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MEDICINES NON-USE IN PRIMARY CARE

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SEPTEMBER 2005

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Thesis Summary

Aston University

Title: Medicines non-use in primary care

Submitted by Adam John Mackridge

For the degree of Doctor of Philosophy

Year of submission: 2005

This study expands the current knowledge base on the nature, causes and fate of unused medicines in primary care.

Three methodologies were used and participants for each element were sampled from the population of Eastern Birmingham PCT. A detailed assessment was made of medicines returned to pharmacies and GP surgeries for destruction and a postal questionnaire covering medicines use and disposal was issued to patients randomly selected from the electoral roll. The content of this questionnaire was informed by qualitative data from a group interview on the subject. By use of these three methods it was possible to triangulate the data, providing a comprehensive assessment of unused medicines.

Unused medicines were found to be ubiquitous in primary care and cardiovascular, diabetic and respiratory medicines are unused in substantial quantities, accounting for a considerable proportion of the total financial value of all unused medicines. Additionally, analgesic and psychoactive medicines were highlighted as being unused in sufficient quantities for concern. Anti-infective medicines also appear to be present and unused in a substantial proportion of patients' homes.

Changes to prescribed therapy and non-compliance were identified as important factors leading to the generation of unused medicines. However, a wide array of other elements influence the quantities and types of medicines that are unused including the concordancy of GP consultations and medication reviews and patient factors such as age, sex or ethnicity.

Medicines were appropriately discarded by 1 in 3 patients through return to a medical or pharmaceutical establishment. Inappropriate disposal was by placing in household refuse or through grey and black water with the possibility of hoarding or diversion also being identified. No correlations were found between the weight of unused medicines and any clinical or financial factor.

The study has highlighted unused medicines to be an issue of some concern and one that requires further study.

Key Words: Unused Medicines, Medicines Waste

Dedication

To my parents, Diane and Ian, without whom this thesis would never have been written.

Acknowledgements

I am indebted to my friend Simon Freytag who has helped me throughout my research with statistical analysis, computing support and proofreading.

I also wish to acknowledge help and support from the medicines management team at Eastern Birmingham Primary Care Trust, namely Helena Pickin, Peter Clewes and Julie Varley for their assistance in the planning and implementation of my research. Additionally, the help of the East Birmingham Local Pharmaceutical Committee, Tom Wedgbury and Rakesh Panesar in the recruitment of pharmacies for the collection of medicines.

I am grateful for the help and participation of all the staff at the community pharmacies and general practice surgeries where medicines were collected for the present study and to the residents of the primary care trust who took part in the group interviews and returned questionnaires allowing me to perform this study.

This work has been performed as a result of funding from the Royal Pharmaceutical Society of Great Britain.

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Abbreviations

Abbreviation	Meaning
ADR	Adverse Drug Reaction
BMA	British Medical Association
BNF	British National Formulary
CD	Controlled Drug
COSHH	Control of Substances Hazardous to Health
CRC	Child Resistant Closure
CNS	Central Nervous System
DUMP	Disposal of Unwanted Medicines and Pharmaceuticals Dispose Unwanted Medicines Properly Disposal of Unwanted Medicines and Pills Disposal of Unwanted Medicines and Poisons
DOOP	Disposal Of Old Pharmaceuticals
DH	Department of Health
EBPCT	Eastern Birmingham Primary Care Trust
EER	Edited Electoral Register
EMA	European Medicines Evaluation Agency
FTE	Full Time Equivalents
FHSA	Family Health Services Authority
GP	General Practitioner
GSL	General Sales List
LREC	Local Research and Ethics Committee
NHS	National Health Service

Abbreviation	Meaning
NPfIT	National Program for Information Technology
NSAIDs	Non-steroidal anti-inflammatory drugs
NSF for CHD	National Service Framework for Coronary Heart Disease
OPCS	Office of Population Censuses and Surveys
OTC	Over The Counter
P	Pharmacy medicine
PAC	Pharmaceutically Active Compounds
PCT	Primary Care Trust
PCO	Primary Care Organisation
PIL	Patient Information Leaflet
PMR	Patient Medication Record
POM	Prescription Only Medicine
PSNC	Pharmaceutical Services Negotiating Committee
rINN	Recommended International Non-proprietary Name
RPSGB	Royal Pharmaceutical Society of Great Britain
SSRIs	Selective Serotonin Reuptake Inhibitors
TCAs	Tricyclic Antidepressants
UK	United Kingdom
VAT	Value Added Tax
WHO	World Health Organisation

CHAPTER 1 : Unused medicines in the community

1.1 Introduction

The problem of unused medicines is widespread throughout the United Kingdom (UK) and the world, with complex, multifaceted causes and multiple effects on the cost of healthcare, public health and the environment.

The cost of prescribed drugs in primary care within the National Health Service (NHS) for England and Wales currently stands at over £8 billion per annum. The money spent on prescribed medicines has risen at a rate of 6% to 13% per annum¹ since 1995 and this growth appears to be continuing. In a resource limited system such as the NHS, there is considerable need to ensure the cost effectiveness of these medicines and a number of studies have been performed, considering the issues of compliance and concordance. In addition, government agencies such as the National Institute for Clinical Excellence (NICE) and the National Prescribing Centre (NPC) have been established to disseminate best practice and promote cost effective prescribing. However, no published studies have assessed the impact of these agencies and their guidance on the incidence of unused medicines. Indeed, unused medicines generally have only been the subject of a small number of studies, both in the UK and worldwide, and consequently the data available on these remains limited and many attempts to minimise the incidence of unused medicines have been based on anecdotal evidence and estimates. The types of medicines that are unused and their financial value are also unknown and previous estimates of the financial value of unused medicines in the UK have varied considerably, ranging from tens to hundreds of millions of pounds per

annum,²⁻⁵ and these have often been based on data from small studies with limited scope. Additionally, little is known of the patients that have unused medicines in their homes and the reasons for the generation of these unused medicines.

In addition to the paucity of data available on the factors leading to unused medicines, the effects of medicines non-use have also not previously been considered in depth. This is surprising given the potential benefits to the NHS of minimising the waste of medicines in this way, such as improved cost effectiveness and minimisation of expenditure. Additionally, the actions of former GP Harold Shipman have demonstrated the potential for unused medicines to cause harm.

The review of the available literature that follows considers the place of medicines in the NHS, the possible causes of medicines non-use, the scale of the problem in the UK and the rest of the world as well as the effects that unused medicines may have on healthcare and society as a whole.

1.2 The National Health Service and the use of medicines in the United Kingdom

Since the founding of the National Health Service (NHS) in 1948 by the then Labour government, healthcare has been provided free at point of delivery. However, charges for the supply of medicines under the NHS were introduced in 1952 by the Conservative government and remained until they were abolished by the Labour government of 1965. Just three years later, the Labour administration were forced by financial pressures to re-introduce the charge and it has remained in place since with numerous rises being introduced by Conservative and more recently New Labour

governments. In order to placate opponents to the charges, a number of exemptions have been introduced and in 2003, 86.2% of the 650 million NHS prescription items dispensed in England were supplied exempt from charge¹. In recent years, the debate on prescription charges has been reopened, with the Welsh Assembly Government pledging to entirely abolish charges and the Scottish Parliament currently reviewing their policy. In England, there are now immediate plans to amend charges, but it is likely that this will happen following the changes being made in the devolved regions. Prescription item charges were £6.50 in England and Scotland and £4 in Wales at 1st April 2005⁶. However, charges in Wales are subject to extended exemptions in comparison to Scotland and England and the charge is currently being reduced each year with total abolition planned for 2007⁶.

Medicines are one of the largest costs for the NHS accounting for over 10% of the entire NHS budget for 2004, with over 686 million prescription items dispensed in England during the year at a cost of over £8.1 billion⁷, a rise of 36.4 million items and £569 million on the prescriptions dispensed in 2003⁸. Considerable effort is being made in many areas of the NHS to ensure medicines are used in a cost efficient manner and that the greatest clinical benefit is gained from the lowest possible outlay. However, unused medicines continue to be a barrier to this and are responsible for expenditure that produces no clinical benefit and costs incurred for their safe disposal. It is only through targeting the problem of unused medicines that true cost effectiveness in the NHS can be achieved.

1.3 The factors that may influence the generation of unused medicines

There is a paucity of published data detailing the specific causes of medicines non-use. However, it is likely that a number of factors influence the quantity and types of medicines that are unused. These factors may include oversupply, changes in therapy, errors in prescribing or in supply, adverse drug reactions, poor compliance or the death of the patient.

1.3.1 Patient compliance with prescribed instructions

One of the most likely factors that lead to unused medicines is patient non-compliance. This was first considered important to research following the work of Joyce in the early 1960s⁹ and has become prominent in the NHS in recent years, with the advent of medicines management initiatives. More recently, the idea of compliance has been replaced by that of concordance, where a patient is encouraged to actively participate in the prescribing process, with these concordant consultations being intended to remove the problems of non-compliance. However, many consultations are not yet truly concordant, with the prescriber directing the patient in their treatment and consequently patient compliance remains a significant issue.

A study of non-compliance in hypertensive patients by Benson and Britten during 2002 reported the factors that influence patients in choosing whether or not to take their medicines.¹⁰ The reasons that were cited included patient's dislike of using medicines, a belief by patients that doctors prescribe drugs that are not necessary and patients inferring that taking medicines indicates that user is ill. Patients were also concerned by the possible long term effects of medicines and necessity for their continual use. A

study of compliance in epileptic patients undertaken in Brazil also reported that patient concern of becoming addicted to the prescribed medicine was a significant precipitating factor leading to non-compliance in this patient group¹¹.

1.3.1.1 Acute medical conditions

A study undertaken in Mexico by Reyes and co-workers, which considered compliance in upper respiratory tract infections (URTI) and acute diarrhoea (AD), reported that just 56% of patients with URTI and 60% with AD followed the prescribed regimen¹². Of those patients that did not take their medicines as prescribed, 79% discontinued their medication early and a further 8% did not start taking the medication, while the remaining 13% took the medication at a different frequency or dose to that prescribed. This study demonstrates the potential for poor compliance with prescribed instructions in acute conditions and this is likely to lead to small amounts of unused medicines in a large numbers of patient's homes. Additionally, anecdotal evidence suggests that patients are often likely to keep unused medicines used in treatment of short lived conditions and therefore it is possible that these small quantities may accumulate into large stockpiles over time.

1.3.1.2 Chronic medical conditions

In contrast to acute conditions, prescribing in chronic conditions is often done on a repeat basis and non-compliant patients may continue to accumulate unused medicines indefinitely until the issue leading to the non-compliance is resolved. Additionally, non-compliant patients with repeat prescriptions may continue to order the medicines to hide their non-compliance from the doctor³, leading to considerable quantities of medicines accruing in these patient's homes.

Studies undertaken in Brazil and Connecticut that considered compliance in epileptic patients reported full compliance in only 60% and 76% respectively of patients studied^{11,13}. Additionally, a study of compliance in hypertensive patients in Missouri reported that patients complied with the prescribed regimen in 59% of cases for those taking medicines three times daily and 84% of cases for those taking medicines once daily¹⁴. It is clear from the data presented in these studies that non-compliance is prevalent in two chronic disease groups where there is clear evidence demonstrating benefit in treatment^{15,16}. This non-compliance will undoubtedly lead to considerable quantities of unused medicines in some cases and would represent a considerable waste of vital resources.

1.3.2 The supply of excess medicines

Evidence suggests that significant quantities of medicines that are prescribed to patients are not strictly clinically indicated or are excessive in relation to the needs of the patient¹⁷⁻²¹. The Audit Commission report *A prescription for improvement* published in 1994 states that it may be possible to save as much as £300 million if over prescribing in primary care were brought under control and also notes that two thirds of GP consultations in the UK ended with a prescription being issued¹⁸. Additionally, recent data indicate that patient pressure on the prescriber and the perceptions of the prescriber on the demand for prescriptions are significant factors leading to unnecessary prescriptions^{19,20}.

A study performed by Cockburn and Pit in Newcastle, Australia during 1992 reported that those patients that went into consultations expecting a prescription were three times more likely to be issued with one in comparison to those patients that did not expect a prescription¹⁷. In situations where the prescriber reported that they perceived the patient

was expecting a prescription, they were ten times more likely to issue one than in situations where there was no perceived demand¹⁷. While in 1994, Webb and Lloyd reported that one fifth of patients left a consultation with a prescription that they did not expect²². Additionally, a 1997 survey of GP opinion of unnecessary prescriptions by Britten and Ukoumunne found that doctors reported issuing prescriptions that were not strictly indicated on medical grounds in over one fifth of consultations²¹. It is likely that prescriptions, which are issued where no clinical need exists and where the patient does not wish to take the medicine, will result in the generation of unused medicines. Additionally, the prescription may never be dispensed and work by Beardon and co-workers reported that 15% of patients surveyed admitted taking prescriptions from their general practitioner and not having them dispensed²³.

The accumulation of excess medicines that go on to be unused may also be related to the system currently in place for supply of repeat medication. Indeed, Jesson and co-workers report that where a novel system was used that assessed clinical need prior to supply only three quarters of the permitted prescription items were supplied²⁴.

In the UK, advertising that is directed at the consumer is not permitted for any prescription only medicines and was previously restricted for the majority of medicines with only the advertising of a few over the counter medicines being permitted. However, there is pressure from the pharmaceutical industry to lift these restriction and recently, the regulation of advertising of over the counter medicines has been relaxed, however the industry continues to apply pressure for a full lifting of the restrictions and the allowing of advertising similar to that permitted in the USA, where there is evidence to suggest that it has a significant influence on patients, increasing their demand for prescriptions²⁵.

1.3.3 The death of a patient

Throughout the treatment of any potentially life threatening condition, it is necessary to tailor the treatment to the needs of the patient, ensuring the best quality of life and the greatest longevity. As a disease progresses, the balance of quality of life and longevity become harder to maintain and there may be even greater need to change the doses or agents used to treat a patient. Additionally, as a condition becomes more advanced, it is likely that co-morbidities will develop, further complicating the prescribing process. In palliative care, it is likely that substantial quantities of unused medicines will be present on the patient's death. This is a result of the continual need to adjust treatment, along with the necessity for supply of sufficient quantities of medication to minimise suffering due to a lack of available medicines. In addition, since the agents used in palliative care are often highly potent or narcotic in nature, the remaining medicines are of particular concern in any large quantity. However owing to high degree of emotional pressure on the patient and their carers in such situations, return of all the unused medicines is generally of low priority and medicines can stockpile in the home in considerable quantities³. Since it is likely that the unused medicines will in many cases include controlled drugs or cytotoxics, the actions of the patient's friends and relatives following death are very important in ensuring both safe disposal and minimising potential for diversion or abuse.

1.3.4 Changes in therapy and adverse drug reactions

Since it is not possible to predict the exact clinical response that will be achieved when using a particular drug in a patient, it is often necessary to adjust the dosing regimen in order to attain the desired outcome. Indeed, as the patient may be unresponsive to a specific drug, it may even be necessary to change the drug or even the class of agent

used. Additionally, all medicines have the potential to cause adverse drug reactions of sufficient severity such as to cause the prescriber or patient to cease therapy, resulting in the need to use an alternative treatment. In situations where the desired clinical response has not been obtained or the patient has suffered from an adverse drug reaction and the medicine has been changed, it is unlikely that all the doses that were supplied will have been used. While there is clearly a good clinical reason for adjustment in the therapy, in cases of poor prescribing it is possible for a patient to have been issued with sufficient medicines for over three months of therapy and since these medicines are unsuitable, large quantities will be unused.

1.3.5 Errors in the prescribing or supply processes

While it is uncommon for errors to be made in the prescribing or supply process, they are made in small numbers, resulting in patients receiving medicines that are not appropriate¹⁷. Common sources of error may include the selection of an incorrect brand or formulation of insulin or an incorrect inhaler type, or the selection of the wrong item on the prescription printing software, resulting in a prescription for the wrong item being issued. Errors in supply have often been ignored as a source of unused medicines in previous studies. However, while these medicines are unlikely to accumulate in significant quantities, they still present a potential cause of harm and their safe disposal is of importance.

1.4 Previous studies that have considered unused medicines

Newspapers and television have raised the issues surrounding unused medicines a number of times in recent years, often focusing on the waste of NHS resources,²⁶⁻³³ and

the Department of Health (DH) has recognised it as a significant problem in the provision of healthcare in the UK³⁴. Additionally, professional bodies such as the Royal Pharmaceutical Society of Great Britain (RPSGB)³⁵ and the Royal College of Physicians³⁶ have acknowledged unused medicines as a problem. However, despite this, there is a paucity of published, peer-reviewed research on unused medicines and their consequences in a primary care or community setting, particularly within the UK. An exhaustive search of the Entrez PubMed, Web of Science and Pharmline literature databases revealed only a small number of published studies that have considered the unused medicines in primary care. Additionally, the website of the Pharmaceutical Services Negotiating Committee (PSNC)³⁷, which lists community pharmacy initiatives, reports only a small number of minor, unpublished projects. Of the published data available worldwide, studies undertaken within the UK are often comparatively smaller and run over shorter periods than those performed elsewhere.

The published data available on unused medicines has been collected in two distinct ways; some studies have collected unused medicines from community sites while others have directly surveyed patients in their homes. The data from relevant studies of these types undertaken in the UK and worldwide are considered below in sections 1.4.1 and 1.4.2 respectively.

1.4.1 Studies of unused medicines in the UK

1.4.1.1 Studies assessing unused medicines collected in the community

Healthcare agencies such as Health Authorities and more recently Primary Care Trusts (PCTs) have run campaigns for the safe disposal of unused medicines for a number of decades often referred to as DUMP campaigns. The source of this abbreviation is

unclear with some references to the campaigns being *Disposal of Unwanted Medicines and Pharmaceuticals*; *Dispose Unwanted Medicines Properly*; *Disposal of Unwanted Medicines and Pills* and *Disposal of Unwanted Medicines and Poisons*. While each campaign has differed in the minor details, the general design and purpose has changed little since the early campaigns of the 1970s. Each consisted of a mass media campaign run at the same time as a collection service in local community pharmacies. In most cases, these campaigns were primarily performed in to order promote the safe disposal of unused medicines rather than to discover new information about their nature. Therefore, the data reported was generally in terms of simple weight or the total number of packs that were returned during the allotted time period. The weights of collected medicines recorded in these campaigns were often reported in the local media, but little other data were recorded and in most cases, nothing was published.

Research studies that considered unused medicines, their causes and consequences began to be published around the time of the early DUMP campaigns, initially taking the same form. Since those published studies, the techniques used have become more developed and the level of detail reported has grown. One of the earliest published studies was performed in 1975 by Bradley and co-workers, who collected all the unwanted medicines returned to 70 community pharmacies and 20 hospital pharmacies in Manchester during a three-week DUMP campaign. The researchers assigned the collected medicines to categories based on their dosage form and reported 387,000 tablets, 820 bottles of liquid medicines, 1400 ampoules of injections, 870 tubes of ointments, 2,300 suppositories and 310 bottles of eye drops that weighed over three quarters of a tonne³⁸. Unfortunately, the medicines collected in this study included those that were simply expired pharmacy stock and the authors note that these made up the majority of collected medicines making this data of little value. Another early study was

performed by Harris and co-workers in 1977, considering the impact of a DUMP campaign on the number of poisonings among children in Birmingham³⁹. The authors reported collecting over 360,000 tablets and capsules and almost 95 litres of liquid medicines during the three-week campaign. A sample of 20% of the collected containers were categorised by therapeutic type and the categories with the most collected containers were antipyretics/analgesics (21%), antibiotics (14%), psychotropics (13%) and cardiovascular medicines (6.5%). Medicines collected during this study had often remained in the home for a considerable amount of time before the campaign prompted their return and 27% had been dispensed over two years previously. The study reported no significant difference in the rate of admission of children following accidental poisoning in the year following the campaign. However, the changes in admission rates over a prolonged period were not considered.

Little data exists from studies between 1977 to 1994, with only one simple assessment of unused medicines returned during a DUMP campaign in 1986 being performed by the Torbay branch of the then Pharmaceutical Society of Great Britain. This study reported the total weight of medicines collected from 65 pharmacies to be three quarters of a tonne, but no break down of the types of medicines returned is published and the duration of the study was not stated⁴⁰. In 1994, a study was performed, which assessed medicines collected in 29 pharmacies in Central Lancashire over a 16-week period. Little data is available since the results were not published, however the principal findings reported on the PSNC website state that of the 4845 items returned, over one fifth (21%) were unopened. Drugs acting on the central nervous system (CNS) and non-steroidal anti-inflammatory drugs (NSAIDs) were reported as being returned in proportions greater than would have been expected when considering the local prescribing patterns³⁷.

The first detailed analysis of unused medicines was published by Hawksworth and co-workers, who performed a pilot study in 15 community pharmacies over two months in March and April 1994⁴¹ and a follow-up study in 30 community pharmacies over 4 weeks in April 1995². Both studies were performed in the Kirklees Family Health Services Authority (FHSA). One of the most important aspects of this work was that it reported the normal activity of patients since no campaign was run prior or during the collection period. The data are therefore more likely to be representative of usual unused medicines and more accurately represent the patterns in unused medicines of the local population. The pilot study reported 1228 returned items with a financial value of £10,681. Drugs acting on the cardiovascular system and central nervous system were the most commonly returned, each accounting for over 23% of the collected items. The follow-up study reported 1091 items with a financial value of £7,762 returned by 366 patients. In the follow-up study, the most common reasons for return of medicines were reported as death of the patient (42%), changes in the prescribed medication (25%), clearout of excess stock in the home (23%) and medicines going out of date (5%). The other reasons given were that an incorrect item had been supplied and that the patient did not know why the medicine had been prescribed. The authors report that a fifth (20%) of returned containers were full and a further 12% had only had a few doses removed. Medicines acting on the central nervous system and cardiovascular system were the most commonly returned and accounted for 25% and 23% respectively of the items. Medicines acting on the gastrointestinal system had the highest financial value, accounting for 19% (£1498) of the total. The authors used their findings to recommend that smaller quantities be supplied on each prescription, suggesting that this would lead to lower quantities of unused medicines⁴². Following this work, unused medicines became the subject of a greater number of published studies, which incorporated a

greater depth of analysis of the collected medicines, and media campaigns, a common feature of previous studies, were no longer used.

In 1998, Braybrook and co-workers performed a study of unused medicines in Gwent Health Authority following a small pilot study, which assessed medicines collected from eighteen pharmacies over eight weeks. They reported 529 discrete return events comprising 1428 items with a total financial value of £19,059, representing 1.5% of the total drug budget for the region studied. Patients aged 60 years or over made two thirds of the return events (67%), the most commonly cited reason for a return event was a change in the prescribed medicine and the majority of medicines were returned within one year of dispensing⁴³.

A study by Grant is the longest of this type to be performed in the UK, assessing medicines collected over a three year period in considerable detail³. However, only one pharmacy was included, which dispensed approximately 8,000 items per month, therefore, while the data are not subject to seasonal variation the population studied is quite small and the generalisability of the findings is doubtful. In this study, Grant considered 3,099 items, which were returned from 924 patients and had a financial value of £27,000. Medicines that act on the cardiovascular and central nervous systems were those most commonly returned accounting for 24% and 23% of the items respectively, while drugs acting on the respiratory system were the third most commonly returned, but represented just 9% of the total items. The author notes that the number of items collected during this study in each therapeutic class closely matched local prescribing, indicating that all types of medicines were equally likely to be returned. The majority of medicines (63%) had been dispensed in the twelve months prior to return and many were both within their expiry date and unopened. Grant

highlighted a number of individual patients that returned large quantities of medicines during this study. One such patient returned sufficient tibolone for 16 months worth of treatment, having been obtaining 84 days of treatment every 28 days when she collected her other medicines. Another patient had 604 morphine sulphate tablets returned following his death. These cases highlight the potential for individual patients to accumulate very large quantities of unused medicines and another case reported in the literature details the return of over £800 worth of medication, amounting to many months of treatment, following a patient's death⁴⁴.

During February and March 2000, McGovern and co-workers performed an audit of medicines that were collected over four weeks in 10 pharmacies in a Glasgow local healthcare co-operative from a population of 50,000 people⁴⁵. This study considered 256 items, which were returned by 100 patients and had a financial value of £2,411. The most commonly cited reason for items being returned was a change in the prescribed medicine, accounting for 44% of all the collected items, with other reasons for return being the death of a patient (34%) and an adverse drug reaction to the prescribed medicine (5%). Those medicines that act on the cardiovascular and central nervous systems were most commonly collected items and accounted for 30% and 22% respectively. The Cherwell Vale Pharmacy Development Group performed a similar study in February 2001; however, this was on a smaller scale and the results were never formally published. This study considered the first 100 items returned or those returned by the first 25 patients in each of four participating pharmacies, two in Banbury, one in Chipping Norton and the other in Brackley,⁴⁶ and a total of 309 items, returned for 102 patients, were assessed. Collected medicines had a total financial value of £2,597 and the mean item value was £9.69, with the death of the patient and changes in the prescribed medication being the most common reasons given for return of medicines,

each accounting for 39% of the returned items. Medicines acting on the central nervous system were those most commonly returned, accounting for over a quarter of all items, while those acting on the cardiovascular system made up a further fifth of returned items.

Up until this point, all of the UK studies that had been performed had only considered those medicines that were returned to community or hospital pharmacies with none looking at alternative means of disposal that may be employed by patients. In response to this, a study was performed by Daniszewski and co-workers that assessed the medicines returned to five general practice surgeries and eight community pharmacies in the Hodeghill and Greater Yardley primary care organisation (PCO) in Birmingham⁴⁷. Medicines were collected from the pharmacies over four weeks in August 2001 and the general practice surgeries over four weeks in March 2002. The authors reported 114 discrete return events, comprising 340 items with a total financial value of £3986. The number of items returned to surgeries represented 12% of the total number of items and accounted for 6% of the total financial value, indicating that general practice surgeries are an important route of disposal utilised by patients that has not previously been studied.

The collection studies outlined above have allowed an assessment of the types of medicines that are unused and some of the reasons for them being unused. However, as has been highlighted by Daniszewski, patients often dispose of medicines by methods other than returning them to a community pharmacy and the data gained through studies that consider returned medicines is only a surrogate marker of the true scale of unused medicines. In order to gain a more complete picture of unused medicines in primary

care, it is necessary to employ other research techniques, which measure the actions and opinions of patients with regard to their medicines.

1.4.1.2 Studies surveying patients in their home

Very little UK data exist on the presence of medicines in patients' homes and the actions of patients with regard to the disposal of unused medicines. Indeed, just three studies considering these areas have been published to date. The first of these studies was a household survey performed in 1990 by Atherton and Rubenstein which involved a self-completion questionnaire completed by 176 households in the Merseyside region⁴⁸. This study asked patients about the quantities and types of unused medicines in the home, the usual method of disposal of unused medicines and whether the patient had heard of the DUMP campaigns that had recently been run. Of the 176 respondents, 49% reported unused medicines in their home. The most commonly reported types of medicines were those acting on the central nervous system (24%) and those acting on the respiratory system (22%). Other unused medicines reported were those acting on the musculoskeletal system (14%), antibiotics (10%) and those acting on the skin (10%). Just 1% of the unused drugs reported were those acting on the cardiovascular system. Over half of the unused medicines were reported as less than a year old while 6% had been dispensed over 10 years previously. The unused medicines reported had a financial value of £478 including both the cost of the drug and the pharmacist remuneration incurred by its supply. Respondents indicated having unused medicines as a result of the patient feeling better (49%), an adverse drug reaction (12%), the patient forgetting to take the medicine (10%), the medicine not working (9%) and the patient preferring not to take the medicine (4%). The most common methods of disposal of unused medicines that were indicated by respondents were in black water (water from domestic toilets)

(41%) and with domestic refuse (18%) while just 11% indicated that they would usually return them to their local pharmacy. These findings indicate that the data from collection studies may only represent one tenth of the scale of the true problem.

A study performed by Gill and Portlock in the same year assessed the actions of residents of the Portsmouth area by face to face interviews of patients attending one hospital pharmacy and two community pharmacies⁴⁹. Sixty-eight patients were interviewed and asked how they usually disposed of liquid and solid dose form medicines. Liquid medicines were most often disposed of in grey water (water from domestic sinks or drains) (30%) with other methods of disposal being in black water (32%) and with domestic refuse (3%). Solid dose medicines were usually disposed of in black water (35%) or with domestic refuse (15%). Patients reported that they returned medicines to their local pharmacy in just 2% of cases for liquid medicines and 10% of cases for solid dose medicines further suggesting that medicines returned to pharmacies may represent only one tenth of all unused medicines.

In light of research such as that above the DH commissioned the Office of Population Censuses and Surveys (OCPS) to include a report on residual medicines in their 1994 Omnibus Survey⁵⁰. The OCPS studied a substantial random sample of 2,082 households distributed throughout Great Britain and gathered data on all unused medicines currently in the home and the usual disposal methods for unused medicines. The study excluded contraceptive medication although the rationale behind this is unclear. The study reported that 11% of households studied had some unused medicines at the time of the study. Of all the medicines currently held, including those being used, 14% were identified as being partially used and stored for possible later use and 8% were identified as residual – medicines that the patient had no intention of taking. Of the 14%

that were being kept for possible further use, 36% were drugs acting on the central nervous system, 17% were those acting on the respiratory system, 15% were medicines used on the skin and 5% were those acting on the cardiovascular system. The most common therapeutic groups making up the 8% residual medicines were medicines acting on the central nervous system (29%), anti-infective agents (18%), medicines acting on the respiratory system (12%) and medicines acting on the cardiovascular system (9%). One fifth of the surveyed households usually kept their medicines for future use and a further 50% reported that they usually threw medicines away, although the method of disposal was not clear and may include disposal in black water systems as well as disposal with household refuse. Households usually returned their unused medicines to a community pharmacy in just 16% of cases, again indicating that the medicines returned to pharmacies represent only a small part of the total amount of those that are unused.

1.4.2 Studies of unused medicines and patient attitudes in primary care performed outside the United Kingdom

The field of unused medicines has been considered by a number of studies outside the UK, in both developed and developing countries, encompassing various different healthcare models. Studies available in the literature ranged from brief reports of collected medicines to full assessments of the types and quantities of medicines and surveys of patients; a review of the principal findings of these studies follows.

1.4.2.1 Study of unused medicines in Canada

The Sudbury and District Pharmacists Association of Ontario, Canada performed a “medicines cabinet cleanup campaign” in 1995, which was comparable to a UK DUMP

campaign and involved the local media, posters and leaflets that requested the return of unused and expired medication to community pharmacies⁵¹. A total of 29 pharmacies participated in the collection of these medicines and details of the returned medicines were recorded throughout November 1995. The most commonly collected medicines were those acting on the cardiovascular system, analgesic and anti-inflammatory medicines and those acting on the endocrine and neurological systems, accounting for 26%, 19% and 15% of returned items respectively. Additionally, medicines acting on the gastrointestinal system made up a further 13% of items and antibiotics another 6%. Prior to this study, it was the accepted opinion in Canada that unused medicines were predominantly those used to treat acute conditions⁵². However, this study identified almost two thirds of the returned items (63%) as originating from prescriptions for chronic treatments. In addition to collecting medicines, this study also included a telephone interview of a random sample of patients to determine the usual method for disposal of unwanted medicines. The most common method of disposal for unused medicines that was identified by respondents to the telephone interviews was in black water systems, with this method being used by almost half (46%) of respondents. Medicines were thrown away with normal household refuse by 31% of respondents and just 17% returned medicines to their pharmacy and 2% to their physician. This is in agreement with the findings of the methods of disposal of unused medicines seen in the UK studies, indicating that the actions of patients in both countries were similar at the time of the studies.

Two large studies were performed in British Columbia, also in 1995, which assessed medicines returned to pharmacies during the EnviRx project. In contrast to the work of the Sudbury and District Pharmacists Association, these studies did not include any

publicity campaign. One incorporated 58 pharmacies while another considered medicines collected from 83 pharmacies, with both running for eight weeks.

The smaller of these studies assessed 2,348 items with a financial value of CA\$60,350 (£26,719) with 27% of items being returned following a patient death, 19% because the patient chose not to take the medicine, 12% following a change in therapy and 8% following an ADR⁵³. The most commonly returned medicine type was anti-infective medication, which accounted for 13% of the items while analgesics medicines and those acting on the cardiovascular system made up a further 12% and 10% respectively.

Interestingly, the larger study collected 1966 items, which were returned by 581 patients. These medicines had a financial value of CA\$44,768 (£19,820) and the medicines that were most commonly returned those acting on the cardiovascular system, analgesic medicines, psychotherapeutic medicines and anti-infectives with the most common reasons for return being patient death, expiry of medication and alteration in therapy⁵⁴.

These data indicate that Canadian patients have some considerable quantities of unused medicines and that there is some local variation in the quantities that are returned to community pharmacies. Additionally, the methods of disposal that were utilised by patients for unused medicines were similar to patients in the United Kingdom, with only a small proportion returning their medicines to pharmacies or their physician.

1.4.2.2 Study of unused medicines in Sweden

A study undertaken by Isacson and Olofsson in 1996 was one of the largest of this type ever performed and assessed the medicines returned during one week in all 65 pharmacies in the Malmöhus region, an area with a population of 817,000⁵⁵. This study

collected 8,014 packs of medicines and 30,000 loose tablets and capsules with a total value of 940,000 SEK (£91,439). A comparison between the drugs that were prescribed in the region and those returned indicated that approximately 3% of prescribed items were returned completely unused or partially used. The medicines that were most commonly returned were drugs acting on the respiratory system (19%), those acting on the central nervous system (19%), those acting on the cardiovascular system (14%) and drugs acting on the alimentary tract and metabolism (13%). Packs were returned unopened in over a third (36%) of cases and a further 18% were over 90% full on return.

Another extensive study of returned medicines was performed in 1999 by Ekedahl and co-workers, which assessed medicines returned over two weeks to all 100 pharmacies that served the 1,150,000 inhabitants of the Skåne region of Sweden⁵⁶. This region incorporated the former Malmöhus region where the 1996 study was performed as well as some new areas and this study is the largest study assessing unused medicines ever conducted, with the population considered representing one eighth of the total for Sweden. Over 20,000 packs of medicines were collected with a financial value of €250,000 (£168,657) and the quantity returned represented around 1.5% of the supplied medicines for the region. Packs were returned unopened in 38% of cases and over two thirds full in a further 27% of cases. The therapeutic classes of medicines that were most commonly recorded were those acting on the nervous system (19%), drugs acting on the respiratory system (18%), those acting on the cardiovascular system (15%) and those acting on the alimentary system (14%). Ekedahl also performed a smaller study in Malmö during 2003, which assessed the medicines returned to two pharmacies over a six-week period⁵⁷. In this study, 1,077 packs were returned by 191 patients and Ekedahl notes that a small proportion of the patients are responsible for a large proportion of

returned packs, with just nineteen (10%) of the patients returning 548 (50%) of the packs. Ekedahl also highlights the influence of age on unused medicines, with all the thirteen patients that returned over 24 packs each being aged over 65 years.

Other research conducted in Sweden reported that eight out of every ten Swedish residents return their unused medicines to pharmacies for appropriate disposal, with just 20% disposing of unused medicines by alternative means^{58,59}.

Unused medicines have clearly been considered in great depth in Sweden and, unlike other countries studies, the Swedish residents are most likely to return their unused medicines to community pharmacies, consequently making a study of these returned medicines more generalisable to all the unused medicines. Additionally, although medicines are unused by the population, they appear to only account for around 1-2% of prescribed medicines. Both the quantity and disposal of unused medicines in Sweden highlight the deficiencies in the UK. UK studies indicate that unused medicines may be equivalent to 10% or more of the total prescribed medicines and between 1 in 10 and 1 in 7 patients return their medicines to a pharmacy compared with 3% of Swedish medicines and 8 in 10 returning medicines for destruction.

1.4.2.3 Study of unused medicines in Germany

Research by Bronder and Klimpel in 1988 and 1998 attempted to quantify the unused medicines in Berlin, Germany and assess the development of the problem in this city over a decade⁶⁰. Both arms of the study considered all the medicines returned to a single public pharmacy over twelve months and 5,164 packs valued at DM 100,000 (£34,600) were returned in 1988 compared with 10,603 packs returned valued at DM 232,920 (£80,600) in 1999. However, packs were returned with less doses remaining in the later

part of the study with the mean doses remaining in each pack and the proportion of packs returned full being 70% and 31% in 1988 and 65% and 24% in 1998 respectively. The authors attribute the higher quantity of unused medicines returned in 1998 to a rise in non-use of prescribed drugs over the intervening period and they note that this was unexpected as patients paid a higher prescription charge in 1998 than in 1988⁶⁰. However, an alternative possibility exists in that patients may have returned a greater proportion of their unused medicines in 1998 and it is likely that elements of both of these factors contributed to the larger number of returned packs returned in 1998. Yet, it is clear that medicines are unused in very significant quantities in Germany and many patients are collecting prescribed medicines that are never used, indicating an oversupply problem.

1.4.2.4 The study of unused medicines in Switzerland

The only major study of note that assesses collected medicines in Switzerland is a dual armed study performed by MediHelp Direct in Zurich and Pharmaciens sans Frontières in the Neuchâtel region in the mid 1990s⁶¹. The Zurich arm assessed the medicines returned to 6 pharmacies over eight weeks without any publicity and collected 4969 packs of medicines while the Neuchâtel arm considered medicines returned to 60 pharmacies over an unspecified period during a campaign that advertised the collection service and collected 5042. A quarter of the packs (24%) collected in the Zurich arm were unopened and a further 42% were over half full while the Neuchâtel arm reported 32% as unopened and 38% as over half full.

Other research on unused medicines in Switzerland includes a domiciliary study performed on elderly patients (≥ 75 years) admitted to the *Centre Hospitalier Universitaire Vaudois* in Lausanne during 1996. This study reported that only 36% of

medicines in the home were being regularly taken, 11% were taken occasionally and over a third (36%) were not being used at all⁶². The medicines that were identified as unused were those acting on the cardiovascular system in 36% of cases, osteoarticular medicines in 18% of cases, neuropsychiatric medicines in 17% and digestive medicines in a further 10%.

While these studies were of very limited scope, they highlight that unused medicines are a very significant problem in Switzerland, with large numbers of packs being returned unopened and elderly patients being very poorly compliant with their prescribed medicines.

1.4.2.5 Study of unused medicines in Thailand

A high quality study of unused medicines in Thailand was performed by Wongpoowarak and co-workers, which included detailed assessment of the types and quantities of unused medicines in patients homes in the Songkhla province⁶³. In this study, 931 householders were interviewed and a visit made to their home where any unused medicines were identified and collected for assessment. Unused medicines were identified in over half (56.2%) of the surveyed homes and 1,004 items were collected for analysis. The medicines had a financial value of €392 (£264) although it should be noted that medicines are of considerably lower cost in Thailand than in Europe. The most commonly reported therapeutic classes were musculoskeletal (23%), anti-infective (19%), respiratory (17%) and gastrointestinal (13%). Patients were also asked about the reasons for the unused medicines identified in their home and 30% responded that they had unused medicines because the disease was not serious enough to require all the medication prescribed. Two thirds (73%) of the participants reported that the symptoms or disease had resolved before all the medicines had been taken and 14% stated that the

medication was ineffective. This study highlights that despite medicines being less freely available than in other countries, Thailand residents have large quantities of unused medicines stockpiled in their homes.

1.4.2.6 Papua New Guinea

In common with many developing countries, Papua New Guinea has experienced some difficulty ensuring sufficient availability of essential drugs and in 1991, Australian researchers visited households in the village of Baruni to assess the levels of compliance with the essential drugs that were being made available⁶⁴. Of the 139 households visited, 73 currently had medicines and these households consisted of 699 people, of whom 282 were children under 12 years. The researchers found 176 medicines that had been prescribed or purchased and of these, 65 (37%) were not being used and had a financial value of US\$78 (£43). However, this sum is considerable in a country such as Papua New Guinea and the financial cost of medicines is not the only factor limiting their availability. The researchers noted a number of incidences of inappropriate self-medication, poor compliance and the use of expired drugs and it is likely that these were as a result of the high value attributed to medicines by the villagers. The study found that patients were less likely to use prescribed medicines appropriately than medicines that had been chosen and purchased by the household – 53 of 115 prescribed medicines were unused compared with just 12 of 61 over the counter (OTC) preparations.

This study indicates that even where medicines are a scarce resource and have a high non-financial value, patients still have unused medicines, although they are much less likely to dispose of them and will often continue to use them even after they have expired.

1.4.2.7 Study of unused medicines in the United States of America

Unused medicines have been recognised as a problem for some time in the USA. Kuspis and Krenzelok performed a study in 1994 that assessed the risks posed to children by poorly disposed of medicines⁶⁵. In this study, they surveyed 500 callers to a poisons information centre about their usual method of disposal for unused medicines in order to identify any links between usual method of disposal of unused medicines and poisoning. Medicines were thrown away with household refuse by over half of the respondents (54%) and a further 35% indicated that they disposed of medicines in grey and black water systems. Just 1.4% of those surveyed stated that they would usually return unused medicines to the pharmacy.

A study in Connecticut that looked at the medicines in the homes of 73 elderly patients (≥ 65 years) was conducted in 1999 and used both questionnaires and home visits to determine the quantities and types of prescribed medication that were unused⁶⁶. The study only included medicines that had been prescribed in the previous year and found that medicines with a financial value of US\$2,011 (£1,105) were unused – 2.3% of the annual medication costs for the patients assessed. The types of medicines most commonly seen were antibiotics (11%), benzodiazepines (9%), antihypertensives (8%) and antidepressants (7%). The authors suggest that the quantities of medicines that are unused may be higher in this population since they do not make co-payments – a payment made by the patient for a proportion of the cost of the medicine – although they admit that it is not possible to assess this from their data. Meanwhile, a study performed by Garey and co-workers in 2002 assessed the medicines returned to a single pharmacy over 6 months during a Medicine Cabinet Cleanup Campaign and reports the return of 1315 containers of medicines, some of which were over 25 years old. The

most common therapeutic groups recorded were NSAIDs (25%), medicines for treatment of coughs, colds and allergies (15%), anti-infective medicines (11%), drugs acting on the cardiovascular system (10%), those acting on the respiratory system (9%) and neurological medicines (8%).

An Illinois study where patients were interviewed on their use of antibiotics in the context of antibiotic resistance found that 25% of patients had antibiotics in their home that they had saved from a previous prescription but were not being used⁶⁷. Additionally, half of these patients had taken or would take these antibiotics without consulting a healthcare provider and a quarter had or would share their medicines with others. While the author admits that the study was small, the study indicates that inappropriate use of unused medicines may be common such as use for an undiagnosed complaint or use of another's medicines and the consequences of this are unknown.

The data collected on unused medicines in the USA indicate that it is a significant problem in this country. Indeed, the author of one study estimates that unused medicines account for US\$ 1 billion per annum in that country alone⁶⁶.

1.4.3 Summary of worldwide research on unused medicines

It is clear from the data outlined above that unused medicines are present throughout the world, being present in all types of cultural, social and economic background. In addition, inappropriate use of unused medicines is apparent in both developed and undeveloped environments and the disposal methods employed by patients are unsafe and potentially harmful in many cases. It appears that, while there are minor differences between each country, the reasons for unused medicines and even the types of medicines that are commonly unused are similar across the world. These studies also

show that large quantities of medicine packs that were returned unopened, demonstrating that a considerable number of prescribed items are never used.

