GP workload and is well publicised compared to MUR”*  
[Focus Group 1 – Participating, Pharmacist 5]

*“the receptionists, they knew about it and they just send the patient to the pharmacist”*  
[Focus Group 1 – Participating, Pharmacist 6]

#### **5.4.7 Recommendations for future service delivery**

The fact that pharmacists felt the MUR service had not been widely publicised which put a burden on them to market the service was a major issue that needed to be addressed. Key themes expressed were awareness, relationships, resources and quality enhancement.

##### **Awareness**

Pharmacists expressed that GPs need to be made more aware of the service and what potential benefits it may hold for them.

*“I think they’ve got to approach the GPs and see where the problems are, if there are any, and try to push it on them that it’s a service which is gonna benefit them.”*  
[Focus Group 1 – Participating, Pharmacist 3]

##### **Relationships**

Suggestions made related to increasing interactions with pharmacists and GPs to improve their relationship.

*“I would say like integration between the local pharmacy and the local surgery is really important and is one way of increasing the interaction”*  
[Focus Group 1 – Participating, Pharmacist 5]

*“GPs and pharmacists should work together for the benefits of the patients rather than antagonise each other all the time”*

[Focus Group 1 – Participating, Pharmacist 4]

*“I think you know that sort of joint pharmacy GP meetings....that will go down really well and because if there are any issues....the pharmacist and the GP practice that are working together so they can actually be more buddy buddy”*

[Focus Group 1 – Participating, Pharmacist 1]

Pharmacists suggested reasons for GP opposition to them undertaking MURs.

*“I think because GPs have always seen themselves as the head of everything .....they feel more threatened”*

[Focus Group 1 – Participating, Pharmacist 2]

## **Resources**

Suggestions for improvements in resources were made.

*“I would like to have the staff working with you trained, you know like the dispensers and the technicians.....so they help you to convince the patient and the pharmacists can then delegate more jobs”*

[Focus Group 1 – Participating, Pharmacist 5]

*“I’m going to get one of my staff to become a checking technician so that she can take a bit of the workload off me which would free up some of my time”*

[Focus Group 1 – Participating, Pharmacist 3]

## **Quality enhancement**

Others suggested receiving feedback so as to improve the quality of their MURs.

*“I think it would be quite nice to have a mentor who will come along and sort of review your MURs and also comment whether you're doing right or not”*  
[Focus Group 1 – Participating, Pharmacist 3]

One further suggestion included making it mandatory for GPs to provide pharmacist with feedback on the actions recommended.

*“I think that one of the things that can be changed....is that if it is made mandatory for GPs if they have known outcomes to notify us so that we can liaise with each other cause remember we're doing something hopefully for the betterment of the patient.... If they've carried out the action plan they should report back to us and say look we've done this or we haven't done it.”*  
[Focus Group 1 – Participating, Pharmacist 4]

*“to get some feedback as to why it hasn't been done if there is a reason behind it that we're not aware of”*  
[Focus Group 1 – Participating, Pharmacist 3]

## **5.5 Discussion of findings in relation to MUR service providers**

Pharmacist providers of MUR services were, as expected, very positive about the new NHS pharmacy contract and in particular MUR services introduced in April 2005. They were very clear on the differences between annual MUR and intervention MUR services. The majority confirmed that it took them 9 to 18 months to engage with this new service and that one of the major drivers had been financial. More a reflection on the potential loss income to the business by non-participation than personal gain although a few did describe company incentives.

Despite their very positive engagement they were realistic about the impact on workload. Interestingly this was not about the time spent doing MURs but the influence on their practice in particular the impact on the dispensing process with

them now taking more time to clinically review prescriptions. This was a view that was strongly supported by all participants.

Two strong themes which emerged under a number of topics were resources and relationships. Resources covered many aspects including: staffing; facilities; pharmacist time; and funding proportional to perceived intensive requirements of MUR services. The latter was expressed with reference to it being easier to undertake ten minor ailments than one MUR with support staff being able to complete the documentation for the former.

In terms of relationships, there was concern that the way in which MUR services had been introduced had negatively impacted on GP's response to referrals and that PCTs could have perhaps facilitated better integration and engagement in this respect. Indeed there was a general feeling of frustration expressed about the lack of awareness of patients and GPs to this new service which added further negative impact on their time.

Not surprisingly awareness, relationships and resources were all raised as recommendations for future service delivery with an additional theme coming through unexpectedly relating to quality enhancement of the service. This quality enhancement included a wish for feedback from GPs on the recommendations that they had made and the adoption of pharmacist mentors both of which would have increased their time commitment to MUR services.

Interestingly only one member of the group expressed personal and professional satisfaction as a driver for participation, considering this was a select group of six



pharmacists accepting an invitation to participate in a focus group discussion drawn from a small population of only 14 pharmacies accredited to provide MUR services in Medway. Although professional satisfaction may have been an original driver for others, it is possible that the early enthusiasm has been suppressed due to the pressure felt by some pharmacists facing targets linked to weekly reporting of MUR activity (in one case daily).

## **5.6 Results of focus group discussions of non providers of MUR services**

A letter of invitation was sent to 28 out of 42 pharmacies in Medway listed as not providing MUR services. Six pharmacists agreed to participate in this focus group. The focus group was held at the Medway School of Pharmacy in December 2007 and was moderated by an independent pharmacist facilitator (CD). The meeting lasted approximately 1 hour.

### **5.6.1 Pharmacists views of the New Community Pharmacy Contract, April 2005**

Overall, the tone was quite negative towards the 'New Pharmacy Contract'. The key themes expressed were that of workload, disempowerment and resistance to change.

#### **Workload**

Pharmacists perceived that the changes made in the new contract were purposely put in place to trip them up into making mistakes and compromising patient safety due to the increase in workload.

*"I agree with what you're saying there's too much pressure on pharmacists, the workload.....they're trying to make you make more errors, mistakes or something"*

[Focus group 2 – Non participating – Pharmacist 4]

*"I think were being asked to do far too much, more and more, running faster and faster as to keep still in a way and, safety in some places has gone out of the window.... I think it's compromising patient's safety"*

[Focus group 2 – Non participating – Pharmacist 3]

### **Disempowerment**

Pharmacists also felt they had no control over what they do as part of the new contract.

*"I write out referral forms as part of the contract and I keep records but I really have no idea what happens to them"*

[Focus group 2 – Non participating – Pharmacist 1]

Others felt disempowered and undervalued. That the job they had been doing for years was seen as small and insignificant such that these new services had been introduced to give pharmacists something to do.

*"what the contract is doing is making us do roles that haven't been traditionally ours while devaluing what we do anyway.....we've somehow managed to make everybody think that what we do is not important so therefore we've been asked to take those extra roles on that really shouldn't be ours"*

[Focus group 2 – Non participating – Pharmacist 6]

### **Resistance to change**

There was a clear view within the group of resistance to the changes that have been made in the contract.

*"they are crazy because we have a niche, we have a niche and I think we've been pushed out of it and its our own fault"*

[Focus group 2 – Non participating – Pharmacist 6]

*“other patients care thing which to my mind is the responsibility of the GP anyway.....the emphasis has gone, it's heading inevitably away from, what I hope I've been doing all my long life which has been dispensing”*

[Focus group 2 – Non participating – Pharmacist 3]

### **5.6.2 Pharmacists views of Medicines Use Review services**

The majority of pharmacists expressed positive views toward MURs with one notable exception.

*“I'm afraid those things are hell loads of rubbish (MUR), I mean SOPs are completely useless”*

[Focus group 2 – Non participating – Pharmacist 1]

Themes expressed were those of resources and pressure.

#### **Resources**

Pharmacists expressed the view that MURs were a good idea. However they lacked the resources to do them.

*“it's unfortunate because it's a good idea, but when it comes down to the practicalities of it, its not always easy”*

[Focus group 2 – Non participating – Pharmacist 2]

*“it's a really good idea in practice, but getting the time.... You've got so many other things you're doing at the moment”*

[Focus group 2 – Non participating – Pharmacist 4]

#### **Pressure**

Pharmacists expressed that view that those providing the service were doing so in response to financial opportunities and not because there was an actual patient need.

*“there is no time to do MURs....there hasn't been with that staffing level or don't have the time to do an MUR without being interrupted at least four or five times.....I don't think they do any good but financial pressure say I will have to do them or be tortured.....there's no need for any MURs to be carried out other than for the financial reasons the patient's are perfectly happy with what we do.”*

[Focus group 2 – Non participating – Pharmacist 3]

*“it's not always easy to do them and yet there is pressure to do them because of the financial thing”*

[Focus group 2 – Non participating – Pharmacist 4]

### **5.6.3 Difference between annual and intervention MURs**

This group of pharmacists overwhelmingly expressed misunderstanding with MUR services, with themes of confusion, disbelief and relationships emerging

#### **Confusion**

Pharmacists expressed a clear misunderstanding of what constituted an intervention MUR.

*“I mean how do you define an intervention? Is telling someone who is on the pill when you know you give them an antibiotic and to use additional precautions, is that defined as an intervention?”*

[Focus group 2 – Non participating – Pharmacist 2]

Some expressed confusion about MURs linked to compliance assessment rather than rationalisation of therapy.

*"I can't see how you get an MUR out of an intervention because that's the safety issue, it's safety even whereas an MUR is just hello show me how you use your inhaler."*

[Focus group 2 – Non participating – Pharmacist 6]

With others expressing confusion between interventions and the counselling they carried out on a regular basis.

*"Im gonna counsel them about when they gonna take these you know, leaving intervals and this sort of thing.....I might write down a little thing saying you know, can you make sure you do this and they will say that's fine.....I don't expect to get paid for this..... But for me I've just done an intervention."*

*"I think when they brought them in they didn't really explain properly"*

[Focus group 2 – Non participating – Pharmacist 3]

## **Disbelief**

Several pharmacists expressed disbelief at the numbers of MURs carried out by other pharmacists.

*"that's where your in a dilemma actually you think, you know, you think when you've found out that somebody's done five in a day, I think how could they do five in a day?"*

[Focus group 2 – Non participating – Pharmacist 2]

*"there was a very interesting article in one of the journals about a year ago.....it was about a fellow...he'd done his 400 MURs, he was a sole pharmacist, did 500 items a day and he was just brilliant, they had him as a pharmacy hero..... he was so disgusting wasn't he ? I sat there thinking this guy is lying and I can't believe they've printed it, how can they do that?"*

[Focus group 2 – Non participating – Pharmacist 6]

*"it's difficult to get it done(MUR) when you've got so many other things you're doing at the moment.....you say you did 400 items a day, we do 200 and I'm having difficulties doing it (MUR), 400 that's impossible"*

[Focus group 2 – Non participating – Pharmacist 4]

## Relationships

A number of the pharmacists reported having good relationships with their GPs

*“we talk about everything, mistakes and errors, everything and I go through it with him.....I think my GP is quite happy”*

[Focus group 2 – Non participating – Pharmacist 4]

*“they’ve been positive apart from one who can’t understand my handwriting”*

[Focus group 2 – Non participating – Pharmacist 2]

Some thought the relationship was so good that there was no need to have MURs

*“I can discuss as I do most days with the doctor or refer people at least twice a day..... I would talk to the doctor myself on a daily basis almost about anything I’m worried about.....we have an excellent relationship with the surgery there’s no need for any MURs to be carried out”*

[Focus group 2 – Non participating – Pharmacist 3]

### 5.6.4 Barriers to MUR service provision

Again the theme of confusion arose regarding, processes, procedures and the purpose of MUR. One other theme expressed was that of workload.

## Confusion

*“I don’t know what paperwork I have to fill out, I don’t know how to claim for them, I don’t know how to start one”*

[Focus group 2 – Non participating – Pharmacist 6]

*“I’ve mislaid my certificate....I can’t find it and you know the PCT wants a copy and I can’t do anything I’ll have to have another shot”*

[Focus group 2 – Non participating – Pharmacist 1]

Some expressed confusion that MUR was not clinical and the training they had gone through did not reflect what they would actually encounter in practice.

*“the fact that it’s clinical... I did the MSOP one and it was full of clinical case studies, with ones you wouldn’t be expecting to do MURs on”*

[Focus group 2 – Non participating – Pharmacist 6]

*“I think the course was too clinically minded and then they didn’t really explain that really all this is not required.... I mean you could use some of the knowledge now and then maybe two out of ten maybe?”*

[Focus group 2 – Non participating – Pharmacist 5]

Not all shared this view and expressed satisfaction at identifying clinical issues

*“I always look at the medicines.....look at the clinical, side effects of medicines and like what might be causing them and touch wood I’ve seen quite a few.....this lady.....she’s having cold hands all the time and I looked at her medication and you could see it was the atenolol that was causing it..... I go the GP to change it over.....I thought to myself its gonna affect a life you know, it’s a good thing I’ve done there innit really”*

[Focus group 2 – Non participating – Pharmacist 4]

## **Workload**

*“we don’t do many MURs, we do about 200 items a day, we do lots of methadone patients and minor ailments and smoking cessation..... I would love to do (MUR) about 20, 30, 50, 60 a day if I could”*

[Focus group 2 – Non participating – Pharmacist 4]

*“I work nine hours straight..... I don’t have tea breaks..... if I can’t sit down for ten minutes at 5 o’clock in the afternoon then how am I going to do a thirty minute MUR?”*

[Focus group 2 – Non participating – Pharmacist 6]

*"I don't have five minutes to a day, I haven't had a cup of warm coffee in ten years"*

[Focus group 2 – Non participating – Pharmacist 3]

Some expressed the view that it took too long to conduct an MUR and that the process of filling in the paperwork slowed the whole process down.

*"the idea was to give it (referral form) straight away but I don't think its practical"*

[Focus group 2 – Non participating – Pharmacist 5]

*"I used to tell them it will take a couple of days or I stick them in the post (referral form)"*

[Focus group 2 – Non participating – Pharmacist 2]

*"that's what I did as well, I'd say a week or something so I have a weekend to write it up"*

[Focus group 2 – Non participating – Pharmacist 4]

### **5.6.5 Overcoming the barriers to MUR service provision**

The main theme expressed by the group was that of resources which included time, money, staffing and training.

#### **Resources**

*"well I think give more fees to start with so people can have another pharmacist just to do dispensing one day a week"*

[Focus group 2 – Non participating – Pharmacist 5]

*"I'd like a little MUR pack, tells me exactly what I need to fill out, exactly how to claim for it, I'd like a little, how to pack, who to talk to."*

[Focus group 2 – Non participating – Pharmacist 6]



*“an MUR training day maybe”*

[Focus group 2 – Non participating – Pharmacist 4]

With all pharmacists in the group reaching a consensus that they needed more, time and staff to perform MURs

### **5.6.6 Other service provision**

Pharmacists expressed strong positive views on other aspects of the contract such as the minor ailments scheme and methadone due to the ease of provision.

*“minor ailment.....because it’s quick and easy to do”*

[Focus group 2 – Non participating – Pharmacist 5]

*“methadone is going well, minor ailment aswell”*

[Focus group 2 – Non participating – Pharmacist 4]

*“I like those traditional services, I like methadone”*

[Focus group 2 – Non participating – Pharmacist 6]

### **5.6.7 Future service provision**

When asked about what services they would like to provide in the future, they expressed a positive attitude to the enhanced services.

*“we can do a lot more diagnosis, you know diagnostic, if we got funded for it”*

[Focus group 2 – Non participating – Pharmacist 3]

*“let them extend the minor ailments, do a little bit more”*

[Focus group 2 – Non participating – Pharmacist 5]

Some then expressed anger at the thought of provision of further services.

*“they seem to be taking too many things from the GP.....I’m not a doctor if I wanted to do that I would have trained to be a doctor and get paid five times as much”*

[Focus group 2 – Non participating – Pharmacist 6]

## **5.7 Discussion of findings in relation to non providers of MUR services**

Conflicting views were expressed by non providers of MUR services. There was a generally negative reaction to the new pharmacy contract. The key themes were resources, change and workload which were similar to those of providers of MUR services. The main difference was the strength of the resistance to change linked to a feeling of disempowerment with emotive words used such as “*crazy*” and “*completely useless*” linked to fears of resulting errors and mistakes compromising patient safety.

Given the strength of these views, it is incredible that the non providers expressed really positive views about MUR being a good idea although they were realistic in identifying the resource issues to be time and staffing. Despite this positive attitude there was a basic misunderstanding of what MUR services actually were and in particular confusion between an intervention leading to an MUR and an intervention made during the dispensing process. It was perhaps not surprising therefore that they expressed disbelief at the numbers of MURs being undertaken by other pharmacists. What was interesting and unexpected was that having a good relationship with local GPs was cited as a reason why MURs were unnecessary. This is in complete contrast to providers of MUR services who see MURs as being facilitated by improved relationships with GPs.

Key themes that dominated the non provider group were workload and resource issues with workload issues expressed as extreme pressure perhaps bordering on that requiring occupational health intervention. It is possible that this group exaggerated the workload as a defensive mechanism to explain their non-participation. It seems inexplicable that such a group, which may be considered on the 'edge', expressed positive views about future service provision including the wish to extend minor ailment services, increase methadone services and establish a new range of diagnostic services. This requires further research.

## **5.8 Conclusion**

Focus group discussions with service providers and non providers demonstrated that both groups of pharmacists had very positive attitudes towards MUR services. The latter was unexpected and in sharp contrast to the negatives attitudes expressed towards the new Community Pharmacy Contract by these non providers of MUR services.

Both groups raised issues to do with awareness of MUR services with the providers expressing frustration at the time having being spent informing patients and GPs of this new service. In contrast the non providers were the ones who lacked awareness of MUR services, had some basic misconceptions about the aims of MUR and did not raise any issues about patients or GPs lack of awareness, which possibly reflects their own lack of activity in this area.

Resources were a key theme for both groups linked to their time, availability of trained staff, facilities and financial return for what was considered a very onerous

service by both groups. Whilst the providers of services raised the issue of quality enhancement linked to mentors and feedback, the non providers wanted an MUR training pack with clear instruction on which form to fill in. The non providers did complain about the clinical content of their MUR accreditation course which they did not feel was relevant to MUR. In contrast, the providers reported that participation in MURs had positively influenced their clinical practice.

Relationships were a strong theme throughout both focus groups, although the views were contrasting with providers expressing a wish to strengthen relationships with GPs to overcome current barriers to MUR services. In contrast non providers cited good relationships as the reason not to engage in MUR services as this good relationship meant they could pick up the phone and make multiple referrals to the GP without the need for documentation. This finding for the non providers is disturbing and has implications for MUR services establishing a pharmaceutical care model in the UK. In their seminal paper, Hepler and Strand (1990), described the pharmaceutical care process and concluded that the most important factor was that individual pharmacists had to accept responsibility for the patient. It is reassuring that the providers of MUR services are grasping this opportunity to extend this responsibility into other service areas.

## **Chapter 6**

### **Patients' Views of Medicines Use Review services**

#### **6.1 Introduction**

Chapters 4 and 5 have described a matched cohort study and focus group discussions undertaken to partially address the hypothesis that 'Medicines Use Review will reduce drug therapy problems and will be well accepted by both pharmacists and patients'. This chapter aims to complete the study by ascertaining the views of patients.

A number of studies have previously evaluated patient's views in relation to a variety of services undertaken by pharmacists. A study of domiciliary medication review found that the visits by the pharmacist gave patients a greater understanding and reassurance of their medications (Coleman et al., 2001). A further study by Petty et al (2003) ascertained the view of patients who had experienced a pharmacist run medication review clinic. Patients welcomed the opportunity to discuss their conditions and treatment with the pharmacist. A community pharmacist run diabetes programme in the USA (Garrett and Martin 2003) reported that patients found that by undertaking the programme they had made lifestyle changes which had improved their quality of life. The views and expectations of patients undertaking MUR need to be explored further to inform future service delivery of this advanced level service within the New Pharmacy Contract.

Patient's views were obtained in two ways; firstly, research study participants were invited to complete a semi-structured questionnaire by post or telephone. Secondly, patients who had experienced MUR services and were not involved in the research

study were invited to take part in a focus group discussion. Patients who took part in the main study were excluded from the focus group discussion as it was acknowledged that these patients had received an MUR in the context of a research project with additional information provided to meet the ethics committee requirement to obtain informed consent in this group.

## **6.2 Aims**

- To obtain feedback from research study participants on MUR services received during the study period.
- To obtain the views of patients who have experienced the MUR service as part of standard care.

## **6.3 Method: feedback from research study participants**

### **6.3.1 Semi-structured questionnaire design**

A semi-structured questionnaire was designed to cover three aspects of MUR services: the interview; actions recommended with information received; and satisfaction with the service. This questionnaire was planned and piloted in accordance with principles outlined by Bowling (2002). Ethical approval for the use of this questionnaire was granted in July 2007.

### **6.3.2 Administration of questionnaire to study participants**

Patients in the active group were posted a questionnaire pack which contained a letter of invitation, copy of the semi-structured questionnaire and self-exclusion form for those who did not wish to participate. Patients were asked to return the questionnaire in the prepaid envelope provided, return the self exclusion form or await the administration of the questionnaire by telephone. Patients who returned the self

exclusion form were not contacted further. Any patients who did not return the questionnaire or self exclusion form were contacted, two weeks later by a research assistant (FS) who then administered the questionnaire by telephone. A copy of the questionnaire is provided in **Appendix 13**.

## **6.4 Results of semi-structured questionnaire**

The semi-structured questionnaire was posted to 118 patients from the active group. Telephone interviews took place in late 2007. 72 (response rate 61%) responses were received of which 58 were returned by post and the remaining 14 conducted by telephone administration.

### **The MUR interview itself**

#### **1. Did you attend the pharmacy or was the MUR conducted over the telephone?**

All active patients reported that their MUR was conducted at the pharmacy

#### **2. Where would you have liked the MUR to have been conducted?**

Sixty four patients (89%) stated that the pharmacy would have been their preferred location with only one patient expressing that they would like to have had the MUR conducted at home. Three patients would have preferred to have had the review at their GP surgery with two patients preferring the review to be administered by telephone.

**3. If you attended the pharmacy, where within the pharmacy did the MUR take place?**

Fifty eight (81%) patients had their MUR in a closed consultation area with a further eight patients stating they had their review in an open consultation room.

The remaining six patients had their review in a private area of the pharmacy.

**4. During the MUR did you feel the discussion was private for you?**

Sixty nine patients (96%) expressed the view that their review was private with only three patients stating that they felt that the MUR was not private. It is interesting to note that these particular patients had their MUR conducted in an open consultation room.

**5. What would be your ideal location for the review and why?**

Sixty two patients (86%) stated their ideal location for their MUR was a closed consultation room with five patients preferring to have their review in a private screened area of the pharmacy. Three patients expressed the preference for an open consultation room with two patients having no preference.

**6. Did you feel the time taken for the MUR was too long, too short or just right?**

All patients stated they were happy with the duration of the MUR interview.



## **7. What did you expect from the MUR?**

Thirty patients (42%) did not answer with a further nine patients stating they were unsure of what to expect. Examples of some patient expectations from the remaining thirty three patients (46%) were:

- *“An explanation of my medications and why I’m taking them”*
- *“Help with my tablets, to know what is for what”*
- *“I was not sure what to expect but any follow up on medication is a good thing. Too many people are put on drugs and left on them sometimes it is not necessary.”*
- *“Was unsure at first but appreciated it much more afterwards”*
- *“To lose weight”*
- *“information on medication taken”*
- *“As to whether all my medication was safe to be taken together”*
- *“To help the chemist so as to help myself”*
- *“To be a waste of time”*

## **Actions arising from the MUR**

### **8. During the MUR were any problems raised about your medication? (by you or your pharmacist)**

Fifty seven patients (79%) stated that problems were highlighted during their review with the pharmacist with the remaining fifteen (21%) having no problems identified.

### **9. Had you discussed these problems with the pharmacist before the MUR?**

Only eight patients (11%) had discussed any of the issues raised during the review with the pharmacist previously.

**10. Have you discussed any problems with your medicines with the pharmacist since the MUR?**

Only twelve patients (17%) stated that they had discussed the issues raised during the review with their pharmacist since their MUR.

**11. During the MUR were you given Information and advice by your pharmacist? referred to your GP? or other.**

Fifty three (73%) patients were given information and advice by their pharmacist with six patients (8%) stating they were referred to their GP by the pharmacist.

Two patients were given information and advice by their pharmacist and referred to their GP with one patient stating they had, had a blood pressure check.

**12. At the end of the MUR did you receive: information and advice from your pharmacist? a change in medication? stoppage of medication? monitoring by your pharmacist? or other?**

Thirty two patients (44%) were given information and advice by their pharmacist with eleven patients (15%) stating they received a change in medication. Seven patients (10%) received monitoring from their pharmacist with three patients having medications discontinued.

**13. What did you do with the action plan, you were given?**

Sixty seven patients (93%) retained the MUR action plan with the remaining five patients stating they discarding the plan after the review.

**14. Did you find the documentation easy to read and understand?**

Fifty eight patients (81%) found the MUR documentation easy to read and understand with only two (3%) patients stating that they had difficulties with the documentation.

**Satisfaction with MUR services**

**15. Were you satisfied with the MUR process?**

Overall seventy one patients (99%) were satisfied with the MUR process with the remaining patient having no opinion.

**16. Were your expectations of the MUR process met? If not please detail**

Fifty three patients (74%) had their expectations of the review met with only three patients (4%) stating that their expectations were not met.

**17. Could any changes be made to this service to improve it for you in the future?**

Fifty eight patients (81%) felt there were no changes that could be made to improve the service for them in the future with only eight (11%) patients expressing the view that something could be done to improve it for them in the future. Of these eight only four commented on what improvements could be made:

- *“Since the pharmacist was also responsible for the current dispensing of prescriptions by his assistants it would be better if they didn't keep “popping in” to the consulting room with queries for the pharmacist to answer”*
- *“There will always be improvements”*
- *“only where it was conducted”*
- *“6 monthly”*

**18. Would you like the pharmacist to carry out MUR on a regular basis?**

Fifty three patients (74%) would like their pharmacist to carry out MUR on a regular basis with only eight patients (11%) expressing they would not like the review regularly.

**19. How often would you like this review to be conducted?**

Thirty eight patients (53%) wanted the review on an annual basis with fifteen (20%) patients stating they would like to have the review more frequently. Nine patients felt that the review should not be carried out on an annual basis, with some suggesting a period of 2 years with two patients expressing they would only like a review if their medication was changed.

## **6.5 Discussion of feedback from research participants**

All patients reported having their MUR at the pharmacy with the majority of patients (89%) expressing that this was their preferred location. It was surprising that only one patient wanted the review conducted at home and that only three patients would have liked to have had the review conducted at their GP's surgery. This finding may suggest patients may have felt more comfortable in the pharmacy and had a good relationship with their pharmacist.

Nearly all patients (81%) had their review in a closed consultation room and expressed that they felt the review was private. Some patients expressed the feeling that the review was not private which was not surprising as they had their reviews in an open consultation room. Notably five patients wanted their review in a private screened area of the pharmacy indicating that some patients may not mind whether

rooms are completely closed off. This may indicate the choice of area for the review in the pharmacy would be best left to the individual patient.

All patients felt that the review was of adequate duration. A proportion of patients (42%) did not state if they had expectations before undertaking the review. For the patients who did have expectations these ranged from an explanation of medicines they were taking to losing weight. What is notable is that 74% of patients stated their expectations were met with only 46% stating any expectations.

The majority of patients had issues raised during the MUR with their pharmacist, what was surprising was that only 11% of patients had discussed any of these issues with their pharmacist previously. What was of greater surprise is that only 17% of patients had discussed the issues raised at the MUR with their pharmacist after the review had taken place. This may indicate that even though pharmacists are conducting MURs they may need to concentrate on patient follow-up to ascertain whether issues raised have been resolved; this may be best done by talking to the patient. For MURs to meet the requirements of a pharmaceutical care model, patient follow up is essential (Hepler and Strand, 1990).

A vast number of patients stated that they had received information and advice from their pharmacist during MUR, with six patients receiving a direct referral to their GP. Only eleven patients confirmed they had any changes to therapy which is surprising as 55% of recommendations made in the main study related to some form of therapy adjustment. Overall nearly all patients retained the action plan with the majority finding the documentation easy to read and understand.

Improvements suggested for the service were few and ranged from having less interruptions during the MUR and increasing the frequency to six monthly reviews. The majority of patients stated they would like to have this type of review on a regular basis. When asked about the frequency of reviews 53% of patients stated they would like to have it annually with 20% expressing the view that they would prefer to have the review more frequently than every 12 months.

This questionnaire was sent to 118 patients from the active group of the main study and received 72 responses (61%). However, questionnaires are easy and quick to administer. One of the disadvantages of this method is that participants can not be probed so reasoning for the answers are rarely obtained.

A limitation of this design may be that patients who filled in the questionnaire administered by post and by telephone may have given answers they thought the researcher may have wanted reported in relation to the service. This bias was overcome by anonymising the questionnaire and using an independent research assistant to undertake the telephone follow-up.

Overall the service was well received with 99% of patients stating that they were satisfied with the service they had received. A study of type 2 diabetes patient's satisfaction with community pharmacy services (Abduelkarem et al., 2003) also confirmed this finding by showing a generally high level of satisfaction with community pharmacy services. However, more in depth discussions with patients is required to explore wider views than those explored with this questionnaire.

## **6.6 Methodology for patient focus group**

A single focus group of patients who had received an MUR as part of standard care was conducted. Focus group methodology was employed for this study as it allows a more in depth discussion about topics raised than would be possible using one to one interviews. Advantages and disadvantages of focus groups have been discussed previously in Chapter 2.

### **6.6.1 Recruitment of patient participants**

1. A formal request was made to Medway Primary Care Trust (PCT) to obtain details of pharmacies in Medway who were delivering MUR services.
2. Letters of invitation together with an information pack about the study was sent to all 14 pharmacies listed as providing MUR services in Medway, which represented a 33% sample of pharmacies in the area.
3. Included in the information pack was a consent form and self-exclusion form for those who did not wish to participate. Pharmacists were asked to return the appropriate form following which a telephone call was made, one week later by the research assistant (SNA), to those who consented to recruit patients for the focus group.
4. Once confirmation was obtained patient information packs were delivered to the pharmacy. Pharmacists then supplied consent packs to patients who had undertaken an MUR. Patient consent packs contained information regarding the study and a consent form. Patients could sign the consent form in the pharmacy or return it in the prepaid envelope provided. A copy of the patient consent pack is produced in **Appendix 14**.

5. A telephone call was then made, one week later by a research assistant (SNA), to those who consented to participate in the focus group. Participants were asked to confirm suitability of possible dates at that time.
6. Once 6 to 8 participants confirmed a particular date the meeting was fixed. A final letter confirming the time, date and venue for the focus group was posted to patients.

### **6.6.2 Topic guide and group facilitation**

A topic guide, to facilitate discussion was researched and designed by a research assistant (SNA) and agreed with the independent pharmacist facilitator (CD). A copy of the topic guide can be found in **Appendix 15**.

### **6.6.3 Participant observation and data recording**

The focus group was digitally recorded and participants were assigned a number so as to facilitate coding and analysis of the resulting transcript. The time at which each participant spoke was recorded by a researcher (AWM) and body language noted by a second research assistant (SNA).

### **6.6.4 Organisational issues**

The focus group was held at Medway School of Pharmacy and scheduled to last approximately one hour. Travel arrangements were made (return taxis from home) for patients for attendance to the group. Lunch was also provided to all participants before the focus group commenced.



### **6.6.5 Data coding and analysis**

The digital recording was transcribed professionally and independently checked by a researcher (AWM) and research assistant (SNA). The confirmed transcript was subjected to content analysis with key themes and concepts representing ideas, opinions and attitudes identified by repeated reading of the transcripts and subsequently categorised by the researcher (AWM). The data were independently analysed by a second researcher (CAM) and the final themes, concepts and categories agreed. Each theme and concept was illustrated by quotes from participants.

### **6.7 Results of patient focus group**

Ethics approval was obtained in August 2007 with local research and development approval being granted in January 2008 for the research team (AWM, CD and SNA). Three pharmacists out of 14 agreed to participate in patient recruitment. After two months, only one pharmacist managed to recruit any patients, with all patients coming from one pharmacy. The focus group discussion was planned for November 2007 and had to be cancelled and rescheduled for January 2008 due to the delays in patient recruitment and obtaining research and development approval. A focus group of five patients was held at the Medway School of Pharmacy in January 2008. The meeting lasted approximately 45 minutes.

Overall the tone of the group was very positive. The participants were unsure what the meeting was about but were quite happy to participate and interact with their peers.

*“I’ve only come for the free grub! (jokingly) – it just seemed interesting to see what it was all about”*

[Focus group - 3 – Patients, Patient 1]

*"I came along purely out of interest to see what it was all about"*  
[Focus group - 3 – Patients, Patient 3]

### **6.7.1 Patients expectations of MUR**

All participants in the group confirmed that they regularly attended one pharmacy and were approached by their pharmacist for an annual MUR. The themes which arose were that of surprise, curiosity and access.

#### **Surprise**

When asked, none were originally aware that their pharmacist could carry out this service but nevertheless thought it was a good idea.

*"it think most people didn't know about it"*  
[Focus group - 3 – Patients, Patient 3]

*"I was amazed"*  
[Focus group - 3 – Patients, Patient 1]

*"I thought it was a good idea"*  
[Focus group - 3 – Patients - Patient 2]

*"I thought about it and then thought.....it was a good idea. This is another safety valve"*  
[Focus group - 3 – Patients - Patient 3]

Some did remark that they had seen the advertising from the “ask your pharmacist”, campaign by the National Pharmaceutical Association.

*“the telly’s forever telling you as I said earlier on, if you’ve got this wrong with you or that wrong with you, go to the pharmacy first”*  
[Focus group - 3 – Patients, Patient 3]

With others stating their local pharmacist was always their first port of call.

*“I’ve always. I used to take my children, with verrucaes and different things, I always went to the pharmacist”*  
[Focus group - 3 – Patients, Patient 4]

### **Curiosity**

Patients were curious about the service but more curious about where it would take place, as they were not aware their pharmacist had a consulting room.

*“I think you’d say I was more curious”*  
[Focus group - 3 – Patients - Patient 3]

*“He said..... “I want to talk to you about your tablets” and I went “where?” and he said, “here”.....because I was thinking I had to go somewhere! He said, “no, I can do it here”. And I was saying “where?”*  
[Focus group - 3 – Patients - Patient 5]

*“He sprang it on us!”(consulting room)*  
[Focus group - 3 – Patients - Patient 3]

*“He keeps his little room quiet!”*  
[Focus group - 3 – Patients - Patient 5]

When asked about how their pharmacist approached them to conduct the MUR, patients remarked on the polite and professional nature of the approach.

*“He just very politely said “how do you feel about getting your medicines computerised?””*

[Focus group - 3 – Patients - Patient 3]

*“very very polite”*

[Focus group - 3 – Patients - Patient 4]

### **Access**

Patients also expressed issues related to the theme of access. They perceived their pharmacist to be easily accessed and convenient.

*“He phoned me up a few days later and made an appointment for Saturday. It was quite interesting”*

[Focus group - 3 – Patients - Patient 1]

*“He made an appointment for me at my convenience to go down and have a chat with him”*

[Focus group - 3 – Patients - Patient 2]

*“he gave me a couple of dates for my convenience”*

[Focus group - 3 – Patients, Patient 4]

They also recognised the duty of care that the pharmacist had always shown towards them to meet their needs.

*“he does stay open as long as the doctors surgery is open so if you get a prescription that you need, you can get it straight away”*

[Focus group - 3 – Patients - Patient 2]

In contrast they viewed access to their GP as more of a challenge.

*“they say I want to see you as soon as possible and then when you phone them up, you’ve got like bloody four weeks to see him”*

[Focus group - 3 – Patients, Patient 1]

*“if you ring down, you’re half an hour sitting on the phone, just to be told, “sorry, no appointments..... so next stop here sometimes it’s the undertakers!”*

[Focus group - 3 – Patients - Patient 4]

### **6.7.2 Location of MUR**

When asked about the location of the MUR, they remarked that they found the room “small” and “cramped”.

*“squeezed into his little cabin. Well I think our knees would be touching if we were all in there”*

[Focus group - 3 – Patients - Patient 3]

Even though patients found the room small, the overwhelming theme of trust emerged. There was no apprehension to entering a small enclosed room with the pharmacist.

### **Trust**

*“He’s more like a friend, isn’t he?”*

[Focus group - 3 – Patients - Patient 2]

*“Just very comfortable to speak to”*

[Focus group - 3 – Patients - Patient 3]

### 6.7.3 MUR interview

All patients agreed that their interview was the right length of time for them, on average a time of 30 minutes was stated. On commenting about the interview process the theme of trust re-emerged.

#### Trust

*“He makes you feel at ease, he always explains everything to you.”*  
[Focus group - 3 – Patients - Patient 2]

*“We were comfortable”*  
[Focus group - 3 – Patients - Patient 4]

*“We all go to him, rather than our doctors”*  
[Focus group - 3 – Patients - Patient 5]

Patients commented that the interview process was useful and informative. With the majority expressing satisfaction with the interventions they had received.

*“I think he did a really professional, polite and useful interview because he answered relevant questions only and was very, very informative if you asked him something you weren't sure about.....it wasn't embarrassing.....or worrying in any way..... he did a really professional, polite and useful interview because he answered relevant questions and was very, very informative, if you asked him something you weren't sure about.....weren't invasive at all”*  
[Focus group - 3 – Patients - Patient 3]

*“I mean I had the pump but I didn't really know what to do with it and he told me to do it twice a day.”*  
[Focus group - 3 – Patients - Patient 4]

*“he always makes you feel at ease, he always explains everything to you”*  
[Focus group - 3 – Patients - Patient 2]

Some expressed that they received reassurances through MUR which they did not get from their doctor.

*“Well I went up there and he said well there is something wrong there..... he said, I'll send you a letter when you've got to come up and have the dye, the dye put through and that's when they found out that it wasn't pumping properly...then they put me on six tablets...ever since then I've been alright.....it did frighten me. I wouldn't even go out! I was frightened to go out.....(pharmacist)He said don't get frightened when you get those attacks, just sit down and take it easy but, as he said, if you're taking your tablets right, you're doing alright.”*

[Focus group - 3 – Patients - Patient 5]

Others expressed their concerns about 'uncomfortable' questions such as those related to lifestyle issues such as smoking. A theme of discomfort emerged.

### **Discomfort**

*“He did ask me one question. He did ask “did I smoke?” and I said “yes” and he said “have you thought about giving up?” and I said “yes, I've thought about it but I'm not..... and my drinking as well he asked about”.*

[Focus group - 3 – Patients - Patient 1]

*“my husband was very quiet..... he smokes and that's one thing he didn't like the pharmacist asking him.”*

[Focus group - 3 – Patients - Patient 4]

### **6.7.4 MUR documentation**

They also commented that they had no reservations about the process being documented

*“He said it's just to keep a record, so we know exactly what you're taking and the dosage. I said “oh yes, that's fine with me. I don't mind at all. I'd be quite pleased..... very, very thorough. You know itemised every single thing on the way down....put it on the computer.”*

[Focus group - 3 – Patients - Patient 3]

Only the patients who had an intervention initiated knew documentation had been sent to their GP but all were happy for their GP to receive a copy.

*"I don't know if he sent on to the doctor"*  
[Focus group - 3 – Patients - Patient 4]

*"he told me he'd send one to my doctor"*  
[Focus group - 3 – Patients - Patient 1]

*"he must have done because I got my other tablet"*  
[Focus group - 3 – Patients - Patient 5]

#### **6.7.5 Patient satisfaction with the MUR service**

Overall all patients were satisfied with the service, expressing the theme of awareness with some confusion about how often they could have an MUR. All thought it was a good idea.