The problem of unused medicines appears to be one that exists irrespective of the structure of the health system and is present in countries where patients pay significant amounts towards their medicines and even in countries where medicines are not freely available. However, despite the large number of studies that have highlighted the problem, with the exception of Sweden, there is still very little robust data on the specific medicines that are unused and the patients that are most likely to have unused medicines. Additionally, there is little known about the consequences of unused medicines including the deleterious effects of those that are poorly discarded.

1.5 The consequences of unused medicines

The nature of medicines is such that they are potentially very dangerous if used inappropriately and in certain medicines, such as cytotoxics, the risk of harm is greatly elevated. In addition, if they are permitted to enter water systems or food chains, they will have unknown pharmacological effects on a wide range of organisms, which may have a serious environmental impact. In the UK, a number of restrictions exist to minimise the risks posed by medicines whilst ensuring that they are available to those that need them. These measures cover all aspects of medicines manufacture and use, from prohibiting manufacturers from dumping pharmaceutically active compounds into watercourses through to restrictions on the persons and situations where medicines may be purchased and supplied. However, unused medicines have not previously been considered in these restrictions and controls and there has always been an implicit assumption that medicines supplied to those with a medical need would always be used

in full. Yet, where a patient has unused medicines, there are only limits on the sale and supply and no restrictions exist on how patients may dispose of their medicines. Where patients hoard their medicines or dispose of them inappropriately this action may pose risks to other members of their household or potentially become a public health or environmental risk. Additionally, as highlighted by a number of studies discussed in section 1.4, individual patients can accrue significant quantities of medicines⁴⁴ and their potential to cause harm can become quite considerable. The sections below consider the potential harm that may be caused by unused medicines in the community.

1.5.1 The diversion, misuse and abuse of unused medicines

The Misuse of Drugs Act 1971 and the Misuse of Drugs Regulations of 2001 exist to limit the potential for misuse and abuse through control of both possession and supply. However, once medicines have been supplied to a patient to treat a medical need, the regulations no longer apply and there is considerable potential for them to be used inappropriately. A study of General Practitioners' (GPs) knowledge and understanding of the relevant regulations and their implementation in general practice found many were confused about the regulations that applied to them. Additionally, many were dissatisfied with the current controls, particularly the lack of control on the return and disposal of unused drugs⁶⁸.

Current regulations, while placing many restrictions on the general public, have a number of loopholes that enable unscrupulous health professionals to obtain medicines inappropriately, either for their own illicit use or to supply to others and while it is hoped that the vast majority of health professionals are trustworthy there is evidence that a small number are exploiting these loopholes. Between January 2001 and August 2004, the General Medical Council found 35 medical practitioners guilty of misconduct

involving inappropriate prescribing or use of drugs⁶⁹ and during the same period, the Statutory Committee of the RPSGB found eight pharmacists guilty of misconduct involving the inappropriate supply or use of controlled drugs⁷⁰. Moreover, the actions of former GP Harold Shipman have clearly highlighted the potential for a malicious health professional to cause considerable harm. Despite restrictions imposed on him, preventing him from holding controlled drugs, Shipman obtained legal supplies of diamorphine hydrochloride both through the writing of false prescriptions and also by collecting unused stocks from deceased patients. He then used these illicit supplies to murder his patients, with some estimates holding him responsible for the death of as many as 400 patients⁷¹.

There is also evidence to suggest that many prescription medicines and controlled drugs are likely to be used for non-medical purposes^{72,73}. The illicit markets for these prescription only medicines clearly demonstrate the demand for these drugs, with agents such as diazepam selling for £2-£5 per tablet and zopiclone for £1 per tablet⁷⁴. It is likely that one of the sources for these illicit markets is unused medicines that have been prescribed to patients and are sold by the patient or stolen.

1.5.2 The environmental impact of inappropriately discarded unused medicines

The environmental impact of unused medicines that have been poorly disposed of has been ignored until very recently and the European Medicines Evaluation Agency (EMA) are only now attempting to introduce requirements for new product licence applications to contain an environmental risk assessment for the agent^{75,76}. Additionally, in Europe, there is no limit placed on the quantities of pharmaceutically active compounds (PACs) – chemicals formed from medicines with a known pharmaceutical

activity – that may be present in drinking water⁷⁷ and there remains a paucity of data on both the presence and outcomes of PACs in drinking water and the environment as a whole.

In England and Wales, the disposal of unused medicines is regulated through The Hazardous Waste (England and Wales) Regulations 2005⁷⁸. However, unused medicines in the domestic environment are not controlled by these regulations except following their removal from the home, such as by a patient returning unused medicines via the Disposal Of Old Pharmaceuticals (DOOP) service. Therefore, patients are permitted to throw away medicines with household refuse which is destined for local landfill sites and there is evidence to suggest that considerable numbers do so^{49,50}. However, if medicines from more than one household are collected together, the regulations come into force and the controls apply on further transportation, storage, sorting and disposal.

There is growing evidence to suggest that medicines may leach in detectable quantities from landfill sites, with a New Jersey study by Turner and co-workers reporting the presence of PACs downstream of a landfill site⁷⁹ and another study that assessed water downstream of a landfill site in Grendsted, Denmark reporting PACs⁸⁰. There is also evidence to suggest that patients dispose of unused medicines in grey and black water^{49,50}. However, normal sewerage treatment processes are not intended to remove medicines and PACs and many pass through completely unchanged⁸¹ with a number of studies across the world detecting them in inland waterways downstream of sewerage treatment centres⁸²⁻⁸⁶.

Medicines are much more difficult to control than other pollutants as they are often resistant to usual biodegradation pathways and many have very long half-lives in the

environment, surviving for an as yet unknown amount of time⁸¹. Additionally, these agents have been produced with the specific intent of altering the physiological function of living organisms and are considerably more likely to have an effect on ecosystems, many of which are not currently known. Additionally, an increasing number of studies that have considered the potential effects of medicines and PACs on simple aquatic life have shown them to be deleterious to the organisms studied^{87,88}. The authors of such studies also suggest that both the co-exposure of multiple medicines and PACs and the long half lives of these agents will lead to more complex and pernicious affects that are difficult to predict^{81,89}. There is currently no published data on the effects that PACs have on larger animals or humans and data on their long-term effects are also limited. However, it is likely that they will have some influence, the scale and severity of which is not known.

1.5.3 The financial impact of unused medicines

Over £8 billion is spent by the NHS each year on medicines, representing over 10% of the total budget for this service.^{90,91} The amount of money spent has been rising at a rate above inflation for the past ten years and does not appear to be likely to slow down and it is essential that the money be spent in the most cost efficient manner to avoid future restrictions on treatments. However, medicines that are unused are the antithesis of cost effective use and previous estimates have placed the financial value of unused medicines at £90 million to £120 million per year across the UK^{3,48}. These estimates have been based on the financial value of medicines that are returned to pharmacies and are often based on data from small studies. If the medicines that are disposed of by other means are included, along with the costs of supply and the money spent running

disposal services, it is likely that the true cost of unused medicines would be considerably higher.

All pharmaceuticals, medicines and veterinary compounds are considered as hazardous waste under the Hazardous Waste (England and Wales) Regulations 2005⁷⁸ and strict requirements are laid down on their storage, sorting, collection and disposal. In light of the hazardous waste status of these medicines and the potential ecotoxicity, pharmacies in the UK have operated a scheme entitled DOOP for some years. This scheme involves accepting unused medicines returned to community pharmacies, including rendering controlled drugs as irretrievable, and the storage of these medicines in designated bins. Medicines are then collected quarterly by a licensed waste carrier and destroyed by high temperature incineration. The DOOP scheme now forms part of the essential services for pharmacy contractors in England and Wales and must be provided in order to receive a full practice payment. While pharmacies in Scotland still provide the service by local negotiation, with some providing the service in return for a payment from the primary care organisation, some providing it free of charge and others not providing the service at all. In addition to local payments and the practice payment made in recognition of this service, the cost of collection by licensed contractor is met by the NHS and currently costs around £1.5 million in England and Wales⁹².

Other indirect costs that may also be associated with unused medicines include those incurred through hospitalisation of patients following a therapeutic failure or accidental and intentional suicides and the costs of environmental clean up of unused medicines that have been disposed of poorly.

1.5.4 The risk of accidental poisoning with unused medicines

Many studies have demonstrated that unused medicines may accumulate in the home in significant quantity and one study in Birmingham in the 1970s highlighted the role of unused medicines in the accidental poisoning of children, reporting that over 600 children were admitted to Birmingham hospitals per annum following poisoning by medicines³⁹. Additionally, a review of childhood deaths in England and Wales from 1968 to 2000 has shown that accidental poisoning by medicines was responsible for 12% of all deaths⁹³ and poisonings by drugs, medicaments and biological substances was responsible for over 76,000 adults and children admitted to hospital in England in 2002⁹⁴. Clearly, the accumulation of medicines that are not providing any clinical benefit is of concern considering the large potential risk that these medicines may pose.

1.5.5 The risk of suicide by self poisoning with unused medicines

During 1997 to 1999, 15,299 deaths were recorded as suicide or open verdict in England and Wales and of these, 4162 (27%) were drug related⁹⁵. The *National Suicide Prevention Strategy for England* reports that self poisoning with medicines is responsible for over 1,300 deaths per year in England⁹⁶ and work by Hawton and co-workers has shown that self poisoning is the method chosen in over 90% of suicide attempts in adolescents⁹⁷. While all medicine in the home provides an opportunity for suicide through self poisoning, unused medicines are of particular concern as both large quantities may accumulate and may include a number of different agents³. Additionally, unused medicines, while posing a specific risk, are providing no clinical benefit and may remain in the home for a considerable period of time. Indeed, one patient in Koscian, Poland committed suicide with unused medicines he had stored in his home for over 20 years⁹⁸.

Almost all medicines may be fatal if taken in overdose, however the agents used in self-poisoning often involved a small number of drugs, possibly because of their reputation or because of known effectiveness. One drug that is commonly chosen for self poisoning is paracetamol with it being present in two thirds of attempted suicides in 1995⁹⁹ and estimates suggest that it is present in 32,000 attempted suicides per year in the UK¹⁰⁰. In light of the popularity of this drug for self poisoning, legislative changes were introduced in 1997 that restricted the quantities that may be sold to the public and following the change there was a corresponding decline in the use of this agent in suicide attempts^{97,101-103}. Another agent that is commonly implicated in self-poisonings is co-proxamol and Hawton and co-workers report it to be the sole drug involved in 5% of suicides and one of the drugs ingested in a further 13% of cases⁹⁵. Data from this study also suggest that self poisoning with co-proxamol is 28 times more likely to result in death than with paracetamol alone. Other popular agents for self poisoning include tri-cyclic antidepressants (TCAs) and selective serotonin reuptake inhibitors (SSRIs) and have been used more often since the legislative changes on paracetamol availability^{97,103}. These findings demonstrate the principal that access to an agent increases the likelihood of it being used in self poisoning and the *National Suicide Prevention Strategy for England* recognises this as an important factor in reducing suicides. It is suggested in the strategy that unused medicines should not be allowed to accumulate in patient's homes and that when prescribers change a prescribed antidepressant, the patient should be required to return their unused stocks of the previous agent prior to supply of the new one⁹⁶.

In addition to access to a method of suicide, the desire to end one's life is an important factor leading to self poisoning and a number of studies have demonstrated a greater likelihood for members of certain patient groups to attempt suicide. One such study,

performed in Finland, has shown a statistically significant increase in suicides among farmers with back pain when compared to farmers without back pain¹⁰⁴ while other work has highlighted the role of chronic back pain¹⁰⁵, pulmonary disease¹⁰⁶ and mood disorders¹⁰⁷ in increasing suicide risk. Since these patients would be likely to be prescribed analgesics with considerable potential to cause harm in overdose, it is important that stocks are not allowed to accumulate in the homes of these vulnerable groups.

It is clear from these data that both the availability of medicines in the home and certain disease states may lead to a patient choosing an attempt suicide by self poisoning. Therefore, the accumulation of unused medicines in the homes of patients with an increased risk of self harm is of concern and there is a need to minimise this risk in order to minimise the suicides by self poisoning.

1.6 The possible re-use of unused medicines that have previously been dispensed

The Code of Ethics for pharmacists published by the RPSGB states that “Medicines returned to a pharmacy from a patient's home, a nursing or residential home must not be supplied to any other patient”¹⁰⁸. Additionally, the British Medical Association (BMA) advise doctors “it is not advisable that medicines previously dispensed to another patient should be reused”¹⁰⁹ and the DH does not recommend the re-use of medicines¹¹⁰. Additionally, the World Health Organisation (WHO) document *Guidelines for Drug Donations* states that “No drugs should be donated that have been issued to patients and then returned to a pharmacy or elsewhere, or were given to health professionals as free

samples”¹¹¹. However, a number of organisations and individuals have suggested that medicines, which have been dispensed to patients and returned to a pharmacy unused, should be made available for re-use, either within this country or through charitable donations to less developed countries¹¹²⁻¹¹⁶. Many studies that have looked at unused medicines returned to pharmacies have reported the proportion of returned packs that were unopened and had not expired, with one study finding that over a third of medicine packs were returned unopened⁵⁶. While the advice of the health agencies may have been appropriate ten years ago when medicines were routinely decanted into tablet bottles and labelled by the pharmacy with the advent of patient packs with expiry dates, batch numbers and security seals, it is perhaps time to revisit this issue and assess potential for reuse of these medicines.

1.7 Summary

As can be seen from the literature reported above, unused medicines have been studied little in both the UK and worldwide. The limited data available indicate that it is a considerable problem in both developed and under developed countries and that it has a significant financial impact.

While the full effects of unused medicines are not entirely clear, the data reported above demonstrate their potential to cause harm and the financial impact that unused medicines may have. Clearly this area requires further study to further understanding of the nature and causes of unused medicines and develop the knowledge base required to appropriately tackle this problem.

CHAPTER 2 : Methodology

2.1 The study aim and objectives

The present study aims to expand the current knowledge of unused medicines in primary care in the NHS environment and consider potential solutions. This aim will be realised through the following objectives.

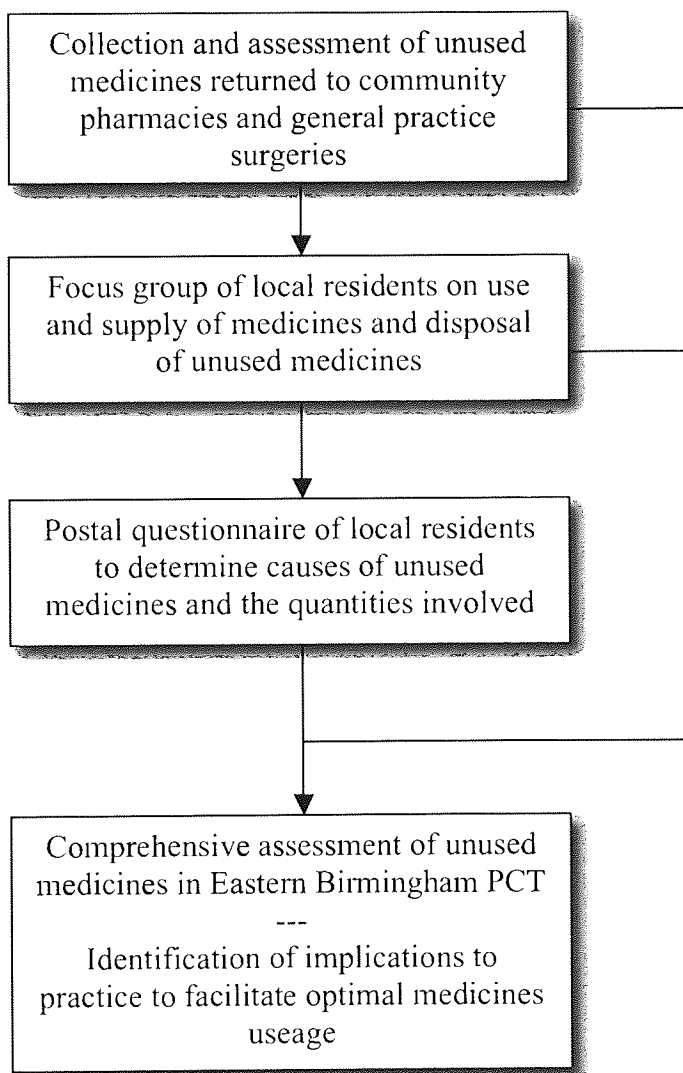
- To identify the types, quantities and financial value of unused medicines in primary care
 - Identify the therapeutic categories of medicines that are most often returned to community pharmacies and general practices
 - Measure the quantities and financial value of medicines that are returned to community pharmacies and general practices
- To determine the factors that influence the generation of unused medicines in primary care
- To identify the usual methods employed by patients for disposal of unused medicines in primary care
- To consider the possible ways in which the incidence of unused medicines in primary care may be reduced

2.2 The study design

Previous studies that have considered unused medicines in the UK have been performed in isolation and generally on small populations. The data from these studies are not easily cross correlated and therefore it has not been possible to assess the problem fully.

The present study attempts to build the most comprehensive data profile to date on unused medicines in primary care. To achieve this, three research methods have been utilised in a single population and the workflow of these is shown in Figure 2.1.

Figure 2.1: The study design



The first stage of the present study involves the assessment of unused medicines that are returned to both community pharmacies and general practice surgeries. This allows collection of base-line data for the medicines that are routinely returned to these sites. These data were then used to inform the themes covered in the second stage of data collection, a qualitative assessment of patient opinions and usual actions with regard to medicines use and unused medicines. The final stage of data collection used the qualitative data collected during the group interview to develop a postal questionnaire, enabling collection of quantitative data on the factors affecting medicines non-use and the activities of patients with respect to these medicines. In the present study, medicines non-use was defined as *the action of not using a medicine that had been supplied*. This differs from the definition for non-compliance in that it excludes situations where a medicine was used in a way that was different to that which was prescribed. Unused medicines were defined as *those medicines that were no longer being used for the purpose for which they were originally supplied*. The medicines that were identified were categorised into therapeutic classes using the chapter of the March 2002 British National Formulary (Edition 42) (BNF)¹¹⁷ in which the primary entry for that drug was listed. Therapeutic subcategories were also taken from location of the primary entry for that drug in the 42nd Edition of the BNF¹¹⁷.

The data collected from all three stages was then collated and used to develop a comprehensive picture of unused medicines in the PCT being studied. This data can then be employed to develop possible resolutions to the problem of unused medicines. Additionally, the large sample sizes allow some extrapolation of the data to the UK population to estimate the scale of unused medicines.

Data were collected in a single primary care trust owing to the complexity of performing a comprehensive study in multiple locations and the limited resources available. The PCT chosen was Eastern Birmingham since this incorporates a large population, diverse in both social and cultural backgrounds, with most ethnicities and age groups being well represented.

2.3 The population of Eastern Birmingham Primary Care Trust

At the start of the study, Eastern Birmingham Primary Care Trust (EBPCT) covered nine political wards; Sheldon, Acock's Green, Yardley, Shard End, Hodge Hill, Washwood Heath, Kingsbury, Erdington and Stockland Green. The PCT population was 208,608 and the demographic data for this population are shown in Table 2.1.

Table 2.1: Demographic data for the populations of the wards within EBPCT (to June 2004)^{118,119}

Ward	Population	Mean age (years)	Minority Ethnic Population (%)	IMD* Score	IMD* Rank
Acock's Green	26,281	37.0	4,963 (18.9)	39.22	1182
Erdington	23,875	38.1	3,342 (14)	34.80	1515
Hodge Hill	24,798	37.4	3,442 (13.9)	39.32	1173
Kingsbury	16,490	37.7	1,465 (8.9)	44.00	878
Shard End	23,147	38.7	1,820 (7.9)	56.36	354
Sheldon	20,138	40.5	1,195 (5.9)	28.21	2204
Stockland Green	23,041	36.3	5,706 (24.7)	43.77	895
Washwood Heath	27,841	31.8	15,863 (57)	64.11	186
Yardley	22,997	38.2	3,458 (15.1)	41.47	1024

* Index of Multiple Deprivation 2000

In June 2004, both the boundaries and wards served by EBPCT were revised and the area covered by EBPCT was moderately changed, increasing the population to 246,911.

The PCT now covers ten of the newly formed wards; Acock's Green, Bordesley Green, Erdington, Shard End, Sheldon, South Yardley, Stetchford and Yardley North, Stockland Green, Tyburn and Washwood Heath and the demographic data for the population of these wards is shown in Table 2.2. Indices for Multiple Deprivation and mean population age are not yet available for the new wards.

Table 2.2: Demographic data for the populations of the wards within Eastern Birmingham PCT (From June 2004)¹¹⁸

Ward	Population	Minority Ethnic Population (%)
Bordesley Green	31,343	22,275 (71.1)
Erdington	22,626	2,496 (11.0)
Hodge Hill	24116	5,023 (20.8)
Shard End	25,310	2,058 (8.1)
Sheldon	20,917	1,255 (6.0)
South Yardley	27,620	8,367 (30.3)
Stetchford and Yardley North	24,837	3,651 (14.7)
Stockland Green	20,799	5,139 (24.7)
Tyburn	22,284	3,211 (14.4)
Washwood Heath	27,059	19,811 (73.2)

2.4 Approval from the Local Research and Ethics Committee

Since the study included NHS patients, approval was required from the Local Research and Ethics Committee (LREC) prior to any work being undertaken as detailed in the *Governance arrangements for NHS Research Ethics Committees*¹²⁰.

An application was submitted in December 2002 and approved in principle in January 2003 meeting of the committee. However, concerns were raised regarding the patient information leaflets (PILs) and these were revised and re-submitted. The committee also requested copies of the patient questionnaire, however owing to the workflow for the project, the questionnaire could not be finalised until the first two stages were complete and an agreement was made that the questionnaire would be submitted for consideration

at a later date. Approval for the first two stages of the study was given in April 2003 and following submission of the final draft of the questionnaire, full approval was given in February 2005.

2.5 An analysis of medicines returned to community pharmacies and general practice surgeries

In this part of the study, unused medicines that were returned to community pharmacies and general practice surgeries were collected and assessed over eight weeks during May and June 2003.

In this element of the study, a return event was defined as *the return of medicines to a community pharmacy or general practice surgery by an individual* and included all the items returned at that time. One item was defined as *all the packs of the same medicine within a return event that had been dispensed for an individual patient on the same date and in the same pharmacy*. Therefore, it was possible for one return event to comprise medicines from more than one patient and medicines belonging to an individual patient might be identified in a number of different return events. A returner was defined as *the individual making a return event*.

2.5.1 Recruitment of community pharmacies and general practice surgeries

When this part of the study was performed, EBPCCT had 60 community pharmacies and 61 general practice surgeries serving the population and in order to record the most comprehensive data on unused medicines in the PCT, all of these community

pharmacies and general practice surgeries were invited to join the study. A list of the pharmacies and surgeries was obtained from a pharmaceutical advisor at the PCT and an introductory letter outlining the aims and basic structure of the project was sent in January 2002. Once approval from the LREC had been received, the pharmacies and surgeries were telephoned to arrange agreement for participation. In the case of pharmacies, agreement was reached with the manager, or where no manager was in post, the senior technician. General practice surgeries were contacted through the practice manager and the lead prescriber, and final agreement made with the practice manager. Each pharmacy or surgery that took part in the study was offered a fee of £100 in order to cover any costs incurred through participation in the study.

The study was not publicised in order that all returns were unsolicited and staff at the PCT were asked to ensure that no promotional materials advertising the DOOP scheme or encouraging return of medicines were issued during or prior to, the study. The staff of participating surgeries and pharmacies were also asked to continue with their normal practices regarding advertising medicines disposal services and local and national media were monitored during April, May and June 2003 to ensure that the usual actions of the PCT population were not influenced in any way.

2.5.1.1 Participating community pharmacies and general practice surgeries

From the 60 Community Pharmacies and 61 General Practices approached, 51 Community Pharmacies (85%) and 42 General Practices (70.5%) agreed to participate, representing 78% of the total sites. The list sizes and number of full time equivalent (FTE) general practitioners in each surgery are shown in Table 2.3 and the average

numbers of items dispensed per month in each participating pharmacy are shown in Table 2.4.

Table 2.3: Patient numbers and numbers of general practitioners for participating general practice surgeries

Research Site Reference	Number of GPs (FTE)	Number of patients	Patients per GP
GP/101	2	5000	2500
GP/102	1	N/A	N/A
GP/103	1	2500	2500
GP/104	1	3500	3500
GP/105	2	N/A	N/A
GP/106	1	1900	1900
GP/107	1	2370	2370
GP/109	1	N/A	N/A
GP/110	4	7400	1850
GP/111	6	11850	1975
GP/112	1	2000	2000
GP/113	1	2500	2500
GP/114	1	2700	2700
GP/116	1	3500	3500
GP/117	2	4000	2000
GP/118	1	2000	2000
GP/119	2	3900	1950
GP/120	4	5800	1450
GP/121	1	N/A	N/A
GP/122	1	2800	2800
GP/123	2	N/A	N/A
GP/124	2	4000	2000
GP/125	2	4100	2050
GP/126	1	N/A	N/A
GP/127	2	1500	750
GP/128	2	4000	2000
GP/129	2	4000	2000
GP/130	2	3500	1750
GP/131	2	4950	2475
GP/132	6	8300	1383
GP/133	1	1500	1500
GP/134	4	9800	2450
GP/135	1	3220	3220
GP/136	1	2300	2300
GP/137	2	2000	1000
GP/138	2	N/A	N/A
GP/139	2	N/A	N/A
GP/140	2	3100	1550
GP/142	1	2300	2300

Research Site Reference	Number of GPs (FTE)	Number of patients	Patients per GP
GP/143	4	7000	1750
GP/144	2	3800	1900

Table 2.4: Mean number of prescription items dispensed per month for participating pharmacies

Reference	Mean items per month	Reference	Mean items per month
PH/201	5000	PH/227	2500
PH/202	4000	PH/228	5700
PH/203	3000	PH/229	6500
PH/204	4000	PH/230	3500
PH/205	N/A	PH/231	3500
PH/206	2500	PH/232	3000
PH/207	6500	PH/233	5000
PH/208	4000	PH/234	6000
PH/209	4000	PH/235	5300
PH/210	4000	PH/236	N/A
PH/211	4500	PH/237	4000
PH/212	5000	PH/238	800
PH/213	2500	PH/239	11000
PH/214	1400	PH/240	N/A
PH/215	1600	PH/241	2400
PH/216	2000	PH/242	2500
PH/217	2500	PH/243	N/A
PH/218	3000	PH/244	6000
PH/219	9000	PH/245	4000
PH/220	5000	PH/246	3200
PH/221	2000	PH/247	8000
PH/222	4000	PH/248	6000
PH/223	4000	PH/249	5200
PH/224	6300	PH/250	3000
PH/225	5500	PH/251	N/A
PH/226	8100		

2.5.2 Risk assessments and standard operating procedures

An assessment was performed of the risks involved in collecting medicines in the pharmacies and surgeries and the risks involved in assessment of the medicines and risk assessment profiles were compiled (Appendix I). In order to minimise the identified risks, standard operating procedures were developed for receipt of unused medicines in

a pharmacy or surgery (Appendix II). Copies of the relevant risk assessments and standard operating procedures were supplied to the research sites prior to commencing the study.

2.5.3 Collection of unused medicines for analysis

Participating pharmacies and surgeries were instructed to place the medicines in each return event into an individual labelled bag, recording the required data on the label and then segregate from other medicines in the pharmacy by placing them in the supplied storage box. Where the medicines in a return event would not fit in a single bag, multiple bags were used and attached together, but only one label was used to identify the return event. The bags were Minigrip[®] polyethylene, 455mm by 330mm and the labels were self adhesive, 95mm by 130mm and printed as shown in Figure 2.2.

Figure 2.2: Example of pre-printed label used to identify each return and record the data collected at time of return

Date of return: ___ / ___ / _____		Return Code: GP/101/05
Why have the drugs been returned? (tick most relevant)		
<input type="checkbox"/> Patient died	<input type="checkbox"/> Clearout	
<input type="checkbox"/> Drugs out of date	<input type="checkbox"/> Supplied in Error	
<input type="checkbox"/> Adverse Drug Reaction	<input type="checkbox"/> Patient stopped drug	
<input type="checkbox"/> Prescriber changed / stopped drug		
Who is the person returning the drug? (tick most relevant)		
<input type="checkbox"/> Patient themselves	<input type="checkbox"/> Relative	
<input type="checkbox"/> Nurse / Carer	<input type="checkbox"/> Friend / Neighbour	
<input type="checkbox"/> Doctor		
Patient's GP _____		
Patient's Date of Birth ___ / ___ / ___	Patient's Postcode _____	
<input type="checkbox"/> Patient refused to answer questions		

These labels contained a unique identifier code and space to record the data to be obtained from the person returning the medicines. When the bags and labels were delivered to the pharmacies and surgeries, staff were appropriately instructed on the procedure for receiving medicines that were returned and the data required from the person making the return. The standard operating procedures outlining the process to be followed were also distributed (Appendix II).

All unused medicines that were returned to the participating sites between Tuesday 6th May 2003 and Friday 27th June 2003 inclusive were placed in labelled bags and stored for collection, a total of 51 days. Where drugs listed on schedules 2 and 3 of the Misuse of Drugs Act 1971 were returned, they were stored appropriately and collected by a registered pharmacist (AJM) within 48 hours in order to minimise storage problems. A form detailing the controlled drugs that had been collected was signed by the pharmacist making the collections and retained by the surgery or pharmacy for their records. Throughout the study, collected medicines were removed from the research sites periodically in order that they did not obstruct the normal working of the surgeries and pharmacies and all research materials and remaining medicines were removed at the end of the collection period. All the medicines were securely stored at Aston University during analysis and then removed by a licensed waste carrier for high temperature incineration.

2.5.4 The assessment of returned unused medicines

The information to be recorded for each returned medicine was determined based on the data collected during previous studies of this type^{2,3,45,47,53,55,121} and is shown in Table 2.5. This information was then used to assemble a list of fields and a database schema created. Two database programs were considered for the storage and analysis of the data

in this section, Statistical Packages for Social Scientists (SPSS) v11 for Windows and Microsoft Access 2002. Owing to the flexibility required in data storage and the opportunity to perform complex queries, MS Access was chosen and the database created.

Table 2.5: The data recorded for each unused medicine that was returned

Data obtained from	Data recorded
<i>Asked of the person returning the medicines</i>	<ul style="list-style-type: none"> • The date of birth of the patient • The date of the return event • The reason for the return event • The relationship to patient of the person making the return • The patient's registered general practitioner and their surgery • The postcode of the patient
<i>Determined from the returned medicine</i>	<ul style="list-style-type: none"> • The legal category or controlled drug schedule of the medicine • The recommended international non-proprietary name (rINN) of medicine • The brand name and manufacturer of the medicine • The therapeutic class and subcategory to which the medicine belonged • The strength of the medicine • The financial value of one dose unit • The dosage form of the medicine • The number of dose units that were returned • The type of packaging • The gross weight of the return

Data obtained from	Data recorded
<i>Identified from the dispensing label placed on the packaging</i>	<ul style="list-style-type: none"> • The pack size • The expiry date of the medicine • The initials of the patient • The sex of the patient • The number of dose units that had been supplied • The number of dose units to be taken per dose • The number of doses to be taken per day • Whether the medicine was labelled “as required” or “as directed” • The date and pharmacy where the medicine was dispensed

The financial value of returned items was calculated in the following way

$$\text{Value per dose unit} = \frac{\text{drug tariff price per pack}}{\text{number of dose units in each pack}}$$

$$\text{Financial value} = \text{value per dose unit} \times \text{number of dose units returned}$$

Where the product was not listed in the June 2003 Drug tariff, the price was taken from the June 2003 Chemist and Druggist price list. All financial values expressed in the results are exclusive of value added tax (VAT).

In order to facilitate comparison of the mean value of returned items with the mean value of those items dispensed in the PCT, an adjusted mean value was calculated for each therapeutic class according to the following formula.

$$\text{Adjusted mean value} = \frac{\text{mean item value}}{\text{mean proportion remaining in the pack}} \times 100$$

In addition to the data listed in Table 2.5, the returned items were also assessed by a pharmacist on their suitability for re-use according to the following criteria:

- The pack must be full and unopened
- For tablets and capsules, packaging must be blister
- For devices, an outer package with an intact security seal must be present
- The pack must not be defaced or damaged
- The expiry date and batch number must be printed on the package
- The drug must not require storage in a fridge or freezer

The schema was used to develop a relational database, which was constructed using both SQL programming code and the MS Access graphical user interface. Once the basic structure of the database was in place, sample data were used to pilot the database and test the queries and any problems identified were resolved at this stage. A graphical user interface was then constructed using a series of forms and a control panel to facilitate data entry and simple analysis and a screenshot of one of the forms is shown in Figure 2.3. This form has a space to enter the data linked to each item and enables the user to move to the relevant form should a new entry be required in another table, such as for a new patient or drug. Other data such as the dosage form and strength of a drug and the address of the dispensing pharmacy are also shown to enable the user to validate these data against that being entered. Additionally, some simple calculated data is also shown on this screen such as the age of the patient at the time of the return and the number of days of treatment that was returned. To ensure confidentiality of any data that may be used to identify an individual, the database was protected with a password prior to any data being entered.

Statistical analyses were performed using Microsoft Excel 2002 and Minitab v.14. Statistical significance among nominal data sets was tested using the chi square test (χ^2) and Kendall's tau (τ) was used to assess the significance of linear relationships between variables. Additionally, a goodness of fit chi square test was used to determine the statistical significance of the difference in the prescribing and return of medicines from each therapeutic class in section 3.3.4.1. All averages presented are the arithmetic mean and are shown \pm the standard error of the mean (SEM). Maps showing the geographical distribution of returned items were produced by use of Microsoft MapPoint and are copyright Microsoft Corporation.

Figure 2.3: A screenshot of the returned items form showing the data entry fields and calculated data*

Returned Items

Return Code:

Date of Return:

Reason for return:

Relationship of returner to patient:

Weight of Return:

Patient Number:

Age: Add Patient

Number of dose units supplied:

Days Treatment Supplied:

Number of dose units returned:

Days Treatment Returned:

Number of dose units used per dose:

Number of Doses per day:

Labelled: PRN MDU

Date Medicine was dispensed:

Record Number:

Pharmacy medication was dispensed from:

address:

Postcode:

Telephone Number:

Notes:

Add Pharmacy

Drug Identifier:

rTN Approved Name:

Proprietary Name:

Therapeutic Group:

Strength:

Value of 1 Dose Unit:

Dose Unit:

Manufacturer:

Dosage Form:

Legal Class:

Type of packaging: Add new drug

Number of Packs: Add new packaging type

Could Pack be Reused?

Find Record

Item Number	Pack Size	Doses Remaining	Expiry Date
1	8	8	30/06/2003
*	0	0	

Record: of 1

Value of Item Supplied:

Value of Item Returned:

Next

* Name and address of dispensing pharmacy removed to protect patient confidentiality

2.6 A group interview considering patient opinion and action regarding unused medicines

The previous section of the study collected gathered data that detailed the nature and types of unused medicines returned to pharmacies and GP surgeries within EBPCT and the reasons for these medicines being returned. These data, along with data from previous studies, were used to develop themes of discussion for use in a group interview to qualitatively explore the factors that may potentially lead to unused medicines.

2.6.1 The themes discussed in the group interview

All aspects of medicines use and supply were covered, along with the usual behaviour of patients with regard to unused medicines in order that all the potential factors that may cause unused medicines, along with their final fate, were discussed. Appropriate themes were identified for discussion and each theme was introduced by the facilitator with a brief statement. Participants were then asked a question to initiate the discussion and prompt questions were used if required to guide the group back to the relevant subject, or to re-initiate a discussion. The themes covered and the orientation statements and initiating questions are discussed below in sections 2.6.1.1 to 2.6.1.5.

2.6.1.1 The reasons why people have unused medicines

A number of previous studies have considered the reasons why patients have returned their medicines to community pharmacies.^{2,47,53,121} However, the data gathered in these studies focus on the reasons given for return of medicines and are not necessarily a true reflection of the reasons for the generation of unused medicines. In this theme, the reasons why people may have unused medicines in their homes are discussed, with

questioning being phrased to be non-threatening, allowing patients to talk about their friends and acquaintances as well as themselves.

The theme was introduced by the facilitator with the statement, “*When people are prescribed medicines, they sometimes don’t take all of the supply that they are given*”. Participants were then asked, “*Why do you think some people have unused medicines*” to initiate the discussion.

2.6.1.2 The ways in which patients dispose of unused medicines

Patients may dispose of medicines in a number of different ways, aside from returning them to community pharmacies. However, previous studies where patients have been surveyed on their usual method of disposal of unused medicines⁴⁸⁻⁵⁰ have only included return to pharmacies, disposal in household refuse and disposal in grey or black water systems. This theme explores the potential methods that may be employed for disposal of unused medicines to ensure that the majority of the possible fates of unused medicines are explored. The theme also covers factors that may influence the disposal method used by patients and the DOOP scheme.

As this theme involves a number of issues, each was introduced to the group by a number of orientation statements and questions and these are shown in Table 2.6.

Table 2.6: Orientation questions and initiating questions for discussion on disposal of medicines

Orientation statement	Initiating questions
	<ul style="list-style-type: none">• When people have unused medicines, what do you think that they do with them?

Orientation statement	Initiating questions
<i>Some of these people throw their old medicines down the toilet, or put them in their bin</i>	<ul style="list-style-type: none"> • What do you think about this? • Do you think this is a sensible way of getting rid of medicines?
<i>Experts have found small amounts of medicines in drinking water in this country. This can happen because medicines that have been flushed down the toilet are not always removed from the water by sewerage treatment processes and medicines leak out of rubbish tips and get into rivers that way</i>	<ul style="list-style-type: none"> • How do you feel about medicines being found in drinking water?
<i>Most of the pharmacies (chemists) in this area run a scheme where you can take your medicines to them and they will send them off for safe disposal. It is sometimes called the 'DOOP scheme' or the 'Green Bin'</i>	<ul style="list-style-type: none"> • Has anyone heard about this scheme before? • Does anyone use the scheme already?

2.6.1.3 The financial costs of unused medicines

The financial cost to the patient in obtaining medicines has been shown to affect the way in which they use their medicine⁶⁶ and anecdotal evidence suggests that perceived financial worth of a medicine might alter the way in which it is treated by a patient. This theme covers the financial value of unused medicines and explores the reaction of patients. The orientation statement for this theme was, *“Unused medicines cost the NHS millions of pounds every year. If there were no waste medicines in this area, we could have an extra 60 district nurses in this area, or another GP surgery”* and the initiating question was, *“Do you think medicines waste is an important problem?”*

2.6.1.4 Obtaining medicines on repeat prescription

Anecdotal evidence suggests that the way in which patients obtain their medicines may influence their use of medicines and therefore might be a contributory factor leading to unused medicines. In this theme, the ways in which patients ordered their medicines

were covered and their experiences of these systems were explored. The orientation statement and initiating questions used are shown in Table 2.7.

Table 2.7: Orientation statement and initiation questions for the discussion of obtaining medicines on repeat prescription

Orientation statement	Initiating questions
<i>Some people get their medicines on repeat prescription, where they have to put a slip in at the doctors to order the next supply of their medicines</i>	<ul style="list-style-type: none"> • Do you find the repeat prescription order system easy to use? • Do you know how to order just the items that have run out? • Do all your repeat medicines run out at the same time? • How much do you get at a time? (How many weeks supply) • Do you think this is enough/too little/too much to get at any one time?

2.6.1.5 The information supplied with prescribed medicines

There is a large amount of information that may be supplied with a prescribed medicine, ranging from details that are specific to the patient such as why they are taking it or what dose and frequency to take to more general information such as possible adverse drug reactions and any cautions to be taken while using the medicine. This information might be relayed to the patient verbally by the doctor or pharmacist, or may be written on the packaging, dispensing label or patient information leaflet. The influence that this information has on the use of medicines is not clear and anecdotal evidence suggests that some patients may be concerned by some information provided, leading to unused medicines. The orientation statement used to introduce this theme and the initiating questions are shown in Table 2.8.

Table 2.8: Orientation statement and initiation questions for the discussion on information supplied with prescribed medicines

Orientation statement	Initiating questions
<i>When you are given a prescription by the doctor and collect your medicines from the pharmacist you may be given information about the medicines</i>	<ul style="list-style-type: none"> • Do you think that Doctors and pharmacists give people enough information about their medicines regarding: <ul style="list-style-type: none"> ○ Side effects ○ How the medicines work ○ What the medicines are for ○ How to take the medicines

2.6.2 The structure and setting of the group interview

Owing to the broad nature of the interview themes, it is likely that any discussion on these themes will not be of great depth. In order to ensure diversity of opinion within the interview responses and to allow a suitable level of discussion, a moderate sized group of 6 to 8 participants and a discussion time of 45 to 60 minutes was planned.

Since the themes often refer to issues of non-compliance, it is likely that patients would feel restricted in discussing these issues in a surgery environment. Patients may also feel uneasy in discussing the issues in any other institutional setting such as a University building and in order to encourage open discussion and the interview was therefore performed in a community social centre.

The group interview was facilitated by the author (AJM) and the proceedings recorded using a Sony multidirectional microphone and minidisk recorder device. Notes were also taken by the facilitator to assist in transcription.

2.6.3 The recruitment of patients to the group interview

All patients that had used medicines in the previous twelve months through services provided by EBPCT were included in the recruitment process with the exception of children under 18 years of age since this age group are less likely to manage their own healthcare. A number of methods were used to recruit people for interview and a summary of these is shown in Figure 2.4.

Eastern Birmingham Primary Care Trust is responsible for providing healthcare to a diverse population (Table 2.1) and three areas of diverse demography were identified for recruitment of participants, in order to maximise the diversity of opinion. These were Castle Vale and Shard End (predominantly white, high deprivation), Acocks Green and Yardley (predominantly white with some minority ethnicities, low deprivation) and Washwood Heath (mixed ethnicity, high deprivation).

In the study design submitted to the LREC, interview participants were to be recruited from established patient participation groups within general practice surgeries. These groups should be set up by each surgery to allow patients to voice opinions on the services offered and the recruitment of members of these groups would ensure that participants already had a rapport with each other and were familiar with the format of group discussions. This would facilitate a greater depth of discussion and enable the participants to be more open about the ideas and opinions. However, at the time of recruitment, there were no patient participation groups operating in the PCT and it was not possible to use this method of recruitment. Since the interviews would only incorporate a small number of participants, it was important to ensure that they were recent or regular medicines users and a general mailing of the local population may have resulted in participants that were not suitable. Therefore, recruitment was directed

at patient groups already established within the local population, and the EBPCT Neighbourhood Health Improvement Officer was asked to distribute flyers (Appendix III) advertising the need for group participants at local meetings.

Owing to the poor response to distribution of flyers, a short talk about the study and the relevance of the findings to the local population was given at a meeting for establishing a local health improvement panel and flyers were distributed to the attendees. The meeting was convened by the PCT in order to establish a Health Improvement Panel and was attended by local community leaders and health workers in addition to local patients. The health workers and community leaders were asked to pass on flyers to local patients and the patients attending the group were recruited directly. A number of people attending the group commented that they felt all patients would take all their medicines, perhaps indicating that patients do not perceive the issue of unused medicines to be worthy of study. In response to this meeting, two patients expressed an interest in being interviewed, however, this was considered an insufficient number for a group interview and no other members could be recruited. Therefore, these patients were not interviewed for the present study.

The Castle Vale Tenants and Residents Alliance, an organisation of local residents and community leaders, were contacted and they agreed to mail a copy of the flyer to all of their members and display the flyers in local community centers. The flyers were mailed to members on two separate occasions and posters displayed for two months. No response was received from members of this organisation. Despite a second mailing of flyers, no responses were received.