#### **Awareness**

*"Well I've only had one MUR in two years. I think it should be every year really because your tablets do change from year to year."*  
[Focus group - 3 – Patients - Patient 2]

*"I don't think most people know about it"*  
[Focus group - 3 – Patients - Patient 3]

#### **6.7.6 Improvements for future service delivery**

When asked about what improvements could be made, the theme of awareness re-emerged, with increasing awareness being the main improvement suggested.



## **Awareness**

Patients suggested various way in which the awareness of the service could be increased.

*“Advertise it!...on the leaflets”*

[Focus group - 3 – Patients - Patient 3]

*“how about in the doctors surgery.....on the doctors board”*

[Focus group - 3 – Patients - Patient 5]

## **6.8 Discussion of patient focus group**

Overall, patients were positive toward the MUR service. Patients generally had little expectations pre-interview and attended mostly out of curiosity but never the less thought it was a good idea. Generally patients were not aware of the service and surprisingly were not even aware that their pharmacist had a consultation room, even though they had regularly attended the same pharmacy for a number of years. The overwhelming theme of access emerged where they felt pharmacy services were more accessible and convenient than going to see their GP with one patient expressing that it takes four weeks to get an appointment with his doctor.

Patients were all invited for an annual MUR with three out of five participants having problems identified. All were satisfied with the outcomes. All patients found the review to be very interesting and informative. In contrast Petty and colleagues (2003) showed some patients were disappointed with some outcomes of their reviews as they had unrealistic expectations.

When asked about the interview, the overwhelming theme of trust emerged. Even though they commented that the consulting room was “small” and “cramped” patients had no reservations of entering the room with their pharmacist. They expressed views that their pharmacist looked after them and was regarded as their “friend”.

All patients from the focus group found the review took the right amount of time.

When asked about paper work, patients in the focus group remarked that the pharmacist had used the computer to document their MUR. Patients also stated that they did not mind their review being documented. They also confirmed that they had received a copy of the action plan, although some members were confused about whether the GP had also received it. Only those which had a change implemented could say for certain that their doctor had received a copy.

When asked what improvements could be made all patients suggested the service required wider advertising to make more people aware. Some suggested advertising the service in their doctor's surgery on the notice board.

Overall the patients who participated in this group were satisfied with the service they had received from their pharmacist and would readily repeat the process on a regular basis.

An unexpected finding of the focus group was the negativity of the patients towards their doctor with two key themes of access and relationships emerging. Patients commented on the ease of access and convenience of attending their pharmacy compared with their doctor's surgery, with one patient stating that it could take up to four weeks to receive an appointment. Patients felt that their relationship was better

with their pharmacist than that with their GP, viewing their pharmacist as more of a “friend” and commenting that they would rather go to their pharmacist than see their GP using words such as “comfortable” and phrases such as “(my pharmacist) puts me at ease”.

## **6.9 Conclusions of patients' views on MUR services**

Results from both the semi-structured questionnaires and the focus group discussions have demonstrated that patients have a very positive attitude to MUR services. Both groups expressed high satisfaction with overwhelming agreement that they would want to participate in this service on a regular basis. The key themes of trust and access emerged, linked to patients relationship with their pharmacist and ease of access of pharmacy services. These themes were also raised with much negativity directed towards GPs.

Overall this new service has been well accepted by patients. Further research is required to explore the views of other health professionals particularly GPs.

## Chapter 7

### Discussion and Conclusions

The aim of this thesis was to develop and evaluate methodologies to assess the clinical impact of medicines use review (MUR) on resolution of DTPs, a new service introduced under the new community pharmacy contract in April 2005 (Department of Health, 2005). The key aims of medicines use review are to improve patient's knowledge, compliance and their use of medicines. This national MUR model has the three key elements of a pharmaceutical care service namely: the practitioner assesses the patient's drug therapy needs; the patient and practitioner construct a care plan to meet those needs; and the practitioner follows up patient outcomes (Hepler and Strand, 1990).

To provide MUR services, accreditation is required of both the pharmacist and the premises. MUR represents an enormous opportunity for community pharmacy to deliver a pharmaceutical care model in line with the principles proposed by Hepler and Strand (1990). This MUR model permits the pharmacist to select any patient, without the permission of their GP, from a wide inclusion criteria: receiving  $\geq 1$  medicine; and regularly attending the pharmacy for three months previously. This service has been commissioned nationally in England and Wales and incorporates a national documentation and referral system with copies of the care plan provided to both patient and general practitioner.

The Nuffield Report (1986) made 26 recommendations relating to community pharmacy with nine of these recommendations being implemented in the new Community Pharmacy Contract in April 2005. It has taken 20 years and still six of

the Nuffield recommendations have yet to be introduced. Four of these relate to discharge of responsibility and accountability linked to the Royal Pharmaceutical Society of Great Britain's (RPSGB) 'interpretation' of the legal framework in relation to control and supervision. The final two relate to the number and size of pharmacies (less in number but larger in size) and, equivalence of dispensing services in rural settings. Such issues, particularly, 'control and supervision', are topics being widely debated at the present time as the RPSGB is undergoing restructuring to separate its regulatory and membership functions.

The starting point of the literature review was 1990 following the publication of the seminal paper by Hepler and Strand (1990) who defined pharmaceutical care as, *'The responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life'*. A review of prospective cohort studies and randomised controlled trials (RCTs) published in English was, conducted over a 15 year period (1990-2005) to identify the evidence base for pharmaceutical care. These were divided into disease specific and general models of pharmaceutical care. To be included in this review, a study was required to include the three key elements of a pharmaceutical care service.

In terms of disease specific models, we concluded that there was some evidence from well designed studies in the area of diabetes such as the prospective cohort study by Cioffi et al (2004) and the RCT by Clifford et al (2005). In hypertension, the evidence of benefit appeared to be stronger with robust study designs employed in several RCTs (Carter et al., 1997, Garcao and Cabrita., 2002 and Vivian et al., 2002). In the case of asthma and hyperlipidemia from the papers reviewed an evidence base was not established partly due to severe limitations of the study design. These limitations

include: subjectivity of inclusion criteria; lack of blinding of physicians; small sample size for multi-centred studies; patient self report of outcome measures; and lack of a control group for studies over twelve months.

Of the general pharmaceutical care models reviewed, a number were dismissed due to limitations of the methodology; Small sample size  $\leq 100$  patients (Jameson et al., 1995; Al-Rashed et al., 2002; Taylor et al., 2003); Short follow-up of  $\leq 3$  months (Lipton et al., 1992; Shalansky et al., 1996, Lowe et al., 2000; Krska et al., 2001; Sorensen et al., 2004); Lack of control group (Lobas et al., 1992; March et al., 1999; Catellier et al., 2000; Coleman et al 2001) and failure to identify equivalent outcome measures in the control group (Ellis et al., 2000; Volume et al., 2001; Sellors et al., 2003). Of the well designed studies several failed to show any benefit (Coleman et al., 1999 and Bernsten et al., 2001; Grymonpre et al., 2001).

Of the remaining studies, two of the studies were limited to a narrow range of DTPs related to ADRs and interactions (Jameson & VanNoord., 2001; Holland et al., 2005). Whilst Jameson and VanNoord demonstrated significant benefit, Holland et al (2005) demonstrated an increase in emergency readmissions in the intervention group without linking this to a positive or negative outcome. This intervention described a limited pharmaceutical care model, which focussed on patient education and compliance including the use of compliance aids. This anomaly of increased emergency admissions was addressed in a recent paper published by the same group (Lenaghan et al., 2007) who concluded that home based medication review by a pharmacist for at risk older patients ( $>80$  years) produced no difference in hospital admissions, care home admissions or deaths. However the team also concluded that there was no positive impact on clinical outcomes or quality of life.

Of the remaining general pharmaceutical care studies direct comparison of findings is difficult due to inconsistency in the reporting of the outcome measures.

Hanlon et al (1996) used a Medicines Appropriateness Index (MAI) which has not been validated to establish a link to clinical outcomes. In addition the MAI lacks the ability to measure adverse drug reactions (ADRs) and drug interactions. A recent well designed RCT (Spinewine et al., 2007) of 203 older patients ( $\geq 70$  years) also adopted the MAI index with pharmaceutical care provided to reduce the MAI score in the intervention group during a hospital admission. Secondary outcomes included: mortality; readmission; and emergency visits up to 12 months post-discharge. Whilst a significant reduction in MAI score was achieved and sustained post-discharge, there was no significant improvement in secondary outcome measures at 12 months follow up. Once again researchers have failed to link the MAI score with clinical outcomes.

Similarly a well designed study by Zermansky et al (2001) reported positive outcomes but is equally difficult to interpret as it focused on process outcomes such as number of drugs, drug changes and costs with no attempt to link these measures to clinical outcomes.

Nevertheless the Hanlon study was a well designed study which informed the study design of Mackie et al (1999). In contrast to Hanlon, Mackie et al (1999) adopted an amended Strand classification system (Strand et al., 1990) which increased the number of categories from 8 to 12 and reported the extent of resolution of DTPs from baseline to follow-up. This well designed study demonstrated positive outcomes but was limited by the partial validation of this classification system by the three research

pharmacists who coded approximately 4000 DTPs (Mackie, 2002). No attempt was made to test the validity and reliability in a wider pharmacist population.

The hypothesis tested in this thesis was 'Medicines Use Review will reduce drug therapy problems and will be well accepted by both patients and pharmacists'. This thesis employed both quantitative and qualitative methodologies to address this hypothesis. To overcome methodological problems of previous studies the starting point was to validate a hierarchical drug therapy problem classification system for use in determining the primary outcome measure for the main study.

Van mil et al (2004) proposed that an optimal classification system should be one which leads the user to one choice of coding, be based on clear definitions, should be validated and easy to use for research and clinical practice, should be structured in a hierarchical manner and should focus on the process of pharmaceutical care and be based on definitions that takes the outcomes of pharmacotherapy into account. An extensive validation process resulting in Version 3 of a hierarchical DTP classification system was undertaken. Reliability and internal consistency were demonstrated and supported by positive comments from participating pharmacists who felt it made it easy to identify and classify DTPs. This version still had limitations such as the small sample of pharmacist participants (31 out of 400 responded) and the reported difficulty in assigning only one DTP category per problem. This was overcome by allowing the pharmacist to freely describe the DTP leaving the research team to apply the classification system post the intervention. Further validation of this classification system is therefore required in clinical practice with a wider group of pharmacy practitioners.



In the main study a matched cohort study design was used to test the hypothesis. Two cohorts were recruited, a prospective cohort who received the intervention (active) and a matched retrospective cohort who served as a control group. Due to the dynamic environment of primary care a prospective randomised controlled trial (RCT) would have been the favoured study design as it allows the study of two cohorts of patients receiving 'standard' care where the only difference between the two groups is the intervention itself. Advantages of RCT study designs are numerous and include: rigor in the determination of cause-effect relationship and include; random assignment with unbiased distribution of confounders with option of blinding more likely. A major disadvantage of RCT designs is that they can be: expensive; exhibit volunteer bias; and may be ethically problematic. It was this latter factor which resulted in the rejection of an RCT design for this study due to the implementation of the New Pharmacy Contract in April 2005 with MUR becoming 'standard care'. In addition to the ethical aspects of withholding standard care, the problem of possible contamination arose as prospective controls may have been invited to have an MUR during the study period.

A matched cohort study design was chosen which overcame the disadvantages of the RCT design with a prospective active group recruited to the main study being matched with a retrospective control cohort. This cohort study design is similar to an RCT in that it permits comparison of outcomes in two groups that did and did not receive the intervention. The main limitation of a cohort study is that the allocation to the two groups is not by chance which may give rise to selection bias which threatens the internal validity of the study. However cohort studies have been advocated to determine whether the efficacy observed in RCTs translates into effectiveness in broader populations and more realistic practice settings (Rochon et al., 2005). In the

present study a cohort design may be a distinct advantage in the evaluation of the effectiveness of MUR in practice.

The active group were a prospective cohort of 120 patients  $\geq 18$  years, invited to have a MUR at one of the seven participating pharmacies (8 pharmacists) during the recruitment period of the study from September 2005 to September 2006. The control cohort of 120 patients were retrospectively recruited from the same GP practices matched to active patients by age, gender, GP practice and number of repeat medicines. The control cohort received a MUR at the time of recruitment to the study and all drug therapy problems assessed for likelihood of presence at baseline six months previously. A disadvantage of the retrospective control cohort is that it relied on patient recall from a period six months earlier together with retrospective extraction of routine clinical data from medical case notes. Both of these have the potential to contribute to under reporting of DTPs at baseline.

The MUR involved a semi-structured interview, recorded using the national documentation template with an action plan forming the GP referral where appropriate. Outcomes were determined using quantitative methods (reduction in drug therapy problems [primary outcome]; changes to number of repeat medicines, changes to primary care consultations, hospital consultations, use of out of hours services, and emergency hospital admissions [secondary outcomes]). All active and control patients received an MUR intervention. Where a drug therapy problem was as defined by Cipolle et al (1998) as: *'any undesirable event experienced by the patient that involves or is suspected to involve drug therapy and that actually or potentially interferes with a desired patient outcome.'* In addition a DTP was deemed to exist

*'when a patient experiences or is likely to experience either a disease or symptom having an actual or suspected relationship with drug therapy'* (Strand et al., 1990).

The primary outcome measure was a reduction in drug therapy problems with a 64% resolution observed in the active group compared to only 3% in the control group over the six month period of the study. Mean number of drug therapy problems was found to be 1.5 ( $\pm$  0.9) for the active group and 1.4 ( $\pm$  1.1) for the control group at baseline. This reduced to 0.6 ( $\pm$  0.6) and 1.36 ( $\pm$  1.1) at follow-up for the active and control group respectively. This effect size is significant ( $p < 0.0001$ ) suggesting that the hypothesis can be accepted. However, the effect size on the control group of only 3% is lower than that reported for previous studies (Mackie et al., 1999, Mackie et al., 2005). The study by Hanlon et al (1996) which used an MAI score reported a 5% resolution in the control group with Zermansky et al (2001) failing to report any clinical measure for the control.

In contrast the study by Krska et al (2001) reported 78% resolution in the active group compared with 39% in the control. However, it should be noted that mean number of pharmaceutical care issues (PCIs) found per patient were 7 for active patients and 8 for control and most of the issues identified in this study were either potential issues or counselling issues which accounted for a total of 58% and 46% of issues in the active and control groups respectively. These results confirm the concern that there was a vast inflation of problems, reported as PCIs, which don't relate to the clinical DTPs reported elsewhere.

Hence to overcome this possible limitation the results were reanalysed using a revised estimate of 21% (Mackie et al., 2005) as was observed for resolution of DTPs in the

control group due to standard care in the community pharmacy medication review study which most closely resembles the current study. Using 21% DTP resolution rate for the control the effect size remained significant ( $p < 0.0001$ ) with an absolute risk reduction of 43% and number needed to treat of 2.3, this means for every 23 DTPs receiving an intervention, 10 DTPs would be avoided over a period of 6 ( $\pm 0.8$ ) months over and above standard care.

There were no changes observed in each of the secondary outcome measures. The number of medicines at baseline and follow-up was consistent indicating that drug therapy problems were resolved without a significant increase in repeat prescribing. This is reassuring and resulted from recommendations to stop medicines, initiate new medicines, and change current medicines, with two thirds of these changes successfully implemented. This is consistent with the findings of several other studies (Al-Rashed et al., 2002; Mackie, 2002; Sellors et al., 2003; Mackie et al., 2005). However, a number of studies have reported significant changes in the number of drugs from baseline to follow up (Lowe et al., 2001; Zermansky et al., 2001). Although statistical significance is expressed by the authors it is unlikely that these changes will be clinically significant as they correspond to a mean of -0.26 and +0.2 respectively. A rise in drug usage should not always be seen as negative when viewed in light of current guidelines for primary and secondary prevention of diseases where additions of medication may contribute to positive outcomes in the longer term. In conclusion, changes in mean number of drugs are more of a process outcome rather than a clinical outcome with researchers being advised to be cautious in the interpretation of this finding when it occurs, perhaps studies should stop reporting this as an outcome measure.

In terms of use of health care services, no significant differences were noted in primary care visits, secondary care visits and hospital admissions between the two groups. This finding is consistent with a number of previous studies (Coleman et al., 1999; Bernsten et al., 2001; Grymonpre et al., 2001; Krska et al., 2001; Zermansky et al., 2001; Mackie, 2002; Mackie et al., 2005; Lenaghan et al., 2007). It should be recognised that all these studies were clinical medication review without a copy of the care plan being given to patients. What is distinctive about MUR is the issuing of the care plan to both patients and GPs. The finding of no increased consultation may be considered a very positive outcome such that if patients needed reassurance regarding changes made by the pharmacist this may have contributed to an increase in consultation rates with other practitioners. This was not observed.

This study used a validated hierarchical classification system to code DTPs for the main study. A particular criticism of MAI is that the score has not been linked to clinical outcomes (Hanlon et al., 1996; Taylor et al., 2003; Spinewine et al., 2007). It is possible that the same criticism could be made of DTPs. However, the classification system used in this study is one that has been refined to clinical problems with clear criteria expressed for each category, for example for the supra category 'Safety' the criteria for classifying a drug interaction was as listed in appendix 1 of the BNF as being potentially hazardous with contraindications confirmed only if listed in the medicines summary of product characteristics.

In the supra category 'Appropriateness', no indication for therapy was categorised when a documented diagnosis or medical conditions could not be found for the particular therapy in question. Inappropriate choice of therapy was categorised when the patient was taking therapy which did not conform to current guidelines in relation

to their medical condition(s). Duplication of therapy was classified when the patient was receiving duplication of treatment for a particular indication. Inappropriate dose/dosing schedule was classified if the patient was receiving an unsuitable dosage in relation to their medical condition according to current guidelines. Finally additional drug therapy required was classified if the patient had a documented diagnosis or co-morbidity which required prophylaxis.

In the supra category 'Effectiveness', ineffective therapy was categorised when objective monitoring results were checked and were not meeting the required target. Unsuitable formulation/ drug delivery was classified when the formulation of the therapy in question was unsuitable for the individual patient as confirmed by the pharmacist at interview. Monitoring indicated was only classified when the pharmacist had a concern and the patient had confirmed that no monitoring had taken place. Non compliance was the only category which was based on subjective assessment in the form of patient self report at interview. This category had no validated measure and no attempt was made at baseline or follow-up to confirm actual patient compliance. Both monitoring and compliance have a subjectivity that remains a limitation of the study. However, the impact of these two categories was not significant as they only represented 5% and 7% of DTPs respectively. Further research into these areas is required as several studies have reported vastly inflated figures (Shalansky et al., 1996; Krska et al., 2001; Sellors et al., 2003).

If the categories represented within each of these groups are reviewed one may anticipate that pharmacists may be confident to report DTPs under supra categories 'Safety' and 'Effectiveness'. Surprisingly 51% of DTPs identified related to the supra

category 'Appropriateness'. This was unexpected as appropriateness of therapy may be traditionally viewed as the domain of the GP.

Participation rates of patients was high with 100% completing the study at 6 ( $\pm$  0.8) months. This high level of participation was matched by the acceptance of the invitation by 100% of nominated GPs who were approached to participate in the study. In terms of pharmacists participation at the time of recruitment to the study only 15 were accredited within Kent region and although the sample of 8 (53%) may appear to be a representative group it is likely that these volunteer pharmacists are not representative of the wider group of community pharmacists but reflect a group of 'early adopters' or 'leading edge practitioners'. However, the findings in this study are consistent with the earlier East London study who recruited from a wider group of community pharmacists (Mackie et al., 2005). These high participation rates may indicate a level of satisfaction and or engagement with MUR services which were explored with a wider group using qualitative methodology. Focus group discussions were held with both patients and practitioners to ascertain if the service was well received.

Focus group discussions with service providers and non providers demonstrated that both groups of pharmacists had very positive attitudes towards MUR services. The latter was unexpected and in sharp contrast to the negatives attitudes expressed towards the new Community Pharmacy Contract by these non providers of MUR services. In the case of providers, two key themes emerged with resources and relationships needing to be addressed in order to further develop MUR services. In addition, providers felt very strongly that PCTs should be doing more to increase awareness of MUR services to both patients and health care professionals. In contrast

non providers were confused about the difference between interventions and intervention MURs. However, the two key themes of resources and relationships were also raised with workload issues dominating the discussions. What is unclear is the true extent of the workload issues or whether this has been overemphasised in an attempt to defend their non-participation. It is recommended that future observational research be undertaken in order to explore this aspect further.

Patient's views were obtained in two ways. Firstly research study participants were invited to complete a semi-structured questionnaire by post or telephone. Secondly patients who had experienced MUR services and were not involved in the research study were invited to take part in a focus group discussion. Patients who took part in the main study were excluded from the focus group discussion as it was acknowledged that these patients had received an MUR with additional information provided to meet the ethics committee requirement to obtain informed consent in this group.

A 61% response rate was obtained to the semi-structured questionnaire administered to research study participants. Overall the service was well received with 99% of participants expressing satisfaction with the majority wanting the MUR service to be available on a regular basis. A closed consultation area appeared to be the preferred location for the majority of patients although some did express the view that it should be up to the individual to decide. Suggestions for improvements to the service were few but included having less interruptions of the pharmacist during the MUR and increasing the frequency to 6 monthly reviews. Future developments in the area of 'control' and 'supervision' may address the former and facilitate the latter. A limitation of these findings is that a semi-structured questionnaire does not allow in



depth exploration of issues raised. In addition these patients experienced a MUR service as part of a research study therefore their views may not be relevant to those receiving standard MUR in routine practice. To overcome these limitations a focus group was held which specifically excluded patients involved in the main study.

Six patients participated in a focus group discussion. A particular strength of the focus group design was that it allowed a more in depth discussion driven by the dynamics of the group. Patients expressed satisfactions with MUR with two key themes emerging relating to awareness and trust. Patients expressed concern about the lack of awareness and promotion of the service. In terms of trust patients had a high level of trust in the pharmacist and a willingness to have a consultation in a small cramped space an unexpected finding was the negativity of patients toward their doctor with two key themes of access and relationships dominating their concerns. Patients contrasted the accessibility of the pharmacist to the difficulties encountered in making appointments to see their GP. In terms of relationships patients expressed a preference for the pharmacist as someone they found more approachable. A limitation of focus groups is that there is potential for an individual to dominate the group. In the actual focus group the fact that the patients were from one pharmacy may have exacerbated this and led to domination of a particular patient which was evident from the transcript despite the moderator attempting to reduce this effect. Whilst a strength was that the focus group was held with patients who had received MUR and not participated in the research it is also a limitation in that patients who participated in the research study may have provided more insight and depth using a focus group than obtained with a semi-structured questionnaire. Had resources permitted focus would have been held with both groups of patients.

A further limitation of data arising from the focus groups was its limited presentation within the thesis with no attempt made to link observed body language with comments made. Finally the presentation of the qualitative data is limited by the lack of explanatory text around the comments of the focus group.

In this thesis we have sought to assess the impact of MUR in practice on the understanding that MUR provides an opportunity to deliver a pharmaceutical care model. A limitation of this assumption is that patient follow-up is not built into the service specification for MUR and may fall short of pharmaceutical care in this respect. In addition many pharmacists delivering MUR may choose to provide a very limited service by reviewing patient's medicines use with a focus on improving patient's knowledge and understanding of their medicines only. In such cases the actions tend to be mainly targeted at the pharmacist providing information with no attempt made to improve the clinical and cost-effectiveness of their prescribed medicines. Perhaps this is a reflection of the title 'Medicines Use Review' rather than the widely accepted terminology of 'medication review' referred to in many national documents (National Service Framework for the Elderly and the 2004 General Medical Services contract). This study deliberately did not seek to assess changes in patient's knowledge or compliance as DTPs were considered to be more robust outcome measures. One may consider this a limitation however knowledge and compliance are multi-factorial and are not unique to MUR as they should be considered at each dispensing of a prescription.

The contractual framework for MUR states that ‘the aims are to improve patient’s knowledge, concordance and use of medicines by:

- Establish the patient’s actual use, understanding and experience of taking medicines;
- Identifying, discussing and resolving poor or ineffective use of their medicines;
- Identifying side-effect and drug interactions that may affect patient compliance;
- Improving the clinical and cost-effectiveness of prescribed medicines and reducing medicines wastage.’

We have interpreted the aims of MUR services as assessment of patient’s use and understanding of medicines in order to identify DTPs. We have not included patient knowledge of medicines or indeed lack of knowledge as a DTP as there is no evidence in the literature to suggest that knowledge has a positive influence on compliance or clinical outcomes.

A limitation in the use of DTPs as the primary outcome in this study is that we have not included lifestyle advice or support unless it was linked to a medicine such as Nicotine Replacement Therapy. This limitation is accepted and it is recommended that future work on evaluating MUR services incorporate this aspect.

Limitations of this work have been discussed and include:

- The low response rate for validation of the DTP classification system (8%). This was overcome by restricting the coding to two researchers allowing the pharmacists to describe the DTPs in a free text format.
- The retrospective control cohort may have resulted in underreporting of DTPs present at baseline and resolved at follow up (3%) due to incomplete data within medical records. Although additional analysis was undertaken using control group resolution from the literature (21%) the problem was not resolved, with the actual DTP resolution likely to be between 3% and 21%.
- Generalisability of the findings with respect to participating pharmacists was limited by the timeline of the research. Of the 15 pharmacists accredited for MUR, 8 participated which may not appear to be a representative sample however only 15 of the 285 pharmacies in Kent were undertaking MUR in September 2005. Therefore the 8 pharmacists who participated in the study are likely to be atypical 'early adopters'.
- Pharmacists were free to recruit patients of 18 years and over who met the MUR service requirements. It is possible that participating pharmacists deliberately selected patients with multiple problems, as evident by patients having 2.9 ( $\pm$  1.3) medical conditions and receiving 6.2 ( $\pm$  2.6) medicines. However one could argue that this is not a limitation but a reality of practice as each pharmacy is limited to only 400 MURs per year. It is hoped that pharmacists would prioritise in this way and target higher risk patients such as those recruited to this study although the service specification allows them to target patients receiving one or more medicines.

- DTPs were objectively measured where possible with an acknowledged limitation of DTPs related to monitoring and compliance. Although these two categories accounted for only 5% and 7% of DTPs respectively.
- It was originally planned to undertake an economic analysis of MUR. However, this was not pursued due to the slow uptake of MUR nationally as it was felt that pharmacists may have taken an unrealistic amount of time in explaining the service to patients and practitioners at this early stage of its implementation.
- The qualitative data could have been enriched by both its presentation and by incorporating focus groups of pharmacists and patients who had participated in the research study. This limitation arose due to resource constraints and is acknowledged and accepted.

### **Recommendations for future research**

1. The hierarchical DTP classification system should be validated in a community pharmacy setting.
2. The study should be repeated using a prospective RCT design to determine the effect size on the control group due to standard care. An RCT design was rejected in this study due to the fact that MUR was anticipated to become standard care raising both concerns of ethics and possible contamination of the control group. In practice MUR has had a very low uptake and has not become standard care making an RCT design the preferred option. The primary outcome measure should continue to be DTPs, however secondary outcome measures should be expanded to include lifestyle and quality of life measures.

3. More in depth qualitative research is required to elicit views of participating pharmacists, patients and GPs including observation of practice of providers and non-providers.
4. Recent changes to MUR documentation (full implementation expected September 2008) need to be evaluated.

### **Recommendations for future service provision**

1. PCT pharmacists should be actively involved in raising awareness of MUR amongst both patients and practitioners.
2. Pharmacists should be provided with appropriate education and training in order to identify and resolve clinical DTPs. This training should be multi-disciplinary and include communication skills and therapeutics as appropriate to individual needs.
3. Pharmacists should be encouraged to provide closed consultation rooms with adequate space for those wishing to choose this location.
4. Pharmacists should be given peer support to deliver MUR services.
5. Pharmacists must provide appropriate education and training for support staff and devolve responsibility to these staff as appropriate (for example accredited checking technicians) to allow them the time to undertake new professional services such as MUR.
6. Pharmacists should be required to demonstrate competency to deliver MUR with periodic re-accreditation.

## **Conclusions**

A range of quantitative and qualitative methods have been developed to evaluate and test the hypotheses that ‘Medicines Use Review will reduce drug therapy problems and will be well accepted by both patients and pharmacists’. On the basis of the results presented and the limitations discussed, one can conclude that the hypothesis can be accepted. These findings make an original contribution to the literature and represent a significant contribution to the development of an evidence base for Medicines Use Review services.

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# Appendices

## **Search terms used**

Cohort Studies

Drug Related Problems (DRPs)

Drug Therapy Problems (DTPs)

Medication Related Problems (MRPs)