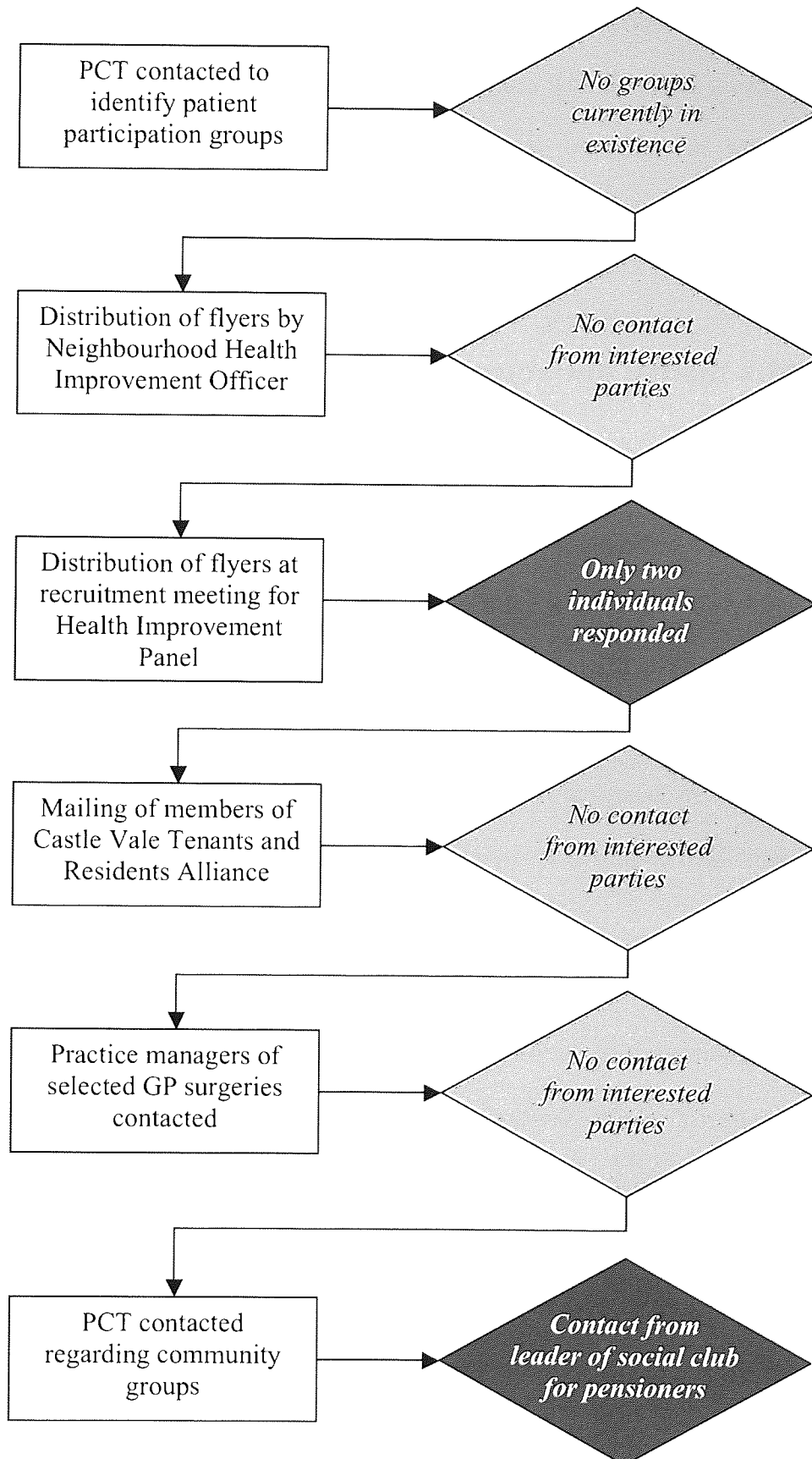
The medicines management group at the PCT were contacted and asked to provide details of surgeries where groups might be recruited. The Head of medicines

management provided contact details for the practice managers of six surgeries with close affiliation with the group and these were contacted by letter and telephone. Two of the practice managers agreed to assist in recruitment and posters were displayed in the surgery waiting areas and flyers placed on the surgery reception desk for a period of two months. No responses were received.

Staff at the PCT were again contacted regarding local community groups and contact was made with the leader of a social club provided for pensioners. The club was attended on an agreed date and seven participants for the group interview were recruited from those attending the meeting who were identified as having used medicines in the previous twelve months. This sample was biased towards older patients, with all participants being aged over 50 years.

Owing to the very poor response to all the recruitment methods utilised, only one interview took place. Further attempts to recruit patients were considered to be inappropriate, since the likely data gained would not justify the input required to any further recruitment.

Figure 2.4: The methods used to recruit participants for the group interview



2.6.4 The analysis of data from the group interview

The responses given during the interview were transcribed verbatim by the facilitator, using the recording of the group in conjunction with the notes taken. The transcript was then visually assessed and recurrent themes identified in MS Word. Illustrative comments were selected for each theme and collated into a report of the interview.

2.7 A postal questionnaire considering patient attitudes and actions regarding medicines

In this section, the data collected during the group interview and those from the unused medicines collected in the first part of the study were used to develop a questionnaire to be administered to residents of the primary care trust. The questionnaire was mailed to recipients for self completion and contained 27 questions, most of which were closed. The questions included in this section were designed in order to complete the comprehensive data required for a full assessment of unused medicines in the PCT.

2.7.1 The structure of the questionnaire

The questionnaire was constructed with mostly closed questions, which required the respondent to tick a box to indicate their answer. Where a respondent may have an answer that was not included in the list, an *other* option was included, along with space for the respondent to specify their answer. An example of one of the questions is shown in Figure 2.5. The questions were structured in this way in order to maximise the rate of response, through ensuring the minimum time was required by the respondents in

completing the questionnaire, while not restricting their answers. A copy of the full questionnaire is shown in Appendix IV.

Figure 2.5: An example of the composition of a question in the postal questionnaire

13. *If the doctor didn't give you a prescription, what would you usually do? (Tick one)*
- Accept his/her advice and do as they ask
 - Ask for a prescription for the medicine you think is best
 - Go to the chemists and buy something
 - Other _____ (please write here)
 - Never happened

The questionnaire structure was piloted in a group of ten postgraduate students and the time taken for completion recorded. The pilot found that some of the questions may not apply to all respondents and statements were included in the final questionnaire that directed respondents past questions which would not apply to them.

The questions were divided into six discrete sections to orientate the respondent and improve the clarity of the document; the areas covered are as follows.

2.7.1.1 Section 1: Your medicines

The questions in this section are concerned with the use of medicines by respondents and any repeat medication they may be prescribed and the questions asked are shown in Table 2.9. Questions cover the recent use of prescribed or purchased medicines, where medicines are usually stored and the ordering and use of repeat medicines.

Table 2.9: The questions asked in section 1 of the postal questionnaire

-
- Have you used any medicines in the last 12 months? Including inhalers, ointments, creams and liquids
 - Where do you normally keep your medicines at home?
-

-
- Are any of your medicines on repeat prescription?
 - Do you find the repeat medicines order system at your doctor's surgery easy to use?
 - When you order your medicines do you order all the items available?
 - How do order your repeat medicines at the moment?
 - How would you like to order your repeat medicines?
 - How many months of treatment would you like to get at a time when you get your repeat medicines?
-

2.7.1.2 Section 2: Old medicines

The section on old medicines covers any unused medicines that respondents may have recently disposed of or currently have in their home. The questions asked are shown in Table 2.10 and are concerned with whether the respondent recently had unused medicines in their home, what these had been originally supplied for and the usual method used for disposal of unused medicines. The questions also ask about the respondent's knowledge of the DOOP scheme and the leaching of medicines from landfill or their passage through sewerage systems. A final question in this section asks about the organisation that respondents think should be responsible for resolving the issues surrounding unused medicines. This question was included following the poor response to recruitment for the group interviews in order to determine whether respondents perceived unused medicines as a significant problem.

Table 2.10: The questions asked in section 2 of the postal questionnaire

-
- Have you got any medicines at home that are not being used or have you disposed of any medicines in the last 6 months?
 - Why were these medicines leftover?
 - What were these medicines being taken for?
-

-
- What do you normally do with old medicines?

A brief description of the DOOP scheme was included

- Have you ever heard about this scheme?
 - If you have not used this scheme before, do you think that you will use it now you know about it?
 - Did you know that Medicines which are put down the toilet are not completely cleaned from the water by the normal sewage treatment process?
 - Did you know that Medicines which are thrown away with normal rubbish can leak out of the rubbish tip and end up in rivers and streams damaging the environment and sometimes getting into drinking water?
 - Do you think that the government should ban people from putting medicines in their toilet or normal rubbish and make them take medicines to their pharmacy?
 - Do you think more should be done to make people aware of the problems caused by getting rid of medicines in the toilet or bin?
 - Who do you think should sort out the problem of medicines waste as a whole?
-

2.7.1.3 Section 3: You and your doctor

In this section, the relationship that the respondent has with their doctor and their interaction with information is examined. Questions were asked about the expectations of the respondent on attending a consultation with their GP and their usual response to not getting a prescription or getting a prescription that they did not want. Questions also covered the information provided with medicines, both verbally by the doctor and pharmacist and in written form. The questions asked are shown in Table 2.11.

Table 2.11: The questions asked in section 3 of the postal questionnaire

-
- When you go to see the doctor, do you expect to get a prescription?
 - If the doctor didn't give you a prescription, what would you usually do?
 - If the doctor prescribed a medicine that you don't want to take, what would you usually do?
-

-
- Do you usually read all the written information given with a new medicine before taking it?
 - Do you think the information provided with your medicines is too much, not enough or just right on:
 - Side effects?
 - Why you are taking the medicine?
 - How to take the medicine?
 - How the medicine works?
 - Where would you like information about your medicines to be available; on their side effects, why you are taking them, how they works and how you need to take them?
 - Is there any other information you would like about your medicines?
-

2.7.1.4 Section 4: Medication reviews

The influence of medication review on unused medicines has not previously been examined in depth and this section covers the medication reviews that respondents have received, along with the health professionals they would like to perform such reviews and where they would like them performed. The questions asked in this section are shown in Table 2.12.

Table 2.12: The questions asked in section 4 of the postal questionnaire

-
- When did you last have a Medication Review?
 - How often would you like to have a medication review?
 - Who would you like to do this medication review?
 - Where would you like to have this review?
-

2.7.1.5 Section 5: The cost of medicines

The influence of the financial cost of medicines, both to the patient and to the NHS, is examined in this section, with questions covering the respondent's perception of the cost of each NHS item, exemption status and opinion of prescription charging. The questions asked in this section are shown in Table 2.13.

Table 2.13: The questions asked in section 5 of the postal questionnaire

-
- *How much do you think the NHS pay for an item on average?*
 - *Do you pay for your NHS prescriptions?*
 - *How much do you think that people should pay for NHS prescriptions?*
-

2.7.1.6 Section 6: About you

A final section comprised questions on the age group, educational achievements, ethnicity, sex and household income bracket of the respondent. These data were used to identify any influence of these demographic factors have on unused medicines.

2.7.2 The selection of questionnaire recipients

In the project summary submitted to the LREC, the recipients of the postal questionnaire were to be drawn from the list of registered patients at a selection of general practice surgeries. However, owing to the local implementation of the *Data Protection Act*¹²², access to these data were restricted. Therefore, the Edited Electoral Register (EER) was used as the basis for selecting recipients. All persons listed on the EER were included in the selection process, with the exception of those that were under 18 years of age on 1st Jan 2005, ensuring that the questionnaire recipients would be

likely to represent the local population. The EER was obtained for all ten wards covered by the PCT, and was supplied in the form of a MS Word document containing a list of names with corresponding addresses. All the names on the EER were transferred to a MS Excel spreadsheet in the same order as they appeared in the original register and names were then assigned a unique number in ascending order. A random number generator was used to select 100 numbers from the total numbers for each ward and these 100 names were then identified as the recipients. Random numbers were generated using a computer program, which uses a radio receiver collecting background radiation to generate a selection of numbers from a given range¹²³. The use of a radio receiver eliminates the bias that is present in all other computer based random number generators and the randomness of this generator has been statistically validated by a number of sources¹²³. The random selection of the recipients in this manner minimises the bias in selection and maximises the representativeness of the PCT population.

2.7.3 Data Analysis

A database schema was developed from the questionnaire schema and this was used to develop a relational database, constructed using SQL code in Microsoft Access 2002. Sample data, gained through the piloting of the questionnaire, were then entered into the database to ensure that the structure was appropriate. A graphical user interface was then developed to facilitate data entry and allow easy assessment of responses, and example of one of the forms used is shown in Figure 2.6.

Analysis of compiled data was performed using Microsoft Excel 2002 and where statistical significance among nominal data sets was tested, the chi square test (χ^2) was applied by use of Minitab v.14. Significance was considered demonstrated where returned p values were less than 0.05. All averages presented are the arithmetic mean

and are shown \pm the standard error of the mean (SEM). *Unused medicines odds ratios* were used to determine the influence of various factors on the likelihood of a respondent having unused medicines in the home or having recently disposed of some and this was calculated by the following equation.

$$\text{Unused medicines odds ratio} = \frac{\text{The number of respondents with current or recently disposed of unused medicines}}{\text{The number of respondents with no unused medicines in the previous six months}}$$

In assessing the questionnaire, a recipient with *recent unused medicines* was defined as one that had unused medicines in their home at the time of completing the questionnaire, or had disposed of some in the previous 6 months.

Maps showing the geographical distribution of questionnaire recipients and responses were produced by use of Microsoft MapPoint and are copyright Microsoft Corporation.

Figure 2.6: A screenshot of the graphical user interface for the database recording questionnaire data*

* Postcode removed to protect patient confidentiality

CHAPTER 3 : An analysis of medicines returned to community pharmacies and general practice surgeries

3.1 Introduction

The analysis of unused medicines returned to community pharmacies as a method for the determination of the quantities and nature of unused medicines in the community has been used in many previous studies^{2,45,55,60,121}. However as suggested by patient surveys^{49,50} and confirmed by Daniszewski⁴⁷, patients commonly dispose of unused medicines by means other than simply returning them to community pharmacies.

The present study represents the largest assessment of returned medicines in primary care, incorporating both general practice surgeries and community pharmacies. Owing to this large scale, the study was conducted over two months during late spring and early summer. Consequently, it is possible that there may be some seasonal variation in the usual activities of patients that is not identified by the data collected. Additionally, as the study did not include any intervention to increase the return of medicines to any sites and all returns were unsolicited, the data collected are likely to represent the usual activities of the local population

3.2 Results

A total of 934 return events were made during the eight weeks of the study and of these, 911 contained items that could be included in the study. These 911 return events comprised 3765 individual items that contained 4934 full or part used packs. The total

financial value of the returned items was £33,608.43 excluding VAT. Table 3.1 shows the numbers and proportions of return events made to community pharmacies and general practice surgeries with the number and proportion of items and packs that they comprised.

Table 3.1: The number and proportions of return events made and items and packs collected in community pharmacies and general practice surgeries

	GP surgeries	Pharmacies
Number of return events	190 (20.3%)	744 (79.7%)
Number of items	431 (11.4%)	3,334 (88.6%)
Value of items	£3,432.63 (10.2%)	£30,175.80 (89.8%)

3.2.1 The pharmacies and surgeries where collections were made

The unused medicines that were assessed in the present study were collected from 51 (85%) of the total pharmacies and 42 (70.5%) of the total surgeries within Eastern Birmingham Primary Care Trust. The geographic distribution of the participating pharmacies and surgeries and those that declined to take part is shown in Figure 3.1 and details of list sizes for surgeries and prescription items dispensed per month for pharmacies are shown in Table 2.3 and Table 2.4.

Figure 3.1: A map showing the geographical distribution of the participating and non-participating community pharmacies and general practice surgeries in Eastern Birmingham Primary Care Trust (community pharmacies = 60 and GP surgeries = 61)



The senior staff contacted at the pharmacies and surgeries that declined to participate in the study gave the reasons shown in Table 3.2.

Table 3.2: The reasons given by practice managers and pharmacy managers or senior technicians for not participating in the study

Reason given for non-participation	Number of sites giving reason
Lack of time	5
No manager	3
Not interested	2
The staff refuse to take part	1
No response	17

3.2.2 The nature of the return events made

A total of 934 return events were made during the present study. Based on population data,¹¹⁸ this suggests that over 2 million return events are made in the UK each year. These comprised an average number of items of 4.13 ± 0.19 (range 1 to 52 items) and the mean weight of the items in each return event was $0.31 \text{ kg} \pm 0.02$ (range 0.005 to 9.6 kg).

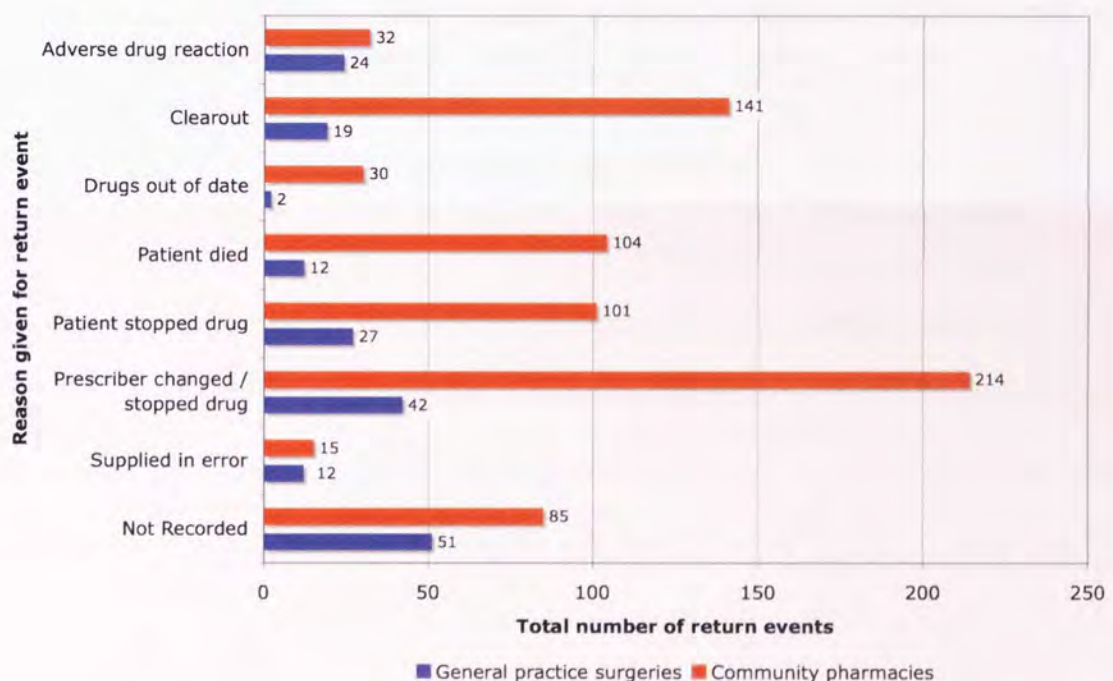
3.2.2.1 The reasons given for the return of unused medicines

A change in the prescribed therapy was the most commonly cited reason for a return event being made to either a surgery or a pharmacy and was responsible for 258 (27.6%) of the return events. A cessation of therapy instigated by the patient was responsible for 131 (14.0%) and return events and clearout of old or expired drugs for a further 203 (21.2%) return events (Figure 3.2).

Those return events made to general practice surgeries were most likely to be as a result of a change made by the prescriber (42 return events (21.1%)). Patients stopping their medication and adverse drug reactions were responsible for a further 27 (14.2%) and 24

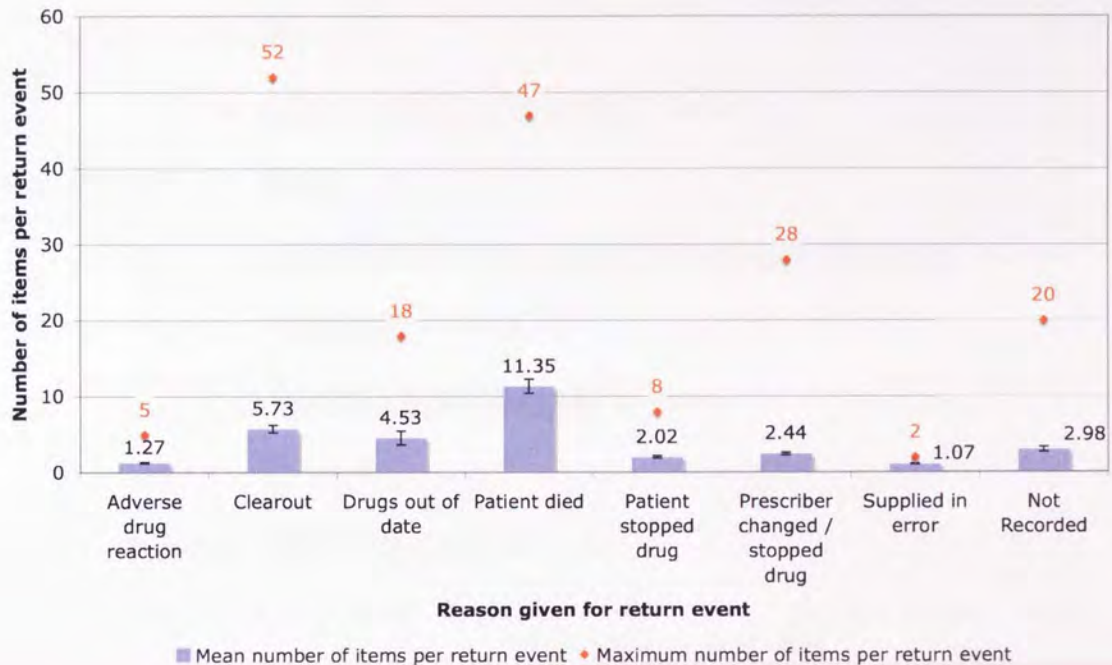
(12.6%) return events respectively. Changes in the prescribed therapy was also the most common reason for return events made to pharmacies, with 216 (29%) events being made for this reason. Clearout of old and expired medicines were responsible for a further 182 (24.4%) return events in pharmacies (Figure 3.2). There was a significant difference in the reasons given for return events between general practice surgeries and community pharmacies (χ^2 , $P < 0.001$).

Figure 3.2: A frequency distribution of the total number of return events made to pharmacies and surgeries for each reason given for the return of medicines (total number of return events = 911)



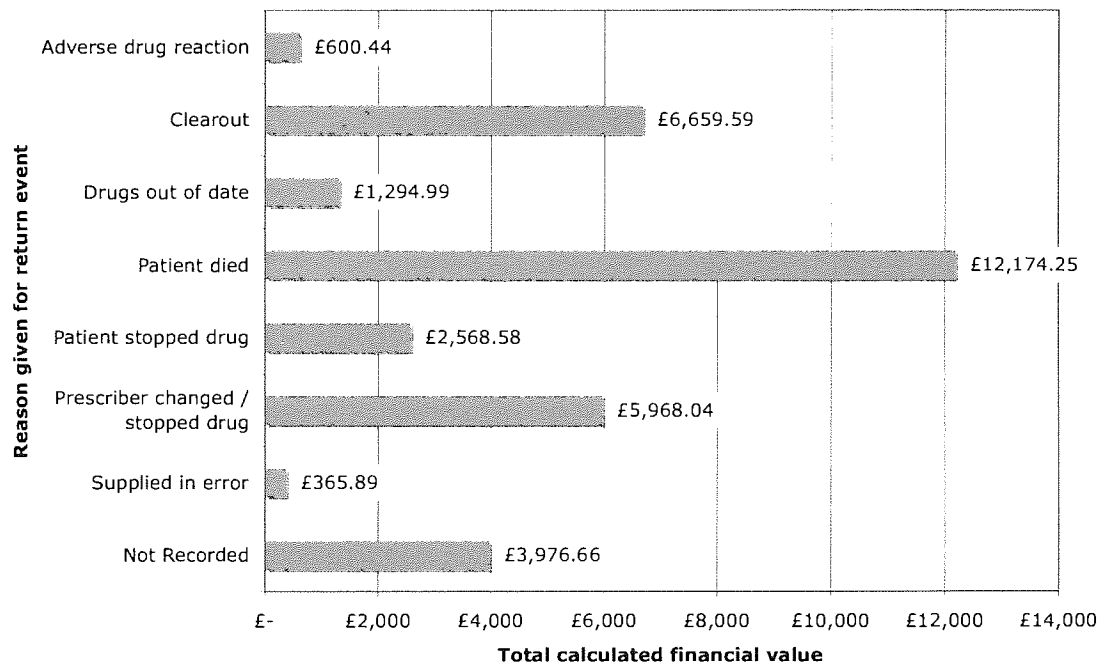
The number of items in each return event differed according to the reason cited for the event and Figure 3.3 shows this variation. One return event contained 52 items and related to a household clearout while each return event following a patient death contained a mean of 11 items \pm 0.90. Return events as a result of an error in supply or adverse drug reaction had means of 1.07 \pm 0.05 and 1.27 \pm 0.09 items respectively.

Figure 3.3: A column chart showing the mean \pm SEM and maximum number of items in each return event shown for each reason given for the return of medicines (total number of return events with recorded items = 911)



In contrast to the number of return events, the majority of the financial value of returned items was as a result of a patient death, accounting for £12,174.25 (36.2%) of the total. Clearout of old or expired medicines also resulted in the return of medicines with considerable financial value, accounting for a further £7954.58 (23.7%) (Figure 3.4).

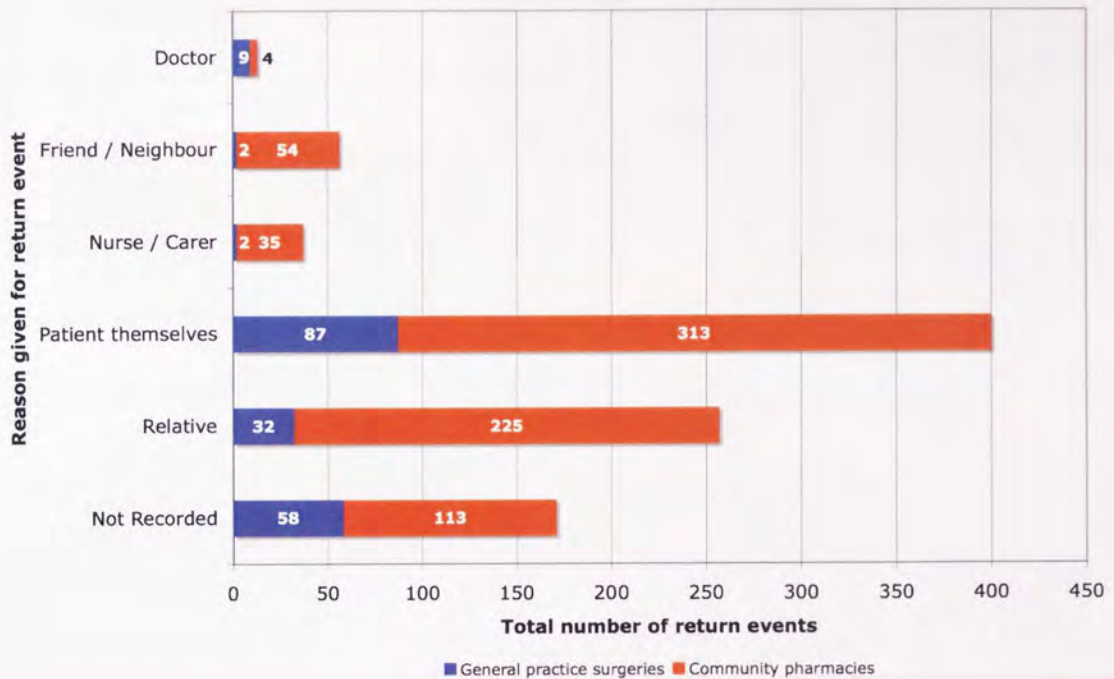
Figure 3.4: A frequency distribution of the total financial value of the returned items for each reason given for the return of medicines (return events with items included in the study = 911)



3.2.2.2 The individuals making the return events

The return events recorded in the present study involved the patient themselves in 400 cases (42.8%) and the patients' relatives were responsible for a further 257 (27.5%) returns on the patient's behalf (Figure 3.5). Healthcare professionals (doctors or nurses/carers) made just 50 (5.3%) return events. There was a significant difference amongst the different types of individuals returning unused medicines and the choice of a pharmacy or surgery as the site for that return (χ^2 , $P < 0.001$).

Figure 3.5: A frequency distribution of the total number of return events made by each type of relationship of the patient to the individual making the return (number of return events = 934)



3.2.2.3 The geographical distribution of the return events made

All of the return events made in the present study were received from patients living within Eastern Birmingham PCT or the surrounding area. Figure 3.6 shows the mean number of return events per household, shown by the postcode sector of the patient's home and shows an approximately equal rate of return per household for each sector within the PCT and a reduction in this rate in the postcode sectors located further from the PCT.

Figure 3.6: A map showing the mean number of return events made per household shown by the residential postcode sector of the patient (number of return events = 580)



Seven collection sites did not receive any return events during the course of the study and the remaining return events were distributed across the remaining collection sites, with no area of the PCT having a substantially greater number of return events (Figure 3.7).

Figure 3.7: A map showing the mean number of return events made per collection site for each postcode sector (number of collection sites = 86)

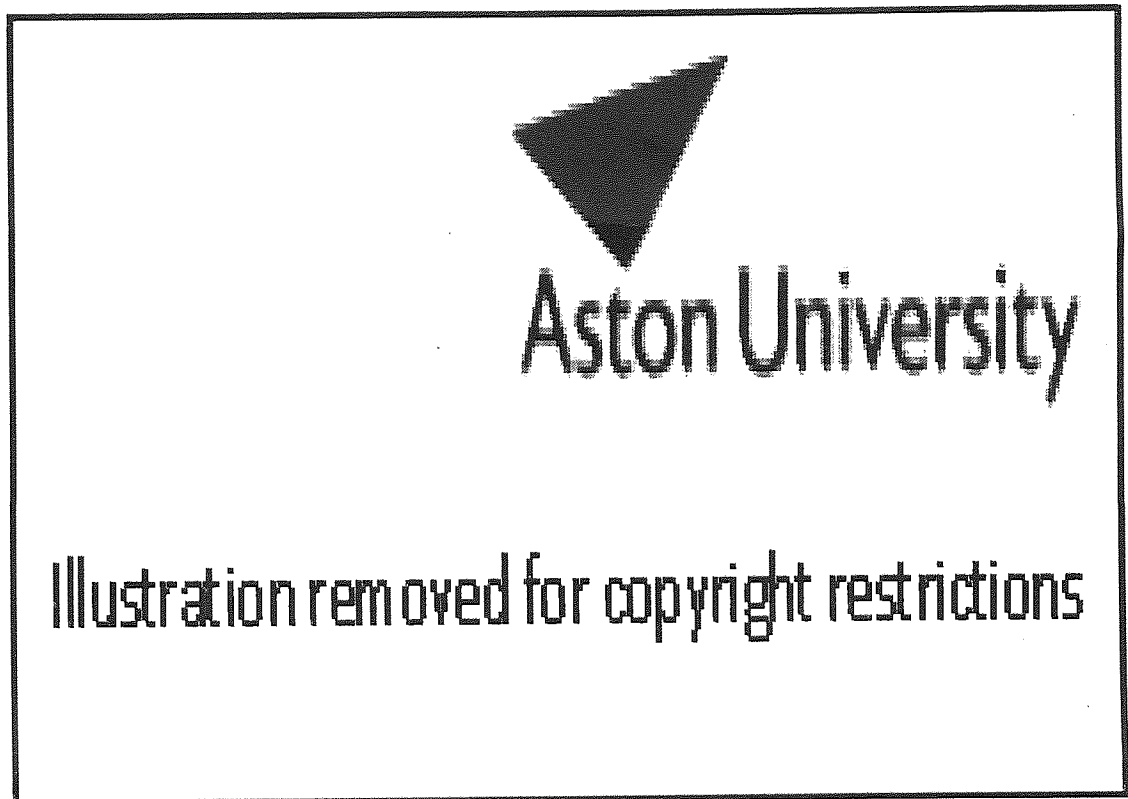
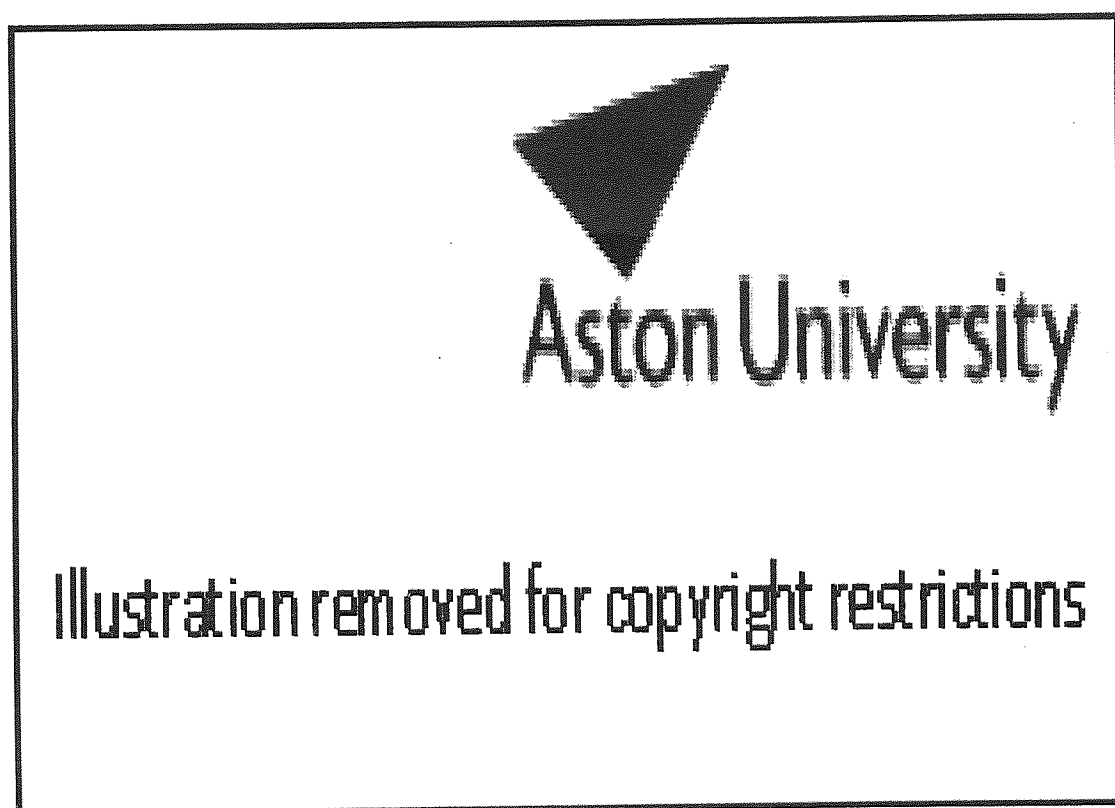


Figure 3.8 shows the total financial value of the items returned from each postcode sector as a mean value per household and demonstrates a moderately raised value in the postcode sectors surrounding the collection sites with an inversely proportional reduction in value as distance from the PCT increases.

Figure 3.8: A map showing the mean financial value of the returned items for each household within the patient residential postcode sector (number of return events = 580)



The financial value of the items returned to each pharmacy and surgery during the study was distributed across the sites and no area of the PCT collected medicines with a substantially higher financial value (Figure 3.9).

Figure 3.9: A map showing the mean financial value of the items returned to each collection site by postcode sector (number of collection sites = 86)

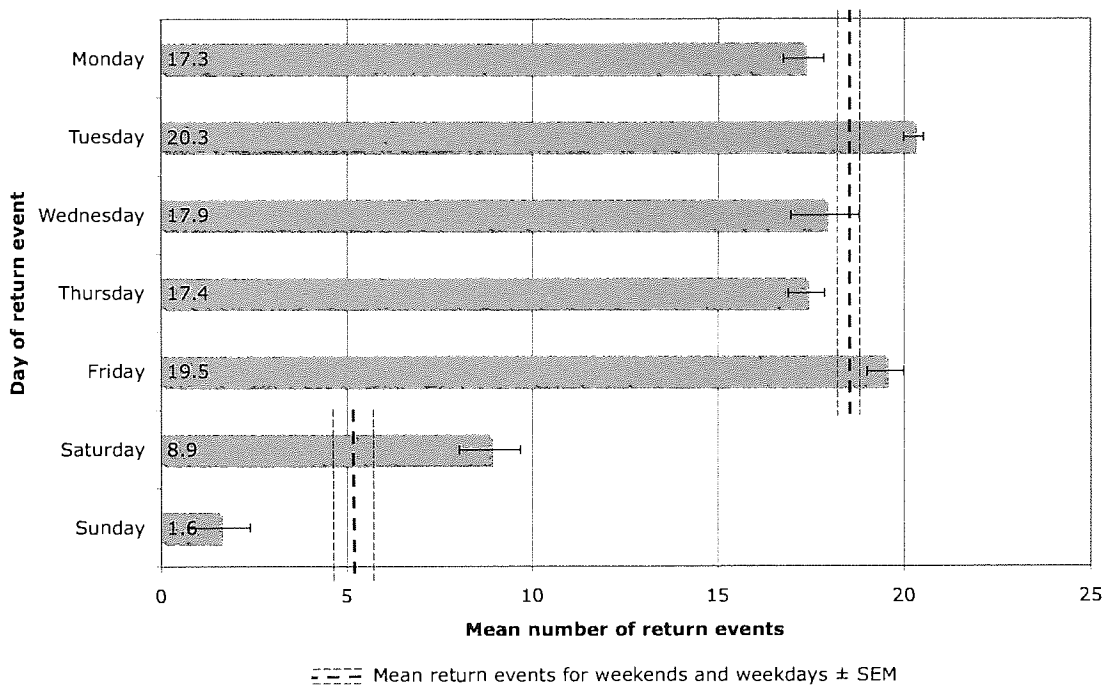


3.2.2.4 The days that return events were made

Return events were recorded each day throughout the study period with the exception of two Sundays and the Late Spring Bank Holiday Monday. The mean number of return events made each day did not differ between the five weekdays. However, as the distribution of return events by the day of the study period in Figure 3.10 shows, a significantly greater mean number of return events were made per day on weekdays

than on weekends (χ^2 , $P < 0.001$). No date of return was recorded for 140 of the return events.

Figure 3.10: A bar chart showing the mean number of return events made on each day of the week (number of return events = 794)



3.2.3 The patients whose unused medicines were returned

The items returned in the present study were from 905 individual patients. The items returned to surgeries originated from 200 patients and those to pharmacies from 756 patients, with some patients returning medicines to both pharmacies and surgeries on different occasions. The demographic makeup of the patients whose medicines were returned is considered in sections 3.2.3.1 and 3.2.3.2.

3.2.3.1 The age of patients returning unused medicines

The patients whose medicines were returned during the present study had a mean age at the time of return of 63.5 years \pm 0.78 (range 10 months to 99 years). More items were returned per patient as the patient age increased and the relationship between the age of the patient and the number of items returned is shown in Figure 3.11. A significant linear correlation exists between the age of a patient and the number of items they returned (τ , $P < 0.017$) (Figure 3.11). However, the influence of patient age on the financial value of the returned items is less clear and no linear correlation exists (Figure 3.12).

The mean number of dose units in each item returned showed no significant correlation with age and the mean financial value of each dose unit returned also showed no correlation with age.