Phar\$

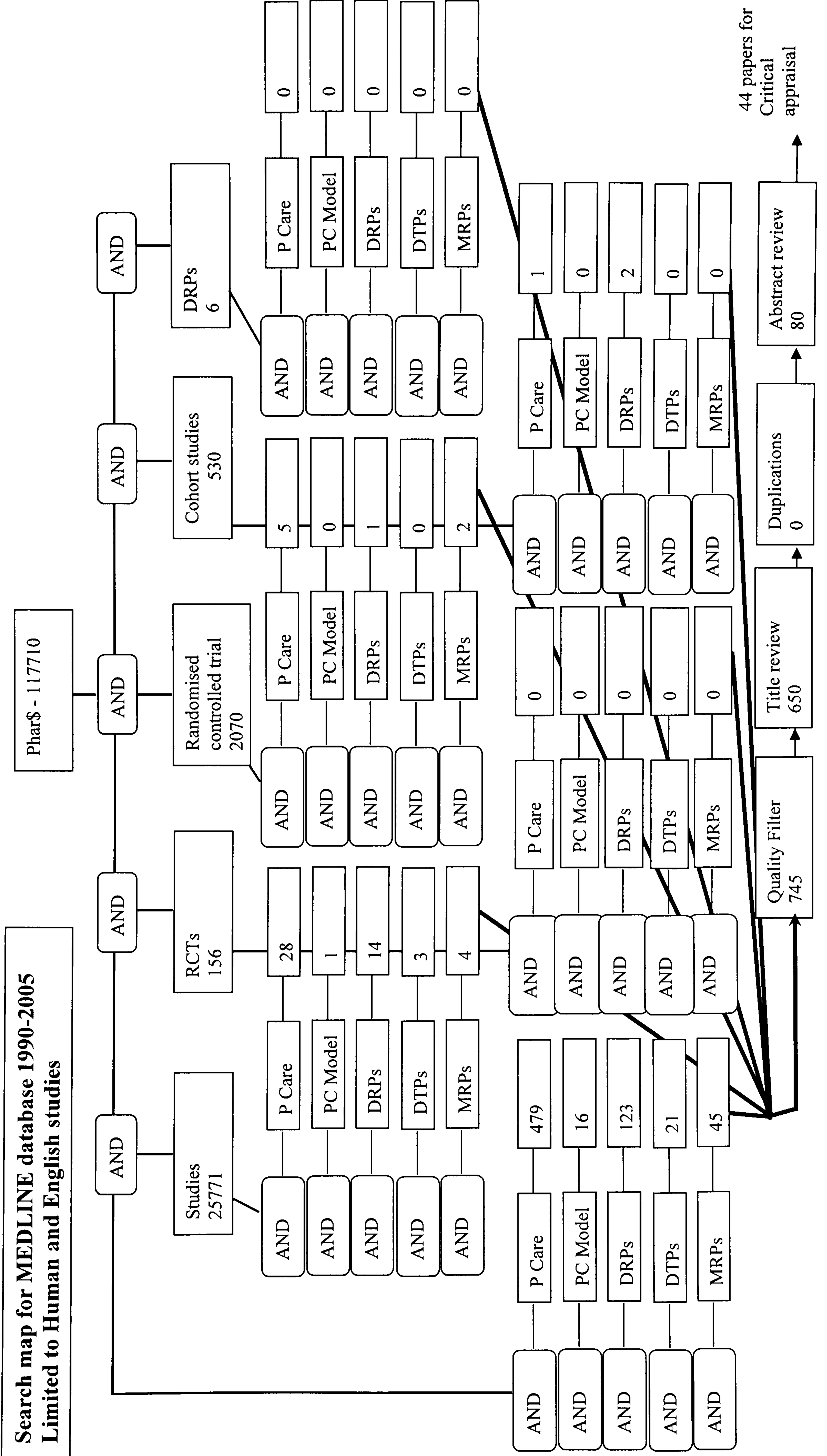
Pharmaceutical care

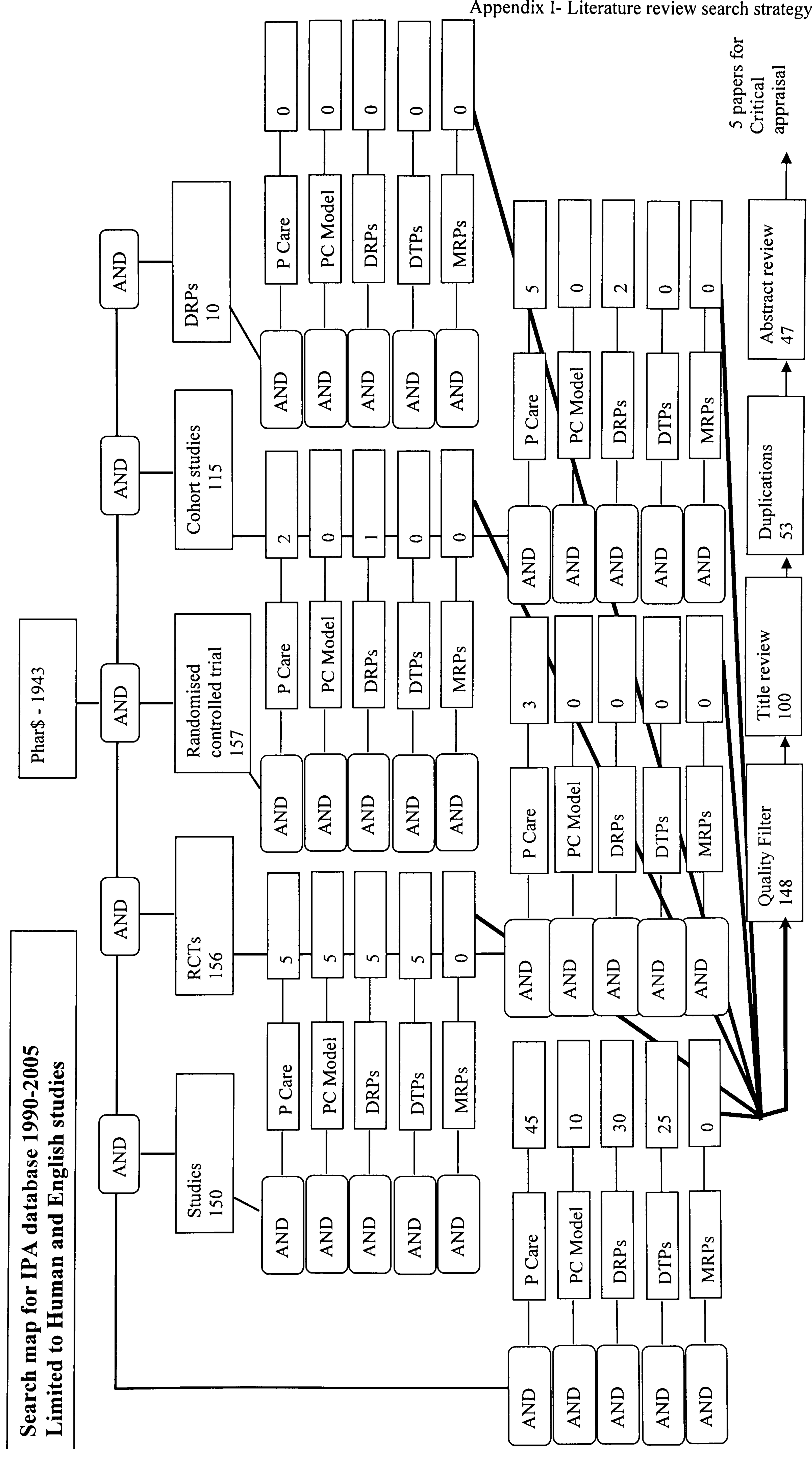
Pharmaceutical care model

Randomised Controlled Trial

RCTs

Studies







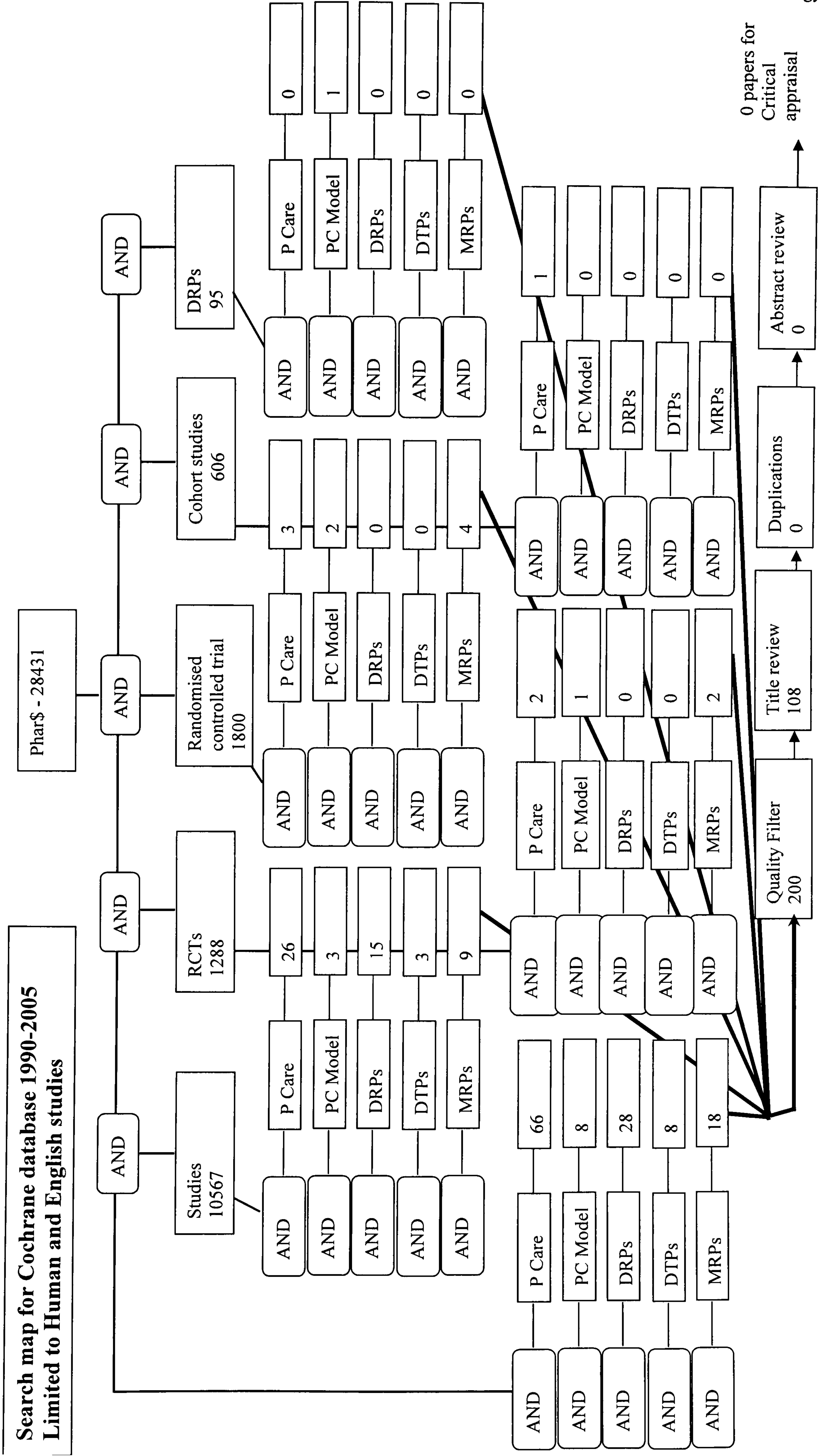




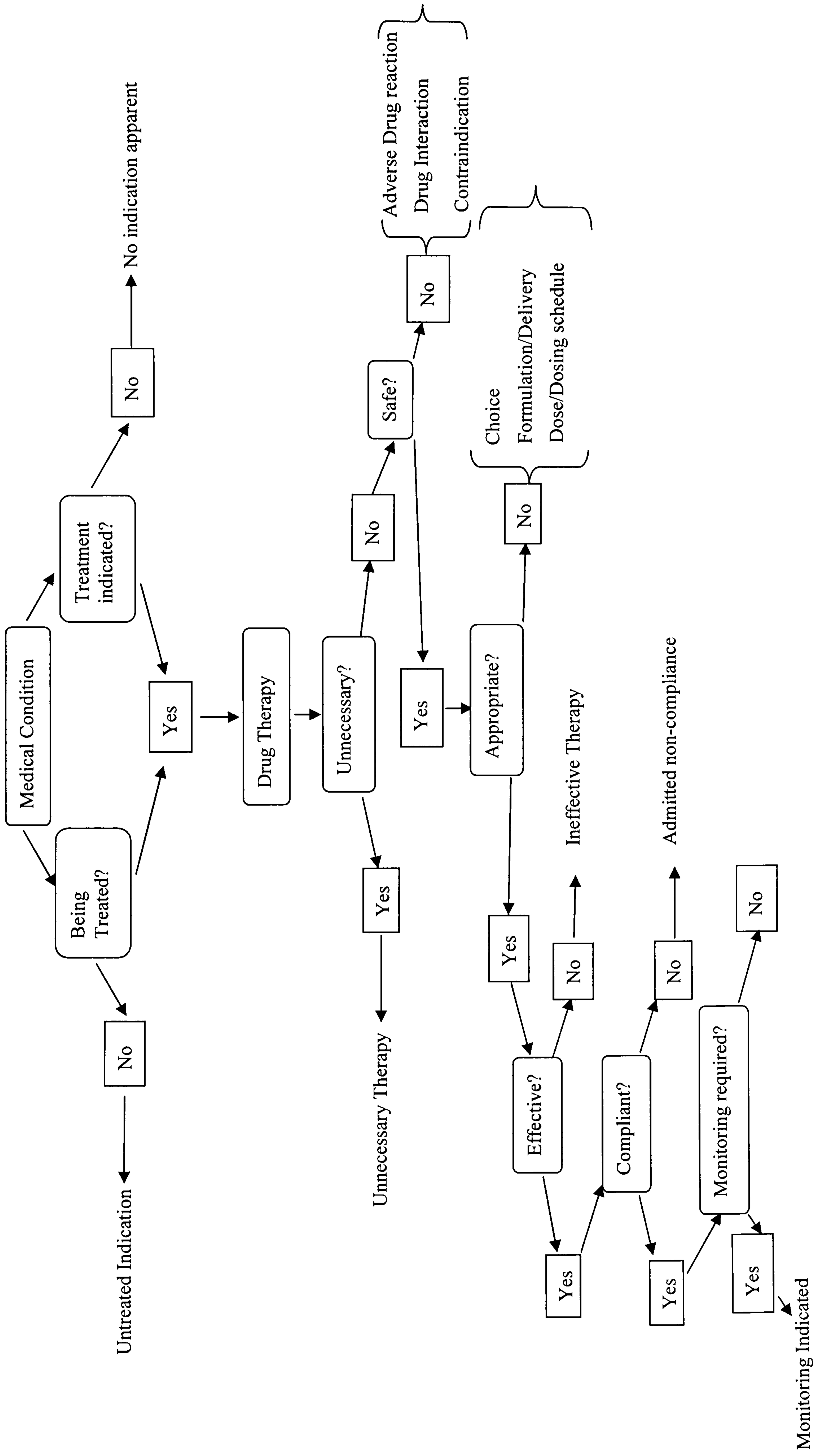
Table of categories, definitions and criteria (Version 1)

Category	Definition	Criteria
<b>APPROPRIATENESS</b>		
Unnecessary Therapy	Patient is receiving therapy where there is a documented diagnosis, but is not currently required.	Check all therapy for duplications and treatments not adhering to current guidelines and treatments.
No Indication Apparent	Patient is receiving therapy for which there is no documented diagnosis.	Check all therapy against documented medical conditions, diagnosis and doses for each condition
Untreated Indication	Patient is not receiving therapy for a documented diagnosis or prophylaxis linked to co-morbidity. The patient has a medical condition that requires drug therapy (a drug indication) but the patient is not receiving a drug for that indication.	Check all patients medical conditions and diagnosis are being treated according to BNF, national guidelines and current national frameworks.
<b>SAFETY</b>		
Adverse Drug Reaction (ADR)	Definition from the WHO, “Any noxious, unintended and undesired effect of a drug which occurs at doses used in humans for prophylaxis, diagnosis or therapy.” (Excluding therapeutic failures, intentional and accidental poisoning).	Check drug side effect profile from BNF and Summary of product characteristics (SPC). Causality of the ADRs may also be checked, using various methods e.g. Naranjo or Jones methods
Clinically significant drug Interaction.	The significant interaction of a drug that may affect the activity, metabolism or toxicity of another drug.	Check Appendix 1 of the BNF (available 6 monthly or on the web) Interactions considered to be clinically significant are indicated with a black dot.
Contra-indication	A condition which makes a particular treatment or procedure inadvisable.	Check BNF for contraindications against each drug (drug monograph, SPC).

Table of categories definitions and criteria continued (Version 1)

Category	Definition	Criteria
<b>EFFECTIVENESS</b>		
Ineffective Therapy	The therapy is not target at the dose being taken.	Check objective monitoring results, where possible and patients feedback for subjective end points such as pain.
Inappropriate choice of Therapy	The therapy being used to treat the patient does not conform to guidelines for the condition being treated taking into account co-morbidity. The patient has a medical condition for which the wrong drug is being taken.	Check guidelines/frameworks for the patient's condition and co-morbidities.
Inappropriate formulation/dose/delivery of therapy	Where the form, route or dose of the treatment is unsuitable for the patient.	Check with patient and assess delivery and formulation are adequate.
Admitted non-compliance	When the patient confirms they are not adhering to their therapy.	Confirmed by interview with patient only
Monitoring indicated	When a particular monitoring test has not been undertaken and is required now	Check patient is being monitored with all tests required as per drugs or medical conditions with reasonable margins.

**Flow Chart: Process diagram to Code DTPs (Version 1)**



**Table of categories, definitions and criteria (Version 2)**

**Please take each of the patient's medical conditions and consider the patient's therapy in terms of Appropriateness, Safety and Effectiveness.**

**Please do not code your actions, only the problems are required.**

**1. Starting with appropriateness, ask your self is the therapy appropriate?**

Category	Definition	Criteria
<b>APPROPRIATENESS</b>		
No Indication Apparent	Patient is receiving therapy for which there is no documented diagnosis.	Check all therapy against documented medical conditions, diagnosis and doses for each condition
Unnecessary Therapy	Patient is receiving therapy where there is a documented diagnosis, but it is not required.	Check all therapy for duplications and treatments not adhering to current guidelines.
Untreated Indication	Patient is not receiving therapy for a documented diagnosis or prophylaxis linked to co-morbidity. The patient has a medical condition that requires drug therapy (a drug indication) but the patient is not receiving a drug for that indication.	Check all patients medical conditions and diagnosis are being treated according to BNF, national guidelines and current national frameworks.

- **Does the patient have a documented diagnosis for their medication?**

- **Is the therapy necessary?**

- **Is there an indication which requires treatment?**

**If all of the above are satisfactory then move onto assess the Safety of the medication. Please note if a problem is found at this stage then Safety and**

**Effectiveness are not relevant as the therapy is inappropriate.**

**Table of categories, definitions and criteria continued (Version 2)**

**If therapy is appropriate then assess the safety of the medication**

Category	Definition	Criteria
<b>SAFETY</b> Adverse Drug Reaction (ADR)	Definition from the WHO, “Any noxious, unintended and undesired effect of a drug which occurs at doses used in humans for prophylaxis, diagnosis or therapy.” (Excluding therapeutic failures, intentional and accidental poisoning).	Check the drug side effect profile from BNF and Summary of product characteristics (SPC). Causality of the ADRs may also be checked, using various methods e.g. Naranjo or Jones
Clinically significant drug Interaction.	The significant interaction of a drug that may affect the activity, metabolism or toxicity of another drug.	Check Appendix 1 of the BNF (available 6 monthly or on the web) Interactions considered to be clinically significant are indicated with a black dot
Contraindication	A condition which makes a particular treatment or procedure inadvisable.	Check BNF for contraindications against each drug (drug monograph, SPC).

- **Is the patient suffering from any Adverse Drug Reactions?**
- **Are there any significant drug interactions with any other medication?**
- **Are there any Contraindications for the medication?**

**If all of the above are satisfactory then move onto the effectiveness of the medication. Please note if a problem is found at this stage then there is no need to move onto effectiveness because if the therapy is not Safe and should be discontinued.**

**Table of categories, definitions and criteria continued (Version 2)  
If therapy is Safe then assess the effectiveness of the medication**

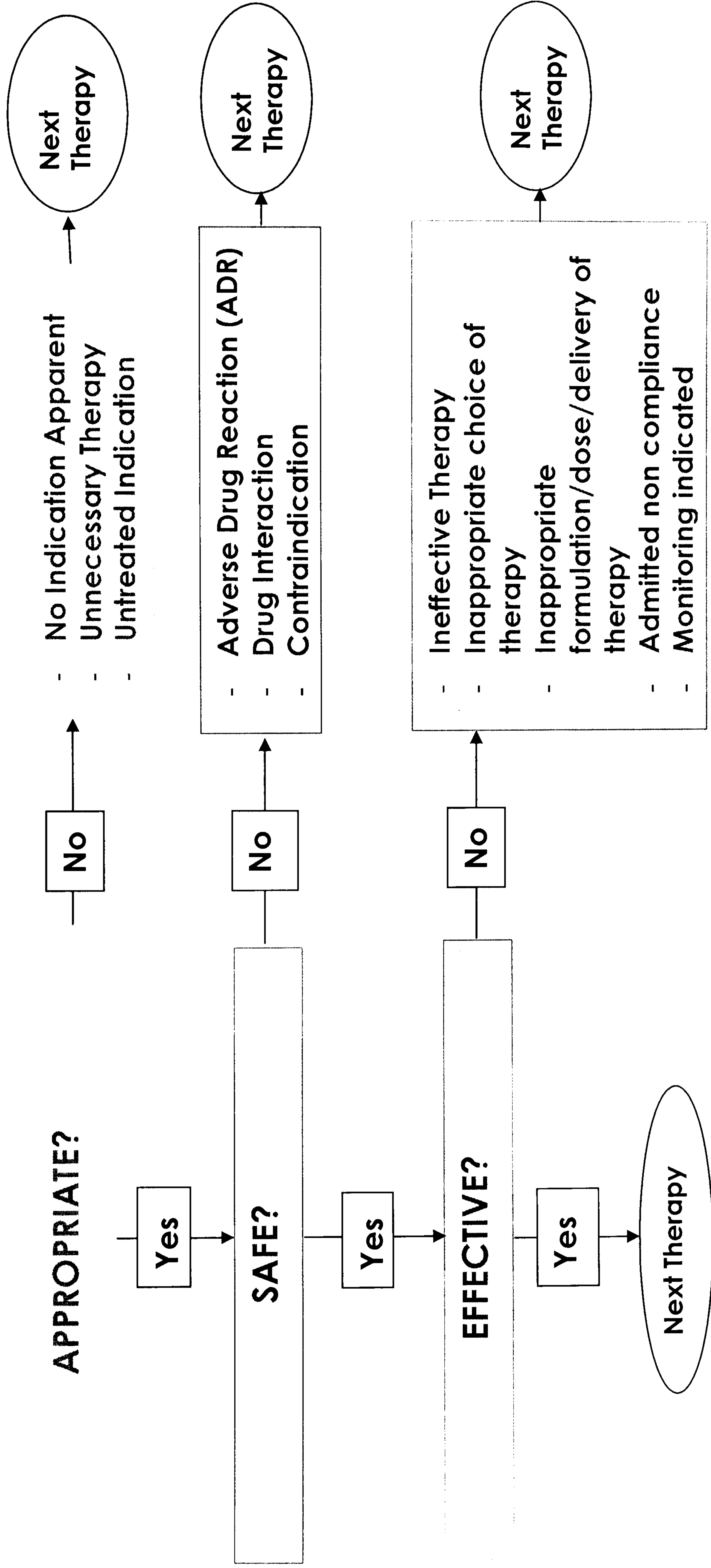
<b>Category</b>	<b>Definition</b>	<b>Criteria</b>
<b>INEFFECTIVENESS</b>		
<b>Ineffective Therapy</b>	The therapy is not optimised at the dose being taken.	Check objective monitoring results, where possible and patients feedback for subjective end points such as pain.
<b>Inappropriate choice of Therapy</b>	The therapy being used to treat the patient does not conform to guidelines for the condition being treated taking into account co-morbidity. The patient has a medical condition for which the wrong drug is being taken.	Check guidelines/frameworks for the patient's condition and co-morbidities.
<b>Inappropriate formulation/ dose/delivery of therapy</b>	Where the form, route or dose of the treatment is unsuitable for the patient.	Check with patient and assess delivery and formulation are adequate.
<b>Admitted non-compliance</b>	When the patient confirms they are not adhering to their therapy.	Confirmed by interview with patient only
<b>Monitoring indicated</b>	When a particular monitoring test has not been undertaken and is required now	Check patient is being monitored with all tests required as per drugs or medical conditions with reasonable margins.

- is the therapy effective in controlling the condition it was prescribed for?
- Does the therapy conform to current guidelines and take into account the patient's co-morbidities?
- Can the patient actually use/take the medication?
- Are they compliant?
- Is the patient being monitored regularly for their conditions as appropriate?

**Please note: As part of the hierarchical system only one code can be used per Drug Therapy Problem**

Flow Chart: Process diagram to Code DTPs (Version 2)

Take each of patient's the medical conditions in turn, e.g. Diabetes, High blood pressure etc



**Medicines Use Review Action Plan**

**Date of review:** 31/3/07

<b>Patient's name:</b> Mr Albert Smith	<b>Date of Birth:</b> 18/5/1942	<b>GP's name:</b> Dr N E Body
	<b>NHS Patient Code:</b> MUR Action plan 1	

Medicines Use Issue	Priority	Proposed Action	Action by	Outcome if known with dates
calcium + vit D patient doesn't like taste	High	start taking calcium regularly . GP to consider change of brand to see if taste preferable	GP/patient	

<b>Pharmacist name (block capitals)</b> N E Pharmacist	<b>RPSGB registration number</b> 123456	<b>Pharmacist signature</b>	<b>Telephone number of Pharmacist:</b> 01634 400000
<b>Next steps:</b>			
<input type="checkbox"/> <b>PATIENT:</b> This is your copy; please retain it for your personal use. You may wish to show it to other health care professionals if you wish to share this information.		<input type="checkbox"/> <b>GENERAL PRACTITIONER:</b> This is your copy; please retain a copy in your patient's notes.	
<input type="checkbox"/> Please make an appointment with your GP to discuss within <input type="text"/> weeks.		<input type="checkbox"/> For information only – no action required.	
<input type="checkbox"/> Take this form to your next scheduled GP appointment.		<input type="checkbox"/> Please review the actions proposed above.	
<input type="checkbox"/> Follow your actions agreed above.			



**Medicines Use Review Action Plan**

**Date of review: 31/3/07**

<b>Patient's name:</b> Mr James Smith	<b>Date of Birth:</b> 18/5/1942	<b>GP's name:</b> Dr N E Body		
	<b>NHS Patient Code:</b> MUR Action plan 2			
<b>Medicines Use Issue</b>	<b>Priority</b>	<b>Proposed Action</b>	<b>Action by</b>	<b>Outcome if known with dates</b>
patient doesn't think has had second cholesterol check	Medium	blood test and review of cholesterol if not checked	GP	

<b>Pharmacist name (block capitals)</b> N E Pharmacist	<b>RPSGB registration number</b> 123456	<b>Pharmacist signature</b>	<b>Telephone number of Pharmacist:</b> 01634 400000
<b>Next steps:</b>		<b>GENERAL PRACTITIONER:</b>	
<input type="checkbox"/> <b>PATIENT:</b> This is your copy; please retain it for your personal use. You may wish to show it to other health care professionals if you wish to share this information.		<input type="checkbox"/> This is your copy; please retain a copy in your patient's notes.	
<input type="checkbox"/> Please make an appointment with your GP to discuss within <input type="text"/> weeks.		<input type="checkbox"/> For information only – no action required.	
<input type="checkbox"/> Take this form to your next scheduled GP appointment.		<input type="checkbox"/> Please review the actions proposed above.	
<input type="checkbox"/> Follow your actions agreed above.			

**Medicines Use Review Action Plan**

**Date of review:** 31/3/07

<b>Patient's name:</b> Mr John Brown	<b>Date of Birth:</b> 18/5/1942	<b>GP's name:</b> Dr N E Body
	<b>NHS Patient Code:</b> MUR Action plan 3	

Medicines Use Issue	Priority	Proposed Action	Action by	Outcome if known with dates
Patient is taking ranitidine for last 10 years, says was given in hospital does not know why he has it	High	Review therapy and discontinue if not required	GP	

<b>Pharmacist name (block capitals)</b> N E Pharmacist	<b>RPSGB registration number</b> 123456	<b>Pharmacist signature</b>	<b>Telephone number of Pharmacist:</b> 01634 400000
<b>Next steps:</b>			
<input type="checkbox"/> <b>PATIENT:</b> This is your copy; please retain it for your personal use. You may wish to show it to other health care professionals if you wish to share this information.		<input type="checkbox"/> <b>GENERAL PRACTITIONER:</b> This is your copy; please retain a copy in your patient's notes.	
<input type="checkbox"/> Please make an appointment with your GP to discuss within [ ] weeks.		<input type="checkbox"/> For information only – no action required.	
<input type="checkbox"/> Take this form to your next scheduled GP appointment.		<input type="checkbox"/> Please review the actions proposed above.	
<input type="checkbox"/> Follow your actions agreed above.			

**Medicines Use Review Action Plan**

**Date of review: 31/3/07**

<b>Patient's name:</b> Mr Harry Smith		<b>Date of Birth:</b> 18/5/1942	<b>GP's name:</b> Dr N E Body
		<b>NHS Patient Code:</b> MUR Action plan 4	
<b>Medicines Use Issue</b>	<b>Priority</b>	<b>Proposed Action</b>	<b>Outcome if known with dates</b>
Furosemide given for ankle swelling	High	Review therapy	GP
<b>Pharmacist name (block capitals)</b>	<b>RPSGB registration number</b>	<b>Pharmacist signature</b>	<b>Telephone number of Pharmacist:</b>
N E Pharmacist	123456		01634 400000
<b>Next steps:</b>			
<input type="checkbox"/> <b>PATIENT:</b> This is your copy; please retain it for your personal use. You may wish to show it to other health care professionals if you wish to share this information.		<input type="checkbox"/> <b>GENERAL PRACTITIONER:</b> This is your copy; please retain a copy in your patient's notes.	
<input type="checkbox"/> Please make an appointment with your GP to discuss within <input type="text"/> weeks.		<input type="checkbox"/> For information only – no action required.	
<input type="checkbox"/> Take this form to your next scheduled GP appointment.		<input type="checkbox"/> Please review the actions proposed above.	
<input type="checkbox"/> Follow your actions agreed above.			

**Medicines Use Review Action Plan**

**Date of review:** 31/3/07

<b>Patient's name:</b> Mr Arnold Smith	<b>Date of Birth:</b> 18/5/1942	<b>GP's name:</b> Dr N E Body
	<b>NHS Patient Code:</b> MUR Action plan 5	

Medicines Use Issue	Priority	Proposed Action	Action by	Outcome if known with dates
Bendroflumethiazide - diuresis still being experienced	High	Review anti-hypertensive medication consider change to alternative therapy	GP	

<b>Pharmacist name (block capitals)</b> N E Pharmacist	<b>RPSGB registration number</b> 123456	<b>Pharmacist signature</b>	<b>Telephone number of Pharmacist:</b> 01634 400000
<b>Next steps:</b>			
<input type="checkbox"/> <b>PATIENT:</b> This is your copy; please retain it for your personal use. You may wish to show it to other health care professionals if you wish to share this information.		<input type="checkbox"/> <b>GENERAL PRACTITIONER:</b> This is your copy; please retain a copy in your patient's notes.	
<input type="checkbox"/> Please make an appointment with your GP to discuss within _____ weeks.		<input type="checkbox"/> For information only – no action required.	
<input type="checkbox"/> Take this form to your next scheduled GP appointment.		<input type="checkbox"/> Please review the actions proposed above.	
<input type="checkbox"/> Follow your actions agreed above.			

**Medicines Use Review Action Plan**

**Date of review: 31/3/07**

<b>Patient's name:</b> Mrs Judith Smith	<b>Date of Birth:</b> 18/5/1942	<b>GP's name:</b> Dr N E Body	<b>Outcome if known with dates</b>
	<b>NHS Patient Code:</b> MUR Action plan 6		
<b>Medicines Use Issue</b>	<b>Priority</b>	<b>Proposed Action</b>	<b>Action by</b>
No aspirin, patient is diabetic	High	Aspirin 75mg if blood pressure control satisfactory	GP

<b>Pharmacist name (block capitals)</b> N E Pharmacist	<b>RPSGB registration number</b> 123456	<b>Pharmacist signature</b>	<b>Telephone number of Pharmacist:</b> 01634 400000
<b>Next steps:</b>			
<input type="checkbox"/> <b>PATIENT:</b> This is your copy; please retain it for your personal use. You may wish to show it to other health care professionals if you wish to share this information.		<input type="checkbox"/> <b>GENERAL PRACTITIONER:</b> This is your copy; please retain a copy in your patient's notes.	
<input type="checkbox"/> Please make an appointment with your GP to discuss within [ ] weeks.		<input type="checkbox"/> For information only – no action required.	
<input type="checkbox"/> Take this form to your next scheduled GP appointment.		<input type="checkbox"/> Please review the actions proposed above.	
<input type="checkbox"/> Follow your actions agreed above.		<input type="checkbox"/>	

**Medicines Use Review Action Plan**

**Date of review:** 31/3/07

<b>Patient's name:</b> Mrs Henrietta Smith	<b>Date of Birth:</b> 18/5/1942	<b>GP's name:</b> Dr N E Body
	<b>NHS Patient Code:</b> MUR Action plan 7	

Medicines Use Issue	Priority	Proposed Action	Action by	Outcome if known with dates
Patient is taking lansoprazole and omeprazole at the same time	High	review therapy and discontinue whichever therapy is not required	GP	

<b>Pharmacist name (block capitals)</b> N E Pharmacist	<b>RPSGB registration number</b> 123456	<b>Pharmacist signature</b>	<b>Telephone number of Pharmacist:</b> 01634 400000
<b>Next steps:</b>			
<input type="checkbox"/> <b>PATIENT:</b> This is your copy; please retain it for your personal use. You may wish to show it to other health care professionals if you wish to share this information.		<input type="checkbox"/> <b>GENERAL PRACTITIONER:</b> This is your copy; please retain a copy in your patient's notes.	
<input type="checkbox"/> Please make an appointment with your GP to discuss within <input type="text"/> weeks.		<input type="checkbox"/> For information only – no action required.	
<input type="checkbox"/> Take this form to your next scheduled GP appointment.		<input type="checkbox"/> Please review the actions proposed above.	
<input type="checkbox"/> Follow your actions agreed above.			

**Medicines Use Review Action Plan**

**Date of review: 31/3/07**

<b>Patient's name:</b> Mr Alan Smith	<b>Date of Birth:</b> 18/5/1942	<b>GP's name:</b> Dr N E Body	<b>Outcome if known with dates</b>
	<b>NHS Patient Code:</b> MUR Action plan 8		
<b>Medicines Use Issue</b>	<b>Priority</b>	<b>Proposed Action</b>	<b>Action by</b>
Patient is taking digoxin 125mcg and amiodarone 200mg	High	reduce dose of digoxin by half	GP

<b>Pharmacist name (block capitals)</b> N E Pharmacist	<b>RPSGB registration number</b> 123456	<b>Pharmacist signature</b>	<b>Telephone number of Pharmacist:</b> 01634 400000
<b>Next steps:</b>			
<input type="checkbox"/> <b>PATIENT:</b> This is your copy; please retain it for your personal use. You may wish to show it to other health care professionals if you wish to share this information.		<input type="checkbox"/> <b>GENERAL PRACTITIONER:</b> This is your copy; please retain a copy in your patient's notes.	
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<input type="checkbox"/> Take this form to your next scheduled GP appointment.		<input type="checkbox"/> Please review the actions proposed above.	
<input type="checkbox"/> Follow your actions agreed above.		(This area is currently blank)	

**Medicines Use Review Action Plan**

**Date of review:** 31/3/07

<b>Patient's name:</b> Mr Derek Smith	<b>Date of Birth:</b> 18/5/1942	<b>GP's name:</b> Dr N E Body
	<b>NHS Patient Code:</b> MUR Action plan 9	

Medicines Use Issue	Priority	Proposed Action	Action by	Outcome if known with dates
Patient is on salbutamol and taking atenolol	High	Review anti-hypertensive therapy	GP	

<b>Pharmacist name (block capitals)</b> N E Pharmacist	<b>RPSGB registration number</b> 123456	<b>Pharmacist signature</b>	<b>Telephone number of Pharmacist:</b> 01634 400000
<b>Next steps:</b>			
<input type="checkbox"/> <b>PATIENT:</b> This is your copy; please retain it for your personal use. You may wish to show it to other health care professionals if you wish to share this information.		<input type="checkbox"/> <b>GENERAL PRACTITIONER:</b> This is your copy; please retain a copy in your patient's notes.	
<input type="checkbox"/> Please make an appointment with your GP to discuss within <input type="text"/> weeks.		<input type="checkbox"/> For information only – no action required.	
<input type="checkbox"/> Take this form to your next scheduled GP appointment.		<input type="checkbox"/> Please review the actions proposed above.	
<input type="checkbox"/> Follow your actions agreed above.			



**Medicines Use Review Action Plan**

**Date of review:** 31/3/07

<b>Patient's name:</b> Mrs Freda Smith		<b>Date of Birth:</b> 18/5/1942	<b>GP's name:</b> Dr N E Body
		<b>NHS Patient Code:</b> MUR Action plan 10	
<b>Medicines Use Issue</b>	<b>Priority</b>	<b>Proposed Action</b>	<b>Outcome if known with dates</b>
patient having trouble manipulating inhaler	High	give haleraid	GP
<b>Pharmacist name (block capitals)</b> N E Pharmacist	<b>RPSGB registration number</b> 123456	<b>Pharmacist signature</b>	<b>Telephone number of Pharmacist:</b> 01634 400000
<b>Next steps:</b>			
<input type="checkbox"/> <b>PATIENT:</b> This is your copy; please retain it for your personal use. You may wish to show it to other health care professionals if you wish to share this information.		<input type="checkbox"/> <b>GENERAL PRACTITIONER:</b> This is your copy; please retain a copy in your patient's notes.	
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<input type="checkbox"/> Follow your actions agreed above.			

**Medicines Use Review Action Plan**

**Date of review:** 31/3/07

<b>Patient's name:</b> Mrs Janice Smith	<b>Date of Birth:</b> 18/5/1942	<b>GP's name:</b> Dr N E Body
	<b>NHS Patient Code:</b> MUR Action plan 11	

Medicines Use Issue	Priority	Proposed Action	Action by	Outcome if known with dates
Patients blood glucose insufficiently controlled	High	review anti-hyperglycaemic medication	GP	

<b>Pharmacist name (block capitals)</b> N E Pharmacist	<b>RPSGB registration number</b> 123456	<b>Pharmacist signature</b>	<b>Telephone number of Pharmacist:</b> 01634 400000
<b>Next steps:</b>			
<input type="checkbox"/> <b>PATIENT:</b> This is your copy; please retain it for your personal use. You may wish to show it to other health care professionals if you wish to share this information.		<input type="checkbox"/> <b>GENERAL PRACTITIONER:</b> This is your copy; please retain a copy in your patient's notes.	
<input type="checkbox"/> Please make an appointment with your GP to discuss within [ ] weeks.		<input type="checkbox"/> For information only – no action required.	
<input type="checkbox"/> Take this form to your next scheduled GP appointment.		<input type="checkbox"/> Please review the actions proposed above.	
<input type="checkbox"/> Follow your actions agreed above.			

**Table of categories, definitions and criteria (Version 3)**

For each case we would like you to take each of the Drug Therapy Problems and look at them and classify them according to Safety, Appropriateness and Effectiveness. (See flow diagram).

**Please do not code the actions, only the problems are required.**

**1. Starting with safety category, look at the problem and consider if it fits any of the definitions listed below for safety?**

Classifications for	Definition	Criteria
<b>SAFETY</b> Adverse Drug Reaction (ADR) – <b>S1</b>	Definition from the WHO, “Any noxious, unintended and undesired effect of a drug which occurs at doses used in humans for prophylaxis, diagnosis or therapy.” (Excluding therapeutic failures, intentional and accidental poisoning).	Check the drug side effect profile from BNF and Summary of product characteristics (SPC).
Clinically significant drug Interaction. – <b>S2</b>	The significant interaction of a drug that may affect the activity, metabolism or toxicity of another drug.	Check Appendix 1 of the BNF (available 6 monthly or on the web) Interactions considered to be clinically significant are indicated with a black dot
Contraindication – <b>S3</b>	A condition which makes a particular treatment or procedure inadvisable.	Check BNF for contraindications against each drug (drug monograph, SPC).

**Table of categories, definitions and criteria continued (Version 3)**

**2. If the problem does not fit into either of these three codes above then move onto appropriateness. Please note if a code for the problem is found at this stage then appropriateness and Effectiveness are not relevant as the therapy is unsafe.**

<b>Classifications for APPROPRIATENESS</b>	<b>Definition</b>	<b>Criteria</b>
No Indication for therapy - <b>A1</b>	Patient is receiving therapy for which there is no documented diagnosis.	Check all therapy against documented medical conditions, diagnosis and doses for each condition
Inappropriate choice of therapy - <b>A2</b>	The therapy being used to treat the patient does not conform to guidelines for the condition being treated taking into account co-morbidity. The patient has a medical condition for which the wrong drug is being taken.	Check guidelines/frameworks for the patient's condition and co-morbidities.
Duplication of therapy - <b>A3</b>	Patient is receiving duplication of a treatment for a particular indication	Check all therapy for duplications of treatments e.g. 2 x PPI, 2X NSAID
Inappropriate dose/dosing schedule – <b>A4</b>	Where the dose/dosing schedule is unsuitable for the patient	Check dosages of therapy are appropriate according to indication
Additional drug therapy required– <b>A5</b>	Patient is not receiving therapy for a documented diagnosis or prophylaxis linked to co-morbidity. The patient has a medical condition that requires drug therapy (a drug indication) but the patient is not receiving a drug for that indication.	Check all patients medical conditions and diagnosis are being treated according to BNF, national guidelines and current national frameworks.

**If the problem does not fit into either of the three codes above in the appropriateness category then move onto effectiveness category. Please note if a classification for the problem is found at this stage then Effectiveness is not relevant as the therapy is not appropriate.**

Table of categories, definitions and criteria continued (Version 3)

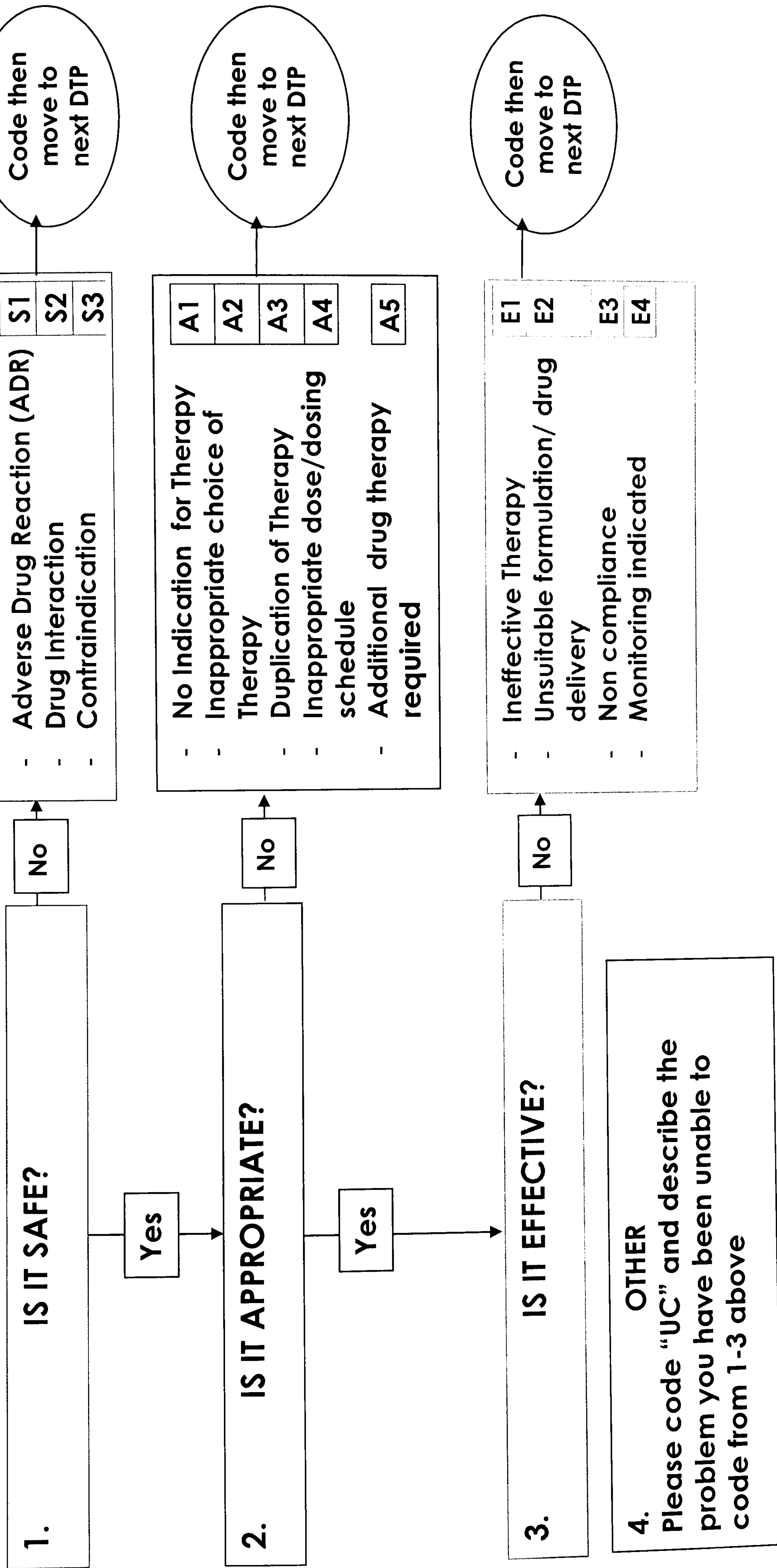
**3. If the problem cannot be classified under the appropriateness or safety category then move onto effectiveness**

<b>Classifications for EFFECTIVENESS</b>	<b>Definition</b>	<b>Criteria</b>
<b>Ineffective Therapy E1</b>	The therapy is not effective the dose being taken.	Check objective monitoring results, where possible and patients feedback for subjective end points such as pain.
<b>Unsuitable formulation/ Drug delivery - E2</b>	Where the formulation or delivery of therapy is unsuitable for the patient.	Check with patient and assess delivery and formulation are appropriate.
<b>Non-compliance E3</b>	When it is suspected that the patient is not adhering to their therapy.	Confirmed by interview with patient and PMR record
<b>Monitoring indicated - E4</b>	When a particular monitoring test has not been undertaken according to current guidance and is required now	Check patient is being monitored as per drugs or medical conditions with reasonable margins.

**Please note: As part of the hierarchical system only one category ie 1.Safety (S1, S2 or S3) if no problem then move to 2. Appropriateness (A1, A2, A3, A4, A5), if no problem move to 3. Effectiveness (E1, E2, E3, E4) code can be used per Drug Therapy Problem. Once a code is found there is no need to move to the next category**

**Flow chart: process diagram to code DTPs (Version 3)**

**Group drugs by therapeutic area and consider is therapy safe, appropriate and effective for each individual patient**



**Validation of Drug Therapy Problem (DTP) Classification system**

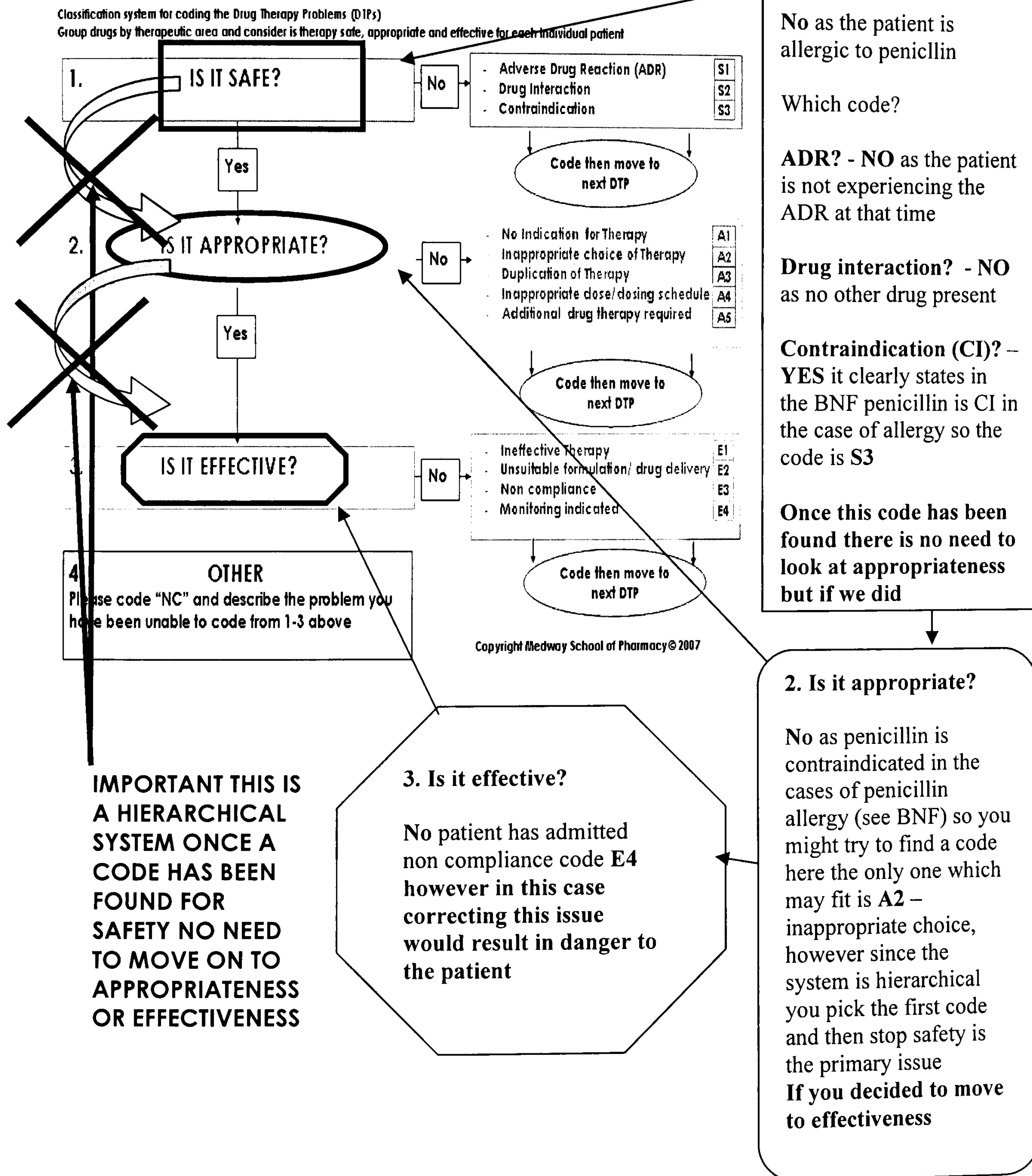
**Worked Example**

Mr AC is 65; he comes to your community pharmacy and asks to speak to you. He goes on to explain that he picked up his antibiotics for his tonsillitis