Figure 3.11: A scatter plot of the number of items returned by each patient by age of patient at the time of return (number of patients = 516)

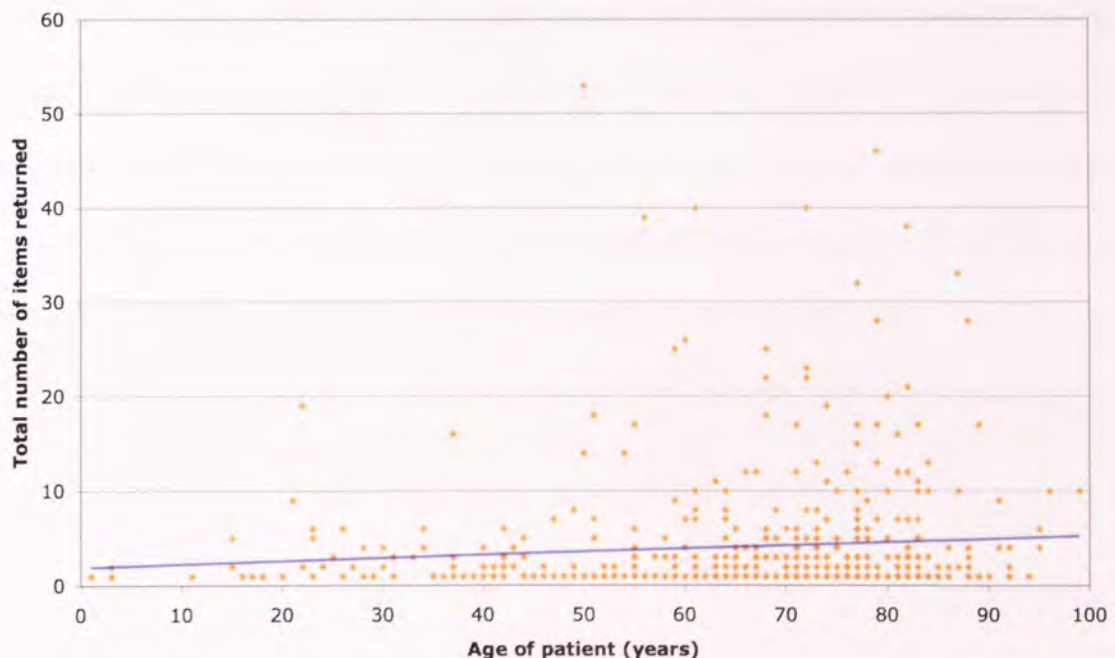
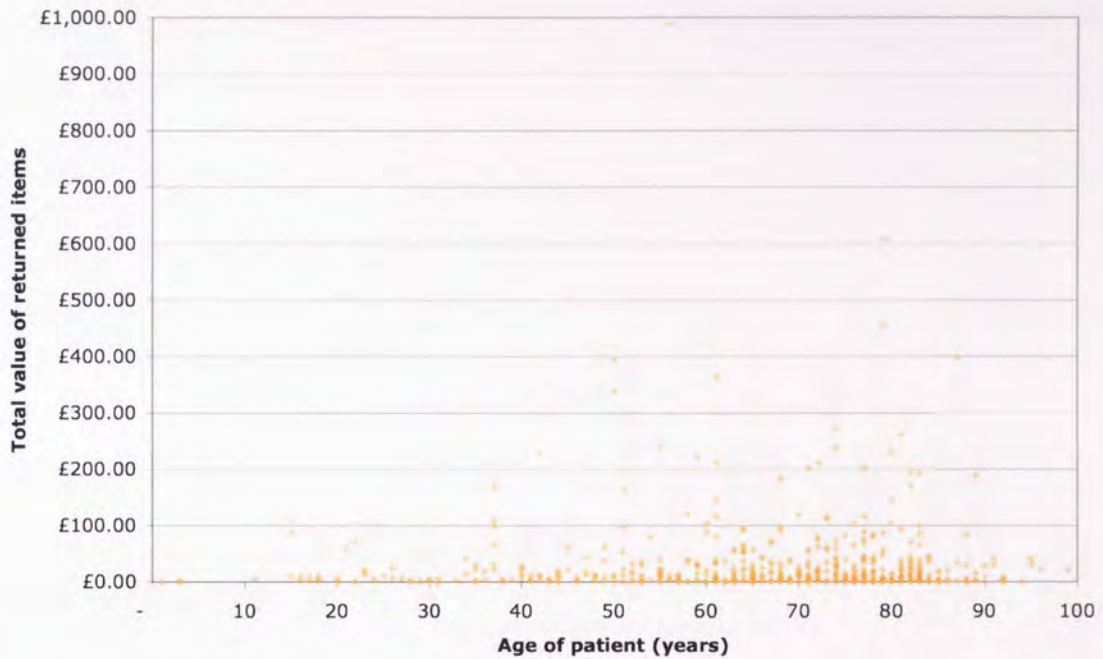
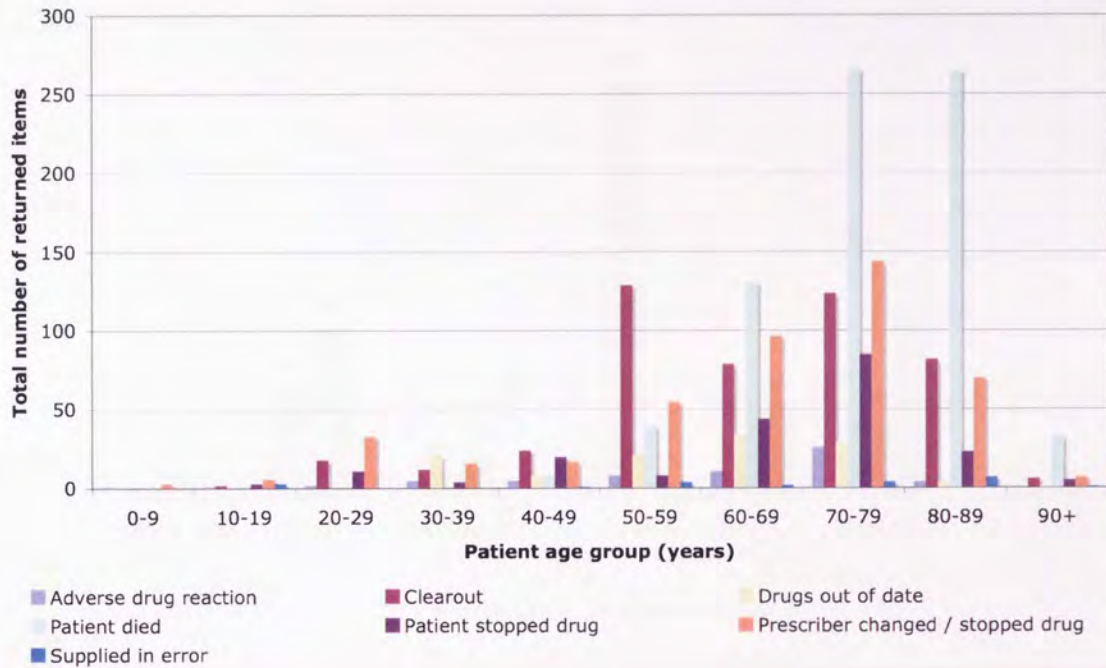


Figure 3.12: A scatter plot of the total financial value of item returned by each patient by the age of the patient at the time of return (number of patients = 516)



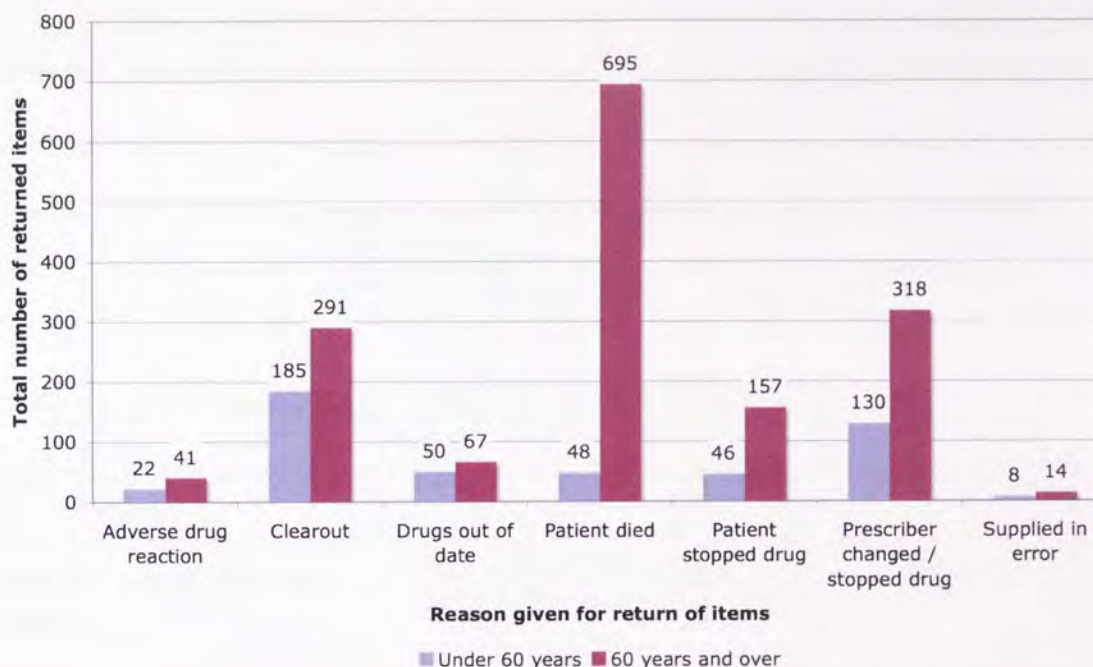
The total number of items returned by patients in each ten-year age group is shown for each of the reasons given for return of medicines in Figure 3.13. This figure demonstrates a small rise in the number of items returned as a result of change in prescribed therapy around the 20 to 29 years group. Additionally, there is a more substantial rise as the age increases, reaching a peak in the 70 to 79 years group, suggesting that this factor is important in the generation of unused medicines in these age groups. Items that were returned following patient death remained low through the younger age groups with more items being returned as the age increases.

Figure 3.13: A frequency distribution of the total number of items returned by patients in ten-year age groups for each reason given for return of medicines (number of items = 2072)



Those patients aged over 60 years showed a significant difference (χ^2 , $P < 0.001$) in the reasons given for returning medicines to patients aged less than 60 years (Figure 3.14). Patients over 60 years of age had the greatest number of items returned following death, while those under 60 years returned the greatest number of items following a clearout.

Figure 3.14: A column chart showing the total number of items returned for patients aged less than 60 years and those over 60 years for each reason given for the return of medicines (number of items = 2,072)



3.2.3.2 The sex of patients returning unused medicines

Male patients, on average, each returned a greater number of items than female patients and the items returned by male patients were also of greater financial value (Table 3.3). However, medicines were returned by a greater number of female patients (483, 53.1%) than male patients (296, 33.0%) and the overall total number of items and the total financial value of these items was consequently larger for female patients.

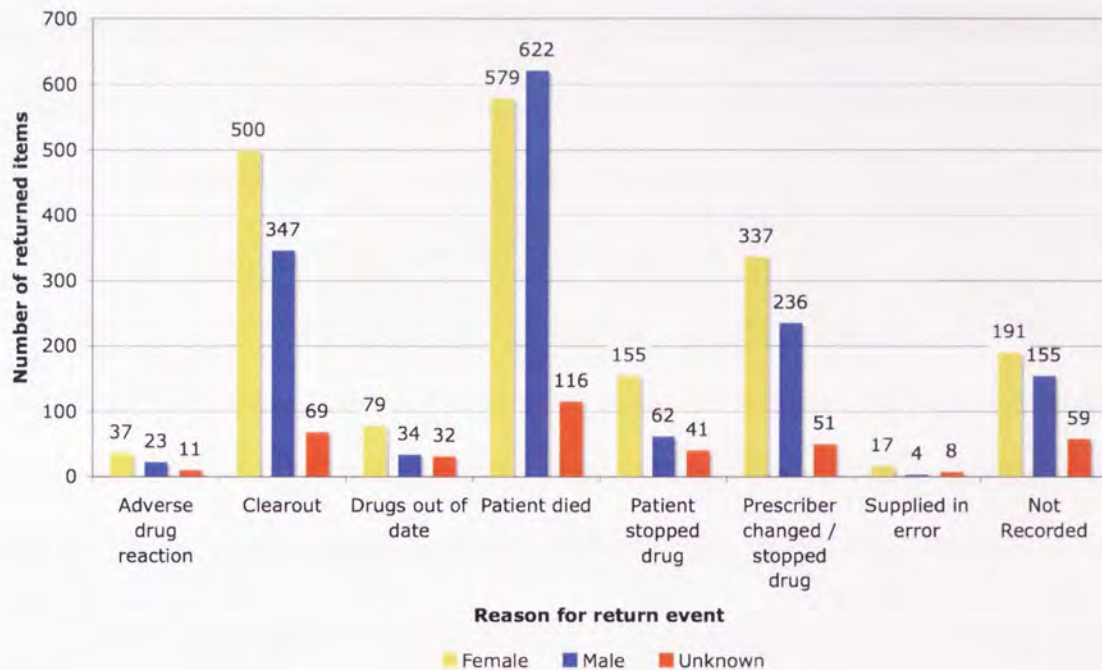
The reasons given for return of unused medicines by male patients were significantly different (χ^2 , $P < 0.001$) to those given by female patients. Items were returned following the death of a male patient in 622 cases, representing 41.9% of all the items returned from male patients. Among female patients, patient death was responsible for

the return of 579 (30.6%) of unused items returned for this group. Male patients that had chosen to stop taking their medicines returned 62 items (4.2%) items while female patients that had stopped their medicines were responsible for the return of 155 (8.2%) items.

Table 3.3: The number and financial value of the items returned by male and female patients

	Female	Male	Unknown
Number of patients	483	296	126
Total number of returned items	1894	1483	388
Total financial value of returned items	£16,077.85	£13,881.07	£3,649.51
Mean number of items per patient	3.92 ± 0.26	5.01 ± 0.40	3.07 ± 0.47
Mean financial value of returned items	£8.49 ± £0.37	£9.36 ± £0.49	£9.41 ± £1.27
Mean proportion of doses remaining in each item	75.8% ± 0.65	76.7% ± 0.72	75.4% ± 1.40

Figure 3.15: A frequency distribution of the number of items returned by each patient sex for each of the reasons given for return of medicines (number of items = 3,765)



3.2.4 The unused medicinal items that were returned

The 3765 items returned in the present study comprised, on average, 1.31 ± 0.02 packs of medicines (range 1 to 34 packs) and the data indicate that over 8 million unused medicinal items are returned to community pharmacies and general practice surgeries in the UK each year with a financial value of approximately £75 million. The majority of the items (96.0%) were dispensed in pharmacies based in primary care, with just 266 (4.0%) items originating in secondary care pharmacies. On average, each item contained sufficient remaining doses for 25.03 ± 0.50 days of treatment (range 0.25 to 360 days) and each pack had $81.28\% \pm 0.38$ of the original doses remaining (range 1.19 to 100%). Of the 4934 packs returned during the study, 3504 were over three quarters full and 2627 (53.2%) of these were completely full.

3.2.4.1 The quantities of unused medicines returned by therapeutic class

The items that were returned in the 8 weeks of the present study are equivalent to 0.63% of the items that were prescribed in the PCT during the same period. Additionally, the proportion of items returned from each of the therapeutic classes differed significantly from the proportion of items prescribed from each therapeutic class (χ^2 , $P < 0.001$). Medicines were returned from all therapeutic classes with the exception of immunological products and vaccines. Cardiovascular drugs were the most commonly returned with 947 (27.3%) items being returned and drugs acting on the central nervous system were also commonly returned with a further 792 items (22.8%) (Table 3.4).

Table 3.4: The total number of items dispensed in EBPCT during May and June 2003 and number of returned items that were dispensed in primary care for each therapeutic class (number of returned items = 3,441)¹²⁴

Therapeutic class	Present Study		EBPCT	
Gastro-intestinal system	323	9.3%	42,079	7.7%
Cardiovascular system	947	27.3%	134,883	24.6%
Respiratory System	346	10.0%	58,373	10.6%
Central Nervous System	792	22.8%	103,558	18.9%
Infections	150	4.3%	35,276	6.4%
Endocrine System	246	7.1%	39,185	7.1%
Obs., gyn. and urinary-tract disorders	59	1.7%	11,741	2.1%
Malignant disease and immunosuppression	19	0.5%	2,417	0.4%
Nutrition and blood	103	3.0%	19,705	3.6%
Musculoskeletal and joint diseases	222	6.4%	27,000	4.9%

Therapeutic class	Present Study		EBPCT	
Eye	61	1.8%	15,789	2.9%
Ear, nose, and oropharynx	53	1.5%	11,482	2.1%
Skin	115	3.3%	42,860	7.8%
Immunological Products & Vaccines	0	0%	4,227	0.8%
Anaesthesia	5	0.1%	463	0.1%

The returned items that had been dispensed in primary care had a financial value of £31,908.79, equivalent to 0.63% of the total cost of prescribing for the PCT during May and June 2003. The cardiovascular medicines that were returned had a financial value of £6,599.58 (27.5%) and central nervous system medicines had a value of £6,107.54 (23.0%). The financial values of dispensed items from these therapeutic classes were £1.397 million (27.8%) and £851,509 (16.9%) respectively (Table 3.5).

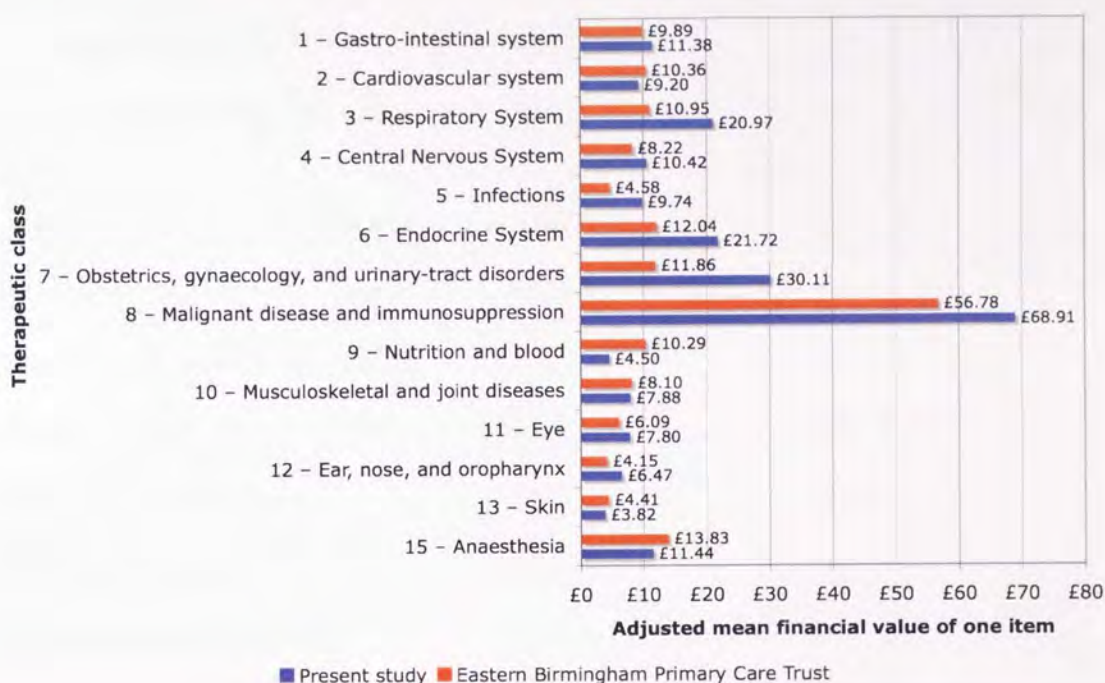
Table 3.5: The total financial value of items dispensed in EBPCT during May and June 2003 and total financial value of returned items that were dispensed in primary care for each therapeutic class¹²⁴

Therapeutic class	Present study		EBPCT	
Gastro-intestinal system	£2,742.85	9.4%	£415,994.69	8.3%
Cardiovascular system	£6,599.58	27.5%	£1,397,981.65	27.8%
Respiratory System	£5,979.53	10.1%	£639,172.96	12.7%
Central Nervous System	£6,107.54	23.0%	£851,509.95	16.9%
Infections	£977.04	4.4%	£161,442.02	3.2%
Endocrine System	£4,300.11	7.1%	£471,945.82	9.4%
Obs., gyn. and urinary-tract disorders	£1,498.75	1.7%	£139,214.07	2.8%
Malignant disease and immunosuppression	£997.75	0.6%	£137,236.85	2.7%

Therapeutic class	Present study		EBPCT	
Nutrition and blood	£356.94	3.0%	£202,823.22	4.0%
Musculoskeletal and joint diseases	£1,267.93	6.5%	£218,661.35	4.3%
Eye	£397.70	1.8%	£96,076.95	1.9%
Ear, nose, and oropharynx	£268.20	1.5%	£47,626.65	0.9%
Skin	£373.69	3.3%	£189,206.95	3.8%
Immunological Products & Vaccines	£0.00	0.0%	£58,444.89	1.2%
Anaesthesia	£41.18	0.1%	£1,626.79	0.0%

Since the returned items were only partially full, an adjustment was made to their value in order to give an estimate of the value of each item at the time of dispensing and the adjusted mean figures for item from each therapeutic class are shown along with the mean value of dispensed items in Figure 3.16. Returned cardiovascular drugs had an adjusted mean value of £9.20 and drugs acting on the central nervous system an adjusted mean value of £10.42 per returned item. Drugs acting in malignant disease and immunosuppression had the greatest adjusted mean value per returned item at £68.91 and items used in treatment of skin disorders had the lowest at just £3.82 per item. Returned items from the therapeutic class obstetrics, gynaecology and urinary tract disorders had an adjusted mean item value of £30.11, while the mean value of a dispensed item from this therapeutic class was just £11.86 and items returned from the nutrition and blood therapeutic class had an adjusted mean value of just £4.50 compared with £10.29 for dispensed items.

Figure 3.16: A bar chart showing the adjusted mean financial value of returned primary care items and the mean financial value of dispensed primary care items for each therapeutic class



3.2.4.2 The individual drugs returned and their detailed therapeutic subcategory

The medicines that were returned during the present study were categorised into 181 different therapeutic subcategories and the most commonly returned medicines were analgesics, with the three analgesic subcategories accounting for 586 (15.5%) of the returned items and of these, 158 included “when required” on the label. Additionally, the twenty therapeutic categories with the greatest number of items returned accounted for 2150 (57.1%) of all the returned items in the study (Table 3.6).

Table 3.6: The twenty therapeutic subcategories with the greatest number of returned items (total number of returned items = 3,765)

Therapeutic subcategory	Subcategory number	Number of returned items
Non-opioid analgesics	4.7.1	250
Non-steroidal anti-inflammatory drugs	10.1.1	176
Opioid analgesics	4.7.2	160
Selective β_2 agonists	3.1.1.1	134
Drugs used in nausea and vertigo	4.6	132
Nitrates	2.6.1	128
Proton pump inhibitors	1.3.5	104
Antiplatelet drugs	2.9	104
Calcium-channel blockers	2.6.2	101
Beta-adrenoceptor blocking drugs	2.4	100
Angiotensin-converting enzyme inhibitors	2.5.5.1	98
Loop diuretics	2.2.2	97
Corticosteroids (inhaled)	3.2	95
Control of epilepsy	4.8.1	84
Tricyclic and related antidepressant drugs	4.3.1	75
Lipid-regulating drugs	2.12	69
Stimulant laxatives	1.6.2	67
Oral anticoagulants	2.8.2	65
Selective serotonin re-uptake inhibitors	4.3.3	56
Thiazides and related diuretics	2.2.1	55

A total of 467 different drugs were received during the present study, of which aspirin was the most common with 102 (2.7%) of all the returned items containing this agent alone. The twenty drugs that were returned most often are shown in Table 3.7 and these account for 1235 (32.8%) of all the returned items.

Table 3.7: The twenty drugs with the greatest number of returned items (total number returned = 3,765)

Recommended International Non-Proprietary Name	Number of returned items
Aspirin	102
Co-codamol	98
Salbutamol	96
Furosemide	90
Glyceryl trinitrate	78
Beclometasone	73
Warfarin	62
Co-dydramol	61
Atenolol	54
Tramadol	53
Lansoprazole	51
Diclofenac	50
Bendroflumethazide	49
Isosorbide mononitrate	48
Co-proxamol	46
Senna	46
Morphine	46
Insulin	45

Recommended International Non-Proprietary Name	Number of returned items
Amitriptyline	44
Paracetamol	43

The analgesic medicines that were returned are of particular note owing to the large number of individual dose units and total quantity of drug that was recorded. Almost 3,000 tramadol dose forms and over 16,000 paracetamol containing dose forms were returned, representing 165g of tramadol drug and 7.7 kg of paracetamol drug. Over 56 grams of morphine was collected from just 25 patients and over four grams of diamorphine from 8 patients (Table 3.8). Additionally, some individual patients returned very large quantities of unused analgesic medication, with one returning 972 co-proxamol tablets and 18 co-codamol 30/500 tablets and another returning 291 tramadol 50mg capsules.

Table 3.8: A detailed breakdown of the quantities of the principal analgesic drugs that were returned

Analgesic	Quantity	
Morphine	56,010	Mg
Fentanyl	69	Patches
Diamorphine	4,305	Mg
Dipipanone (Diconal)	50	Tablets
Dextromoramide	28	Tablets
Other strong opiates	1,580	Tablets & capsules
Tramadol	2,840	Tablets & capsules
Paracetamol containing compounds	16,630	Tablets & capsules
<i>Co-proxamol</i>	3,485	<i>Tablets & capsules</i>
<i>Co-codamol</i>	6,008	<i>Tablets & capsules</i>

Analgesic	Quantity
<i>Co-dydramol</i>	4,734 <i>Tablets & capsules</i>
<i>Paracetamol</i>	2,403 <i>Tablets & capsules</i>

Also of interest are the psychoactive medicines that were returned, with a few patients returning considerable quantities. Seven hundred benzodiazepine tablets were returned by just 25 patients and two further patients returned 35 barbiturate tablets. Other antipsychotic and antidepressant agents were returned by 134 patients with one individual returning 212 amitriptyline 10mg tablets in a single return event (Table 3.9).

Table 3.9: A detailed breakdown of the quantities of the principal psychoactive drugs that were returned

Psychoactive Agent	Number of dose units (tablets or capsules)
Benzodiazepines	677
Barbiturates	35
Antipsychotics (all)	845
<i>Typical Antipsychotics</i>	335
<i>Atypical Antipsychotics</i>	510
Lithium	46
Antidepressants (all)	5,028
<i>Tricyclic Antidepressants</i>	2,831
<i>Selective Serotonin Reuptake Inhibitors</i>	1,879
<i>Other Antidepressants</i>	318
Anti-epileptics	4,285

The therapeutic categories with the greatest financial value of returned items were inhaled corticosteroids and opioid analgesics, accounting for £2,454.57 and £2,091.18

respectively (Table 3.10) and the twenty therapeutic groups with the greatest calculated financial value in the study had a combined financial value of £22,079.39, representing two thirds (65.7%) of the total financial value of all the returned items.

Table 3.10: The twenty therapeutic subcategories with the greatest financial value of returned items

Therapeutic subcategory	Subcategory number	Total financial value
Corticosteroids (inhaled)	3.2	£2,454.57
Opioid analgesics	4.7.2	£2,091.18
Intermediate- and long-acting insulins	6.1.1.2	£1,806.34
Proton pump inhibitors	1.3.5	£1,801.47
Lipid-regulating drugs	2.12	£1,487.76
Compound bronchodilator preparations	3.1.4	£1,450.66
Selective beta2 agonists	3.1.1.1	£1,413.56
Non-steroidal anti-inflammatory drugs	10.1.1	£1,175.60
Calcium-channel blockers	2.6.2	£1,064.83
Angiotensin-converting enzyme inhibitors	2.5.5.1	£873.48
Control of epilepsy	4.8.1	£859.55
Selective serotonin re-uptake inhibitors	4.3.3	£854.87
Nitrates	2.6.1	£790.82
Diagnostic and monitoring agents for diabetes mellitus	6.1.6	£673.77
Bisphosphonates	6.6.2	£660.04
Drugs for urinary frequency, enuresis and incontinence	7.4.2	£631.27
Drugs used in nausea and vertigo	4.6	£622.03
Non-opioid analgesics	4.7.1	£491.03

Therapeutic subcategory	Subcategory number	Total financial value
Antipsychotic drugs	4.2.1	£461.87
Antiplatelet drugs	2.9	£410.69

The twenty drugs with the greatest financial value of returned items are shown in Table 3.11 and accounted for £14,511.83 (43.2%) of the total financial value. Insulin had the greatest financial value at £1,903.24 and combined fluticasone and salmeterol inhalers the second greatest financial value at £1,423.74.

Table 3.11: The twenty drugs with the greatest financial value of returned items

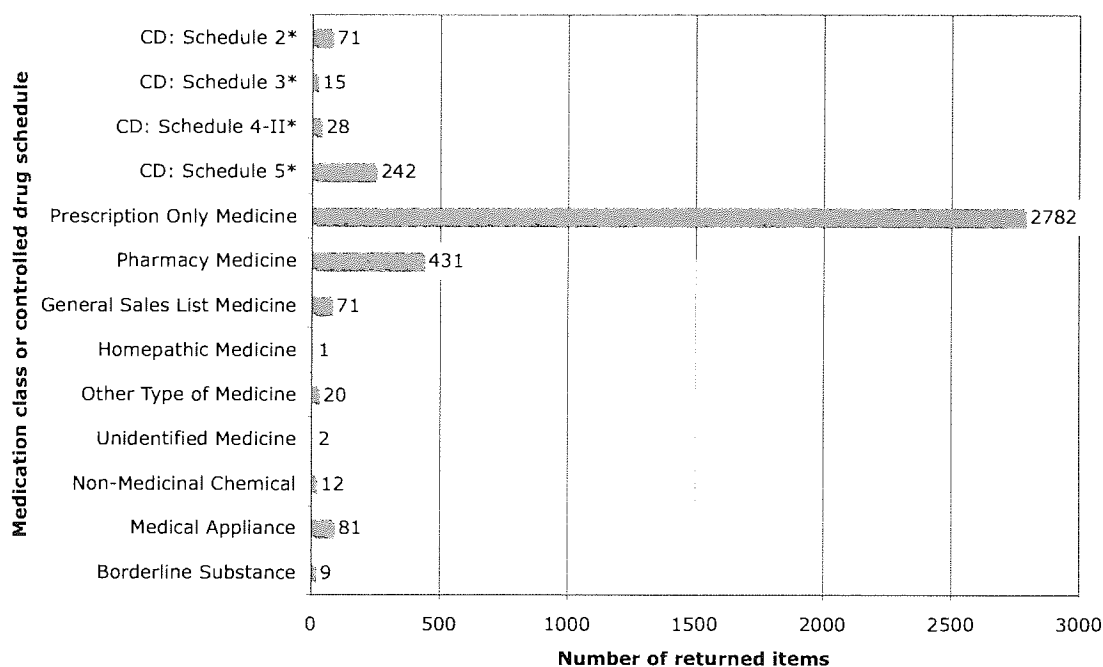
Recommended International Non-Proprietary Name	Total item value
Insulin	£1,903.24
Fluticasone / Salmeterol	£1,423.74
Beclometasone	£1,389.33
Salmeterol	£892.05
Fentanyl	£832.07
Lansoprazole	£774.18
Simvastatin	£769.73
Test strips (blood)	£673.77
Gabapentin	£658.37
Ipratropium / Salbutamol	£534.10
Isosorbide mononitrate	£526.66
Omeprazole	£518.75
Tolterodine	£515.89
Fluticasone	£501.66
Morphine	£486.44

Recommended International Non-Proprietary Name	Total item value
Amlodipine	£458.40
Sodium clodronate	£443.44
Salbutamol	£408.34
Ramipril	£408.18
Rabeprazole	£393.49

3.2.4.3 The regulatory category of the returned medicinal items

The returned items were principally prescription only medicines (POMs), with 73.9% of the returned items being POMs not listed in schedules 2, 3, 4-II or 5 of the Misuse of Drugs Act 1971 and a further 9.4% of the returned items were controlled drugs (CDs) as listed in the Act. Pharmacy medicines and those on the General Sales List (GSL) accounted for a further 11.4% and 1.9% of the returned items respectively (Figure 3.17).

Figure 3.17: A bar chart showing the number of returned items in each medicine class and controlled drug schedule (number of returned items = 3,765)

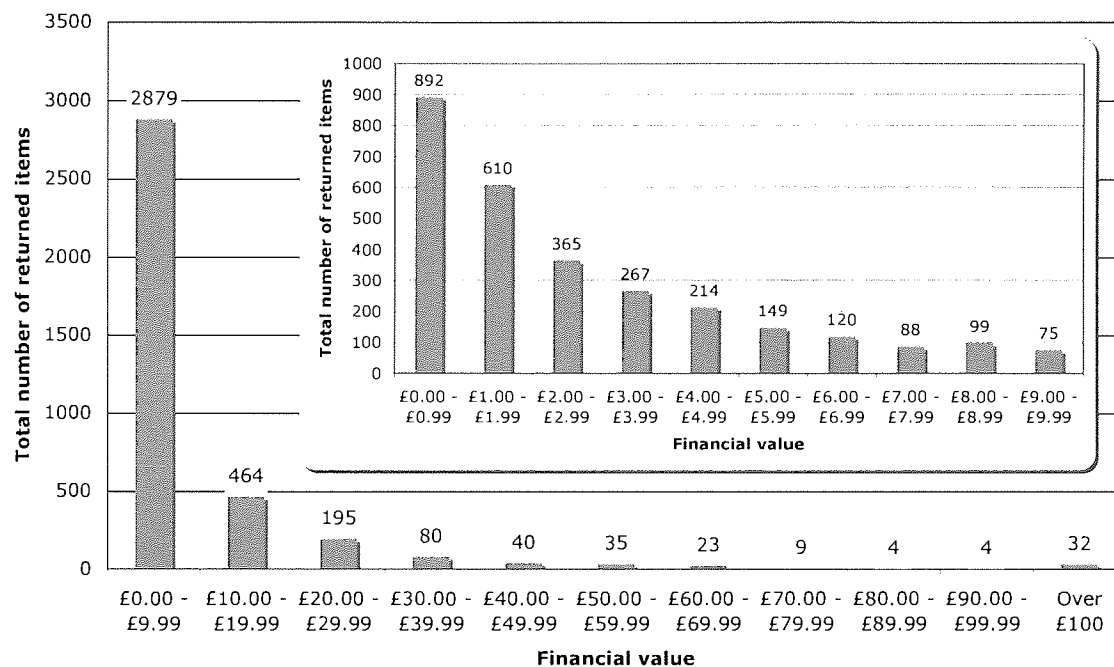


* Items recorded as CDs may also have been POM or P status.

3.2.4.4 The financial value of the returned items

The financial value of medicines returned in the present study was £33,608.43 and the average value of each return event was £36.90 ± £2.42 (range £0.01 to £892.14). Individual items had a mean financial value of £8.93 ± £0.30 (range £0.01 to £358.20) and packs a mean value of £6.81 ± £0.16 (range £0.01 to £167.28). The medicines returned were generally of low financial value, with the majority (2879) of the returned items having a financial value of less than £10 and 892 of these a financial value of under £1 (Figure 3.18).

Figure 3.18: A column chart showing the number of items returned by their financial value (number of items = 3,765); inset shows a breakdown of those items with a financial value of less than £10 (number of items = 2,879)



3.2.4.5 The time between the dispensing and return of unused medicines

On average, items were returned 1 ± 0.03 years (range 1 day to 18 years) from the date of dispensing and the time that elapsed between the dispensing and return of each item is shown in Figure 3.19. Of the items where a dispensing date was identifiable, 71.1% were returned for destruction within 1 year of dispensing. Figure 3.20 shows the mean time from dispensing to return for items from each therapeutic class.

Figure 3.19: A scatter plot showing the total number of items returned by the elapsed time from the dispensing of a medicine until its return (number of items = 3,030)

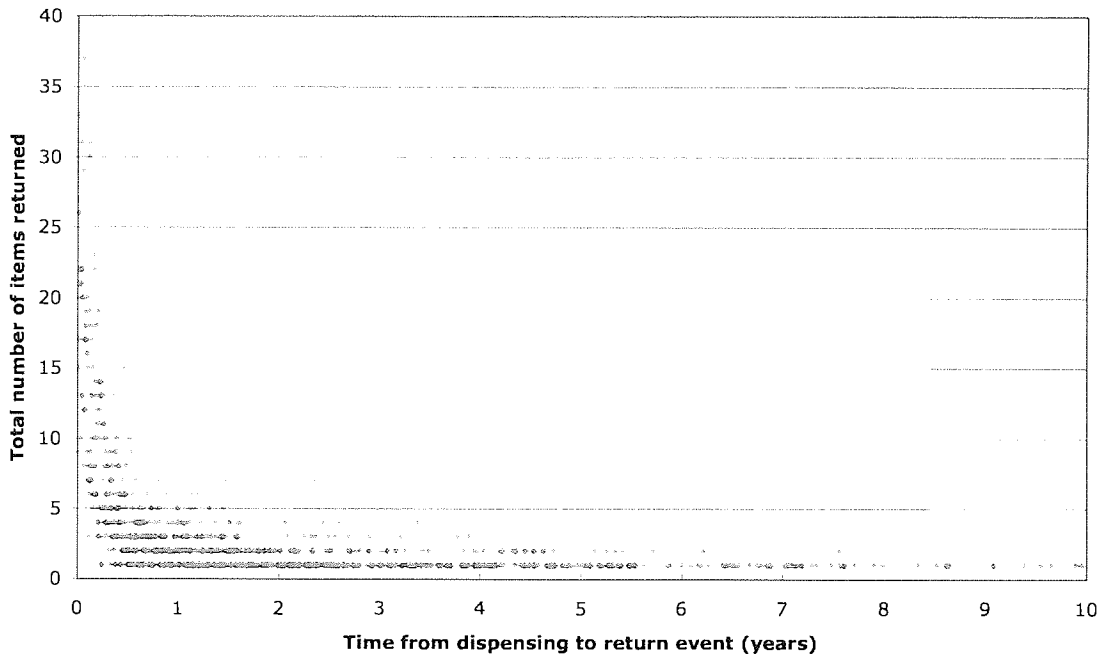
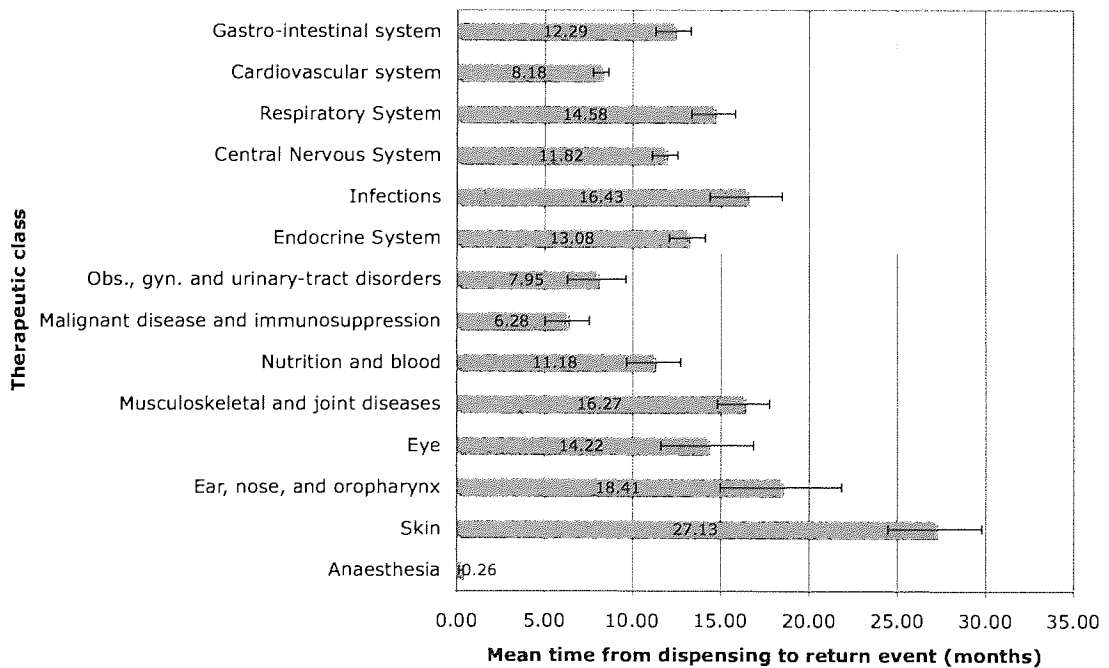


Figure 3.20: A bar chart showing the mean time \pm SEM from dispensing to return for each therapeutic class (number of items = 3,030)



3.2.4.6 The condition of the returned medicines

The returned medicines were packaged in various ways, ranging from full and unopened patient packs to loose tablets in envelopes and 17 of the items returned had been repackaged by the patient since dispensing. Many of the packs of medicines were returned before their expiry and had an average 15.44 months \pm 0.33 (range 0 to 67 months) remaining. Of these, 3406 packs were returned with at least two months remaining prior to expiry and had a total financial value of £26,195.44. A total of 1361 of these packs were classified as suitable for re-use according to the criteria detailed in 2.5.4 and had a financial value of £11,581.07 – equivalent to £26 million per annum if extrapolated up to the UK population. Of these packs classified as suitable for reuse, 592 contained drugs listed on the WHO list of essential drugs¹²⁵ and had a financial value of £3,091.50.

3.2.4.7 The miscellaneous items that were returned

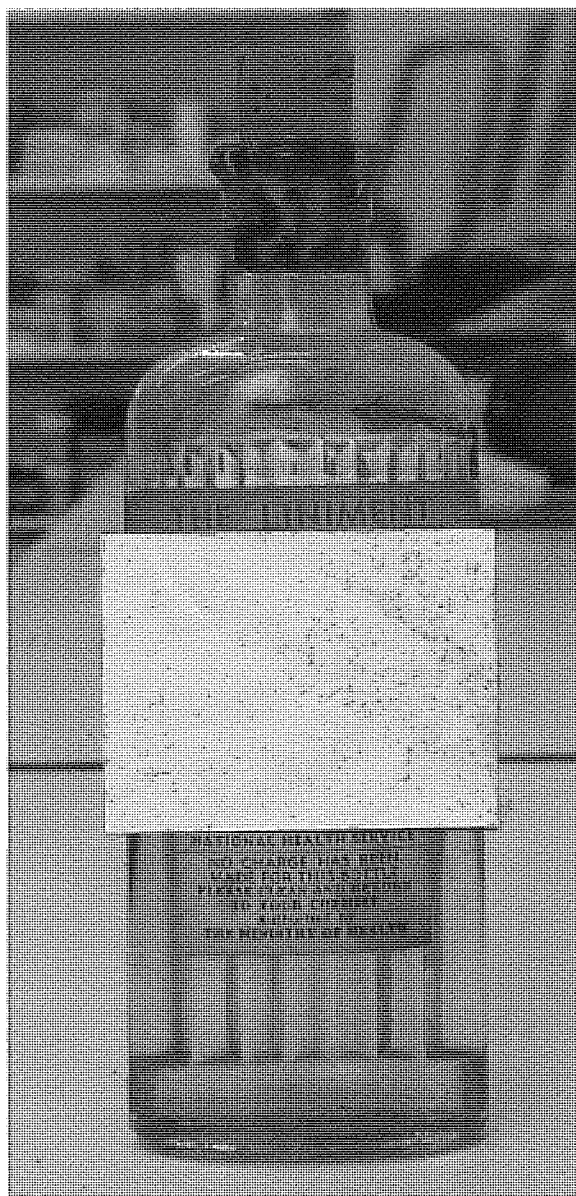
In addition to the items that were included in the above data, a number of miscellaneous items were returned to community pharmacies and general practice surgeries that were not included in the main data. Some of the more interesting items are detailed in Table 3.12 and an example of one of them is shown in Figure 3.21. This medicine bottle contained an unidentifiable liquid thought to be soap liniment and was closed with a traditional cork stopper; the dispensing date was estimated to be approximately 1960.

Table 3.12: The miscellaneous items that were not included in the main study data

Return event code	Details of the items
PH/227/10	Complete blood glucose monitoring system with case

Return event code	Details of the items
PH/245/07	Two glass tubes, one labelled with "Herpes Zoster 30 Tablets" containing 3 senna tablets an isosorbide mononitrate capsule and a paperclip, the other being unlabelled and containing 18 green gelatin capsules
PH/226/01	A collection of very old, unidentifiable medicines, in poor conditions generally some medicines 20-30 years old
PH/205/01	A bottle of dark, pungent liquid with label detailing dose, patient's name and 'Boots Health and Beauty Services'. No other information provided
PH/249/08	8 unused refillable insulin pens
GP/125/03	A new, unopened refillable insulin pen with case
PH/226/30	A 'breast reliever' milking device
PH/250/14	9 x Sterile Plastic Forceps
PH/216/11	An envelope containing badly degraded loose tablets and capsules
PH/206/01	500ml H2O2 35% 210g aerosol of Dichlorotetrafluoroethane
PH/232/20	A surgical truss

Figure 3.21: A medicine bottle containing 'The Liniment' returned during the study

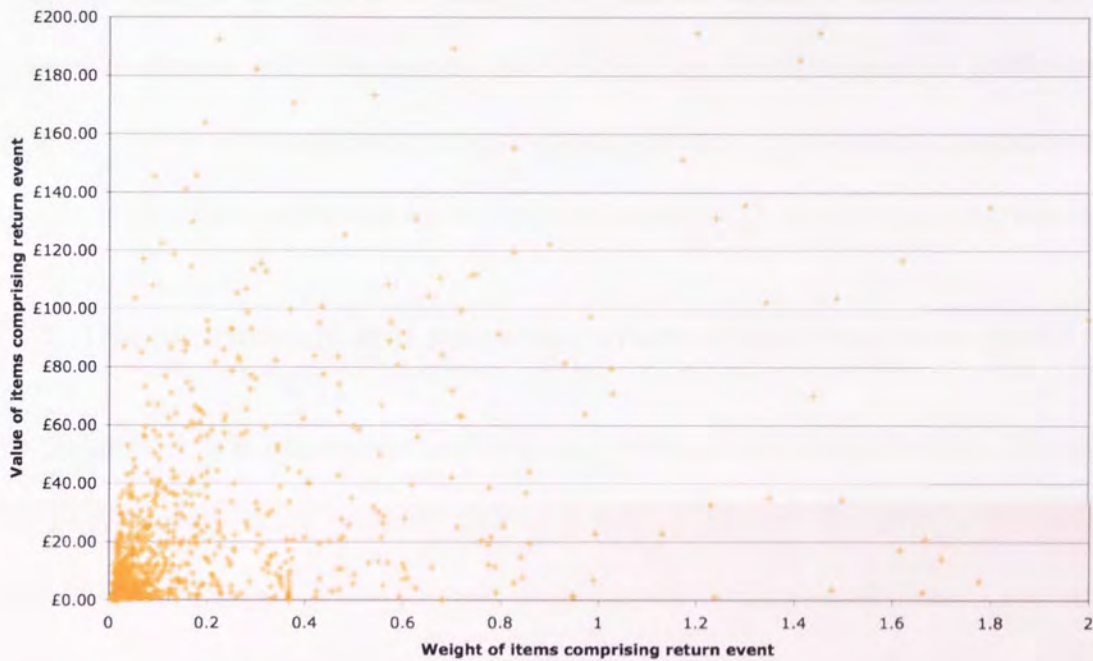


3.2.5 The weight of the returned medicines and their financial value

Some previous studies and current government statistics have measured unused medicines by their weight. For comparison purposes, the total weight of the items returned in the present study was 293.5 kilograms. However, Figure 3.6, showing the weight of the returned items comprising each return event plotted against the financial

value of these items shows considerable variance and there is no linear correlation between these two variables.

Figure 3.22: A scatter plot showing the financial value of the returned items making up each return event by the weight of the items comprising that return event (number of return events = 862)*



* Those outlying points above 2 kilograms and £200 have been excluded in order to allow better representation of the majority of the points.

3.3 Discussion

In the present study 934 return events were made to the 51 community pharmacies and 42 general practice surgeries that participated. These return events comprised 3,765 items, made up of 4,934 individual packs and in many cases these items were returned following changes in prescribed therapy and patient death. A higher incidence of returned medicines was clear among drugs acting on the cardiovascular and central nervous systems with analgesic medicines being returned in substantial quantities and the data suggest that patient age and sex may influence the return of unused medicines.

3.3.1 The pharmacies and surgeries where collections were made

The major barriers to pharmacies and surgeries participating in the collection of unused medicines was a lack of available staff or a lack of interest. However, a substantial proportion of the surgeries and pharmacies in Eastern Birmingham Primary Care Trust did participate and these were geographically distributed across the PCT. Participating pharmacies were broadly representative of the type usually seen in the UK and included a range of dispensing volumes from 1,400 to 11,000 items per month as well as a variety of business structures including supermarkets, high street pharmacies, health centre pharmacies, independently owned pharmacies and small, medium and large chains. Participating surgeries were also representative and had list sizes ranging from 1,500 to 11,800 patients and included single-handed practices through to large health centres with six full time general practitioners.

3.3.2 The nature of the return events made

The majority of return events made in the present study contained greater than one item and it is unlikely that all of these items would have become unused at precisely the same moment in time. Therefore, it is likely that medicines are commonly stored for a period after they become unused and are not immediately discarded. Additionally, the number of return events made during the present study is equivalent to 1 per annum for every 40 households in the PCT, suggesting that unused medicines are routinely allowed to accumulate over a period in households across the PCT.

3.3.2.1 The reasons given for the return of unused medicines

Over one quarter of the return events made in the present study were attributed to a change in the prescribed therapy while a study by performed by Daniszewski in 2001 within an area of EBPCT reported that over half of the return events made were attributable to changes in prescribed therapy⁴⁷. The reduction in the incidence of return events attributed to this reason may be as a result of the improved use of medicines through evidence based medicine, with fewer changes in therapy being required and consequently, a reduction in the unused medicines that are generated. However, while evidence based medicine and national prescribing guidelines may potentially minimise the changes required in prescribed therapy, they may also be exacerbating the problem, since not every patient responds to the recommended first line therapy and the treatment goals that have been shown to reduce mortality and morbidity may be difficult to attain. This may necessitate the trial of a number of different agents and doses before the desired results are achieved and with the wide range of medicines available to treat each condition the myriad treatment choices available may add to the number of changes made. Additionally, evidence suggests that one fifth of prescriptions are issued without

a definite clinical need²¹ and it is possible that patients may demand that their prescription be changed to accommodate their own beliefs or opinions, accumulated through the media and from the Internet.

While the high number of return events attributed to changes made by the prescriber may appear to be a negative finding, it may be the direct result of improved patient care and patients may be experiencing better clinical outcomes, with more modification of therapy in line with developing good practice and the clinical evidence base. Furthermore, the proportion of return events may have risen owing to a more concordant prescribing relationship, with the patient working in partnership with the prescriber and taking responsibility for their own healthcare. In such situations, patients would be more likely to return their medicines, with no fear of remonstrations and in 42 cases, the medicines were actually returned to the patient's general practice surgery. However, while these returns may be the result of appropriate implementation of better practice, the medicines returned following a change in prescribed therapy had a financial value of almost £6,000. Additionally, a number of examples of the need for the prescribing of small quantities when initiating or amending therapy to minimise the quantity of unused medicines were seen in the present study, including the return of two complete and unopened packs of 84 Kliofem tablets by one patient, with a financial value of £31. Clearly in this case, the patient had a considerable quantity of treatment in excess of their need and when the prescribed therapy was amended, this medicine was returned unused.

Despite evidence suggesting that patients do not follow the prescribers' directions in as much as 60% of cases¹², only 14% of return events were attributed to the patient stopping their medicine. It is possible that this is as a result of patients attempting to

hide their non-compliance and past research has shown this secretive attitude by patients in this respect,^{3,126} where patients have continued to order medicines that they are no longer taking to avoid confrontation. In particular, these secretive patients may actually be accumulating their medicines in the home, or disposing of them by throwing out with household refuse or in grey and black water. Additionally, it is likely that any medicines accumulated owing to non-compliance that are returned to pharmacies and surgeries would be under the guise of a clearout.

Currently, no formal communication pathway exists for details of return events made to community pharmacies to be related to the prescriber. Indeed data protection legislation would prohibit the sharing of such information without the express permission of the patient and therefore only those return events made to the general practice surgery are likely to elicit any intervention to patient care. However, those return events made to a pharmacy following a patient alteration of therapy represent an ideal opportunity for a pro-active intervention to be made by the pharmacist. This may range from a short discussion on the reason for the changes made by the patient to a medicines use review or clinical medicines review. For example, during the present study, one return event received from a single patient that was attributed to a patient change in therapy contained 5 salbutamol inhaler devices, dispensed on three separate occasions, one beclometasone inhaler device and one containing ipratropium. All of the boxes containing the inhaler devices were unopened with their security seal remaining intact. This return event would indicate a poorly compliant patient, possibly suffering from asthma and could be an ideal opportunity to discuss the patient's current asthma status and the need for continued treatment, perhaps taking peak flow readings and advising on the appropriate treatment needs for that individual, thereby improving patient care and reducing the waste of medication in the future.

Current population death rates for England are 10 per 1,000 people,¹²⁷ therefore it would be expected for approximately 300 deaths to have occurred in the PCT during the study collection period. However, just 120 return events were made that were attributed to a patient death. While some of the people that die may not be on any medicines, it would be reasonable to assume that greater than 50% would be using at least one medicine at the time of their death. Additionally, those patients that die in a hospital or hospice setting would be expected to have unused medicines remaining that were being used prior to admission and these will require disposal. Just 13% of return events were attributed to a patient death, yet these accounted for 36% of the total financial value of returned items and each return event contained an average of 11 items. The data demonstrate a large quantity of unused medicines were returned following patient deaths would be expected owing to the difficulties in tailoring treatment in palliative care and the need to ensure that the patient has sufficient supplied to alleviate suffering.

Other reasons for unused medicines being returned during the study were as expected but the potential to minimise unused medicines as a result of these reasons is limited. Adverse drug reactions may become known at any point during the use of a medicine and all attempts are already made to minimise these events, particularly those that would result in a change in therapy. Additionally, expired medicines and those returned following expiry are likely to have become unused because of poor compliance or a patient death, but it is not possible to determine the reasons for their non-use.

3.3.2.2 The relationship to the patient of the individuals making the return events

While almost half of the return events were made by the patient themselves, in many cases, a representative returned the medicines on the patient's behalf. This would be

expected in the case of very young or old patients or where patients had died, however it does limit the opportunities for further action as outlined above. Where the individual returning the medicine is not the patient, it not possible to intervene directly and it would also be difficult to convey a message through the patient's representative owing to data protection issues. This is particularly true in the 56 cases where the return event involved a friend or neighbour.

Medicines were only returned by healthcare professionals such as the patient's doctor or nurse/carer in a small number of cases. This may be related to the current situation whereby medicines remain the property of the patient and pass to their estate upon their death. However, there are a number of issues surrounding the removal of medicines from the home by health professionals, some highlighted by the former GP Dr Harold Shipman and these are discussed in section 1.5.1.

3.3.2.3 The geographical distribution of the return events made

Unfortunately, the patient postcode was not recorded in 325 (36%) of cases and it is therefore difficult to draw any significant conclusions from the patient's residential locality. However, it is possible to consider the location of those patients where a postcode is known and also the locations of the pharmacies and surgeries where medicines were returned.

It would be reasonable to expect that medicines would be returned to the patient's local pharmacy or to the patient's own GP surgery. This is apparently confirmed by the data from the present study, with the majority of patients returning medicines living within the PCT, or a short distance outside. However, some patients did live a few miles from the PCT, indicating that they may return medicines to pharmacies and surgeries near

their place of work, or during an afternoon out. This would further compound the difficulties in making an intervention as a result of returned medicines since patients may be returning medicines to a range of locations where they may not be known.

The data appear to show a similar return rate per collection site for each postcode sector, with the exception of postcode sectors B8 1 and B8 3. However, it is likely that the apparently low return rate per site in these sectors is related to high density of collection sites along the Alum Rock Road area of the sector, leading to return events being distributed over a number of sites. The postcode sector B34 6 also shows a low rate of return events per site and when considered with the corresponding data showing patient residential postcode, it would appear that patients in this area are less likely to return their medicines to a community pharmacy or GP surgery within the PCT. It is possible that residents routinely return their medicines to pharmacies and surgeries outside their postcode sector such as those in the adjoining B34 7 or outside the PCT such as those in B36 9. Alternatively, patients resident in this sector may not have significant quantities of unused medicines or may dispose of their unwanted medicines by alternative methods.

The financial value of medicines returned across the PCT show very similar patterns to the number of items in most postcode sectors, indicating that there are no areas where items are returned that have a higher or lower financial value. The notable exception to this is the postcode sector B36 8, where there appears to be a considerably higher value of items per household than number of items per household when compared to the rest of the PCT. The reasons for this are unknown and further study may be required to determine the cause.

3.3.2.4 The days that return events were made

Return events were recorded on every day of the study, with the exception of two Sundays and the Bank Holiday Monday. It is likely that the significant difference between the rate of return events on weekdays and weekends is a direct result of the closure of many of the surgeries and pharmacies on Saturdays and Sundays. None of the participating surgeries and only four of the pharmacies were open on a Sunday and just one surgery and 39 pharmacies were routinely open on Saturdays. This highlights a possible problem with the current provision of unused medicines collection since many pharmacies are now closing on Saturdays and almost all surgeries are now closed all weekend, making it difficult for those who work full time to access this service.

3.3.3 The patients whose unused medicines were returned

Medicines were returned for over 900 patients in the two months of the present study and 51 of these patients had medicines present in two return events. Assessment of the age and sex of those patients whose medicines are returned is important when considering unused medicines in order to target any initiatives at those individuals with the greatest quantity of unused medicines, or those that are not currently using the service.

3.3.3.1 The age of the patients whose unused medicines are returned

Data published by the DH states that 57% of prescription items dispensed in 2003 were to patients aged 60 years and over¹. Additionally, other DH data suggest that the number of prescription items supplied per head of population increases with age¹²⁸ and it is therefore expected that the number of returned items per patient would increase

with age. The data from the present study do reveal a significant correlation between increasing patient age and an increase in the number of returned items per patient and the number of patients returning unused medicines also increases with age. Despite this increase in number of items, no significant correlation exists between the total financial value of the items returned from a patient and their age and this is likely to be as a result of a combined effect of variation in the mean number of dose units in each item and the value of each dose unit.

In patients under 50 years of age, very few items were returned as a result of a clearout, while in those over 50 years of age, a large number of items were returned by each patient for this reason. Although this may be as a result of a more conscientious attitude to disposal of medicines in older patients, as stated above, evidence suggests that use of medicines increases with patient age¹²⁸. Therefore, elderly patients are more likely to have increased numbers of items in the home, with some of these being used in active treatment while others are unused. It is therefore expected that the medicines returned following a domiciliary clearout would yield a greater number of items where the patient is older. Additionally, it would be expected that following the death of an older patient, larger quantities of medicines would have accumulated than in a younger patient and this is represented in the number of items returned following the death of patients over 60 years of age. The increased use of medicines by these older patients, combined with the complex co-morbidities seen in the elderly, make clinical outcomes harder to predict resulting in a greater need for adjustment of therapy in these patients and this is reflected in the increased number of items being returned unused for older patients as a result of changes in prescribed therapy.

3.3.3.2 The sex of the patients whose unused medicines are returned

Evidence suggests that male patients comply with prescribed therapy to a greater extent than female patients^{129,130} and it would therefore be expected that male patients would have less unused medicines. In the present study, a greater number of medicinal items were returned for female patients than males, further indicating that female patients are less likely to take the full quantity supplied. This is confirmed by the reasons given for return of medicines, with a greater proportion of medicines returned from female patients being attributed to a patient decision to stop therapy. However, the items returned for male patients contained considerably more dose units and had a consequential higher value and this may be related to the fact that male patients received, on average, a greater number of dose units in each item than female patients. Female patients were dispensed a mean 86 dose units per item and returned a mean 66 dose units per item, while males were dispensed a mean 145 dose units per item and returned a mean of 115 dose units per item. The reason for greater quantities being supplied to male patients is unclear, however, these data demonstrate the potential for greater wastage of medicines when large quantities are supplied.

Medicines from male patients are significantly more likely to be returned following their death or a general clearout in comparison to female patients. Female patients also returned proportionately more items following a change in the prescribed therapy and adverse drug reactions further indicating that male patients are less proactive in disposal of medicines than female patients. Female patients appear more likely to return medicines in response to a specific event while medicines from male patients are usually returned in more general situations or are permitted to accumulate until the death of the patient, when they are disposed of by a friend or relative.

3.3.4 The unused medicinal items that were returned

The medicines returned in the present study represented a substantial quantity of unused medicines, equivalent to approximately 30,000 items in the PCT per annum. These medicines had sufficient doses remaining to continue treatment for almost one month and over half of all the packs returned were completely full, suggesting that medicines are supplied in quantities that are substantially greater than those required by the patient.

Medicines returned to community pharmacies and general practice surgeries originate from a number of sources including NHS or private prescriptions dispensed in primary or secondary care, over the counter purchases or foreign medicines. The unused medicines returned during the present study were predominantly from prescriptions dispensed in primary care with just 4% being dispensed in a secondary care pharmacy. Any medicines that appeared to have been purchased over the counter were excluded from the main data and no medicines dispensed outside the UK were received in the study. It was not possible to determine if returned items had been dispensed privately or under the NHS and for the purposes of comparison with prescribing data, it has been assumed that the medicines that were returned originated from NHS prescriptions.

3.3.4.1 The quantities of unused medicines returned by therapeutic class

In the UK, much prescribing in primary care is driven by national and local guidelines such as the National Service Framework for Coronary Heart Disease (NSF for CHD), which details the patients most at risk of CHD and the types of drugs that should be used for primary and secondary prevention of coronary events. Additionally, a number

of incentives have been introduced to encourage prescribers to identify patients that may benefit from primary or secondary prevention for CHD. These factors have led to an increase in the use of medicines that act on the cardiovascular system, with this group accounting for 22% of prescribed items in England during 1999 and 30% of items in 2004^{7,131}. It is therefore not surprising that drugs acting on the cardiovascular system represent the largest expenditure for EBPCCT and also account for the greatest number of prescription items over all other therapeutic classes. However, the proportion of returned medicines from this category is significantly higher than the proportion that were prescribed, indicating that this group of medicines may be more prone to non-use than other medicines. This may be related to the nature of preventative medicine, where a patient has no identifiable symptom and can therefore fail to understand the rationale behind the therapy leading to non-compliance¹⁴. A study performed in Birmingham in 1977 reported just 6.5% of returned items were medicines acting on the cardiovascular system³⁹. However, UK studies undertaken between 1997 and 2001 in Birmingham, Glasgow, Cherwell and Kirklees reported the returned cardiovascular medicines as 24% to 30% of all the returned items in each study^{3,41,45-47}. These data indicate that while prescribing of cardiovascular medicines has risen over the past few years, the return of these medicines has not risen at a corresponding rate. This suggests that compliance with these medicines may now be higher than previously.

Anecdotal evidence suggests that anti-infective medicines are used poorly, with many courses being incomplete. This is not reflected in the data from the present study, with a lower proportion of medicines being returned from this therapeutic class than were supplied, indicating that these medicines are used more fully than medicines from other categories. While it is possible that the publicity campaigns that have been run in recent years to encourage patients to complete the full course of anti-infective agents have

been successful, it is also possible that patients are disposing of these medicines in domestic refuse or through grey and black water systems. Additionally, patients may be storing unused anti-infective medicines in the home for possible later use if the infection recurs⁶⁷.

Considerable differences between the adjusted mean values of returned items and the mean item value of dispensed items is seen in the medicines acting on the respiratory or endocrine systems and obstetrics, gynaecology and urinary tract medicines. The adjusted mean value of returned items was two to three times the value of the mean dispensed item value indicating that it is the more costly medicines that are returned from these therapeutic classes. Unfortunately, the study data do not reveal whether these are the only medicines from these categories that are not used by the patients.

3.3.4.2 The individual drugs returned and their therapeutic subcategories

While the returned medicines were from almost 200 therapeutic subcategories, the majority (57%) fell into just 20 categories, with a seventh of all the returned medicines being analgesics. This last finding is comparable to the findings of similar studies conducted in Canada and Sweden^{51,56} where analgesic medicines accounted for 12-19% of returned items. Analgesic drugs are of particular interest when considering non-use owing to their potential to cause harm, through diversion, poisoning, suicide, and the likelihood of them being stockpiled in the home. Anecdotal evidence suggests that it is common for large quantities of analgesic medicines to be supplied on prescription in order that the patient does not consume the complete supply and be unable to obtain further supplies. Additionally, owing to the variability and subjective nature of pain, the quantities supplied can often be considerably in excess of the quantities required for

treatment. The data indicate that a number of patients stockpile analgesic medicines, with one individual returning almost 1,000 co-proxamol tablets in a single return event and another returning almost 300 tramadol 50mg capsules on a single occasion.

3.3.4.2.1 The return of analgesics and psychoactive medicines

The actions of former GP Harold Shipman have also demonstrated the potential for a malicious individual to cause considerable harm with unused medication. During his career, Shipman collected approximately 24 grams of diamorphine, partly through issuing false prescriptions, but also much of this was obtained from unused supplies of the medicines that he had prescribed to his patients prior to their death⁷¹. Shipman then used this diamorphine to murder patients under his care, with some estimates suggesting that he may have murdered up to 300 patients in this way. The patients whose diamorphine was returned during the present study had an average of 500mg each, sufficient to kill over ten opiate naive people. Additionally, 500mg of pharmaceutically pure diamorphine has a value of over £2,000 on illicit markets and the four grams collected in the present study suggests that over nine kilograms of unused diamorphine is returned to pharmacies and GP surgeries annually in the UK. It is not known what proportion of unused medicines are diverted to illicit markets, however, a number of analgesic medicines have a developed illicit market, with drugs such as MST tablets selling for up to £20 per 60mg tablet.

As a result of the growing number of suicides by self-poisoning with paracetamol^{100,132}, legislative changes were introduced in 1998 that limited the purchase of paracetamol containing products over the counter to a maximum of 32 tablets, or up to 100 tablets in exceptional circumstances. Since this change was introduced, studies have reported that the number of attempted and successful suicides by self-poisoning with paracetamol has

fallen considerably¹⁰². However the supply of large quantities of paracetamol containing products and the stockpiling of these medicines has resulted in continued availability of large quantities of paracetamol. Indeed, over 16,000 tablets of paracetamol containing products were returned in the present study, indicating that approximately 40 million tablets of paracetamol containing compounds may be returned to pharmacies and surgeries in the UK each year. Clearly greater care is needed in the supply of analgesic medicines since there is considerable potential for harm. Additionally, data suggest that patients suffering from conditions characterised by chronic pain have a greater risk of suicide by self poisoning^{104,105}.

Owing to the nature of mental health disorders, many patients suffering from conditions such as depression or psychotic conditions may act irrationally or have no insight into the consequences of their actions. This may lead to low compliance with prescribed medication and also may increase suicide attempts. Data suggest that self-poisoning attempts that involve tricyclic antidepressants are 12 times more likely to result in death than those involving paracetamol and between 1997 and 1999 over one fifth of deaths from deliberate self poisoning were attributed to tricyclic antidepressants⁹⁵.

A number of studies have shown compliance among epileptic patients to be as low as 60%^{11,13} and the potential for large quantities of these medicines to accumulate is demonstrated by the number of dose units returned in the present study. Data from both the USA and Europe have detected the anti-epileptic agent carbamazepine in ground water and it is likely that a proportion of this is due to the leaching of poorly disposed of medicines from landfill sites and passage from sewerage systems.

3.3.4.2.2 The return of medicines used in the treatment of diabetes

The diverse range of insulin formulations that are now available and the variable response of individual patients to different doses of each insulin formulation, coupled with the complex nature of diabetes, will increase the need for careful tailoring of doses, formulations and the individual insulin used. Additionally, owing to the number of similarly named insulin formulations, there is a greater risk of errors in prescribing and supply. This is also true of blood glucose test strips, where there are a range of manufacturers of patient testing equipment, all with a number of different models with exclusive strips being required for each machine. This is exacerbated when patients change the testing equipment they use and the prescriber is not made aware. Anecdotal evidence also suggests that patients are obtaining testing strips in greater quantities that would normally be required for testing. While this may be as a result of the patient over-testing their plasma glucose levels, it is also true that patients may inadvertently accumulate these test strips, which will become unused should the equipment be changed. Additionally, both new insulin formulations and the test strips for plasma glucose testing have considerable financial value and consequently these two products account for a considerable proportion of the financial value of all the returned items.

3.3.4.2.3 The return of medicines used in the treatment of respiratory diseases

Respiratory diseases such as asthma are an increasingly common cause of morbidity in the UK^{133,134} and the prescribing of inhaled β_2 agonists and corticosteroids such as salbutamol, salmeterol and beclometasone is correspondingly high⁹¹. Since β_2 agonists are usually prescribed for use on a *when required* basis, the quantity of the drug that is used is variable between patients and will change over time in an individual. Additionally, anecdotal evidence suggests that since many patients with respiratory diseases who pay for their medicines, they may seek to obtain larger quantities of

medicines each time they are prescribed, with up to 4 devices containing 200 doses being supplied on each occasion. This may lead to accumulation of medicines and there is an increased likelihood that they will expire, or fall into non-use over a period and consequently be returned unused on a periodic basis. The return of medicines from this sub category was substantial and it is clear that unused inhaled preparations used in treatment of respiratory disorders account for a substantial financial value among returned medicines. Selective β_2 agonists accounted for over £400 worth of returned items, inhaled corticosteroids a further £1400 and the returned salmeterol and combined salmeterol and fluticasone inhaler units alone had a value of £2000.

3.3.4.3 The regulatory category of the returned medicinal items

While unused medicines are categorised as Hazardous waste under UK legislation⁷⁸, no distinction is made between the different regulatory classes of medicines, nor are there currently any special handling requirements for controlled drugs as listed in the schedules of the Misuse of Drugs Regulations 2001¹³⁵. One item in every ten returned was classified as controlled drugs and, in light of the restrictions applied to their manufacture, sale and supply, the lack of extra control on unused medicines in this class seems inappropriate. Controlled drugs are more susceptible to misuse and have considerable potential to cause harm, as highlighted by the actions of Dr Shipman. The findings of the Shipman report have led to a revision of the supply and handling of controlled drugs listed in the Regulations, including the fate of unused medicines in this group. The details of any legislative changes have yet to be finalised and the effect that this will have on the diversion and abuse of these agents is currently unknown. However it is hoped that the changes will facilitate the use of these medicines whilst protecting the public from their inappropriate use and abuse.

3.3.4.4 The financial value of the returned items

The medicines returned in the present study had a total financial value of over £33,000 and suggest that over £250,000 of unused medicines are returned within EBPCCT each year. Any initiative to minimise the quantities of unused medicines in primary care will incur a cost to the PCT, however these data indicate that considerable savings may be made through reduction of non-use. One return event made in the study contained medicines with a financial value of almost £900 and over 100 items had financial values over £50 each. These data suggest that considerable savings could be made with minimal input by the targeting of resources to the areas of unused medicines with the highest financial value. However, the data also indicate that the majority of unused medicines are of low financial value and minimisation of much of the unused medicines in the PCT may incur greater cost than the potential savings. The data from the present study suggest that there is considerable scope for reduction in unused medicines in prescribing for treatment of respiratory diseases and diabetes along with analgesic medicines. This would have corresponding financial savings and through targeting of resources to these areas it may be possible to make small changes to practice that would substantially reduce the financial impact of unused medicines.

3.3.4.5 The time between dispensing and return of a medicine

Medicines pose a number of risks throughout the time they are in the home, and in the present study, medicines were retained in the home for an average of one year from the time they were dispensed. This suggests that medicines are not returned immediately they become unused. The storage of medicines that are not being used has potentially harmful consequences, and patients have been reported as attempting self poisoning with medicines that have been stored in their home for over twenty years⁹⁸. In the

present study, 14 items were returned over 10 years from dispensing and one was retained in the home for over 18 years, demonstrating that patients may routinely store medicines for considerable times and even after they have expired. Additionally one item was returned in the present study that was estimated to have been dispensed over 40 years previously and is shown in Figure 3.21. However, while some items were of considerable age, over half of the items were returned within 12 months of dispensing and 5% of items were returned within a week. Additionally, medicines acting on the cardiovascular system, those used in treatment of obstetric, gynaecological and urinary tract disorders and immunosuppressants and drugs used in treatment of malignancies were routinely returned after a shorter time had elapsed from dispensing. This is likely to be a result of the greater contact that patients using medicines in these classes often have with their GP for monitoring and increased visits to the pharmacy to have prescriptions dispensed.

3.3.4.6 The condition of the returned medicines

The items returned in the present study were assessed for their potential for re-use, with the expiry date and general condition being recorded. Most of the items were returned with over a year remaining before expiry and over 90% had 2 months remaining until expiry. Of these, those that were considered as possibly suitable for re-use by a pharmacist had a financial value of over £11,000 and over £3,000 worth of these were medicines listed as essential drugs by the WHO. The data suggest that £26 million worth of medicines are returned unopened and unused to pharmacies and surgeries per year within the UK, £7 million of which would be WHO essential drugs. The destruction of these medicines does not appear rational when some developing countries are unable to obtain sufficient supplies of these essential medicines. However, the WHO

guidance on drug donation prohibits the supply of previously dispensed medicines and the RPSGB, BMA and DH all oppose the re-use of these unwanted medicines. However, these policies have been in place for some time and were developed at a time when most dispensed medicines were decanted into tablet bottles. The majority of dispensed medicines are now supplied in patient packs and this is likely to become compulsory in the future as the UK come into line with European practice. The sealing of tablets and capsules in blister strips, often under controlled atmospheres, has considerably minimised the risk of degradation of dispensed medicines in the patient's home and, along with tamper evident seals and clearly printed expiry dates and batch numbers, it is possibly time for these agencies to reconsider their policies. Despite the guidance from these agencies, some charitable organisations already collect unused medicines and distribute them in countries where medicines are not freely available. However, this is not regulated and there are no controls or input from the main health organisations, increasing the risk for possible harm and resulting in entirely inappropriate medicines being donated in some cases¹³⁶.

3.3.4.7 The miscellaneous items that were returned

The DOOP scheme that is operated by community pharmacies is intended to allow patients to dispose of unused medicines in a safe and appropriate manner. However data from the present study indicate that patients, and organisations may be using this service inappropriately, returning a number of items that are not suitable for inclusion in the dedicated DOOP disposal bins and resulting in possible health and safety problems for the receiving pharmacy. For example, a bottle of 35% hydrogen peroxide and an aerosol containing dichlorotetrafluoroethane was returned by a dental practice, which may have posed a significant health and safety risk to the pharmacy staff. If these items had been

inadvertently placed in the DOOP container they are likely to have led to an explosion when the bin was incinerated.

3.3.5 The weight of the returned medicines and their financial value

A number of previous studies have referred to the weight of collected medicines as a measure of the scale of the problem of unused medicines in primary care. Additionally, the DH publish figures of weights of medicines collected each year through the DOOP scheme in England and Wales. These figures are a poor representation of the financial value of unused medicines and data from the present study indicate that there is no correlation between weight and financial value of returned medicines. Additionally, no correlation was found to exist between the weight of returned medicines and any of the factors assessed in the present study, indicating that weight of returned medicines reveals almost nothing about the medicines themselves, nor the factors that influence the quantities returned and the collection and publication of data on the weight of returned medicines provides little benefit.

3.3.6 General practices as a point of return of medicines

A fifth of the return events in the present study were made to general practice surgeries, a method of disposal that has not been previously considered. This highlights the importance of surgeries in the disposal of unused medicines in primary care and while pharmacies are provided with collections from an appropriate waste carrier, there is no formal system in place for general practice surgeries to dispose of returned medicines and the fate of these medicines is unknown. It is possible that some surgeries place unused medicines in their clinical waste disposal containers. However, this is not permitted under the Hazardous Waste Regulations since different categories of

hazardous wastes should not be mixed. It is therefore necessary for consideration of the need for formal disposal services to be provided via general practice surgeries and the need for appropriate disposal routes for hazardous wastes returned to these establishments.

3.4 Summary

The medicines collected in this element of the present study indicate that unused medicines include a wide range of products and the reasons for return of these medicines is varied. The sex and age of the patient appear to influence the return of unused medicines, in terms of both the quantities returned and also the reasons for such return events occurring. Medicines used in the treatment of coronary heart disease, diabetes and respiratory diseases in addition to analgesic medicines were the most commonly returned, reflecting the high use of these medicines in primary care. However, the data indicated that medicines acting on the cardiovascular system were more likely to be returned unused than other types of medicines, but there is an indication that compliance with these medicines may have improved in the past decade.

The quantities collected indicate that approximately 1% of the prescribed medicines in the PCT are returned for disposal and the financial value of these is substantial. The current provision of collection and disposal services is being used by some patients, there may be a need for further expansion of this to include general practices and greater access over the weekend. Additionally, there is considerable potential for re-use of these returned medicines and more research is needed to further inform this debate.

CHAPTER 4 : A group interview considering patient opinions and actions regarding unused medicines

4.1 Introduction

The data presented in section 3.3.4 provide an insight into the types of medicines that are unused in primary care. However, these data only present information on one element of unused medicines, namely the types and quantities that are returned to community pharmacies and general practice surgeries. In order to gather more complete data on unused medicines in primary care, it is therefore necessary to consider those medicines that are not returned for destruction. The majority of the previous research considering unused medicines in the UK has only assessed medicines returned to community pharmacies,^{2,38,39,45} with little work considering the other aspects of medicines non-use⁴⁸⁻⁵⁰. Owing to this limited data availability, it is difficult to construct a quantitative research tool that accurately assesses all of the relevant aspects of medicines non-use and unused medicines. It was therefore necessary to perform a qualitative assessment of these factors and influences in order to facilitate the creation of the postal questionnaire used in the present study to gather quantitative data.

The qualitative data required were collected through interviewing a group of patients drawn from the population of Eastern Birmingham Primary Care Trust. This considered both the factors leading to medicines non-use and those influencing the generation of unused medicines that participants considered to be important.

4.2 Results and discussion

Despite the wide range of recruitment methods employed (section 2.6.3), patient response to them was limited and it was only possible to perform one interview of seven participants. The participants were drawn from a social group for the elderly and were all females aged over 60 years old. It is therefore likely that this group is not representative of the whole population of the primary care trust. However, the data presented in section 3.2.3.1 indicate that female patients and those aged over 60 years are the most likely to return unused medicines and the elderly are the largest users of medicines in the NHS¹. It is therefore reasonable to expect that the factors influencing medicines non-use and the attitudes towards unused medicines in this group would be indicative of those most prevalent in the population as a whole.

The interview consisted of four main themes; the reasons for unused medicines being present in the home, the methods used for disposal of these medicines, the systems in place for obtaining medicines on prescription and the information provided with prescribed medication.

Since evidence suggests that patients may be secretive about their non-compliance with prescribed medicines³, all the questions used in the interview were devised to be non-threatening. Participants were also informed that they may discuss incidents of which they were aware that involved friends and family as well as those involving them directly. Additionally, the interview was performed in a community hall, a neutral location where patients would be more likely to feel able discuss the relevant issues freely.

4.2.1 The reasons for unused medicines in the home

Initially, debate on the reasons for unused medicines in the home only made reference to medicines that had been purchased over the counter and medicines prescribed for treatment of acute conditions. Group participants suggested that patients might purchase greater quantities of OTC medicines than were required, with excess quantities being stored for possible future use, resulting in the accumulation of unused medicines. It was also suggested that unused medicines in the home would be more likely to have been purchased than prescribed. *“They buy something over the counter and take it for a short period, and when they’ve had enough, it’s just shoved in the cupboard”* (Subject #1). *“It is the medicines that you buy [that are likely to be unused], not necessarily the ones you’ve been prescribed”* (Subject #2).

The debate was developed further by the facilitator to include the reasons for unused prescribed medicines being in the home. In response to this, participants made a distinction between medicines prescribed for the treatment of chronic conditions or for management of health risks and those prescribed for treatment of acute conditions or simple symptom management, suggesting that unused medicines would most likely be of the latter type.

Participants also demonstrated an understanding of the need for compliance with medicines used in preventative therapy. *“That’s a tablet that has to be taken... blood pressure ones”* (Subject #3). In addition, participants indicated that they would expect all medicines that had been prescribed for treatment of a chronic condition to be taken, since patients would have attended their GP in order to obtain these medicines. *“Well if they are not going to take them, why the hell do they go to the doctors in the first place?”* (Subject #1).

The debate further expanded on the specific factors that may lead to unused medicines in the home and five main reasons were identified. These were adverse drug reactions, prescriber relationships with the patient, difficulties patients may have in taking medicines, errors in supply and the storage of medicines in anticipation of need.

4.2.1.1 Unused medicines as a result of adverse drug reactions

As reported in section 3.2.2.1, adverse drug reactions are a potential cause of unused medicines and the group subjects in the present section also suggested ‘side effects’ as a possible factor leading to unused medicines. Additionally, some comments demonstrated how a patient’s experience of an adverse reaction can lead to them developing negative attitudes towards a medicine. *“They are terrible, [ibuprofen] the yellow one can cause haemorrhage, and the red one can cause everything else”* (Subject #3). This comment also highlights that patients may become confused about the harm medicines may cause, possibly resulting in inappropriate advice being provided to friends and colleagues, which may lead to the non-use of these medicines. Another participant gave an example where an adverse drug reaction, in conjunction with an apparently discordant relationship with the prescriber, had led to unused medicines. *“They called [my husband] in at the doctors [and] said his cholesterol was up and gave him some tablets. He fell and cut his head. When we read [the patient information leaflet], it was the side effects, he was having nightmares, he kept waking up, finding himself sat on the side of the bed, he fell and cut his head. He went back to the doctors and they [gave him] something different. He brought the tablets home, they are still there in the house, because he will not take them...”* (Subject #2). In this example, a number of factors initiated by an adverse reaction had resulted in the non-use of a medicine by the patient. The initial problem was compounded by a poor

relationship with the patient's doctor and the information provided with the medicine; these factors are discussed below in sections 4.2.1.2 and 4.2.4.

4.2.1.2 Unused medicines resulting from a poor relationship between the prescriber and patient

In the above example reported by Subject #2 (4.2.1.1), an adverse drug reaction had led to the patient returning to their GP, where an alternative drug was supplied. However, this consultation was apparently non-concordant and the patient did not take the replacement medicine owing to a fear of further side effects. This was catalysed by the information on adverse drug reactions detailed in the patient information leaflet supplied with the second medicine and exacerbated by a lack of understanding of the need for treatment of raised plasma cholesterol. *"The cholesterol is no problem to him; he's never had it before. He's on the low fat diet and everything else"* (Subject #2). This example demonstrates a deficiency in the relationship between the patient and the prescriber, where the patient does not understand the need for a medicine, but feels unable to refuse treatment. In such situations, the prescriber is usually unaware of the patient's dissatisfaction and continues to prescribe the medicine, which is never used. Group participants also referred to patients stopping their medicines or not completing the course, indicating that patients may not always appreciate the importance of taking a medicine as prescribed. *"[Patients] don't take the full course that's been prescribed"* (Subject #1), *"they get fed up with taking them"* (Subject #2). The comments made in the debate demonstrate how sub-optimal communication between the prescriber and their patient may lead to medicines non-use and unused medicines. Additionally, the data indicate that if a patient does not understand the rationale for using a medicine, or

if they are unaware of the need to continue therapy, then they may simply stop taking the medicine.

In addition to poor communication between the prescriber and the patient, participants also referred to dogmatic prescribing as a potential cause of unused medicines. Participants suggested that while younger patients may be more assertive with the prescriber, older patients are more submissive and will agree with the doctor during the consultation, but not take the medicine as prescribed. *“If something doesn’t suit you, younger ones will go back to their doctor and say “look I’m not happy with this”, but the older ladies [will] not always do that, [they] just won’t take it”* (Subject #4). The implications of this are concerning with regard to unused medicines. In such situations, medicines are unused from the initial supply and the patient may continue to obtain the medicine to hide their non-compliance, further increasing the quantity of unused medicines³. Additionally, the prescriber, being unaware of this non-compliance, may found decisions on future therapy based on the apparent failure of this treatment.

4.2.1.3 Unused medicines arising from the difficulties that patients may have taking their medicines

The use of child resistant closures (CRCs) is a well-established practice in the dispensing of medicines and a requirement in the UK¹⁰⁸. While the group participants recognised the benefits of CRCs in minimising risk of accidental poisoning in children, a number of comments were made regarding the difficulty that patients may have in accessing medicines supplied in bottles with these closures. *“These new bottle tops, some of them are so awkward, how the hell do they go on, [people with] arthritis in their hands, it’s got to be such a problem for them”* (Subject #1). While it is permitted for a pharmacist to supply medicines in a container without a CRC at the request of the

patient, anecdotal evidence suggests that this is rarely done in practice. In such situations where the patient is unable to access the medicines owing to difficulties with the container, it is likely that at least some of the doses, if not all, will not be taken.

Participants did not report any similar problems with medicines packaged in blister packs, even on direct questioning by the facilitator, indicating that blister packaging may be preferable in patients with reduced dexterity. Additionally as the medicines in the UK are increasingly supplied in blister packaging, it is likely that unused medicines as a result of these difficulties will become less common over time. However, it is important where medicines are supplied in bottles with CRCs that there is greater communication between the dispensing pharmacist and the patient to minimise this problem.

Patient confusion was also highlighted as a possible cause of unused medicines, where patients may not be able to remember the dosing instructions and are unable to read printed instructions. *“They can’t remember what the doctor says, if they can’t read [the instructions] properly, they either don’t take it as they should, or they don’t take it at all”* (Subject #4). This demonstrates the need for clear communication between patients and healthcare professionals with clear dosing instructions provided with all medicines and ensuring that the patient is aware of how to use their medicine. The introduction of the Medications Use Review under the advanced services of the new Contractual Framework for Pharmacies in England and Wales will possibly improve the use of medicines and lead to a decline in unused medicines resulting from these difficulties¹³⁷.

4.2.1.4 Errors in supply leading to unused medicines

Errors in supply have been identified in section 3.3.2.1 as a potential cause for unused medicines and group participants also referred to these as a possible factor leading to medicines non-use. However, while it is important that robust systems are in place for both prescribing and dispensing to ensure that the minimum number of errors are made and that patient safety is not compromised, since these errors are unintentional, it would be difficult to significantly reduce the incidence of unused medicines attributed to this factor.

4.2.1.5 The storage of medicines in advance of need leading to their non-use

Anecdotal evidence suggests that patients hoard supplies of their medicines in advance of their actual need. This is particularly noticeable around the Christmas and Easter bank holiday periods, where there is an apparent perception among patients that pharmacies will be closed for long periods. The group participants indicated that ordering of extra supplies of medicines occurred in order to minimise the risk of running out of the medicine concerned. Over ordering of medicines can be minimised through the implementation of processes that ensure repeat prescriptions are not generated earlier than would be reasonable and group participants identified examples of this happening. *“When I order something on the repeat prescription, they write on the back, they are not due yet”* (Subject #3). In addition to over ordering of prescribed medicines, it is also likely that over the counter medicines are routinely purchased in anticipation of a future need and that the doses remaining in unfinished packs of both these medicines are retained for possible later use. Participants suggested that it was

usual for patients to have stocks of purchased medicines in the home. *"I think everybody keeps [purchased medicines] in the house anyway"* (Subject #1). The storage of medicines is likely to lead to their becoming expired in many cases and this will inevitably lead to these medicines being unused.

4.2.2 The methods utilised for the disposal of unused medicines

The majority of group participants reported that they returned their unused medicines to the community pharmacy for destruction. *"I had a daughter who died, she was on a lot of tablets and my husband just put them all in a big carrier bag and took them to the chemists. There was too many to dispose of myself. Plus, there was packets that hadn't been opened"* (Subject #3). However, in making the comment *"There was too many to dispose of myself"*, Subject #3 alludes to the fact that they often dispose of medicines by an alternative method to returning them to a pharmacy. Additionally, this participant referred to packs as being returned unopened, suggesting a belief that unused medicines returned to community pharmacies are re-used in some way. In light of this, the facilitator asked participants if they were aware of what happened to medicines that were returned to community pharmacies. While the majority of participants were unsure of the fate of these medicines, some suggested that returned medicines were incinerated and two highlighted that they would not be re-used. *"They are not recycled"* (Subject #4), *"You can't use them again."* (Subject #2).

Comments that were made during the debate also indicated that some participants may routinely dispose of liquid medicines in grey or black water systems. *"Well if it's [a liquid] medicine, you flush it down the toilet, down the sink"* (Subject #1). However, some participants identified that this was not an appropriate method of disposal for medicines. *"A lot of people I know put them down the toilet, which you shouldn't do"*

(Subject #4). Subject #1 also commented that medicines should be not disposed of in normal domestic refuse, suggesting that these may be found by playing children. *“Never put them in a dustbin... I mean there are children that play round rubbish”* (Subject #1). This attitude may lead patients to preferring disposal in grey and black water systems rather than domestic refuse, but does not appear to encourage return to community pharmacies for disposal.

It is possible that the lack of understanding of the final fate of medicines returned to pharmacies is a contributory factor in patients not using the DOOP services and they may believe that returned medicines are re-used by the pharmacy and that contractors profit from the return of these unused medicines. Additionally, it is possible that patients may assume that returned medicines are discarded with normal pharmacy refuse and they may simply dispose of them in their own household refuse believing this to be adequate.

Participants were given information regarding a recent BBC article that reported the finding of fluoxetine in drinking water¹³⁸ and the possibility that medicines may leach from landfill sites or pass through sewerage treatment processes unchanged⁷⁹⁻⁸¹. The discussion that followed this indicated that such information would be likely to encourage participants to return medicines to a pharmacy and not dispose of them in grey and black water or in domestic refuse. This illustrates a potential to change disposal behaviour through provision of appropriate information on the effects of poor medicines disposal. *“Well, they won’t go down the toilet any more, after hearing all this”* (Subject #3).

The participants also raised the possibility that unused medicines may be hoarded in the home or that they may be sold in illicit markets. *“They buy something over the counter*

and take it for a short period, and when they've had enough, it's just shoved in the cupboard" (Subject #1). *"If they are any good, they might sell them... If they are going to put them on an upper or a downer... What are they called? Temazepam"* (Subject #1). This comment indicates that patients are aware of the potential for illicit sale of certain prescription medicines and the diversion of unused medicines to illicit markets from legitimate supply routes is an area requiring further study.