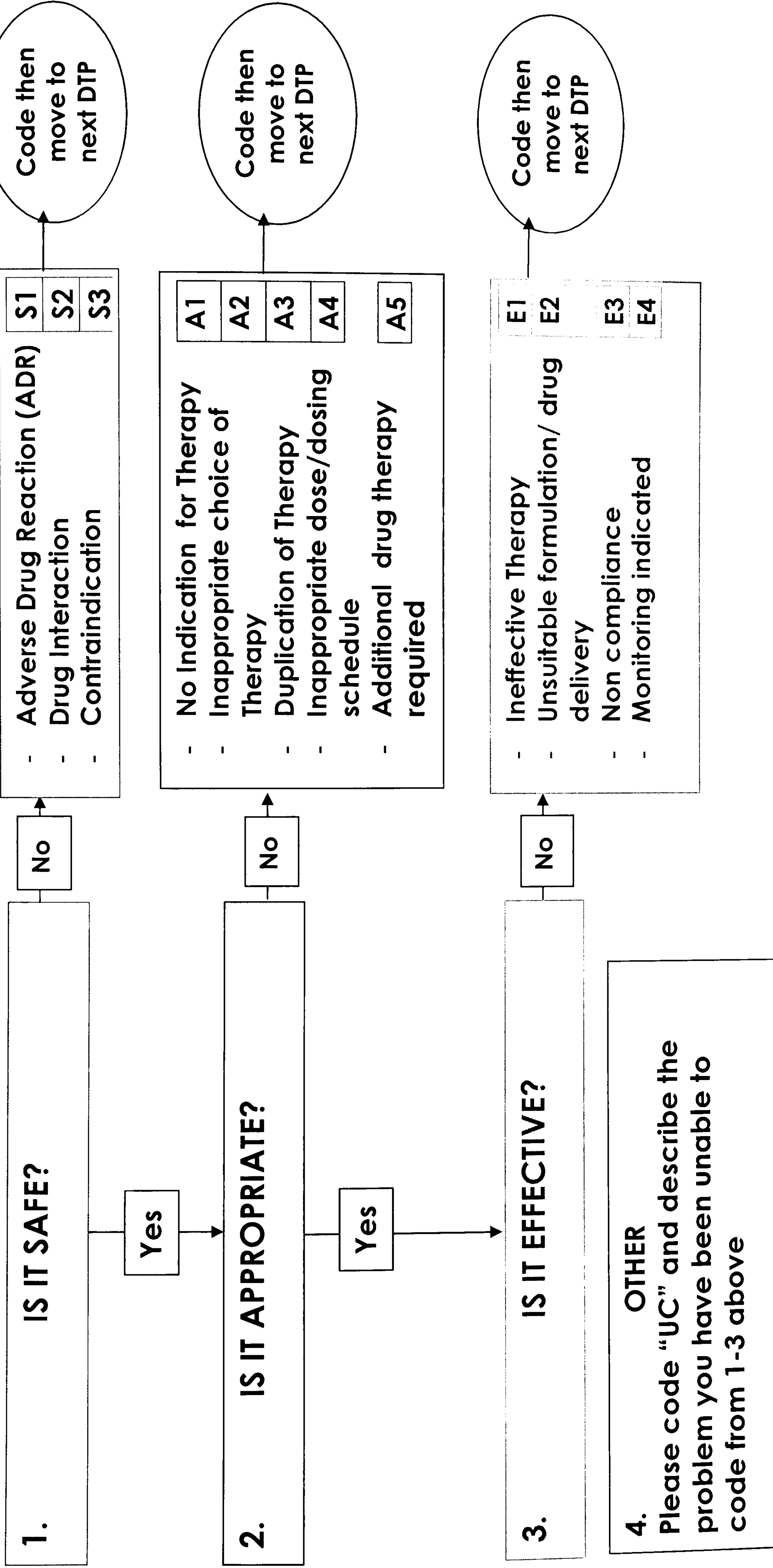
The antibiotics are penicillin V 250mg tabs – 2 tablets to be taken four times a day.

He goes on to explain his tonsillitis had not gone away because he is not taking them. He read the leaflet inside the box and it says not to take them if you have a penicillin allergy. He seemed to remember when he was younger he broke out in a rash when he took penicillin.

If we take the above case and look at the flow chart



Group drugs by therapeutic area and consider is therapy safe, appropriate and effective for each individual patient





**You have 4 number of cases. We would like you to code the problems you find according to the classification system below.**

For each case we would like you to take each of the Drug Therapy Problems and look at them and classify them according to Safety, Appropriateness and Effectiveness. (See flow diagram).

**Please do not code the actions, only the problems are required.**

**1. Starting with safety category, look at the problem and consider if it fits any of the definitions listed below for safety?**

<b>Classifications for</b>	<b>Definition</b>	<b>Criteria</b>
<b>SAFETY</b> Adverse Drug Reaction (ADR) – <b>S1</b>	Definition from the WHO, “Any noxious, unintended and undesired effect of a drug which occurs at doses used in humans for prophylaxis, diagnosis or therapy.” (Excluding therapeutic failures, intentional and accidental poisoning).	Check the drug side effect profile from BNF and Summary of product characteristics (SPC).
Clinically significant drug Interaction. <b>S2</b>	The significant interaction of a drug that may affect the activity, metabolism or toxicity of another drug.	Check Appendix 1 of the BNF (available 6 monthly or on the web) Interactions considered to be clinically significant are indicated with a black dot
Contraindication <b>S3</b>	A condition which makes a particular treatment or procedure inadvisable.	Check BNF for contraindications against each drug (drug monograph, SPC).

**2. If the problem does not fit into either of these three codes above then move onto appropriateness. Please note if a code for the problem is found at this stage then appropriateness and Effectiveness are not relevant as the therapy is unsafe.**

<b>Classifications for APPROPRIATENESS</b>	<b>Definition</b>	<b>Criteria</b>
No Indication for therapy - <b>A1</b>	Patient is receiving therapy for which there is no documented diagnosis.	Check all therapy against documented medical conditions, diagnosis and doses for each condition
Inappropriate choice of therapy - <b>A2</b>	The therapy being used to treat the patient does not conform to guidelines for the condition being treated taking into account co-morbidity. The patient has a medical condition for which the wrong drug is being taken.	Check guidelines/frameworks for the patient's condition and co-morbidities.
Duplication of therapy - <b>A3</b>	Patient is receiving duplication of a treatment for a particular indication	Check all therapy for duplications of treatments e.g. 2 x PPI, 2X NSAID
Inappropriate dose/ dosing schedule – <b>A4</b>	Where the dose/dosing schedule is unsuitable for the patient	Check dosages of therapy are appropriate according to indication
Additional drug therapy required– <b>A5</b>	Patient is not receiving therapy for a documented diagnosis or prophylaxis linked to co-morbidity. The patient has a medical condition that requires drug therapy (a drug indication) but the patient is not receiving a drug for that indication.	Check all patients medical conditions and diagnosis are being treated according to BNF, national guidelines and current national frameworks.

**If the problem does not fit into either of the three codes above in the appropriateness category then move onto effectiveness category. Please note if a classification for the problem is found at this stage then Effectiveness is not relevant as the therapy is not appropriate.**

**3. If the problem cannot be classified under the appropriateness or safety category then move onto effectiveness**

<b>Classifications for EFFECTIVENESS</b>	<b>Definition</b>	<b>Criteria</b>
<b>Ineffective Therapy E1</b>	The therapy is not effective the dose being taken.	Check objective monitoring results, where possible and patients feedback for subjective end points such as pain.
<b>Unsuitable formulation/ Drug delivery - E2</b>	Where the formulation or delivery of therapy is unsuitable for the patient.	Check with patient and assess delivery and formulation are appropriate.
<b>Non-compliance E3</b>	When it is suspected that the patient is not adhering to their therapy.	Confirmed by interview with patient and PMR record
<b>Monitoring indicated - E4</b>	When a particular monitoring test has not been undertaken according to current guidance and is required now	Check patient is being monitored as per drugs or medical conditions with reasonable margins.

**Please note: As part of the hierarchical system only one category ie 1.Safety (A1, A2 or A3) if no problem then move to 2. Safety (S1, S2, S3), if no problem move to 3. Effectiveness (E1, E2, E3, E4 or E5) code can be used per Drug Therapy Problem.**

**Once a code is found there is no need to move to the next category. PLEASE NOTE IF YOU CANNOT CLASSIFY A PROBLEM INTO ANY CATEGORY PLEASE USE CODE "UC" = UNCLASSIFIED**

**Case 1**

Mrs AC is a 65 year old non smoker and attends your pharmacy for an MUR

**Past medical history**

Myocardial Infarction (10 years previously)

**Current problems**

Hypertension

Angina

Type 2 Diabetes

**Current medications**

Atenolol 100mg tabs – One daily

Simvastatin 40mg tabs – One at night

Amlodipine 5mg tabs – One daily

Ranitidine 150mg tabs – One twice a day

Metformin 500mg tabs – One twice a day

GTN spray – when required

**Recent monitoring (last 6 months)**

Total serum cholesterol – 8.4mmol/L

BP – 125/75

Hb<sub>A1c</sub> - 6%

Mrs AC regularly collects her repeat prescription from your pharmacy and has been on the above drugs for 10 years without any dosage changes.

Identify and code **three** drug therapy problems using the flow diagram provided. Please insert the codes in the boxes below. If you cannot find a code insert UC for unclassified and describe in the free text box

1.	2.	3.
Other (unable to code from list provided) please describe problem identified		

**Case 2**

Mr GF is a 76 year old, non smoker and attends your pharmacy for an MUR

**Past medical history**

Duodenal ulcer (10 years previously) – now resolved

**Current problems**

Atrial Fibrillation

Osteoarthritis

**Current medications**

Digoxin 125mcg tablets – one tab daily

Warfarin – 1 and 3mg tablets – adjusted according to INR

Indomethacin 50mg caps – one cap three times a day

Paracetamol 500mg tabs – two tabs four times a day

**Recent monitoring (last 6 months)**

INR – 2.7

OA –no acute symptoms reported

Mr GF regularly collects his repeat prescription from your pharmacy. There have been no changes to his medication for the last ten years. Until recently when he was started on Amiodarone 200mg tablets – one three times a day for one week, then one twice a day for one week then one daily thereafter. On this occasion he complains that the paracetamol tablets are hard and he is having problems crushing them

Identify and code **three** drug therapy problems using the flow diagram provided. Please insert the codes in the boxes below If you cannot find a code insert UC for unclassified and describe in the free text box

1.	2.	3.
Other (unable to code from list provided) please describe problem identified		

**Case 3**

Mrs HR is a 60 year old, non smoker and attends your pharmacy for an MUR

**Past medical history**

See current problems

**Current problems**

Hypertension

Asthma

Osteoporosis

**Current medications**

Atenolol 50mg tablets – One daily

Salbutamol inhaler – two Puffs when required

Beclometasone 100mg inhaler – two Puffs twice a day

Calcium D3 Forte tabs – one twice a day

Risedronate 35mg tabs – one weekly

Omeprazole 20mg cap – one daily

Terbutaline inhaler – two puffs when required

**Recent monitoring (last 6 months)**

PEFR 280mls/L (400mls/L normal for HR)

Blood pressure 122/65

Mrs HR regularly collects her repeat prescription from your pharmacy. You notice she has requested everything apart from her Risedronate on the last 3 occasions.

Identify and code **three** drug therapy problems using the flow diagram provided. Please insert the codes in the boxes below. If you cannot find a code insert UC for unclassified and describe in the free text box

1.	2.	3.
Other (unable to code from list provided) please describe problem identified		

**Case 4**

Mrs JB is a 74 year old, non smoker and attends your pharmacy for an MUR

**Past medical history**

See current problems

**Current problems**

Asthma  
 Hypertension  
 Type 2 Diabetes  
 Hypercholesterolemia

**Current medications**

Bendroflumethiazide 10mg tabs – one in the morning  
 Ramipril 5mg caps – one daily  
 Salbutamol inhaler – two Puffs when required  
 Simvastatin 40mg tabs – one at night  
 Beclometasone 100mcg inhaler – two Puffs twice a day  
 Metformin 500mg tabs – one three times a day  
 Aspirin 75mg tabs – one daily

**Recent monitoring (last 6 months)**

PEFR 370 mls/L (400mls/L normal for JB)  
 BP – 120/60  
 Hb<sub>A1c</sub> - 7%

Mrs JB regularly collects her repeat prescription from your pharmacy. She complains of a dry cough that she has throughout the day.

Identify and code **three** drug therapy problems using the flow diagram provided. Please insert the codes in the boxes below If you cannot find a code insert UC for unclassified and describe in the free text box

1.	2.	3.
Other (unable to code from list provided) please describe problem identified		

**DTPs to be identified for each case****Case 1**

- Patient taking Simvastatin 40mg tabs one at night, monitoring of total serum cholesterol indicates a level of 8.4 mmol/L, on going in a step wise fashion through the flow chart the therapy can be seen to be ineffective. So a code of E1 – ineffective therapy is assigned
- Patient is taking Ranitidine 150mg tabs, there is no indication in the current problems for this medication, so the code of A1 – No indication for therapy is assigned
- Patient's current problems are Hypertension, angina and type 2 diabetes. On looking through current medication, Aspirin is missing for primary prevention, so the code assigned is A5 – Additional drug therapy required.

**Case 2**

- The patient is taking Digoxin and has recently been started on Amiodarone, the BNF advises that this is a clinically significant drug interaction and that the dose of Digoxin should be reduced by half, the code assigned is S2 – Drug interaction.
- The patient is taking Indomethacin for Osteoarthritis, recent monitoring suggests that the patient has no acute symptoms at present. The patient did have a duodenal ulcer 10 years previously but it had resolved. The code assigned to this case was A2 – Inappropriate choice of therapy.
- The preamble states the patient is having difficulty crushing his Paracetamol tablets, paracetamol is not supposed to be crushed so the code assigned would be E2 – Unsuitable formulation/drug delivery.



**Case 3**

- This patient has a current active problem of Asthma and has been given Atenolol 50mg tablets, it can also be seen from the recent monitoring the PEFR is 280mls/L (400mls/L normally) so the code assigned would be S3 – Contraindication
- This patient is taking Salbutamol and Terbutaline at the same time, therefore the code assigned would be A3 – Duplication of therapy
- The preamble states that the patient has requested every medication apart from her Risedronate on the last three occasions, therefore the code assigned to this problem would be E3 – non-compliance

**Case 4**

- This patient is being treated with Bendroflumethiazide 10mg tablets for hypertension, therefore the code assigned would be A4 – inappropriate dose/dosing schedule
- This patient is also taking Simvastatin 40mg tabs, however monitoring has not been conducted for the last six months, there is no serum cholesterol levels recorded, therefore the code would be E4 – monitoring indicated
- The preamble states that the patient has a dry cough throughout the day and is taking Ramipril 5mg capsules, therefore the code is S1 – Adverse drug reaction.



Medway School of Pharmacy



## Patient information sheet

The following answers some questions we think you might have about the study. If you have any more questions, please feel free to ask the research Pharmacist at any time.

### What is the study about?

The study will look at how pharmacists can help people get better use of their medicines.

### *What will the pharmacist researcher be doing?*

The pharmacist researcher will carry out another Medicines Use review(MUR) approximately six month after your first review

### Why should I take part?

The information gathered from the study may help to improve the future care of patients. You may or may not benefit personally from participation in the study. You will, however have the opportunity to find out more about your medicines.

### Will this study replace the usual care provided by my doctor?

No. Your usual care will be maintained throughout the study.

**Where will the study take place?**

The interview with the pharmacist researcher will take place at either your local doctor's surgery or in your local pharmacy. A venue that suits you and the pharmacist researcher will be arranged.

**When will the study take place?**

This study will start in August 2005 and will continue for approximately 12 months

**What will happen if I agree to participate?**

You will be interviewed once approximately six months after your MUR with your local pharmacist. Your doctor will only be informed of your participation with your consent.

**What will happen at the interview?**

You will be asked to bring along your current medicines (both prescribed and purchased) and the researcher will discuss them with you. The interview will last approximately 30 minutes and no physical examination will be involved.

**What will happen if I decide not to take part?**

You will continue to receive your usual care from your doctor and pharmacist.

***Is it possible to withdraw from the study?***

You are free to withdraw from the study at any time without giving reason and future treatment will not be affected.

### Who is paying for the study?

The pharmacist researcher receives no payment for carrying out the reviews. Your doctor will not be paid extra for their involvement, and there is no commercial sponsorship of any description for the study

### What will happen at the end of the study?

You will continue to receive usual care from your own doctor and pharmacist. Any changes that need to be made will be done with your permission.



Medway School of Pharmacy



## Patient information sheet

The following answers some questions we think you might have about the study. If you have any more questions, please feel free to ask the research Pharmacist at any time.

### What is the study about?

The study will look at how pharmacists can help people get better use of their medicines.

### *What will the pharmacist researcher be doing?*

The pharmacist researcher will access your medical notes to make a comparison with other patients in the study.

### Why should I take part?

The information gathered from the study may help to improve the future care of patients. You may or may not benefit personally from participation in the study. You will, however have the opportunity to find out more about your medicines.

### Will this study replace the usual care provided by my doctor?

No. Your usual care will be maintained throughout the study.

**When will the study take place?**

This study will started in August 2005 and will continue for approximately 24 months

**What will happen if I agree to participate?**

The researcher will go to your surgery and look at your medical notes. Your doctor will only be informed of your participation with your consent.

**What will happen if I decide not to take part?**

You will continue to receive your usual care from your doctor and pharmacist.

***Is it possible to withdraw from the study?***

You are free to withdraw from the study at any time without giving reason and future treatment will not be affected.

**Who is paying for the study?**

The pharmacist researcher receives no payment for carrying out the reviews. Your doctor will not be paid extra for their involvement, and there is no commercial sponsorship of any description for the study

**What will happen at the end of the study?**

You will continue to receive usual care from your own doctor and pharmacist. Any changes that need to be made will be done with your permission.



## Community Pharmacy Medicines Use Review & Prescription Intervention Service

### Patient Details

<b>Date of review:</b>	<b>Title:</b>	<b>Name:</b>	<b>NHS Patient Code:</b>
			<b>Pharmacy (PMR) ID:</b>
<b>Address:</b>			<b>DOB:</b>
			<b>Tel:</b>
<b>GP:</b>		<b>GP address:</b>	

### Recording of patient's informed consent (must be completed before the review can proceed)

Patient has received information on and consented to the review process.

Patient has agreed that information may be shared with their GP

Patient has agreed that information may be shared with others such as carers.