Two alternative methods of disposal were suggested by participants and a member of the social club who was not participating in the interview, but had been listening to the discussion. These were intended to facilitate the disposal of unused medicines among the elderly and those that may find accessing pharmacies difficult. *"Why not have one of these bins that they have in the hospital for waste [at a pensioners' social club], that is collected on a regular basis, then as they go into the club, they can put them in there. A lot of older people don't want to make the effort"* (Subject #1). *"If [chemists] had a safe like the night safes on a bank, then people could take unwanted medicines, or at the doctors"* (Social club member). Considerable resources would be required to implement these suggested service adjustments and a number of potential problems may arise for example they may be inappropriately used for disposal of contaminated syringes or biohazardous waste. However, the suggestions highlight that some people may chose not to use the services currently provided from community pharmacies and certain patients may not be able to access these services as they presently stand. Since the DOOP service that is currently offered has now been used with little variation for over three decades and has been shown to receive only a small proportion of all unused medicines^{49,50}, there is a clear opportunity to develop this service further and possibly improve the disposal of unused medicines.

4.2.3 The requisition and supply of medicines

Participants reported considerable variation in the methods that they employed to obtain supplies of regular medication on repeat prescription. Some participants attended the surgery in person, others ordered their prescription over the telephone and others over the Internet. There was an indication that in some cases, the method used was imposed by the surgery rather than through personal convenience and this appeared to cause certain patients considerable difficulty. *“It’s wrong though that you have to go actually to the doctors to order a repeat prescription. If [someone has] no help and they’re running short on their tablets, you can’t phone up, you’ve got to go to the surgery”* (Subject #1). Participants were also unhappy about the time required to order a repeat prescription and the process involved was the subject of some negative comments. *“The trouble is, with repeat prescriptions you have to wait so many... 2 days is it?”* (Subject #1), *“And you can’t get them from the surgery after 11 o’clock”* (Subject #5).

The debate also covered the quantities of medicines that were usually received in each supply of medicines, and there was notable variation between participants. The quantities that were usually supplied ranged from sufficient for one month’s treatment to sufficient for three months and in some cases, the quantities supplied were not synchronised, increasing the frequency of ordering that was required. *“No [medicines do not run out together], because some you only take one a day, others you take more a day”* (Subject #3).

Ease of access to supplies of regular medicines may have important consequences with regard to the generation of unused medicines, since those patients that find the system unwieldy and awkward to use may order excess medicines in order to minimise the inconvenience caused by numerous trips to their GP surgery and pharmacy. This is

likely to increase the quantity of medicines that are routinely held at any one time in the domestic environment, increasing the risk of accidental or intentional poisoning. Additionally, the increased quantities of medicines obtained in advance of any need is likely to increase the quantities that become unused in the event of a change to the prescribed therapy or death of the patient. It is therefore important that the systems in place for ordering and supply of regular medicines take into account both the needs of the patient and operational constraints, whilst to ensure appropriate access to medicines without promoting over ordering. Participants identified examples where their doctor had restricted supply of medicines based on the anticipated completion date of the previous supply. However, this caused some difficulty to certain participants owing to a disparity between the quantity the patient had in the home and that believed to be present by the prescriber. *“If I tick for more and he knows I’m not due for a week, he crosses it out”* (Subject #6). *“When I order something... they always write on the back, they are not due yet... I said, ‘what are you talking about’, he says, ‘You must have loads up in your cupboard’”* (Subject #3).

Jesson and co-workers have shown that the new repeat dispensing services offered under the New Contractual Framework for pharmacies in England and Wales have the potential to reduce the quantities of unused medicines that are generated in primary care²⁴. However, this study was undertaken as part of a pilot program where pharmacies were sufficiently resourced to provide this service and it is possible that the staffing pressures present in community pharmacies may cause sub-optimal implementation of this service and unintentionally raise the quantity of unused medicines that are generated. Further work is needed to determine the true effect of introducing this service.

4.2.4 The information provided with prescribed medicines

The information provided with medicines is important in both ensuring that the patient is fully informed of all aspects of their medicines and also in affecting the way in which they use their medicines. Anecdotal evidence suggests that some information provided with prescribed medicines, particularly that supplied in printed form, may lead to the patient becoming fearful of using a medicine, perhaps as a result of the listed adverse reactions. This was demonstrated by the comments of Subject #2 whose husband had not taken a prescribed medicine for fear of an adverse reaction as detailed in the patient information leaflet (section 4.2.1.1). However, some participants demonstrated a knowledge of the benefits of taking preventative therapies and illustrated the potential for information may also have a positive influence on patient compliance.

The group participants were generally in favour of increased availability of information on prescribed medicines and indicated that they would like clear verbal and written information on many difference aspects of the use of medicines. Some participants reported that they currently received useful information from their general practitioner. *“The print should tell you that taking certain tablets you cannot drive. It should be made plainer”* (Subject #3). *“I mean I’ve got a doctor who’ll tell me straight away if there’s... they are going to interfere with me at all”* (Subject #2).

Participants showed an interest in information on adverse drug reactions (ADR), yet information on ADRs led to unused medicines in one example given by the participants indicating the polarised influences that information may have on patient compliance, having a positive or negative effect in different situations. A number of comments made during the debate also indicated that patients may become confused regarding the information provided to them. *“Always ask your GP while you’re taking antibiotics, if*

you can take paracetamol, with that particular antibiotic” (Subject #1). In this example, Subject #1 has apparently misunderstood the advice on not taking more than one paracetamol preparation concurrently. This has led the patient to believe that antibiotics routinely interact with paracetamol and through making this error, it is possible that the patient would not observe the original advice and may inadvertently use two paracetamol containing products. It is important that the information given to patients is clear and unambiguous, delivered in a form that is suitable for their needs in order to minimise the potential for misinformation to perpetuate among patient groups. The group participants suggested that information on medicines provided by pharmacies should be promoted, where it may be tailored to the individual. *“[Patients] should be encouraged to go back to [the] chemist and say, I’ve got a funny head’ and if [the drugs] are not suitable and he can always say then ‘well I suggest you go back to your doctor and if the tablets aren’t any good, would you be kind enough to pop them back to me and I’ll dispose of them’”* (Subject #4). While pharmacists would be expected to have the appropriate pharmaceutical and pharmacological knowledge to provide this information, since pharmacists currently have no access to patient medical records, it would be difficult to provide full and complete advice. This would necessitate referral to the general practitioner in many cases where the query could easily have been resolved by the pharmacist. Indeed, if pharmacists were able to access the patient’s medical record, it would be reasonable to include the discussion of various aspects of medicines use and interactions during consultations on OTC medicines and also during the supply of repeat medication. This would have the benefit of resolving many patient concerns regarding the use of medicines and consequentially reducing the incidence of medicines that have been unused as a result of patient confusion or fear.

In order that patients are able to take greater responsibility in their healthcare, it is important that they are provided with sufficient information on the medicines they are using to enable them to make a reasoned choice. However, participants indicated that verbal and written information currently available on medicines is variable in both quality and quantity. It is important that any information provided to patients, whether printed or verbal, is carefully tailored to their needs and that they are not overloaded with irrelevant or misleading information. Through the provision of high quality information on the medicines supplied, it is likely that patient compliance can be raised and the incidence of unused medicines minimised. However, the way in which this information influences the use of medicines use requires further study.

4.3 Summary

The qualitative data gathered during the group interview are useful in both confirming some anecdotal evidence and highlighting the necessary areas for further quantitative study. The findings made in this element of the study have been taken forward and used in the construction of the self completion postal questionnaire to identify those factors that commonly influence the generation of unused medicines in primary care thereby allowing a more comprehensive assessment of the issues involved.

CHAPTER 5 : A postal questionnaire considering patient attitudes and actions regarding medicines

5.1 Introduction

The majority of data currently available on unused medicines have been gained through the assessment of medicines returned to hospital or community pharmacies. Throughout the world, only a small number studies have considered unused medicines in the domiciliary setting and just 3 such studies having been performed in the UK to date. The first of these studies was undertaken in Merseyside during 1990⁴⁸, the second in Portsmouth during 1990⁴⁹ and the third was an OCPS survey undertaken in 1994 and sampled the whole of the UK population⁵⁰.

In this element of the present study, patient attitudes and activities with respect to the use of medicines and unused medicines are considered through issuing a detailed self-completion postal questionnaire which was developed using the findings of the group interview as outlined in section 4.2. The questionnaire was issued to a sample of 1000 residents of Eastern Birmingham PCT, the same population that was assessed in the previous elements of the present study. This permits the findings from each of the three elements to be combined, allowing a comprehensive and detailed assessment of unused medicines. In the postal questionnaire, no distinction was made between purchased and prescribed medicines in order to simplify the process for respondents. Therefore, unused medicines in this element of the study are taken to include all medicines in the home that the patient is no longer using. Patients were deemed to have *recent unused medicines* if unused medicines were currently present in the home or had been disposed

of in the six months prior to the completion of the questionnaire as detailed in section 2.7.3.

5.2 Results

The questionnaire recipients were geographically distributed across EBPCT through selection of 100 residents in each of the ten political wards in the PCT. Of the questionnaires that were issued, 12 were returned by the Post Office as undeliverable. Therefore the total number of residents that were sampled was 988. Two follow up mailings of the questionnaire were sent to non-responders and in total, 404 (40.9%) of the 988 recipients returned valid questionnaires. Of these 404, 219 were returned following the first mailing, 143 following the first follow up and 42 following the second follow up. A further 58 recipients returned the letter declining to take part in the study and the reasons given for this are shown in Table 5.1. Some of the 404 returned questionnaires were not fully completed and where a question was not completed left blank by some respondents, only the valid responses are reported.

Table 5.1: The reasons given for declining to participate in the postal questionnaire (number of returns 58)

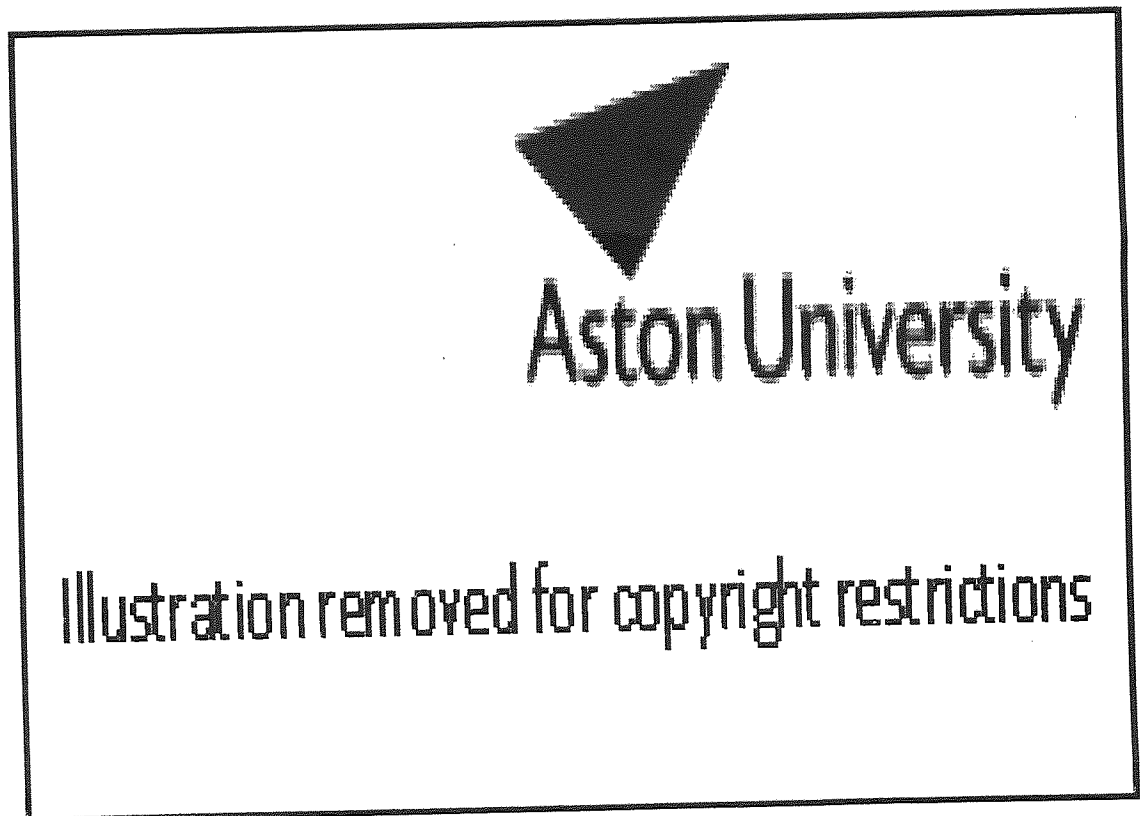
Reason for declining to participate	Number of recipients
Do not like completing questionnaires	33
Never take medicines	7
Can't read English	4
Do not have time	4
Recipient had died	3

Reason for declining to participate	Number of recipients
Medicines waste does not interest me	1
No reason given	6

5.2.1 The geographic distribution of postal questionnaires

Figure 5.1 illustrates the distribution of the questionnaires across the PCT. The response rates were not significantly different between the political wards (χ^2 , $p = 0.104$).

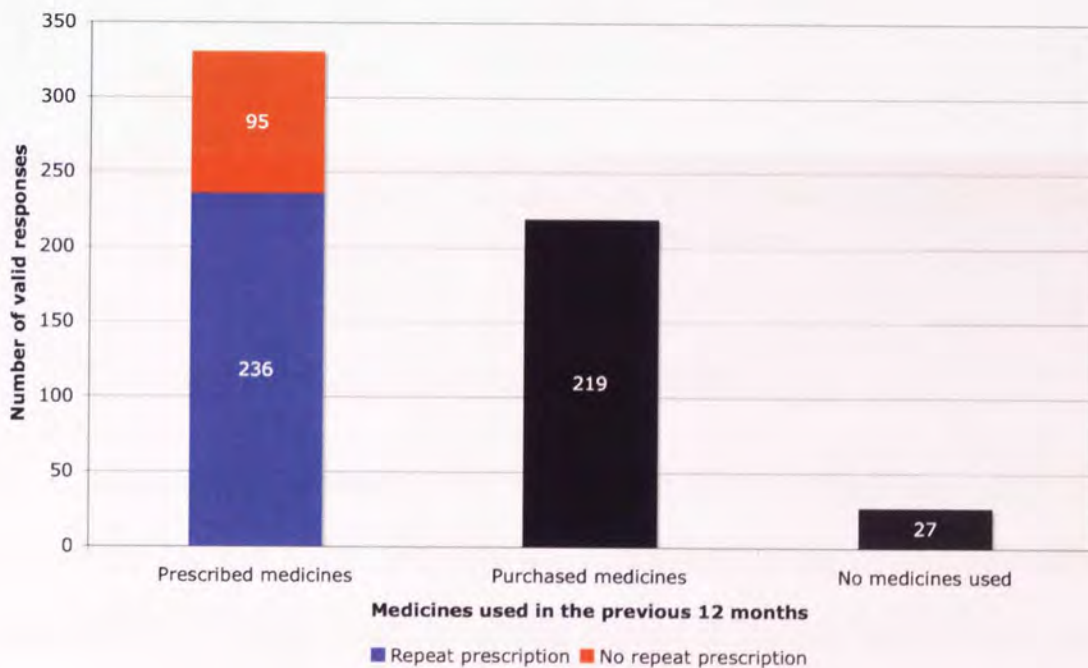
Figure 5.1: The response or non-response to questionnaires by the recipient postcode (questionnaires issued 1000)



5.2.2 The use and storage of medicines

The majority of valid responses (83.0%) indicated the use of prescribed medicines in the previous twelve months and of these 236 were medicines received on repeat prescription (Figure 5.2). Additionally, 219 responses indicated the use of purchased medicines or supplements and 178 of these respondents had also used prescribed medication. Just 27 respondents (6.8%) indicated that they had not used any medicines in the previous 12 months.

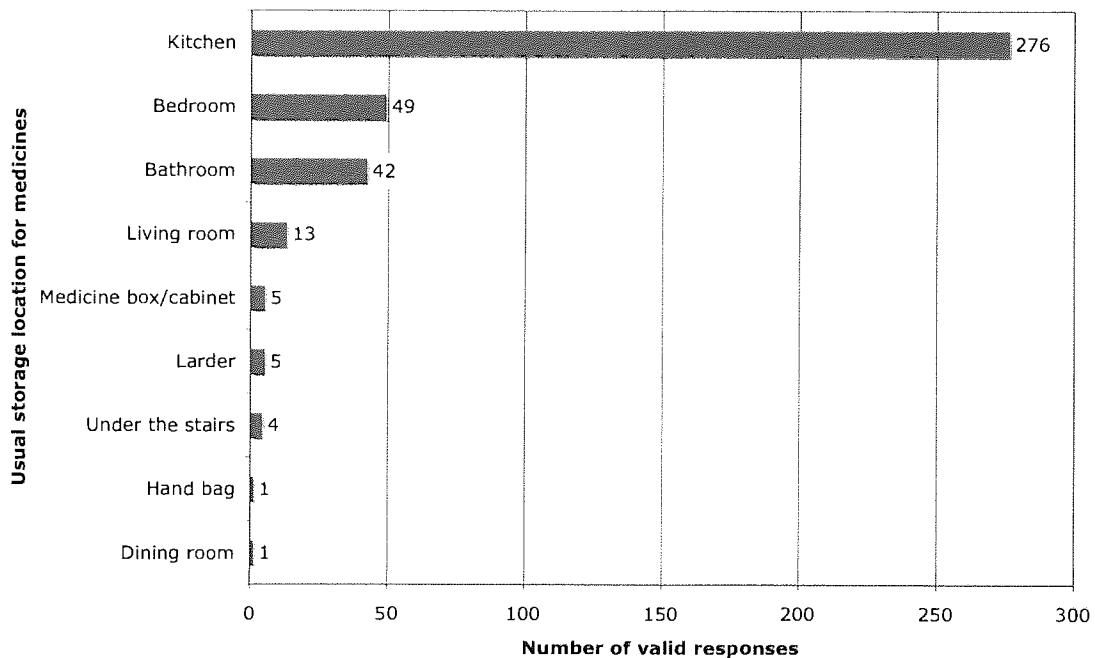
Figure 5.2: The frequency distribution of respondent use of medicines in the previous twelve months (responses: valid 399, invalid 5)



Medicines were usually stored in the kitchen or bathroom by 80.3% of valid respondents. Other rooms that were commonly used for storage of medicines included the bedroom, living room or lounge, larder and the dining room with these rooms accounting for 17.1% of valid responses. A small proportion (1.3%) of respondents also

indicated that they stored their medicines in a box or cabinet allocated for this purpose (Figure 5.3).

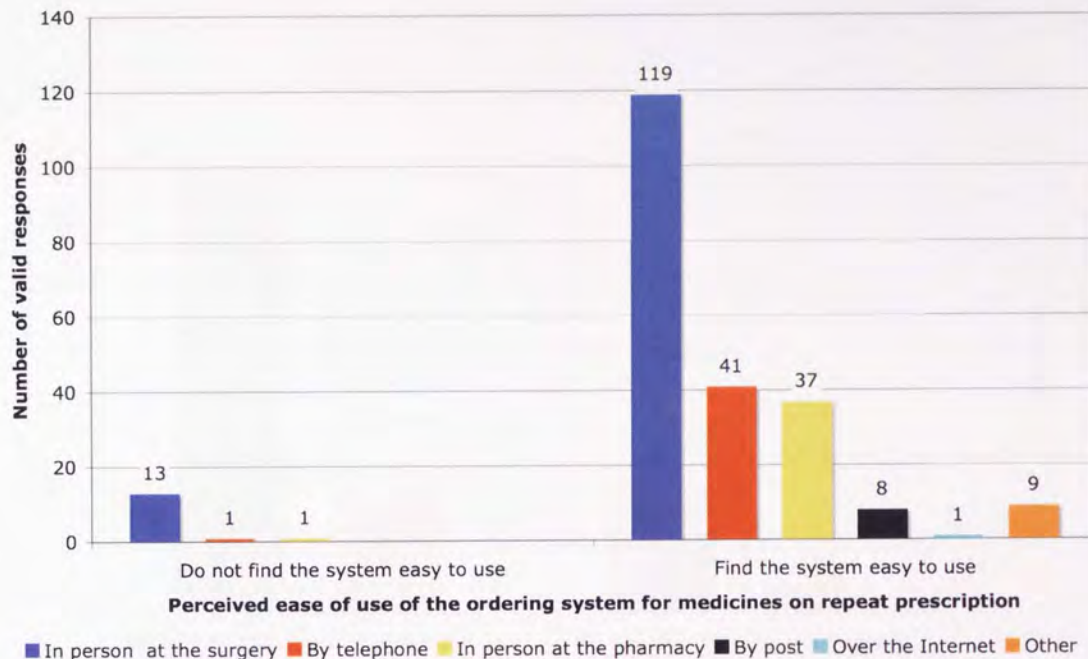
Figure 5.3: The frequency distribution of storage location for medicines indicated by respondents (responses: valid 396, invalid 8)



5.2.3 The requisition and supply of medicines

The majority of valid respondents (93.5%) reported that they found the system they used for ordering their medicines easy to use. Additionally, of the 15 valid respondents who expressed difficulty with their ordering system, 13 (86.7%) reported their usual method of ordering as visiting the surgery in person (Figure 5.4). Ordering of all the items available on the repeat prescription was not influenced by the reported difficulty with the ordering process. One in five valid respondents in each group indicated that they usually ordered all of the available items and the remaining four indicated that they only ordered the items that were required.

Figure 5.4: The frequency distribution of the usual method for ordering medicines on repeat prescription and the perceived ease of use (responses: valid 230, invalid 6)



In order that the number of trips be minimised or in case of unforeseen circumstances, 47 (20.1%) of the valid respondents indicated that they usually ordered all of the items available on their repeat order form. The data indicate that patients who pay for their prescriptions are less likely to order all of the items available in comparison to those patients that are exempt from NHS levies Figure 5.5. However, there were insufficient data to confirm a significant link between the ordering of all the available items and the payment of NHS levies (χ^2 , $p = 0.569$).

Figure 5.5: The frequency distribution of the NHS levy exemption status of respondents and the ordering of the medicines available on repeat prescription (responses: valid 225, invalid 5)

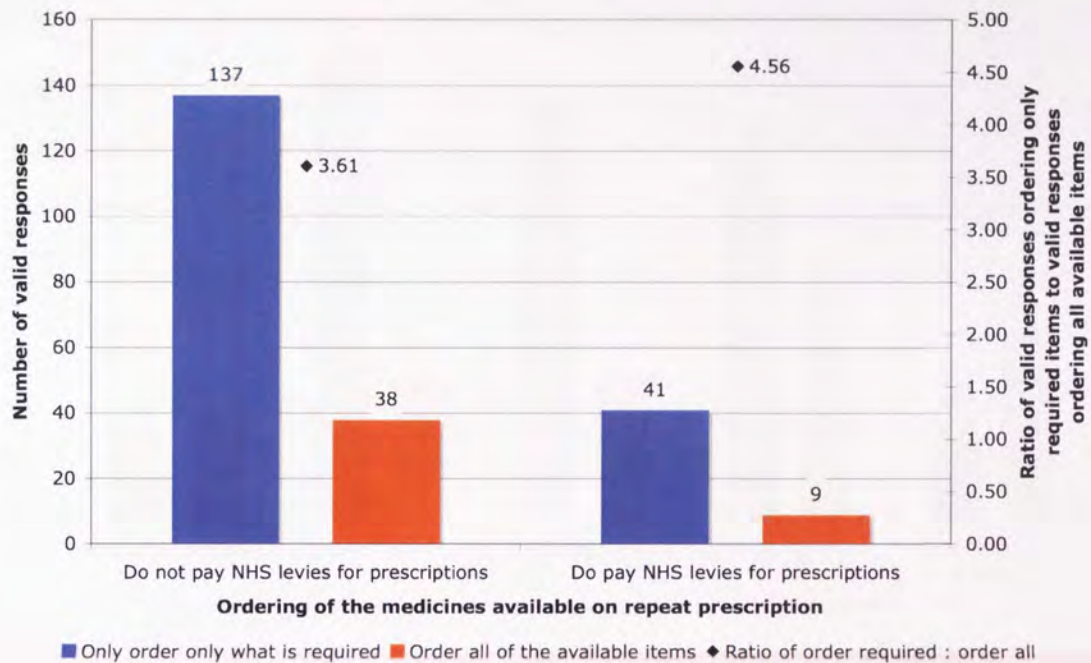
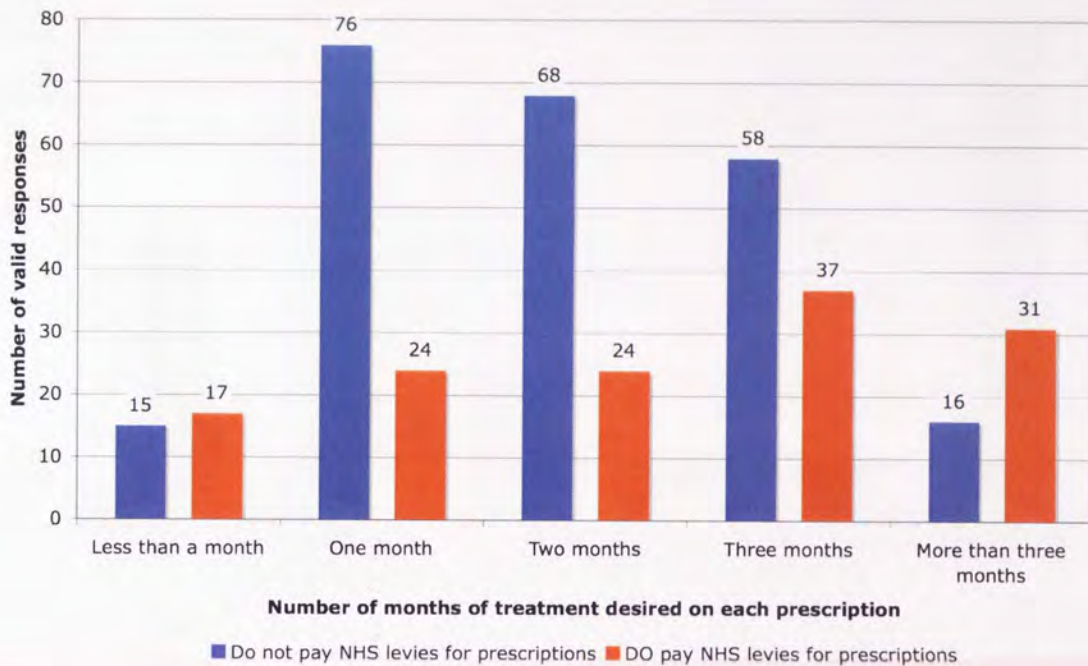


Figure 5.6 shows the NHS levy exemption status of respondents in comparison with the number of months of treatment each respondent would like to receive on each prescription. While respondents in general showed little preference in the quantity they would like to receive, there was a significant difference between those patients that were exempt from NHS levies and those that were not (χ^2 , $p < 0.001$), with respondents in the latter group indicating a greater preference for larger quantities of medicines to be supplied (Figure 5.6).

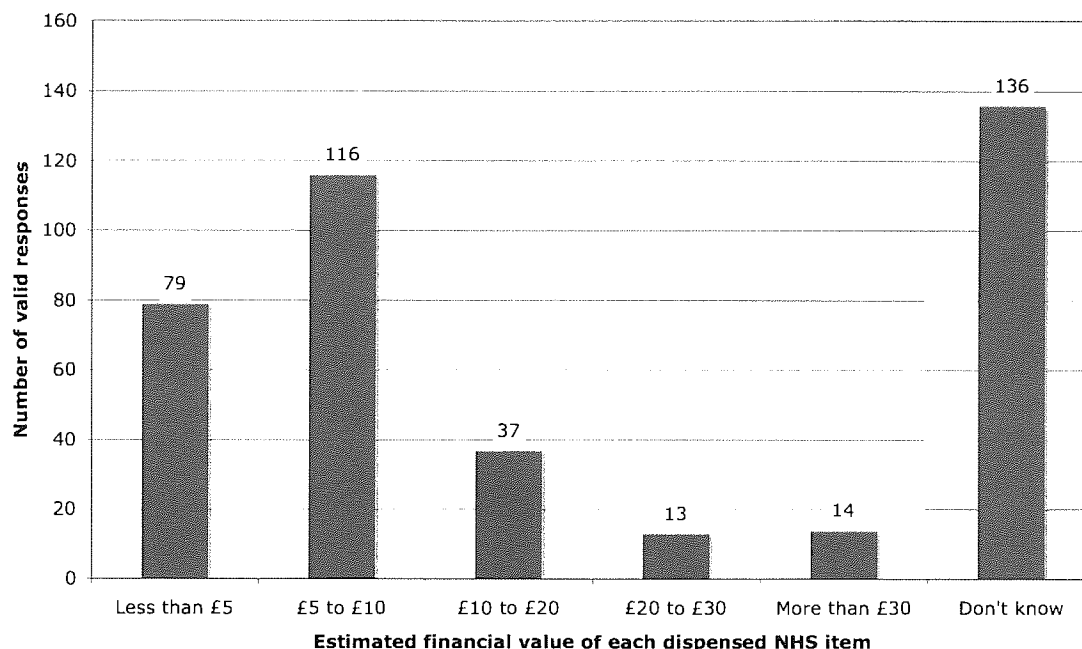
Figure 5.6: The frequency distribution of the desired quantity of treatment supplied on each repeat prescription and the NHS levy exemption status of the respondent (responses: valid 366, invalid 44)



5.2.4 The financial value of medicines

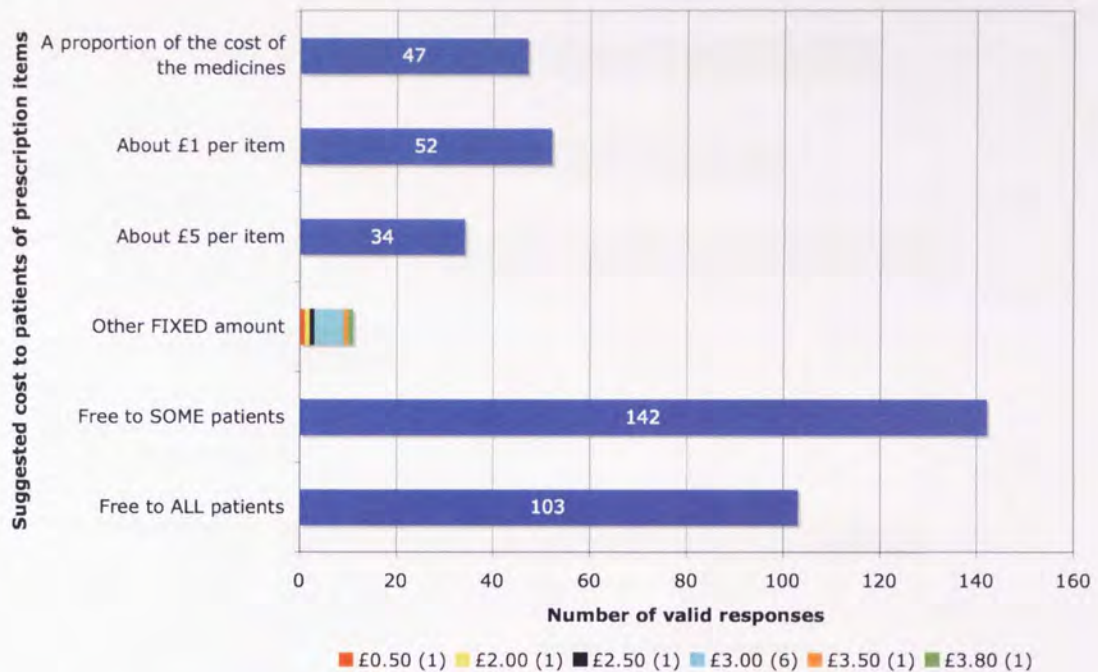
The mean financial value of each item dispensed in England during 2004 was £11.78⁹¹ and just 37 (9.4%) of the valid respondents estimated this value correctly. Respondents indicated that they did not know the financial value of dispensed medicines in 145 (36.7%) of valid responses and dispensed medicines were overvalued in a further 27 (6.8%) valid responses. Notably, 195 (49.4%) of valid responses estimated the financial value of dispensed medicines to be less than £10 per item (Figure 5.7).

Figure 5.7: The frequency distribution of the estimated financial value of dispensed items (responses: valid 395, invalid 9)



The majority of respondents showed support for the charging of NHS levies and 286 (73.5%) of the valid responses indicated that they were in favour of patients paying towards their medicines. Of the respondents in favour of charging, 142 (49.7%) suggested that a fee should be paid by some, but not all, patients and 97 (33.9%) proposed a fixed fee that ranged from £1 to £5. The remainder (16.4%) of these 286 respondents indicated that patients should pay a proportion of the cost of the medicine. Just 103 (26.5%) of the valid responses were in favour of free prescriptions for all patients.

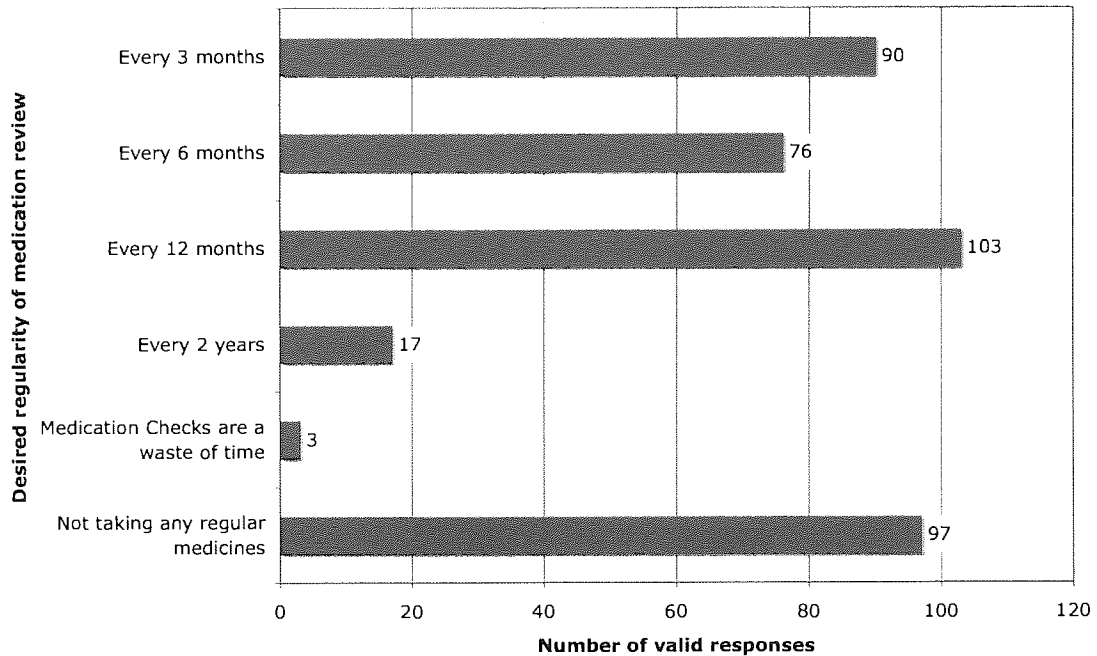
Figure 5.8: The frequency distribution of respondent opinion of NHS prescription levies for medicines (responses: valid 389, invalid 15)



5.2.5 Patient experience and attitudes regarding medication reviews

Medication reviews were introduced to the questionnaire recipients as a situation where a healthcare professional reviews all the medicines that are currently being used and discusses adverse drug reactions, the most appropriate use of the medicines and the purposes of the medicines, making changes to therapy where appropriate. Respondents showed considerable support for medication reviews and just three (0.8%) valid responses indicated that they were unnecessary. The majority of valid responses (94.3%) in favour of reviews indicated that they would like them at least annually and 17 respondents indicated that they would like a review every 2 years.

Figure 5.9: The frequency distribution of the desired regularity for medication reviews
(responses: valid 386, invalid 18)



General practitioners were the most common health professional that respondents indicated they would like perform medication reviews and they were selected by 336 (87.7%) valid respondents. Nurses were selected by 111 (30.0%) valid respondents and pharmacists by just 37 (9.7%) (Figure 5.10). One respondent suggested that medication reviews should be performed by a consultant and another indicated that anyone qualified to do so would be appropriate.

Respondents favoured the doctor's surgery as the ideal location for medication reviews with 351 (92.4%) valid responses. Patient homes and pharmacies less popular attracting just 50 (13.2%) and 32 (8.4%) of the valid responses respectively (Figure 5.11). Other possible locations that were suggested by respondents were the hospital (1 valid response), a specialist medication centre (1 valid response) and one respondent suggested that these could be performed over the telephone.

Figure 5.10: The frequency distribution indicating the health professionals that patients would like to perform medication reviews

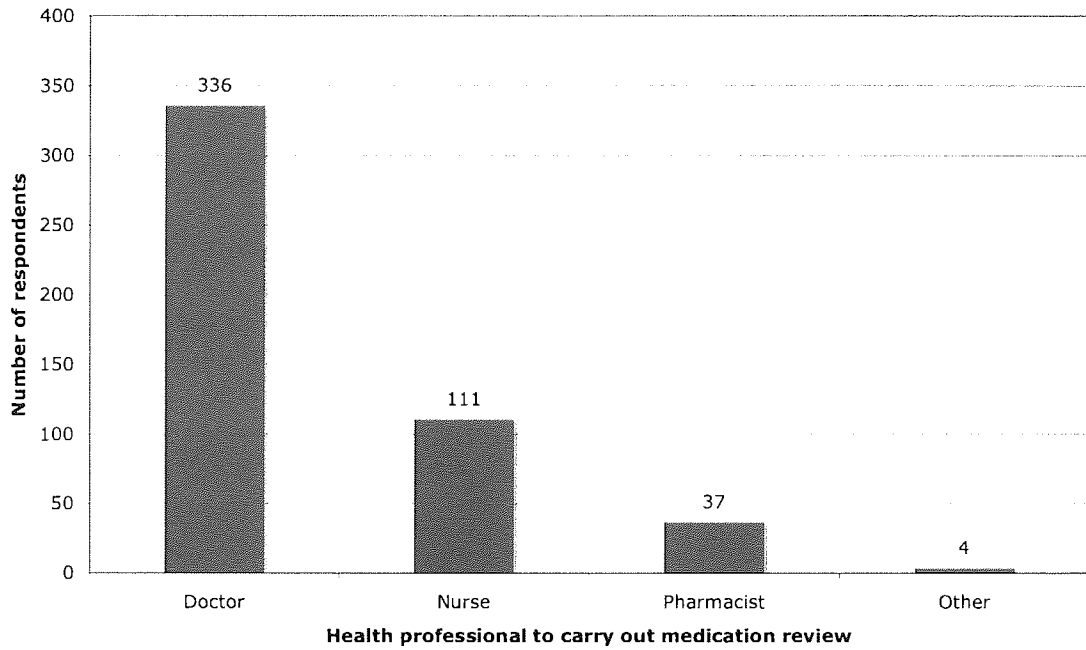
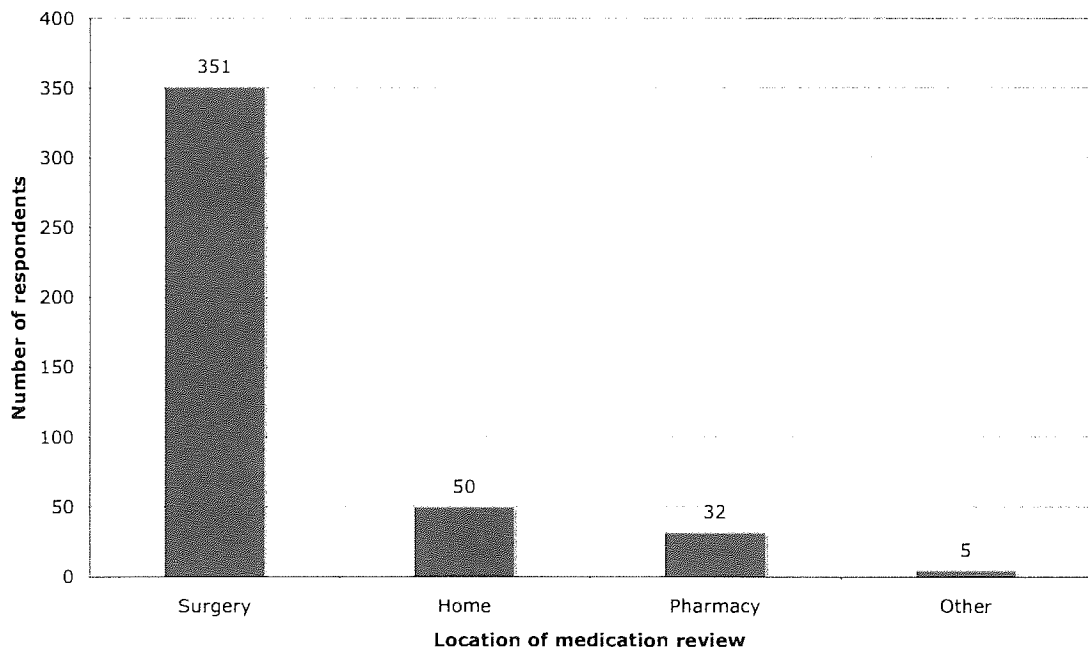


Figure 5.11: The frequency distribution indicating the locations where patients would like medication reviews to be undertaken

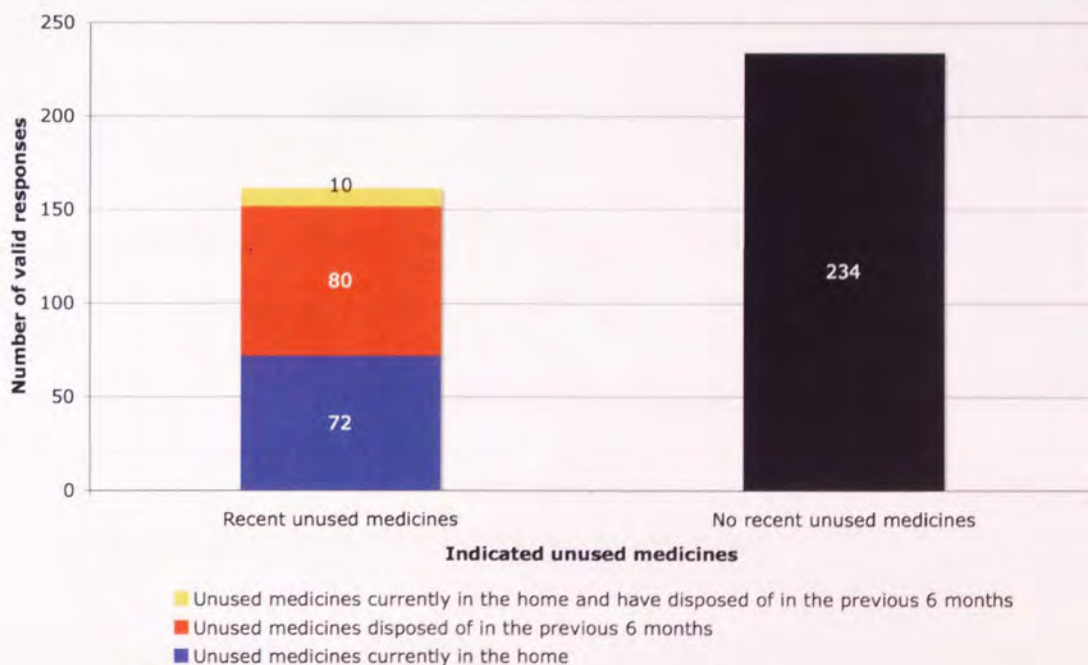


5.2.6 Unused medicines in the home and their disposal

5.2.6.1 Respondents with recent unused medicines

A total of 162 valid respondents (40.1%) indicated recent unused medicines with 80 having disposed of unused medicines in the previous six months, 72 currently having unused medicines in the home and 10 indicating that both scenarios were true (Figure 5.12). The ratio of valid respondents indicating recent unused medicines to those with no recent unused medicines was 0.69.

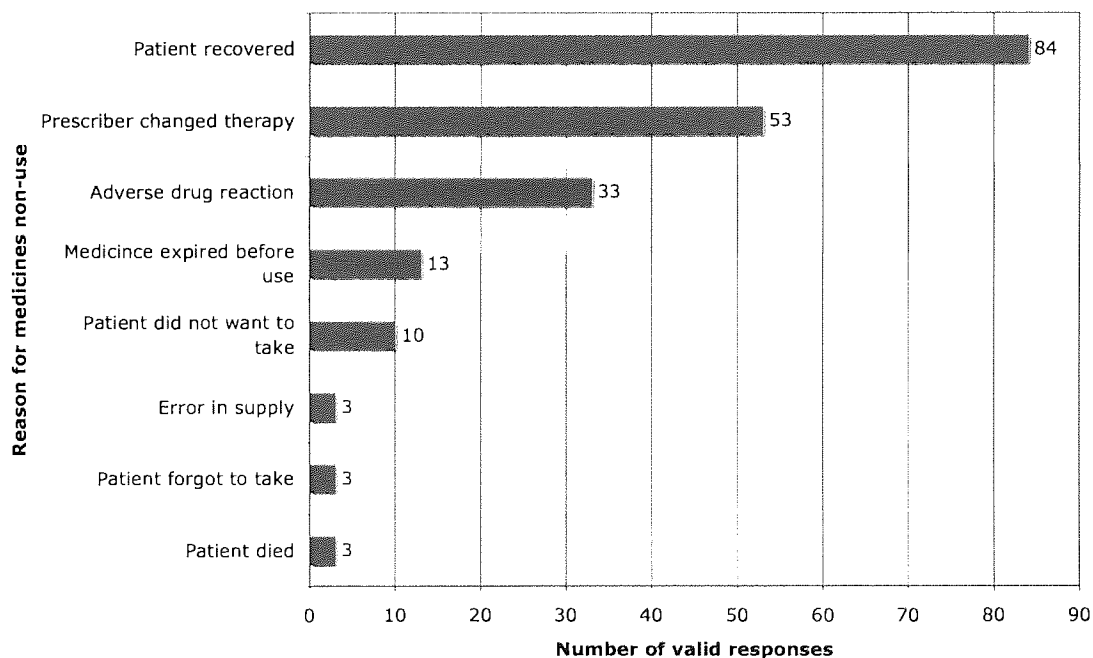
Figure 5.12: The frequency distribution of the number of valid respondents with unused medicines disposed of in the past 6 months or currently in the home (responses: valid 396, invalid 8)



5.2.6.2 The reasons for unused medicines

The 162 respondents with recent unused medicines gave a range of reasons for their non-use and some individuals indicated a number of different reasons.. The most common reason reported was the patient got better, which was indicated in 84 (53.5%) of the valid responses. Changes to the prescribed therapy and adverse drug reactions were also commonly reported, with 53 (33.8%) and 33 (21.0%) valid responses respectively (Figure 5.13).

Figure 5.13: The frequency distribution of the reasons reported for unused medicines in the home (valid respondents =157, invalid 5)

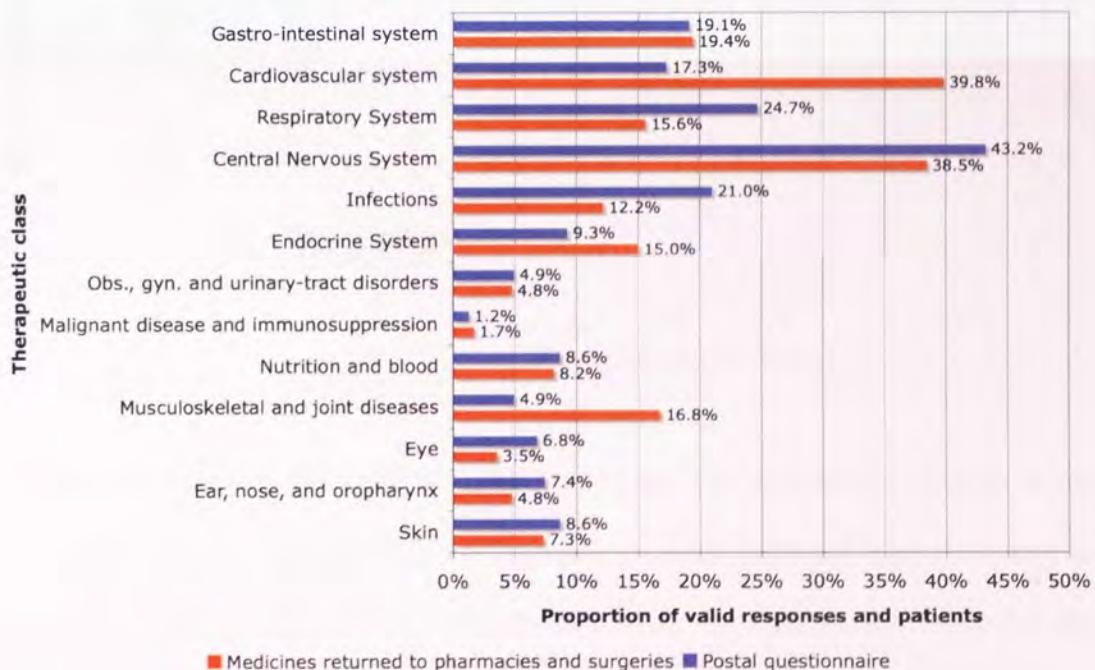


5.2.6.3 The therapeutic class of unused medicines

Figure 5.14 shows the proportion of valid responses indicating recent unused medicines in each therapeutic class in the present element of the study and the proportion of patients returning medications from each therapeutic class in the collection element of

the study as detailed in section 3.3.4.1. Cardiovascular medicines and those acting on the central nervous system were most commonly returned by patients in the collection element of the study. Whereas medicines that act on the central nervous system were the most commonly reported in the questionnaire, with 70 valid responses indicating recent unused medicines from this therapeutic class. Respiratory medicines, anti-infective agents, gastro-intestinal medicines and medicines acting on the cardiovascular system were also commonly identified by respondents with recent unused medicines with 40, 34, 31 and 28 valid responses respectively.

Figure 5.14: The proportions of patients returning unused medicines and valid responses of recent unused medicines in each therapeutic class (responses: valid with recent unused medicines 162, number of patients returning unused medicines 905)

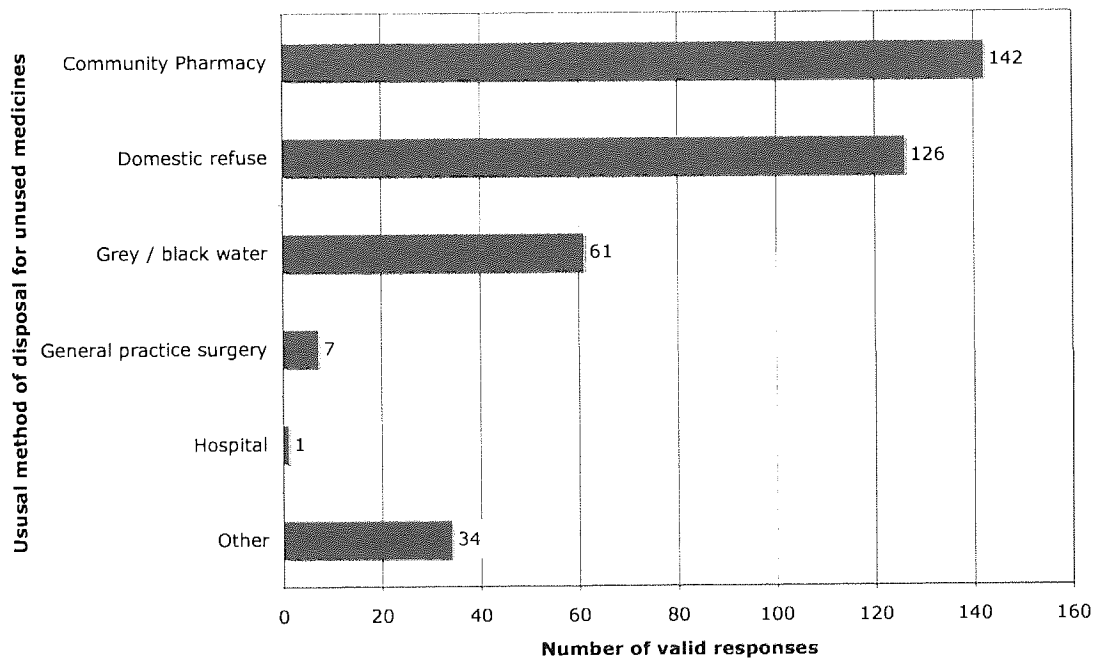


5.2.6.4 The usual method used for disposal of unused medicines

The most common method employed by respondents for disposal of unused medicines was to return them to a pharmacy, with 142 (38.3%) of valid respondents indicating that

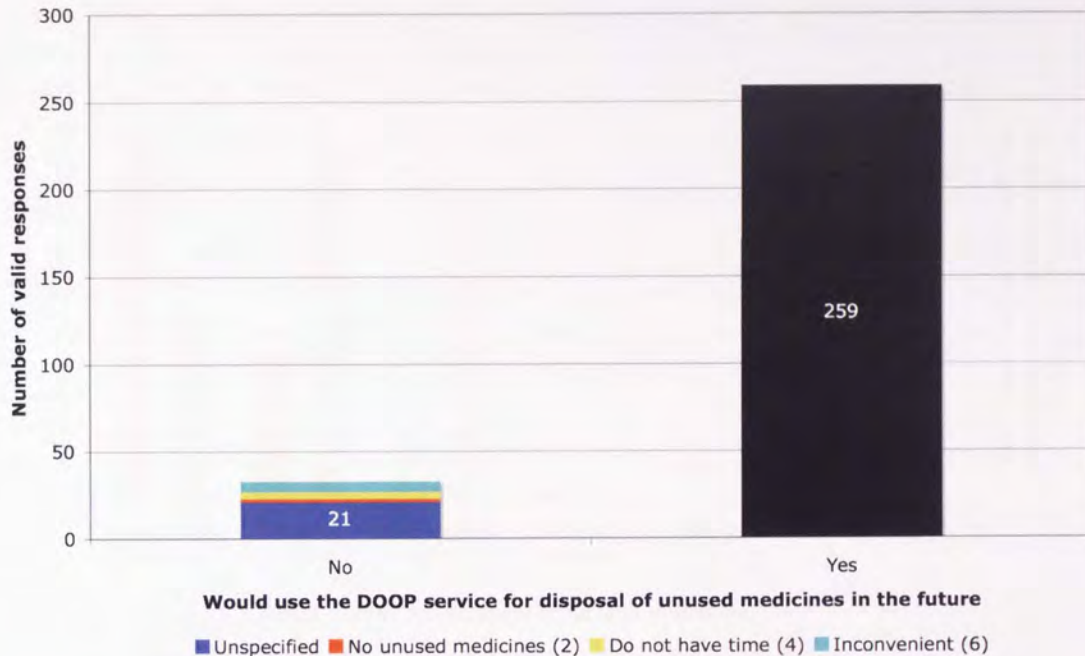
this as the usual action (Figure 5.15). A further 7 valid responses (1.9%) indicated that unused medicines were routinely returned to their general practitioner's surgery and one individual usually returned their unused medicines to their local hospital. Sixty one (16.4%) of valid responses indicated disposal of unused medicines in grey and black water and a further 126 (33.9%) valid responses disposed of them in domestic refuse.

Figure 5.15: The frequency distribution of the usual method for disposal of unused medicines employed by respondents (responses: valid 371, invalid 33)



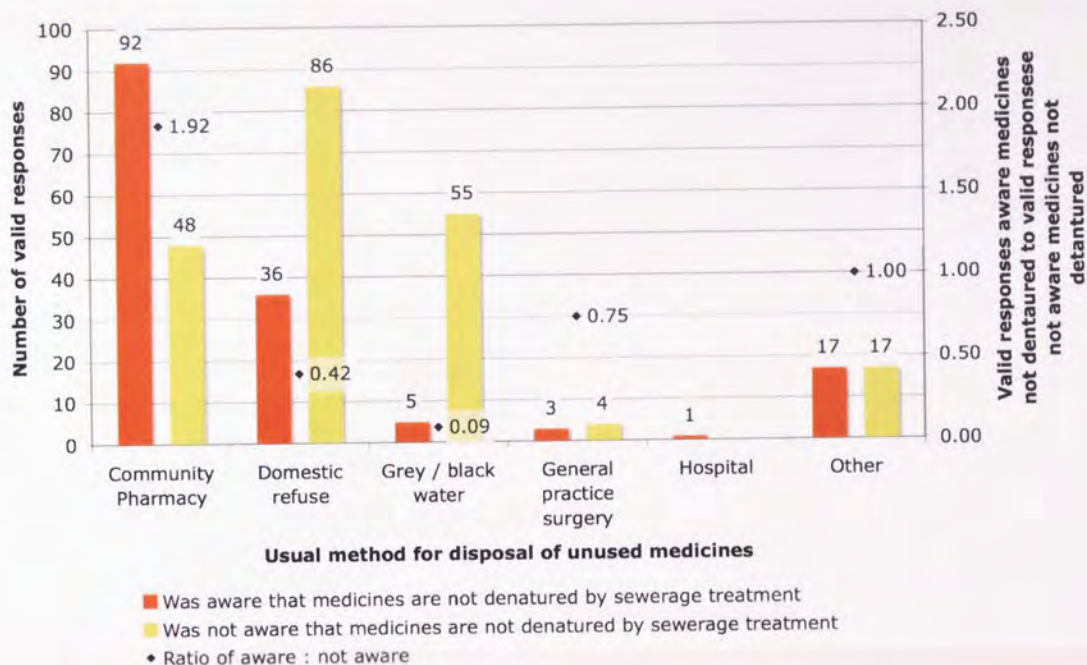
The disposal of old pharmaceuticals (DOOP) scheme was indicated as familiar in only 90 (22.8%) valid responses. Of the respondents who indicated that they had not previously heard of the scheme, 259 (88.7%) valid respondents indicated that they would use it now that they were aware of it (Figure 5.16).

Figure 5.16: The frequency distribution of the use of the DOOP scheme by respondents that had not previously heard of the scheme (responses: valid 292, invalid 13)



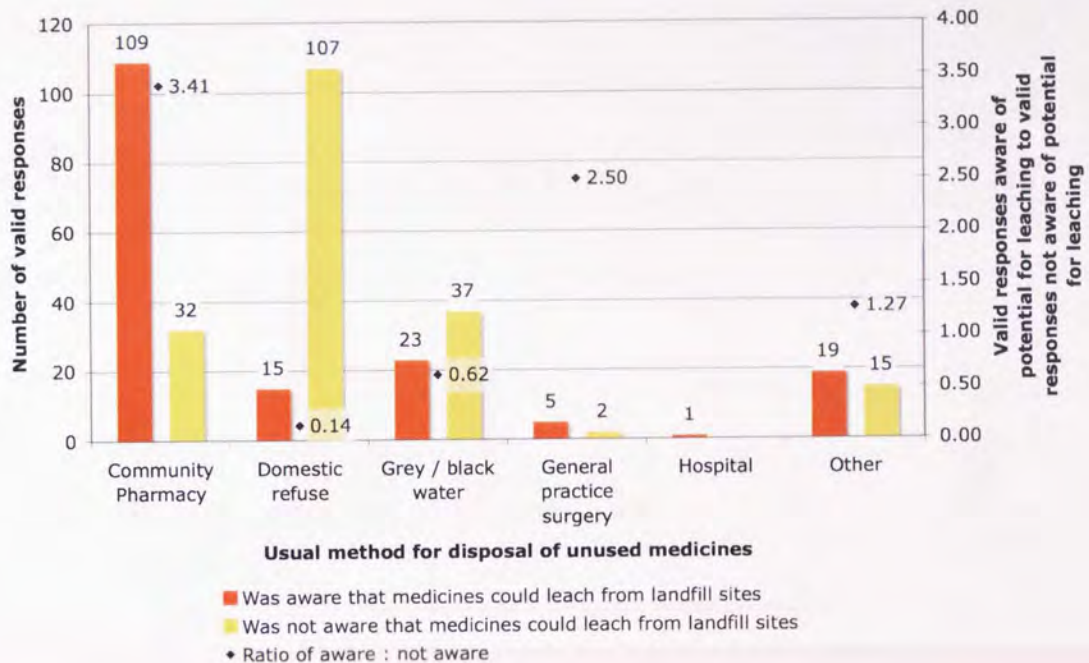
Respondents were informed that sewerage treatment processes would not normally remove medicines from wastewater and that medicines disposed of by grey and black water may be passed into local watercourses. Of the valid responses, 165 (45.3%) indicated that they were already aware of this (Figure 5.17) and there was a significant reduction in this group in the proportion of respondents disposing of unused medicines by grey and black water (χ^2 , $p < 0.001$).

Figure 5.17: The frequency distribution of respondents usual disposal method for unused medicines and their awareness of the effectiveness of sewerage treatment in denaturing medicines (responses: valid 364, invalid 40)



Respondents were also informed of the potential for unused medicines, which had been disposed of in domestic refuse, to leach from landfill sites and into local water courses. Of the valid responses, 185 (50.7%) indicated that they were already aware of this (Figure 5.18) and there was a significant reduction in this group in the proportion of respondents disposing of unused medicines by domestic refuse (χ^2 , $p < 0.001$).

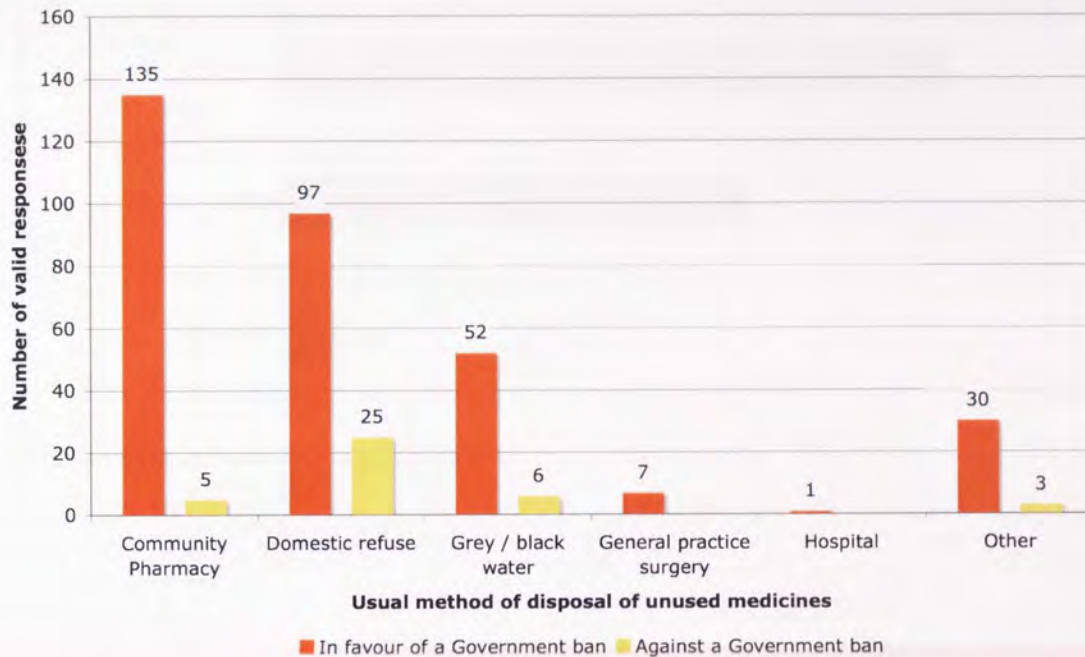
Figure 5.18: The frequency distribution of the usual disposal method adopted for unused medicines and the awareness of the potential for leaching of medicines from landfill sites (responses: valid 365, invalid 39)



The majority of valid responses (96.1%) showed support for a government ban on disposal of unused medicines by household refuse or grey and black water (Figure 5.19). Additionally, the respondents that were against a ban were significantly more likely to dispose of their medicines in domestic refuse or by grey and black water (χ^2 , $p < 0.001$).

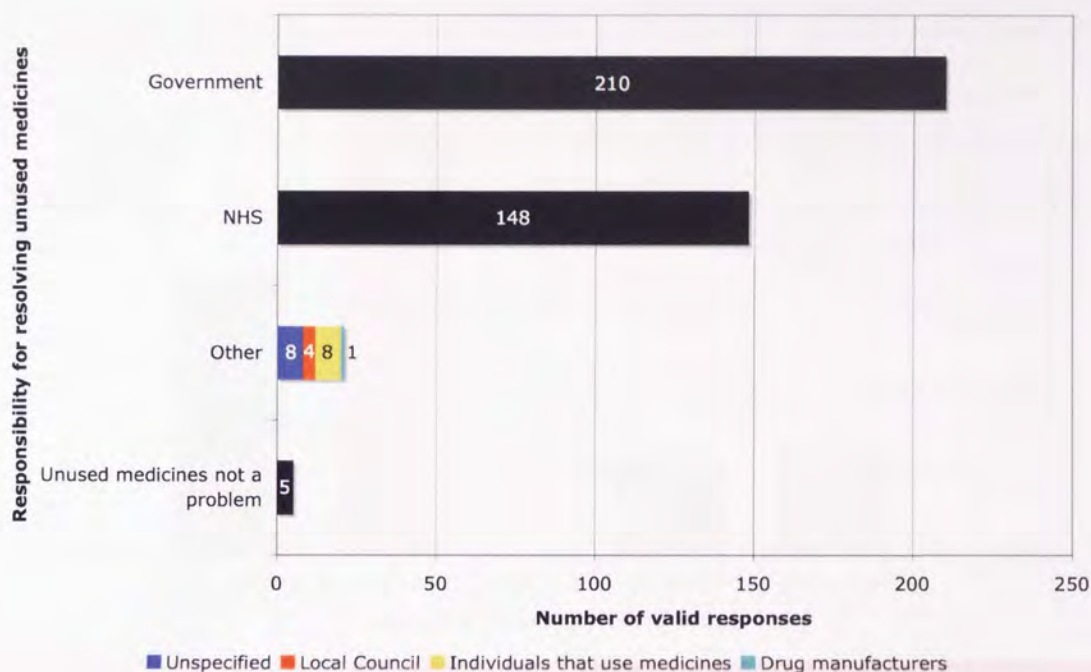
Respondents were also overwhelmingly in favour of greater availability of information on the potential problems that may be caused by poor disposal of unused medicines, with 387 (99.7%) valid responses supporting this idea and just one response indicating that more information should not be made available.

Figure 5.19: The frequency distribution of the usual method for disposal for unused medicines and respondent attitude to a Government ban on disposal of medicines in domestic refuse and grey and black water (responses: valid 361, invalid 43)



The majority of valid responses (96.6%) were in favour of an organisation working to resolve the problems posed by unused medicines and just 3 valid responses indicated that they felt unused medicines were not a problem (Figure 5.20). The respondents clearly endorsed a national response to the problem, with 94.4% of responses in favour of action identifying the NHS or Government as the appropriate organisation to tackle the issue.

Figure 5.20: The frequency distribution of the organisations identified by respondents as most appropriate to resolve problems caused by unused medicines and their disposal (responses: valid 384, invalid 20)

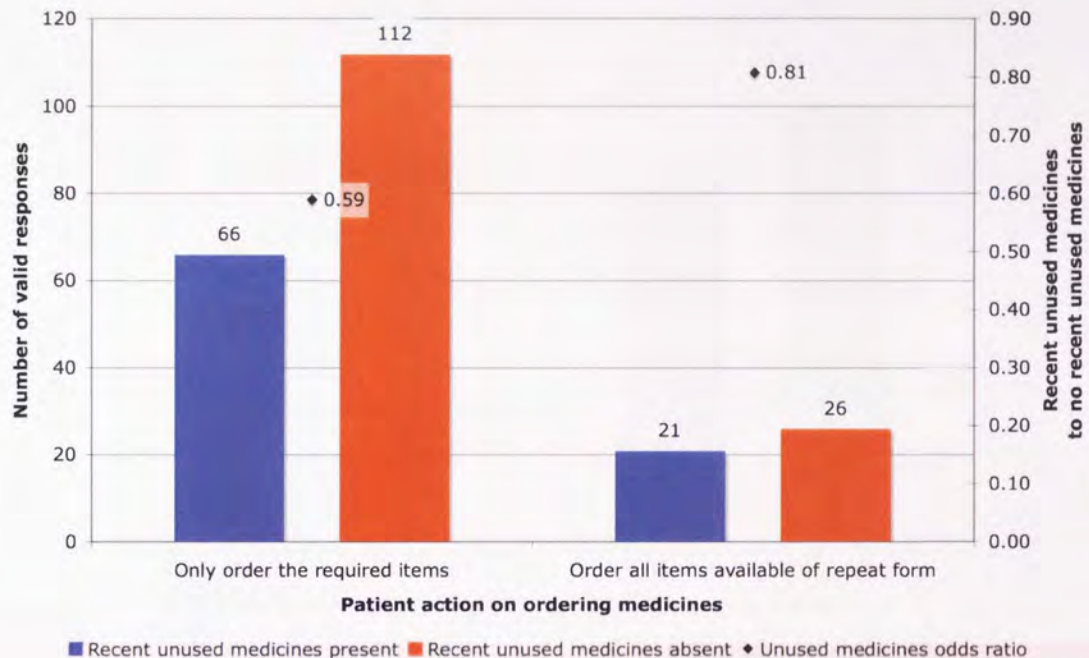


5.2.7 Possible precipitating factors for recent unused medicines

5.2.7.1 The ordering of repeat medication

Respondents that ordered all of the available items on their repeat order form showed a moderately increased likelihood of having recent unused medicines with an unused medicines odds ratio of 0.81 compared with a 0.59 for respondents that only ordered the items they required (Figure 5.21). Insufficient data are available in this element to determine whether this finding is significant (χ^2 , $p = 0.341$).

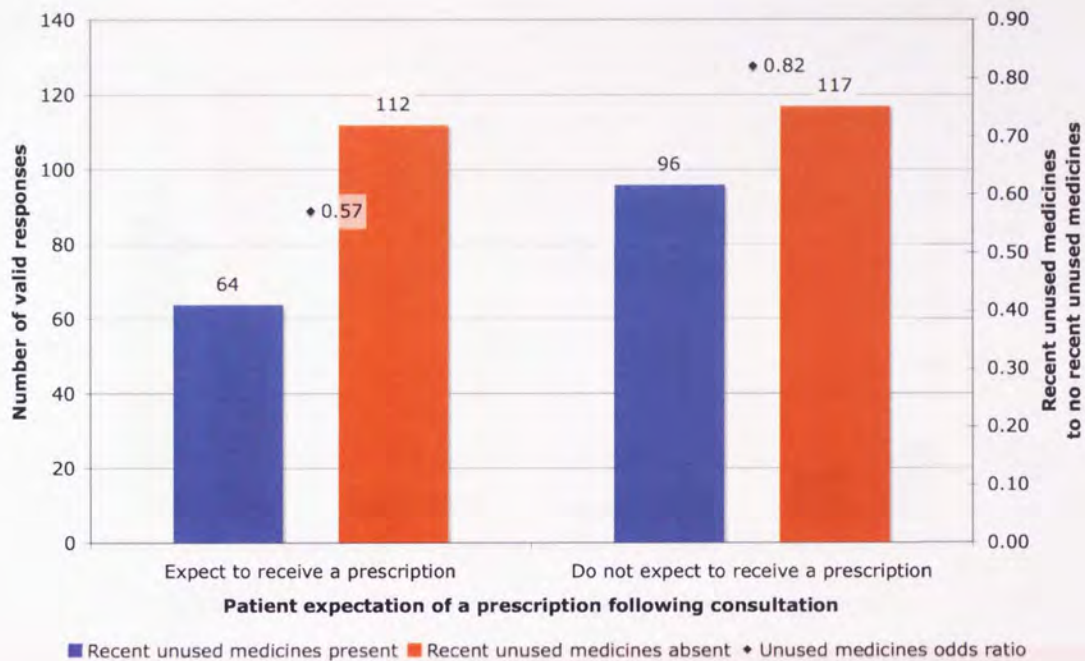
Figure 5.21: The frequency distribution of the usual behaviour when ordering repeat medicines and the presence of recent unused medicines (responses: valid 225, invalid 11)



5.2.7.2 Respondent expectations and experiences of prescribing of medicines

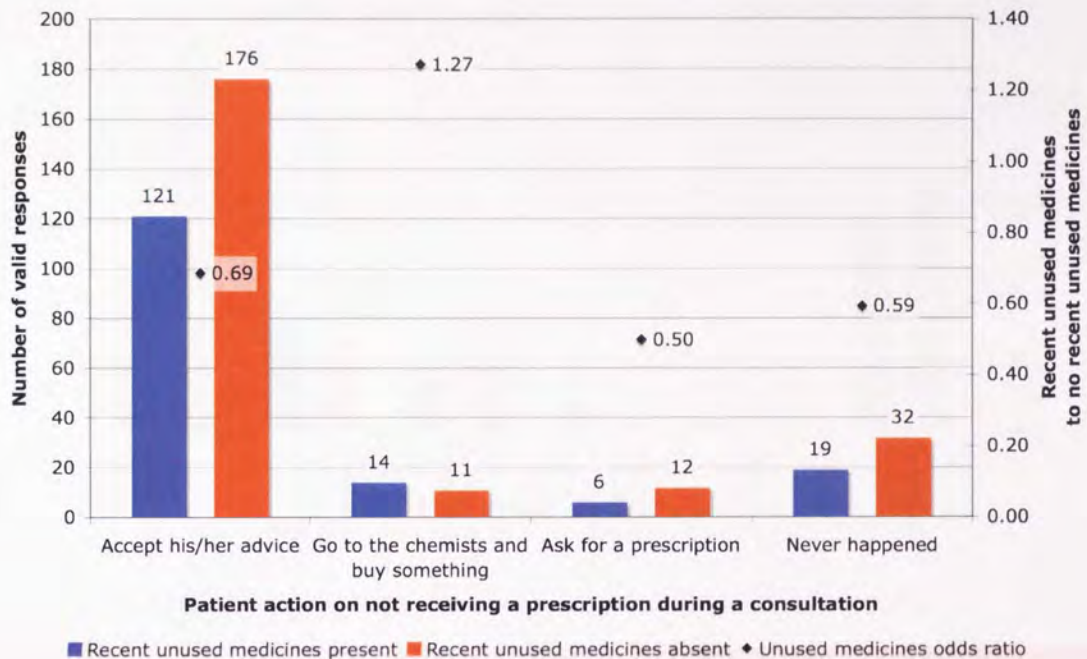
When visiting their general practitioner for a consultation, 180 (46.3%) of the valid responses indicated that they would usually expect a prescription. Respondents expecting a prescription appeared to be less likely to have recent unused medicines with an unused medicines odds ratio of 0.57 compared to 0.82 for those respondents that did not usually expect a prescription. 0.69 (Figure 5.22). The responses received were not sufficient in number to demonstrate significance (χ^2 , $p = 0.082$).

Figure 5.22: The frequency distribution of usual expectation of receiving a prescription following a GP consultation and the presence of recent unused medicines (responses: valid 389, invalid 15)



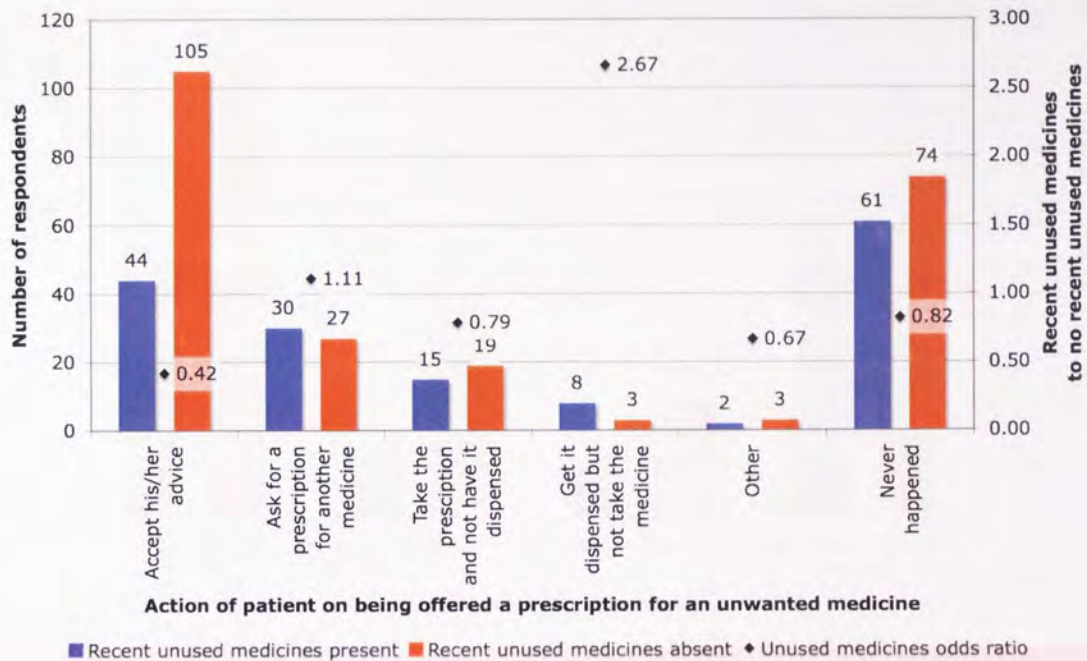
Where patients were not offered a prescription during a consultation, those respondents that indicated they would purchase something over the counter were considerably more likely to have recent unused medicines, with an unused medicines odds ratio of 1.27 (Figure 5.23). Respondents that indicated they would normally ask for a prescription if one were not offered were less likely to have recent unused medicines and had an unused medicines odds ratio of 0.50. Significance could not be determined owing to limited data availability (χ^2 , $p = 0.381$).

Figure 5.23: The frequency distribution of the action of respondents in response to not being offered a prescription and the presence of recent unused medicines (responses: valid 391, invalid 13)



In cases where a prescription was offered, but for a medicine that the patient did not want to take, a notable difference was seen among the different actions taken in the likelihood of having recent unused medicines. Those respondents that indicated they would have the medicine dispensed and not use it were considerably more likely to have recent unused medicines (Figure 5.24). Whereas, respondents that followed the advice of the prescriber had a much lower likelihood of having recent unused medicines, showing an unused medicines ratio of just 0.42.

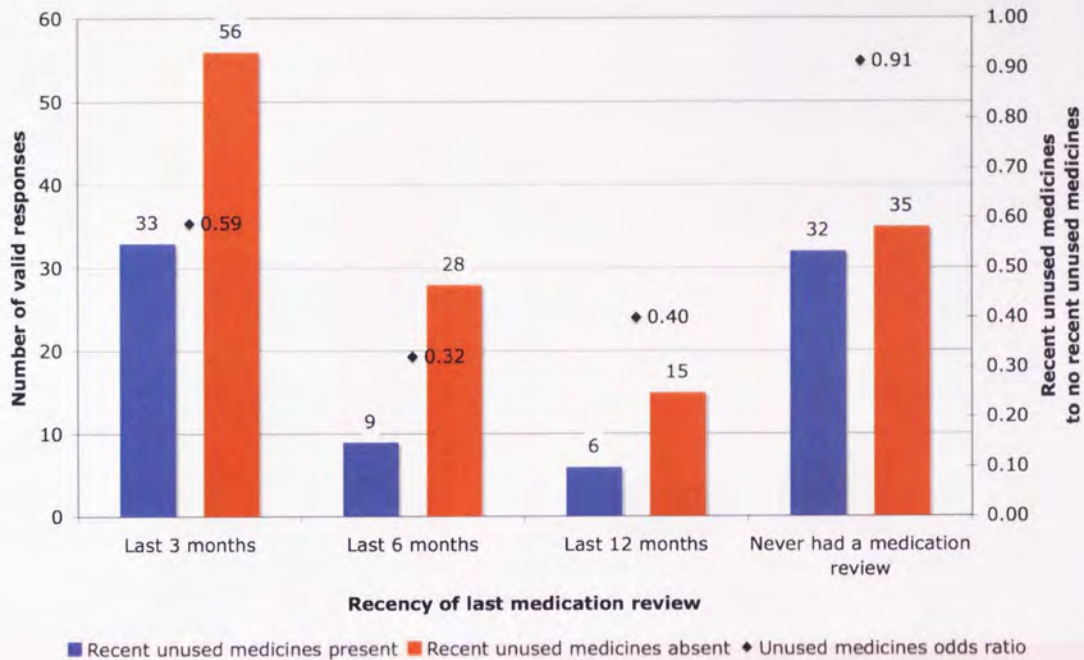
Figure 5.24: The frequency distribution of the response to a prescription for an unwanted medicine and the presence of recent unused medicines (responses: valid 391, invalid 13)



5.2.7.3 Medication reviews

Those respondents using regular medication that had recently had a medication review had a significantly (χ^2 , $p = 0.034$) lower likelihood of having recent unused medicines and had a combined unused medicines odds ratio of 0.48. Whereas, the respondents using regular medication that had not had a recent medication review had an unused medicines odds ratio of 0.91 (Figure 5.25).

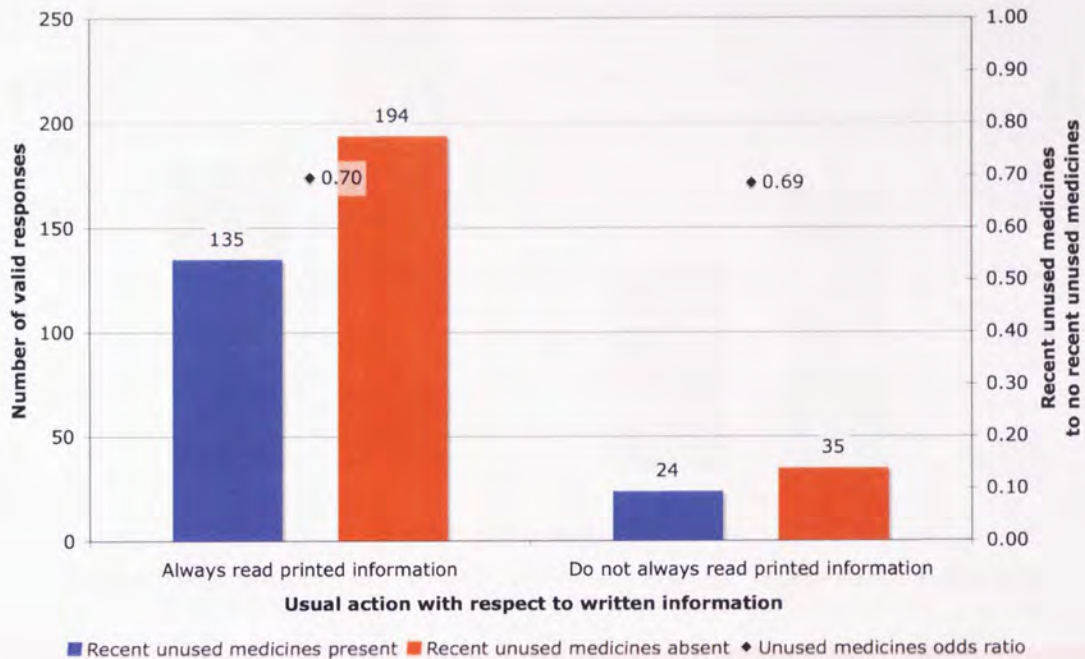
Figure 5.25: The frequency distribution of the timing of the last medication review and presence of recent unused medicines for patients using regular medicines (responses: valid 214, invalid 22)



5.2.7.4 The information provided with prescribed medicines

The information provided with prescribed medicines was usually read by 329 (84.8%) of the valid respondents (Figure 5.26). The reading of information appears to have no significant (χ^2 , $p = 0.959$) affect on the presence of recent unused medicines, with unused medicines odds ratios of 0.70 for those respondents that always read the information compared with 0.69 for those that do not.

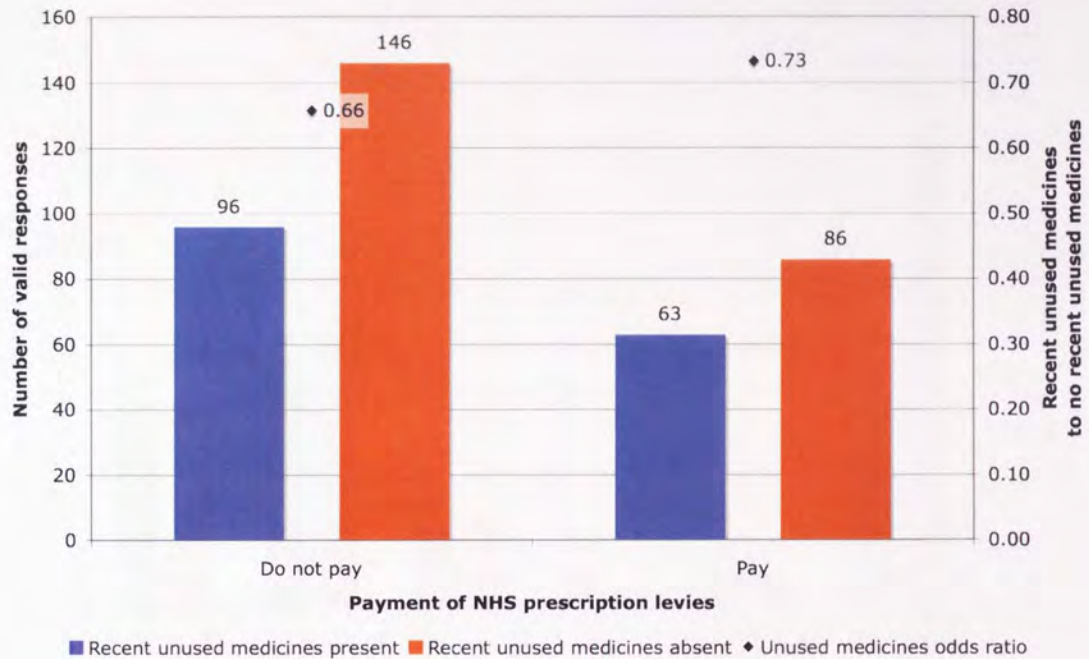
Figure 5.26: The frequency distribution of the usual behaviour of respondents with respect to written information and the presence of recent unused medicines (responses: valid 388, invalid 16)



5.2.7.5 The financial aspects of obtaining medicines

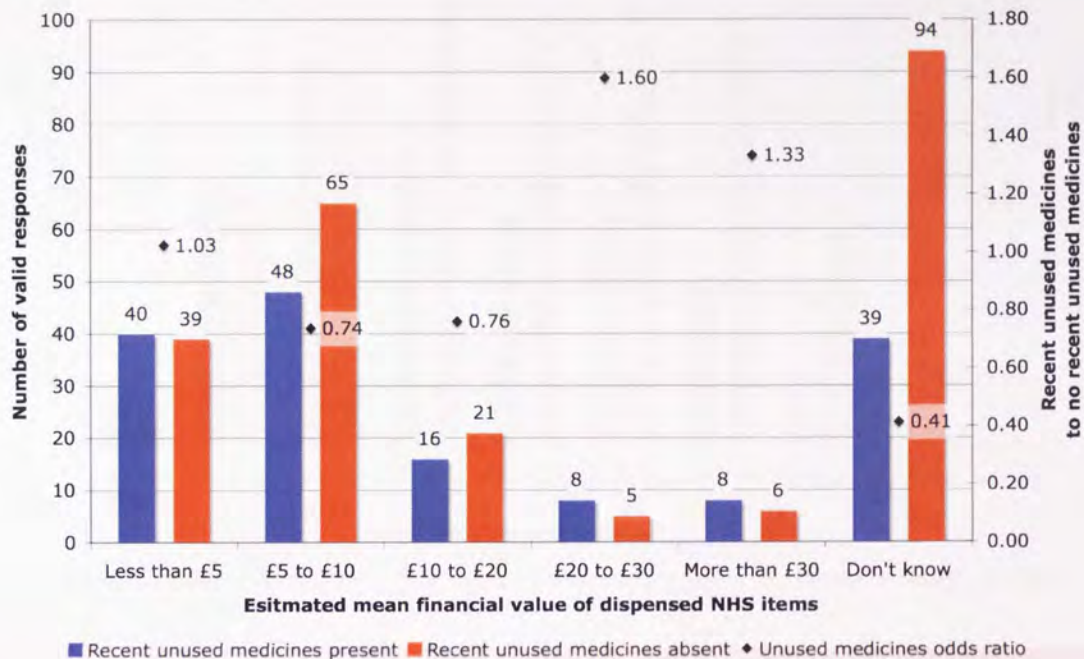
A total of 242 respondents (61.9%) indicated that they were exempt from NHS prescription levies and of these, 96 (39.7%) had recent unused medicines. Respondents that were exempt from NHS charges appeared to be marginally less likely to have recent unused medicines than those respondents that usually paid for their prescriptions, with recent unused medicines odds ratios of 0.66 and 0.73 respectively (Figure 5.27). The limited data were insufficient to determine significance (χ^2 , $p = 0.610$).