Specify others by name:

#### Reason for review:

Annual Review (MUR)

Prescription Intervention

Pharmacist identified  
Referral from

#### What would the patient like to get out of the review? (including the need for information)

#### Basic health data

Significant previous ADRs:	Known allergies/sensitivities:
Medical history as described by patient and from information recorded in PMR	Monitoring as described by patient and from information recorded in PMR

#### Name of Pharmacist conducting the review:

#### Pharmacy name & address:

#### Location of review:

Pharmacy

Other location

(state location used)

Telephone

(record reason why face to face was not possible)

#### Outcome of Review:

Copy of care plan given to patient

Referral made to GP

Pharmacist actions completed and recorded in care plan

Patient Name:	DOB:	Prescribed medicine and dosage regimen	Dosage regimen as patient takes it (including OTC & complementary therapies)	Patient's knowledge of the medicine's use	Compliance			
					always	frequent	seldom	Never
1.					<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.					<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.					<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
4.					<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.					<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.					<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.					<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.					<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**Explanatory notes:**

**Patient's knowledge of the medicine's use** – record what the patient thinks the medicine is for and highlight where response would indicate need for further information.

**Compliance** – Use open, non-judgemental questions to establish how the medicine is being taken, and tick the box which best indicates the patient's level of compliance, i.e. always takes the medicines as prescribed through to never takes the medicine as prescribed. Leave blank for 'PRN' medicines.



DOB:

Patient Name:

Is the formulation appropriate?	Is the medicine working?			Are side effects present?		General Comments
	yes	no	unknown	yes	no	
1. <input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
2. <input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
3. <input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
4. <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
5. <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
6. <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
7. <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
8. <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

**Explanatory notes:**

**Is the formulation appropriate?** – use to identify problems with formulation, e.g. swallowing difficulties suggest a liquid product may be more suitable, include poor technique with inhaler devices here.  
**Is the medicine working?** – if you have objective evidence such as BP or cholesterol level then you may indicate whether the medicine is effective or not. In many cases this may be a subjective response based on the patient's view of their treatment. In other cases it may be unknown such as antiplatelet therapy.  
**Are side effects present?** – indicate patients reported response supplemented by a professional decision as to which drug a particular side effect may be attributable to.  
**General Comments** – add any additional information here for example if you have ticked a positive response for side effects present it would be helpful to add detail (such as cough and skin rash) which may help you when you develop your action plan and when completing a follow up review with the same patient at a later date.

**Medicines Use Review Action Plan**

**Date of review:**

<b>Patient's name:</b>	<b>Date of Birth:</b>
<b>NHS Patient Code:</b>	<b>GP's name:</b>

Medicines Use Issue	Priority	Proposed Action	Action by	Outcome if known with dates

<b>Pharmacist name (block capitals)</b>	<b>RPSGB registration number</b>	<b>Pharmacist signature</b>	<b>Telephone number of Pharmacist:</b>
<b>Next steps:</b>			
<input type="checkbox"/> <b>PATIENT:</b> This is your copy; please retain it for your personal use. You may wish to show it to other health care professionals if you wish to share this information.	<input type="checkbox"/> <b>GENERAL PRACTITIONER:</b> This is your copy; please retain a copy in your patient's notes.		
<input type="checkbox"/> Please make an appointment with your GP to discuss within <span style="border: 1px solid black; display: inline-block; width: 40px; height: 15px; vertical-align: middle;"></span> weeks.	<input type="checkbox"/> For information only – no action required.		
<input type="checkbox"/> Take this form to your next scheduled GP appointment.	<input type="checkbox"/> Please review the actions proposed above.		
<input type="checkbox"/> Follow your actions agreed above.			

## **MUR service providers – Topic Guide**

### **Group Discussion Questions:**

*Please discuss the following issues as a group with each member participating in the discussion. You may not reach a consensus on each issue, but all ideas are valuable.*

### **Perceptions of the new Pharmacy contract/ advanced service:**

- A. What are your views (both positive and negative) on the new Pharmacy contract/Advanced service? Medicine use review?
- B. Do you provide both MUR and Prescription based Interventions in your pharmacy?
- C. In your opinion, what is the difference between MUR and PBI?
- D. How soon did you engage in the provision of the service?
- E. When did you start providing the service? Or doing MURs

### **Uptake of Advanced service: Probing Questions**

- A. What influenced you as a pharmacist to provide the service?  
**OR** What motivated you or persuaded you to provide the service?
- B. What are the challenges you faced with providing the service?
- C. How have you overcome the challenges?
- D. How much time do you spend on MUR?
- E. Has doing MUR stopped you providing other services?
- F. Which aspects of the contract in your own view have gone well? Explain your answer.

### **Future service delivery**

- A. If you were in the position of the PCT prescribing advisor, what recommendations will you make to improve future service delivery?
- B. What changes would you make yourself?

Has your view of MUR service changed during this discussion? If so, How?

Have we missed anything?

*That's all the questions I have. Thank you for participating in this discussion. Your comments will be invaluable in making recommendations for future service delivery.*

## **Non providers of MUR services – Topic guide**

### **Group Discussion Questions:**

*Please discuss the following issues as a group with each member participating in the discussion. You may not reach a consensus on each issue, but all ideas are valuable.*

### **Perception and understanding of the new Pharmacy contract/ advanced service**

- F. What are your views (both positive and negative) on the new Pharmacy contract/Advanced service? Medicine use review?
- G. In your opinion, what is the difference between MUR and PBI? What does it involve?

### **Opportunities and barriers in the provision of the advanced service.**

- G. What do you perceive to be a barrier in providing this service?

#### **Listen for:**

- Time
- Accreditation process
- Lack of support from GPs
- Lack of consultation area
- Lack of motivation/ confidence
- Other

#### **Probe if necessary**

- H. How can you overcome these barriers?
- I. Do you get any support from your PCT towards the provision of the service? If yes, what kind?
- J. What would get you to participate in this service?
- K. Which aspects of the contract in your own view have gone well and less well? Explain your answer.

### **Future service delivery**

- C. If you were in the position of the PCT prescribing advisor, what recommendations will you make to improve future service delivery?

**OR**

If you were in charge, what kind of changes would you make?

### **ACKNOWLEDGEMENTS AND CONCLUSIONS**

(5 minutes)

Has your view of MUR service changed during this discussion? If so, How?

Think about all that we have talked about today, what do you think it's most important?

Our discussion tonight was to explore barriers to participation in MUR service. Have we missed anything? Is there anything that we should have talked about but didn't?

*That's all the questions I have. Thank you for participating in this discussion. Your comments will be invaluable in making recommendations for future service delivery.*

Appendix 13 - Semi-structured questionnaire administered to active patients  
**To evaluate the impact of the medicines use review (MUR) service recently introduced as part of the community pharmacy NHS contract in April 2005**

REC reference number: 05/Q1801/95

**FORM A**

**Introduction**

**In the last year, your regular local pharmacist had a chat with you about all your medications, under a new service provided by the NHS called Medicines Use Review (MUR). We would like to ask you a few questions on three aspects of the service.**

**A. Interview**

1. Did you attend the pharmacy or was the MUR conducted over the telephone?

**Pharmacy**                       **Telephone**                       **Can't Remember**

2. Where would you have liked the MUR to have been conducted?

**Pharmacy**                       **Telephone**                       **Home**                       **GP Surgery**

**Other (please detail)**.....  
 .....  
 .....

3. If you attended the pharmacy, where within the pharmacy did the MUR take place?

**Closed consultation room**                       **Open consultation room**                       **Private screened area of pharmacy**                       **Open pharmacy area**

4. During the MUR did you feel the discussion was private for you?

**Yes**                       **No**

**If no please Detail**.....  
 .....  
 .....

5. What would be your ideal location for the review and why?

**Closed consultation room**                       **Open consultation room**                       **Private screened area of pharmacy**                       **Other**

**If other please detail** .....  
 .....  
 .....

6. Did you feel the time taken for the MUR was

**Too long**                       **Too short**                       **Just Right**

**Other (please detail)**.....  
 .....

7. What did you expect from the MUR? (Please detail)

.....  
.....  
.....

**B. Actions**

8. During the MUR were any problems raised about your medication?(by you or your pharmacist)

**Yes**  **No**

**Details**.....  
.....  
.....  
.....

9. Had you discussed these problems with the pharmacist before the MUR?

**Yes**  **No**  **Can't remember**

10. Have you discussed any problems with your medicines with the pharmacist since the MUR?

**Yes**  **No**  **Can't remember**

11. During the MUR were you

**Given Information and advice by your pharmacist**  **Referred to your GP or other**   
**Other (please detail)**

.....  
.....

12. At the end of the MUR did you receive?

**Information and advice by your pharmacist**  **A change in medication**  **Stoppage of medication**  **Monitoring by your pharmacist**   
**Other (please detail)**

.....  
.....

13. What did you do with the action plan, you were given?

**Kept It**  **Threw it away**  **Discussed it at your next GP visit**

**Other(please detail)**  
.....  
.....

14. Did you find the documentation easy to read and understand?

Yes  No

If no please  
Detail.....  
.....  
.....

**C. Satisfaction**

15. Were you satisfied with the MUR process?

Yes  No  Neither

16. Were your expectations of the MUR process met? If not please detail

Yes  No

If no please Detail.....  
.....  
.....

17. Could any changes be made to this service to improve it for you in the future?

Yes  No

If no please Detail.....  
.....  
.....

18. Would you like the pharmacist to carry out MUR on a regular basis?

Yes  No  Unsure

19. How often would you like this review to be conducted?

3 months  6 Months  1 year  2 years

Other (please detail)  
.....  
.....  
.....

All answers and comments will be anonymised, so feel free to share your views in the knowledge that they will not be attributed to you personally.  
You will not be identifiable from the report that is written. (Summary of which will be sent to you direct

**THANK YOU FOR YOUR TIME**

**To evaluate the impact of the medicines use review (MUR) service recently introduced as part of the community pharmacy NHS contract in April 2005**

**REC reference number: 05/Q1801/95**

**FORM B**

I do not wish to take part in this last step of the study.

Signed.....

Date.....

BLOCK CAPITALS .....

All participants will be sent a copy of summary results. Thank you for your time





Medway School of Pharmacy

University of  
**Kent**

## **A qualitative study of Medicines Use Review (MUR): users views**

### **Patient (subject) Information and Consent**

#### **Patient information sheet**

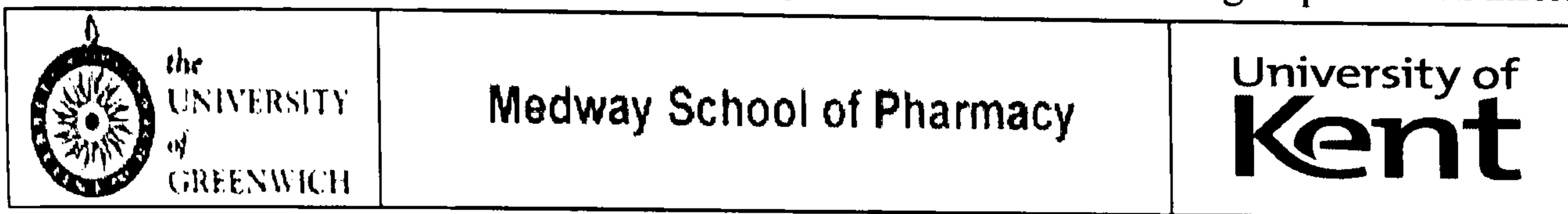
The following answers some questions we think you might have about the study. If you have any more questions, please feel free to ask the research Pharmacist at any time.

#### **What is the study about?**

The study will look at how you (the patient) feel about the Medicines Use Review (MUR) service.

#### **Why should I take part?**

The information gathered from the study may help to improve the future care of patients. You may or may not benefit personally from participation in the study. You will have the opportunity to share your views on the service.



**What will happen if I agree to participate?**

You will come to the university to take part in a group discussion with five other people who have also had a MUR, to explore all of your views and experiences of the service.

**Where will the study take place?**

The discussion with the researcher will take place at the university (Medway School of Pharmacy). This will take place over one afternoon session, transport and lunch will be provided.

**What will happen at the discussion group?**

The researcher will discuss various topics regarding the MUR service and ask about your view.

***What will the researcher be doing?***

The researcher will listen to and record your and five other people's views (as part of a group) on the MUR service.



Medway School of Pharmacy

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**Kent**

***What will happen to the information recorded?***

The discussion will be recorded on a digital recorder and key information will be extracted by the researcher.

Direct quotes will be used as part of an undergraduate student research project. These quotes will be completely anonymous and you will not be identified in any manner.

The information will be stored on one computer with secure password in a double locked room. It will be kept for 5 years and then destroyed.

***What will happen if I decide not to take part?***

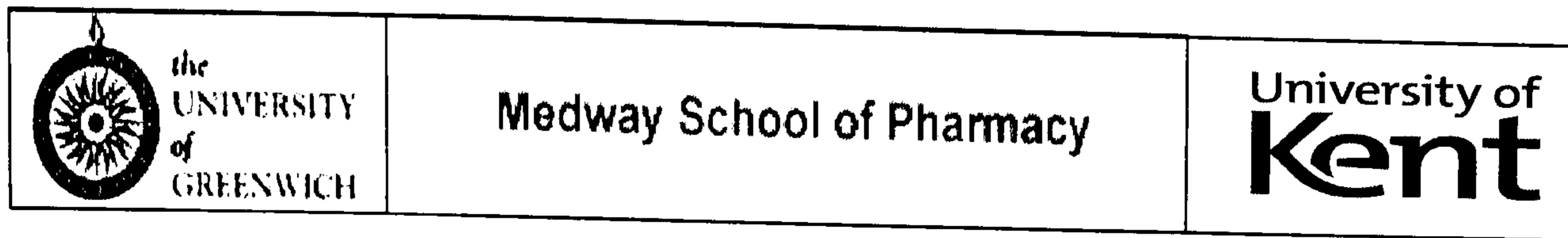
You will continue to receive your usual care from your doctor and pharmacist and we will not contact you again.

***Is it possible to withdraw from the study?***

You are free to withdraw from the study at any time without giving reason and future treatment will not be affected.

***Who is paying for the study?***

This study is part of an undergraduate student research project. The pharmacist researcher receives no payment for carrying out the reviews. Your doctor will not be paid extra for their involvement, and there is no commercial sponsorship of any description for the study.



**What will happen at the end of the study?**


You will continue to receive usual care from your own doctor and pharmacist. Your views will be used to improve future MUR services.

**What if I need further information?**

You can contact Abdul W Mohammad at The Medway School of Pharmacy on 01634 883481 between the hours of 9am and 5pm. He will be happy to answer any questions you may have.

**Can I see how the information is used?**

You may request a copy of results by contacting Abdul W Mohammad on 01634 883481 at The Medway School of Pharmacy. You will receive this by post.

 <p>the UNIVERSITY of GREENWICH</p>	<p>Medway School of Pharmacy</p>	<p>University of <b>Kent</b></p>
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<b>SCHOOL/DEPARTMENT</b>		
Title of Study Evaluation of MUR : Users Views		
Investigator's name(s) Abdul W Mohammad, Professor Clare A Mackie, Sinéad Ní Aoláin		
<i>to be completed by the patient</i>		
1.	Have you read the information sheet about this study?	YES/NO
2.	Have you had an opportunity to ask questions and discuss this study?	YES/NO
3.	Have you received satisfactory answers to all your questions?	YES/NO
4.	Have you received enough information about this study?	YES/NO
5.	Which researcher/investigator have to spoken to about this study?	
6.	Do you understand that you are free to withdraw from this study?	
	• at any time	YES/NO
	• without giving a reason for withdrawing	YES/NO
	• without affecting your future with the University/studies/medical or nursing care	YES/NO
7.	Do you agree to take part in this study?	YES/NO
<b>Signed</b>		Date
Name in block letters		
Head of School ( <i>if you are a member of the University</i> )		
<b>Signature of investigator</b>		Date

### **General Introduction**

Hello and welcome to you all today. My name is Catherine Dewsbury and I am going to be facilitating this group today. Abdul, Sinead are also present at the meeting as they will be taking notes. The reason we have a number of people taking notes is to ensure we have an accurate record and what you say and we can truly represent what you have to say in the final research report. Thank you very much for agreeing to take part and for taking the time to come here today.

Just a few housekeeping words to get us on our way and to make sure we all know how the discussion is going to run today. Firstly the basics – fire exits, alarms and toilets. The microphone you see is part of a taping device and this entire meeting is being recorded, however there is no need to be alarmed and if you do not feel comfortable with this feel free to let me know. We are recording this meeting purely for research. All the data which we will hear will be between the people in this room, any information used for the purpose of the study will be anonymised and the recording will be kept safely in the Medway School of pharmacy for a period of 24 months following this discussion in order to complete this research. Is everybody comfortable with this? (At the end of 24 months the information will be destroyed, The Head of the School of pharmacy Prof Ian Cumming is the lead for information held in the school and is responsible for ensuring we destroy information according to the agreed processes.)

As you are aware the reason you have been invited to join us today is because you have recently taken part in a Medication Use Review at your local pharmacy. The purpose of the research is to find out how you felt about this review. There are no wrong answers and no right answers – we want your views good and bad. As we do not have much time today it will not be possible to explore all the themes which arise however this does not mean they are irrelevant and it is possible that we will return to these in future research, and so for the purposes of today's meeting we may need to park some topics temporarily.

Due to the tape recorder it is necessary to have a few guidelines

- There are no wrong answers, only differing points of view.
- We're tape recording, so we can only have one person speaking at a time.
- We're on a first name basis to protect your confidentiality.
- You don't need to agree with others, but you must listen respectfully as others share their views
- My role as a moderator will be to guide the discussion
- Talk to each other not the machine!

(Introduction of Focus Group – 5 mins)

### **Patient's own introductions**

For the purposes of the tape would you all like to introduce yourselves? Maybe you could tell us your name, whereabouts you're from and why you agreed to take part in this study? Have any of you before this meeting?

(Patient Introductions – 5 mins)

### **Medication Use Review or Prescription Based Intervention?**

Do you take regular medications? On average how often would you visit your local pharmacy? Did you know about the MUR/PBI service prior to having one? Please tell us what you knew? How did the medication use review come about for you? Did the pharmacist suggest it or did you have concerns about your medicines which lead to the review?

### **Patient's Expectations**

What did you expect from the medication use review meeting? Were these expectations met? Did you have any prior thoughts as to the way the meeting might run or to the information you may gain from it? Was this the case on the day? How long did you expect the meeting to last? How long did it last? Was the time well spent?

### **Location**

How did you feel about the location of the meeting? Did you feel comfortable? What could have been done to make you feel more comfortable?

### **The Interview**

Did you feel comfortable discussing your medications with your local pharmacist? Why is that? Did the in interview allow you enough time to discuss your concerns? Did the interview bring about any new concerns? Did the pharmacist suggest any changes to your medicines or the way you take medicines?

Since the interview has anything changed in the way you take your medicines? How did the review influence the changes in your medicine taking?

**Paper work**

During the interview the pharmacist made some notes using a form? How did you feel about this? Do you think this could have been in anyway distracting to you or the pharmacist? There was a choice about whether you would like the GP to receive a copy of this form. Did you choose for your GP to have a copy? If no then why not?

**Patient's Satisfaction**

Did you think the MUR was worthwhile? If you were telling a friend about your experiences, what would you say? What were the most positive aspects of the interview for you? What were the most disappointing aspects of the meeting for you? Was the length of time of the MUR appropriate for the task of giving a medication review in your eyes? If no then why?

**Improvements for future service delivery.**

Do you think there was anything the pharmacist could have done to improve the service?

(Questions – 35 mins)

**Summary and Conclusion**

- Key themes which we have discussed here this evening are;
- How your medication review came about
- Your prior expectations of the service
- The location of the interview
- The review itself
- The paperwork during the interview
- Your satisfaction following the interview
- Any improvements which you think could be made to this service.

Is there anything else which you have now remembered which may be relevant to any of these themes? Are there any other issues which you feel are important in understanding patient's views of this service?

(Summary - 5 mins)

I think we have come to the end of our meeting for today. Thank you very much for taking the time to join us, I hope you will join us for some refreshments and a buffet lunch in a few moments.

Thanks Again.