Figure 5.27: The frequency distribution of respondent exemption status from NHS levies and the presence of recent unused medicines (responses: valid 391, invalid 13)



Respondents that estimated the value of dispensed NHS items as less than the true value (<£10) were significantly (χ^2 , $p = 0.013$) less likely to have recent unused medicines than those that overestimated the value (>£20) with unused medicines odds ratio of 0.85 and 1.45 respectively. Respondents that were unsure of the value were the least likely to have recent unused medicines (Figure 5.28).

Figure 5.28: The frequency distribution of respondent estimates of mean financial value of dispensed NHS items and the presence of recent unused medicines (responses: valid 389, invalid 15)



5.2.7.6 The age, sex, household income and ethnicity of patients

The influence of respondent age on the likelihood of having unused medicines can be seen in Figure 5.29. Younger respondents appear to have a higher likelihood of recent unused medicines than older patients, with those aged 19 years or under having an unused medicines odds ratio of 1.33 and those aged 80 years to 89 years having an unused medicines odds ratio of 0.37.

Respondent sex also appeared to influence the likelihood of having recent unused medicines, with female patients being more likely to have recent unused medicines than male patients (Figure 5.30). Significance could not be shown owing to limited data (χ^2 , $p = 0.111$).

Figure 5.29: The frequency distribution of respondent age group and the presence of recent unused medicines (responses: valid 387, invalid 17)

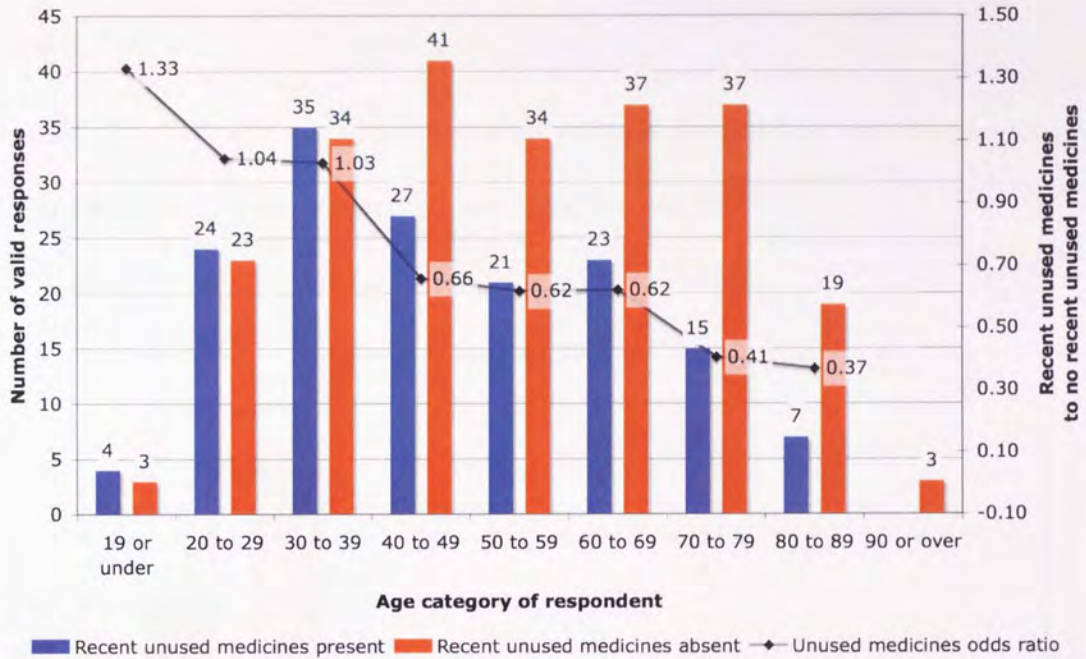
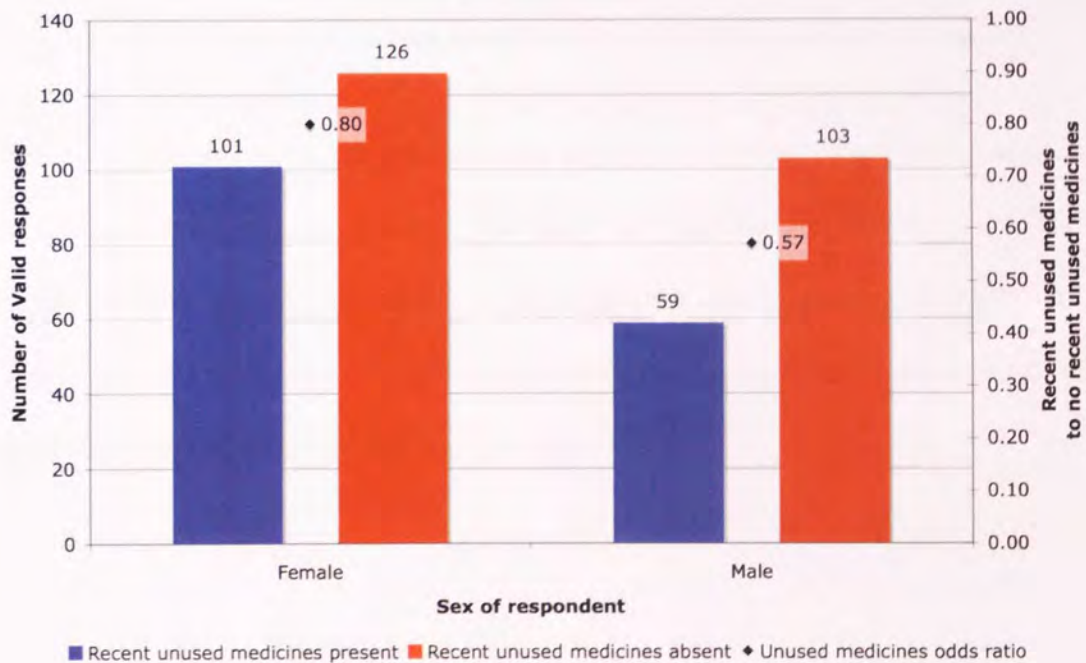
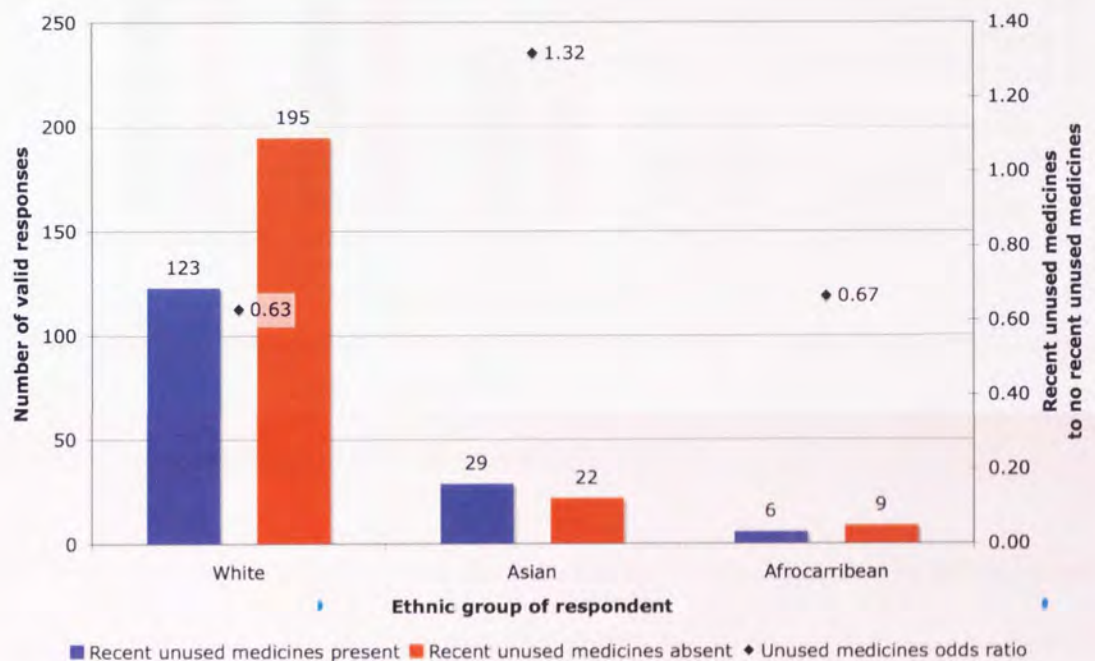


Figure 5.30: The frequency distribution of respondent sex and the presence of recent unused medicines (responses: valid 389, invalid 15)



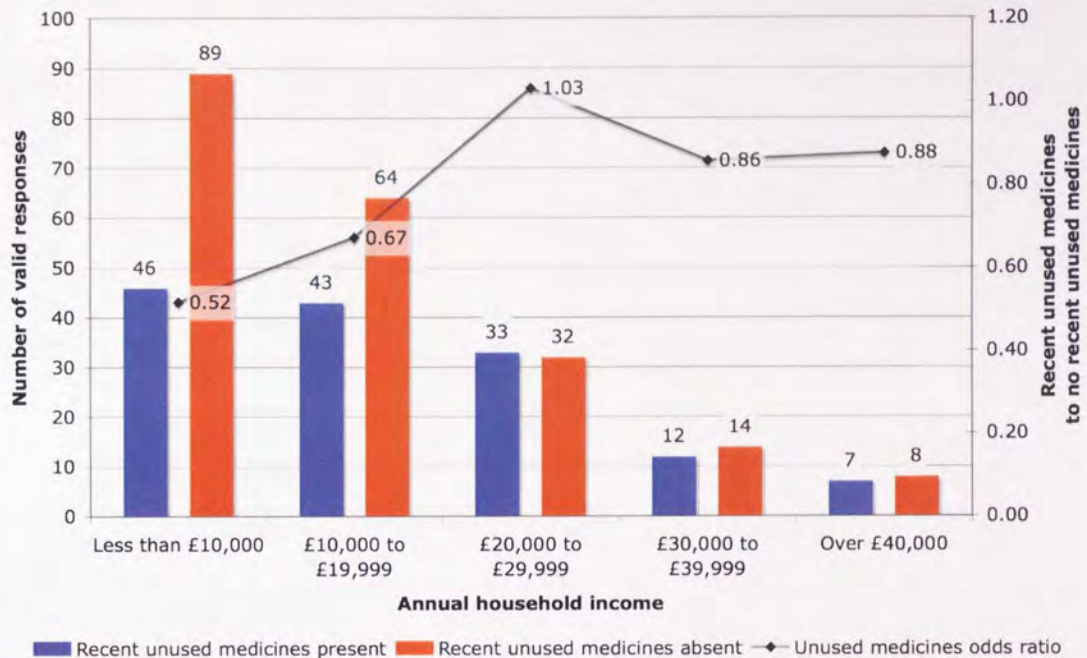
Respondent ethnicity had a significant effect on the likelihood of having recent unused medicines (χ^2 , $p = 0.050$). White and Afro-Caribbean respondents were less likely to have unused medicines than respondents of Asian decent, with unused medicines odds ratios of 0.63, 0.67 and 1.32 respectively (Figure 5.31).

Figure 5.31: The frequency distribution of respondents ethnicity and the presence of recent unused medicines (responses: valid 384, invalid 20)



The household income of a respondent also appears to influence the likelihood of that respondent having recent unused medicines as revealed by Figure 5.32. Those respondents that live in households with a lower annual income (<£20,000) were significantly less likely to have unused medicines than those living in households with higher annual incomes (>£20,000) (χ^2 , $p = 0.032$).

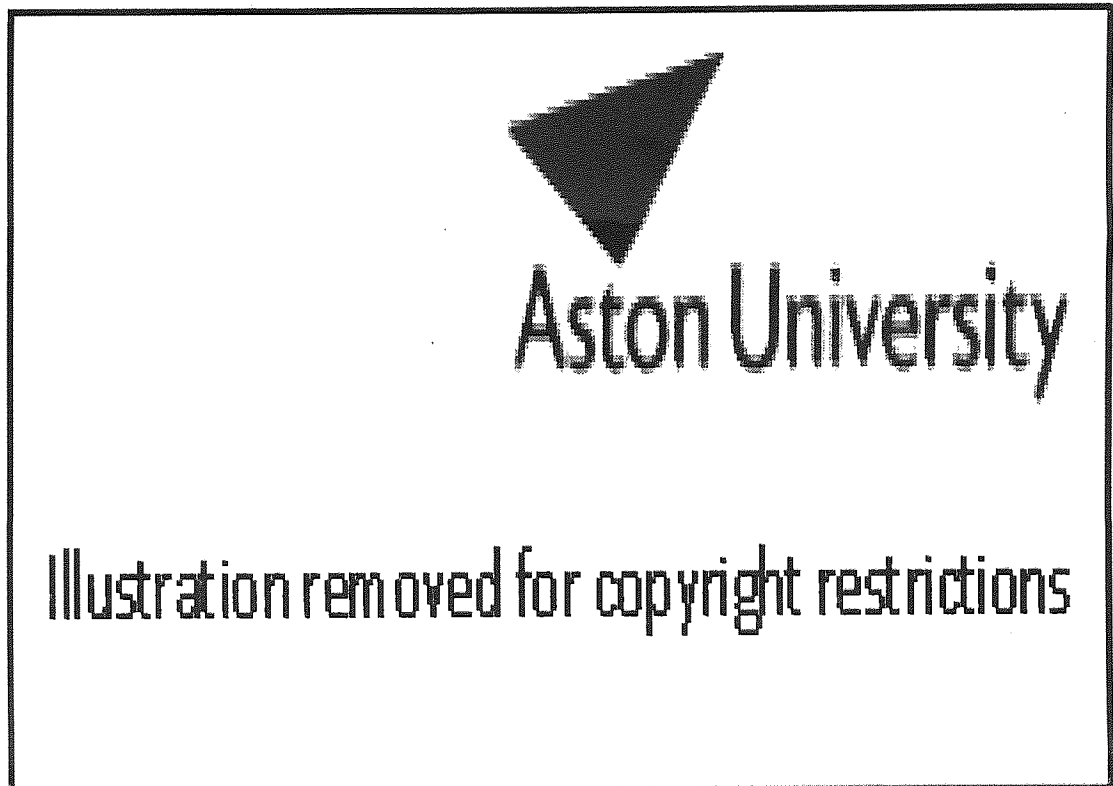
Figure 5.32: The frequency distribution of household income and the presence of recent unused medicines (responses: valid 348, invalid 56)



5.2.7.7 The geographic distribution of patients

The data shown in Figure 5.33 show the distribution of respondents with recent unused medicines and those without. There was no significant difference between the number of respondents indicating recent unused medicines in each of the ten political wards making up EBPCT (χ^2 , $p = 0.646$).

Figure 5.33: A geographic distribution of respondent residential location and recent unused medicines (responses: valid 396, invalid 8)

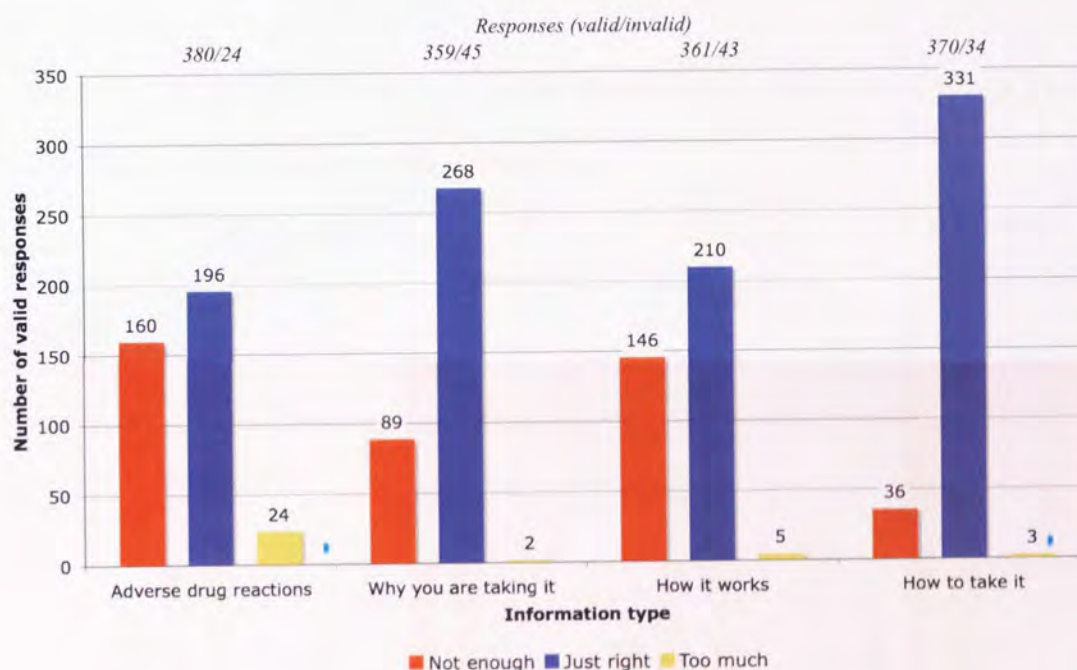


5.2.8 Patient experience and requirements regarding information on their medicines

Respondents showed a range of attitudes towards information, particularly on adverse drug reactions where 160 (42.1%) of the valid responses indicated that the information they currently received was insufficient and a further 24 (6.3%) felt that they were already given too much information (Figure 5.34). Respondents also indicated that they would prefer more information on how medicines worked, with 146 (40.4%) of the

valid responses to this indicating they were not given sufficient information at present. The majority of respondents appeared content with the information provided on how to take their medicines and why they were taking it with 89.5% and 74.7% of the valid responses to these questions indicating they were happy with the current information that was provided on these topics.

Figure 5.34: The frequency distribution of respondent satisfaction with the information provided with their medicines.

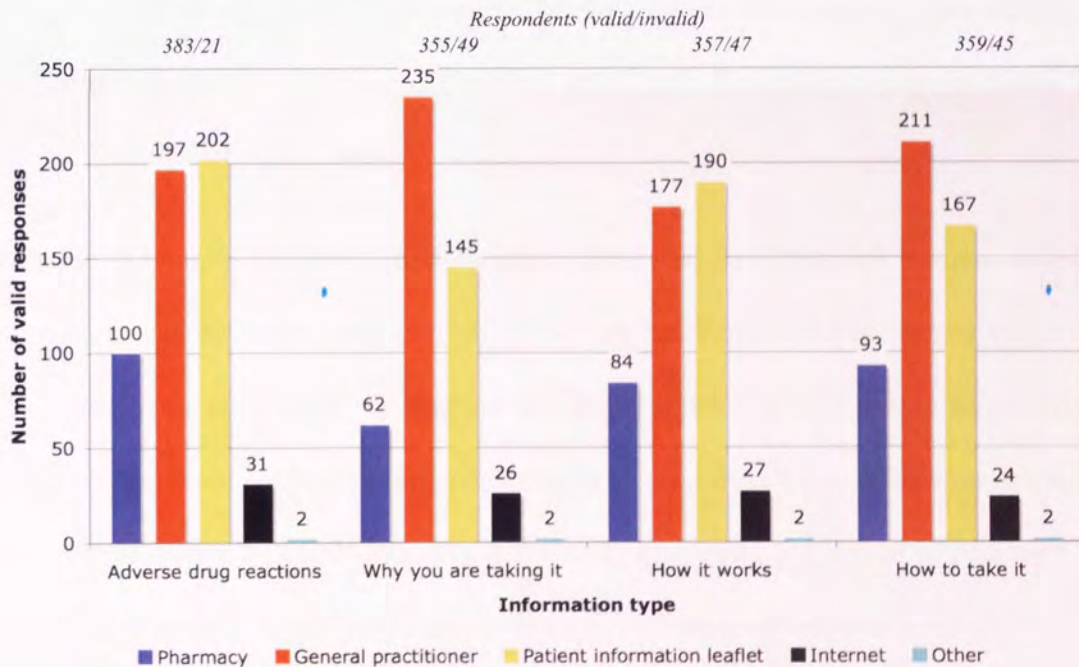


Respondents showed only moderate support for information being provided in pharmacies, with 17.1% of all valid responses indicating pharmacies as a place that they would like to be able to access information. The respondent's general practitioner was the most popular information source, accounting for 41.4% of valid responses and patient information leaflets were also popular with 35.6% of valid responses (Figure 5.35). The other areas on which respondents indicated a desire for further information are detailed in Table 5.2.

Table 5.2: The aspects of medicines use on which respondents desire information

Information desired	Valid responses
Likelihood of addiction	1
Availability of alternatives	5
Financial value	3
Long term effects	4
Interactions	4

Figure 5.35: The frequency distribution of the locations that respondents would like to be able to access information on their medicines.



5.3 Discussion

The rate of return for the postal questionnaire was 47% and the valid response rate 41%. These are somewhat lower than the response rates reported in other pharmaceutically based studies that have sampled the electoral register, where rates ranged from 60% to 66%¹³⁹⁻¹⁴⁴. The relatively low return rate in the present study, in conjunction with the recipients that declined to complete the questionnaire suggest that unused medicines are not considered to be an issue of importance among the general population and this was also reflected in the low recruitment for the group interviews. The number of valid questionnaires returned was sufficient to allow the identification of a number of statistically significant differences among the data. However in some instances, where valid responses were low or the differences small, insufficient data were available to determine statistical significance.

Owing to the nature of postal questionnaires, there will have been an element of self-selection bias in the responses received, with those recipients that have strong views on the subject being most likely to respond and thereby potentially resulting in polarised data. Attempts were made to optimise the rate of return through two follow-up mailings of the questionnaire to non-responders and also by providing the option of declining to participate in order to identify the factors that may influence non-response.

5.3.1 The geographic distribution of postal questionnaires

The primary care trust being studied comprises a widely diverse population in terms of social and ethnic backgrounds and levels of deprivation (section 2.3). In the north of the

PCT, the population are predominantly white with areas of low household income, while the central parts of the PCT has a greater proportion of ethnic groups among the population and levels of affluence vary markedly. In the southern part of the PCT there are areas of considerable affluence with the populations in some of these being predominantly white and others containing a greater mix of ethnic groups. The postal questionnaire was administered by the random selection of 1000 members of the edited electoral roll. In order that the diverse population was sampled appropriately, with all relevant groups represented, 100 recipients were selected from each of the ten political wards that make up the PCT. This sampling resulted in participants being well distributed geographically and the valid responses received were equally well distributed.

The sex distribution of valid respondents was broadly similar to that of the resident population of the PCT¹¹⁹. Additionally, the age distribution was similar between respondents and residents. However, owing to the sampling method excluding residents under 18 years of age, a considerably lower proportion of responses were received from people under 20 years of age. The 17% of valid responses received from ethnic minority groups was moderately lower than would be expected, since these groups account for 30% of the PCT population¹¹⁹. In light of the demographics of the valid responses, and owing to the random nature of the selection process, with each elector having equal chance of selection, it is likely that the data gathered from the postal questionnaire are broadly representative of the PCT as a whole. However, data concerning ethnic groups and young patients may not be truly illustrative of these groups.

5.3.2 The use and storage of medicines

It is not possible to determine the number of people that are currently prescribed medicines in the UK. However, in England during 2004 over 680 million items were dispensed against NHS prescriptions, approximately 14 items per head of population^{91,118}. It is therefore unsurprising that over four fifths of the questionnaire respondents indicated that they had recently taken prescribed medicines. Additionally, the proportion of respondents that indicated they had taken purchased medicines is also expected since the combined markets for over the counter and complimentary medicines now exceed £2 billion and continues to grow each year with the increased availability of medicines following POM to P changes¹⁴⁵.

The manner in which patients choose to store medicines is of importance in ensuring their stability. The majority of medicines require storage at either 2-8°C or below 25°C and storage outside these recommended temperatures is likely to lead to accelerated degradation¹⁴⁶. Additionally, humid environments also accelerate the degradation of certain pharmaceutical compounds¹⁴⁶. The majority of valid responses in the present study indicated storage of medicines in either a bathroom or kitchen, where both humidity and temperature may be raised, thereby affecting the stability of some products. This may be related to patients' management of their medicines through locating them in a prominent position in order to remind themselves of the need to take them. For example a medicine that is taken each morning with food being stored with the breakfast cereals. If, as suggested in section 1.6, the re-use of medicines that have already been issued to patients were to become commonplace, further assessment of the effects of these storage habits would be needed to ensure the stability of the products concerned. Many pharmaceutical manufacturers may have already undertaken such

stability testing at raised temperatures and humidities. However these data are not in the public domain and it would be commercially difficult for the manufacturers to issue such data since this may facilitate the re-use of products where new units would have otherwise been purchased.

5.3.3 The requisition and supply of medicines

As identified in the group interview (section 4.2.3), GP surgeries provide a number of different methods to facilitate patient ordering of repeat prescriptions and in some cases these systems may be imposed on the patients against their wishes. Many surgeries have also imposed restrictions on the times at which these prescriptions may be collected from the surgery (section 4.2.3), possibly as a result of limitations in staff time. These restrictions are likely to be some of the factors that have led to a number of patients taking up prescription collection and ordering schemes offered by community pharmacies as shown in the present study. Despite restrictions being imposed on the ordering of repeat prescriptions, the majority of valid respondents indicated that they found their system easy to use and there was no apparent correlation between over ordering of medicines and difficulty in use of the usual ordering system.

There is a widely held belief among pharmacists that certain patients order medicines that are not required simply because they are listed on the repeat prescription order form. The data of the present study confirm that this is indeed the case, with one fifth of the respondents directly admitting to this. As expected, the data also indicate that patients that pay NHS levies for their prescriptions are less likely to order prescription items that are not required.

Anecdotal evidence suggests that patients desire the greatest quantity possible when obtaining medicines on repeat prescription. However, the valid responses to the postal questionnaire demonstrate that while a few individuals would like greater than three months treatment at any one time, there is substantial support for smaller quantities with over a quarter of respondents indicating that they would be happy with just one month of treatment at a time. Unsurprisingly, it is predominantly those respondents that pay NHS levies that are in favour of larger quantities of supply.

5.3.4 The financial value of medicines

Many countries outside the UK require patients to pay a proportion of the cost of any medicines that they are supplied on prescription and therefore, the patient is considerably more aware of the true cost of medicines. However, the fixed fee model used in the UK, combined with the complex and generalised exemption system currently in place results in patients being distanced from the cost of their medicines. There is a widely held belief amongst many health professionals that patients do not value their medicines and believe that they are of inconsequential cost. This view is, to some extent supported by the findings of the present study, with almost half of the respondents believing that dispensed medicines had a financial value of less than £10 per item. The true cost of an NHS dispensed item is £11.78⁹¹. Additionally, one third of valid respondents indicated that they did not know the financial value of dispensed items, further illustrating the distanced position that patients have with regard to the cost of medicines. This lack of appreciation of the true financial value of medicines may be one of the contributory factors leading to the generation of unused medicines.

Owing to the structure of the question in the postal questionnaire covering respondent opinions of charging schemes for NHS prescriptions, it was not possible for respondents

to indicate a preference for a charging scheme with exemptions *and* to identify an appropriate charge per item. Therefore, those respondents that indicated *some patients should pay* were unable to suggest the rate and those that suggested a specific levy were unable to indicate if they felt *all patients should pay* or if they favoured an system of exemptions. Despite this limitation, the data clearly indicate considerable support for a prescription charges and over three quarters of respondents suggested that some form of payment system should be in place. This finding suggests that the general public would be generally in favour of charging of a small levy to all patients and the data reported in section 5.2.3 indicate that this would be likely to reduce any over ordering of medicines that currently takes place. Additionally, an amended charging system or printing of the financial value on the dispensing label of each item may lead to a reduction in medicines non-use. However, difficulties may arise where the financial value of the medicine is less than the levy that is charged to the patient. Unfortunately, no data are currently available on the proportion of prescriptions where this currently occurs.

5.3.5 Patient experience and attitudes regarding medication reviews

Medication review is a broad term, which incorporates a wide range of activities, carried out by various health professionals, and involves the consideration of one or more aspects of medicines use in a given patient¹⁴⁷. The formal review of medicines use is a relatively new concept and not all patients have yet been the subject of such a review. Indeed some patients may not even be aware of the concept of medication review. The National Service Framework for Older People set a target of an annual medication review for all patients over 75 years of age and 6 monthly reviews for those on 4 or more medicines¹⁴⁸. However, no formal guidance exists for patients under the age of 75 years and it would not be feasible to perform reviews in all patients at 6 or

even 12 monthly intervals. The data gained via the postal questionnaire in the present study indicate that medication reviews are popular among patients with 99% of those taking regular medicines indicating that they were in favour of reviews.

A number of studies have previously shown the benefits of pharmacists undertaking medication reviews^{149,150} and the Medicines Partnership document *Room for Review* advocates the undertaking of this role by pharmacists¹⁴⁷. It is therefore disappointing that respondents indicated little support for pharmacists performing medication reviews or for them being conducted in community pharmacies or patients' own homes. Almost 90% of valid respondents were in favour of GPs performing medications reviews compared to just 10% supporting pharmacists. Additionally, 92% of valid respondents indicated a preference for reviews to be performed in a general practice surgery, whereas patients' own home and pharmacies were only supported by one in ten respondents. This may be linked to a genuine apprehension of pharmacists undertaking reviews, or may in fact be an indication that patients are not aware of the skills of pharmacists or the opportunities to have medication reviews performed in locations other than the surgery. If the profession of pharmacy is to progress further into this clinical role, more information needs to be made available to patients on their options with regard to medication review.

5.3.6 Unused medicines in the home and their disposal

It is widely acknowledged that some medicines are not used as intended by the prescriber and in certain cases, this will result in unused medicines in the home. The reasons for this non-compliance have been well documented¹⁰⁻¹², but the majority of these do not differentiate between those medicines that are unused and those that are simply used in a manner other than that directed by the prescriber. Additionally, the fate

of unused medicines has not been studied in depth in the UK and no substantial work has been undertaken for 10 years. This is surprising considering that collection of unused medicines has been made an essential service of the new contractual framework for Pharmacies in England and Wales¹⁵¹ and also in light of emerging evidence of environmental pollution by poorly disposed of medicines^{77,79-81}.

5.3.6.1 Respondents with recent unused medicines

A national study performed in 1994 by the OPCS reported that 11% of the 2082 households surveyed reported unused medicines as present in the home⁵⁰, and work undertaken by Atherton and Rubenstein during 1990 reported 49% of 176 households surveyed in Merseyside had unused medicines present⁴⁸. In the present study, 18% of valid respondents indicated having unused medicines present at the time of completing the questionnaire and a total of 40% of valid respondents reported the presence of unused medicines in the home in the previous 6 months. In another study, Atherton and co-workers reported that 54% of items were returned within one year of dispensing⁴⁸, compared with 71% in the present study (section 3.2.4.5). Medicines use has also risen substantially over the same period, with approximately 9 prescription items issued per annum during 1992, compared to 14 items per head in 2004^{91,152}. These data indicate that the presence of unused medicines in the home has fluctuated over time, with patients appearing to be more pro-active in disposing of medicines in the present day. However, medicines non-use as a whole does not appear to have changed substantially over the past two decades, with the quantities of unused medicines appearing to rise broadly in line with increased prescribing of medicines.

5.3.6.2 The reasons for unused medicines

Respondents to the postal questionnaire often indicated more than one reason for the presence of unused medicines in their home. Additionally, purchased medicines that were unused were also included in the present element of the study. Therefore, the reasons for unused medicines in this element of the study do not easily relate to those reasons given for return of medicines as presented in section 3.2.2.1. However, the data clearly indicate that changes in patients' conditions and their prescribed therapies were responsible for a substantial quantity of unused medicines.

Owing to a limitation of the questionnaire design, data on the unused medicines generated by recently deceased recipients were not collected. Therefore, the proportion of valid responses indicating recent unused medicines owing to a patient death is likely to be lower than the true quantity present in the community. It is likely that the three respondents that indicated unused medicines resulting from a patient death were including medicines belonging to other members of the household.

Respondents to Atherton's study reported having unused medicines as a result of patient recovery (49%), adverse drug reactions (16%), the patient forgetting to take the medicine (10%) and non-compliance owing to the medicine not having the desired effect (9%)⁴⁸. While these data have some similarities with the findings of the present study, a greater proportion of patients had forgotten to take their medicines in Atherton's study. Additionally, Atherton reported no respondent as citing a change in therapy by the prescriber as the reason for unused medicines. Since there is no reason to suspect that changes in prescribed therapy or in the forgetfulness of patients have changed substantially, it is likely that the differences in these data are a direct result of differences in structure in the questions used in each study.

5.3.6.3 The therapeutic classes of medicines that were unused

The proportion of valid respondents identifying medicines from each therapeutic class as being unused or recently disposed of were generally similar to the proportions of patients that returned medicines from these categories; however, there were some notable exceptions. For example, a considerably greater proportion of valid respondents to the postal questionnaire identified that they had unused respiratory medicines and anti-infective agents than the proportion of patients returning medicines from these therapeutics classes. It is possible that these respondents were deliberately storing medicines such as antibiotics, antihistamines and inhaled sympathomimetics, with the intention of using them at a later date, thereby apparently increasing the proportion of unused medicines in the home. This is reflected in the findings outlined in section 3.3.4.5, where medicines in these therapeutic classes were retained for 14.6 and 16.4 months following dispensing, compared with the overall mean retention time of 12 months.

Medicines acting on the cardiovascular system were reported as unused by just 17% of valid respondents to the questionnaire, whereas medicines from this class were present in the medicines returned by 40% of the patients in the collection element of the study (section 3.3.4.1). It is likely that since patients regularly receiving cardiovascular medicines are often frequent visitors to both their GP surgery and local pharmacy they would be exposed to campaigns on safe disposal of medicines more often and that they would dispose of them with greater regularity. This is supported by the findings outlined in section 3.3.4.5, with cardiovascular medicines being routinely returned 8 months following dispensing in comparison to the overall mean of 12 months retention time.

The apparent disparity in the proportions for the musculoskeletal and joint diseases therapeutic class is likely to be a direct result of a project limitation. The structure of the questionnaire did not contain a response for anti-inflammatory medicines and it is likely that this would lead to respondents indicating that these medicines were used for treatment of pain. Therefore, anti-inflammatory indicated as *pain* – rather than being indicated as anti-inflammatory in the *other* category – would have been incorrectly interpreted as CNS medicines. It is therefore possible that the true proportion of valid respondents with unused medicines from the musculoskeletal and joint diseases therapeutic class is higher than the present data suggest.

The therapeutic classes of unused medicines reported in the present study are considerably different to those reported in the OCPS study⁵⁰ with similarities between the two only being evident in gastrointestinal medicines, respiratory medicines and endocrine system medicines⁵⁰. Cardiovascular medicines were unused in just 6% of cases in the OCPS study, while they were indicated by 17% of valid responses in the present study. The use of cardiovascular medicines has increased substantially in the past ten years, with 200 million prescription items dispensed in 2004 compared with just 98 million in 1994.^{91,153} However, this would be expected to only account for a twofold increase in the proportion of patients with unused medicines yet the present study shows a threefold increase over the OCPS study. Therefore the data appear to indicate that non-use of cardiovascular medicines is increasing, possibly as a result of increased use of medicines from this class in the primary prevention of cardiovascular disease following the recommendations made in the NSF for CHD¹⁵. Use of medicines in primary prevention is possibly more likely to result in non-compliance owing to a lack of perceived need in the patient, as highlighted by the comments made by Subject #2 during the group interview (section 4.2.1.2).

Medicines acting on the central nervous system were indicated as unused by 43% of valid respondents to the postal questionnaire compared to 28% of patients reporting medicines as unused in this class in the OCPS study⁵⁰. From 1994 to 2004, the number of prescriptions dispensed in this category has risen from approximately 90 million to 120 million;^{91,153} an increase of around 30% and the proportion of respondents reporting these medicines as unused has risen by approximately 50%. These medicines do not appear to be retained for a greater length of time than other medicines (section 3.2.4.5) indicating that this increase is likely to be due to a higher degree of non-use of medicines in this class.

The OCPS reports a substantially larger proportion of respondents with unused anti-infective medicines than the present study being 39% and 21% respectively. This difference is considerable, even if the higher retention times of these medicines are taken into account and is possibly due to more judicious prescribing of these agents. Dispensing of medicines from this class has fallen from 58 million items in 1994 to 42 million items in 2004, while over the same time period that the total number of dispensed items has risen from 442 million to 668 million^{91,153}. Additionally, greater public awareness of the importance of completing a course of antibiotics following considerable media attention and public health campaigns is likely to have influenced the reduced presence of these medicines in the home¹⁵⁴.

5.3.6.4 The methods of disposal utilised by respondents and their understanding and knowledge of the DOOP scheme

A number of studies have now shown the potential for medicines to leach from landfill sites and the passage of pharmaceutically active compounds through sewerage treatment systems^{77,79-81}. Additionally, consideration of the possibility of environmental damage

arising from these PACs has recently been the focus of a number of studies^{87,88}. However, the full environmental effects of these pollutants remains unknown. Therefore, the disposal of medicines in domestic refuse or grey and black water may potentially lead to significant problems in the future.

The Department of Health currently spend in excess of £1.5 million providing the DOOP scheme in England and Wales.⁹² However, just one third of valid respondents in the present study indicated that they currently returned unused medicines to community pharmacies or general practice surgeries for destruction and almost half dispose of them in grey or black water or with domestic refuse. While this is a disappointing finding, when a comparison is made with studies undertaken in the early 1990s, there is a clear indication that there has been a considerable shift towards more appropriate disposal methods by patients. One Merseyside study of 1990 reports that 11% of the respondents would usually return their unused medicines to community pharmacies, while 59% were putting them in domestic refuse or grey and black water⁴⁸. Additionally, a Portsmouth study of the same year found that just 9% indicated the pharmacy as the preferred method of disposal and an astonishing 85% of respondents indicated that they disposed of unused medicines in domestic refuse and grey and black water systems⁴⁹. In 1994, an OCPS study showed little change in these activities with 16% of respondents returning medicines to community pharmacies, with the remainder disposing of medicines by alternative means⁵⁰. It is possible that this apparent shift to more appropriate disposal of unused medicines seen in the present study is a result of publicity campaigns run by PCTs and other organisations.³⁷ Additionally, anecdotal evidence suggests that health professionals adopt a more pro-active approach in encouraging safe disposal of medicines and this may, in part, be responsible for the changes seen. When the usual methods of disposal that were uncovered in the present study are compared with those

of Swedish patients, it is clear that appreciable scope for improvement remains. In the present study, one in three patients disposing of medicines appropriately compared to eight in ten in the Swedish population¹⁵⁵.

The data from the present study suggest that patients are generally not aware of the DOOP service, but would use it if they were appropriately informed of its availability. The majority (89%) of valid respondents who had not previously heard of the scheme indicated that they would use the service in future now that they had been told about it. The poor knowledge of the scheme indicates that current publicity is insufficient and more advertising is needed to encourage patients to use this service more. It is interesting to note that 33 (11%) respondents indicated that they would not use the DOOP scheme even though they were now aware of it, stating that it would be inconvenient or require too much of their time. While this proportion is relatively low, if this attitude were to be repeated across the UK, a substantial number of people would be disposing of medicines inappropriately with unknown effects on the environment. Further exploration of ways in which return of unused medicines can be facilitated is needed in order to minimise this.

Those respondents that were aware that medicines might leach from land fill sites were significantly less likely to throw medicines away with household refuse than those that were not. Also those respondents that were aware of the potential for medicines to pass through sewerage treatment processes unchanged were significantly less likely to dispose of medicines in black water compared with those that were not. This indicates that if patients are provided with information regarding the effects of poor disposal, a substantial proportion would be likely to alter their current behaviour in respect of disposal of unused medicines. Indeed, the majority of respondents supported a ban on

disposal of medicines with domestic refuse or in grey and black water in response to the information on potential environmental exposure. However, some individuals did indicate that they would continue to dispose of their unused medicines even while aware of the risks and there may be some need for incentives or disincentives for using pharmacy disposal services in order to minimise inappropriate disposal. It is perhaps useful to note that among those that were opposed to a ban, a significant majority usually disposed of medicines by this method, indicating that there may be some enmity to making this more difficult.

An overwhelming majority of respondents were in favour of resolving unused medicines, with only a tiny minority believing that it is not a problem. This appears to countermand the previous assertions that patients do not generally believe unused medicines to be of importance, although it is likely that there would be a larger proportion of patients of this opinion among those recipients that did not respond in the present study.

5.3.7 The links between recent unused medicines and potential precipitating factors

Previous studies have identified over ordering or compliance as potential causes of unused medicines.⁴⁸ The data from earlier elements of the present study have identified a number of other possible reasons such as adverse drug reactions, patient death, errors in supply and prescriber changes in therapy (sections 3.2.2.1 and 4.2.1). However, these factors are complex in their nature and difficult to predict. Therefore a number of potential features of medicines supply and use along with various patient factors have been considered in the present study and a comparison made between these factors and the presence of *recent unused medicines*. This section outlines the effects that these

factors may have on the likelihood of medicines being unused and attempts to draw conclusions regarding the relevance of such features.

5.3.7.1 The ordering of repeat medication

As discussed in section 5.3.3, a number of patients order all the medicines listed on their repeat order form despite there being no immediate need and it would be expected that these individuals would accrue a greater quantity of unused medicines. This is supported by data from the present study and recent unused medicines were reported in a greater proportion of the homes of respondents that would usually over order medicines in comparison with the homes of respondents that usually ordered only the items that were required. Through minimising the potential for over ordering to occur and the education of patients on the deleterious effects that wastage of medicines can bring about, it may be possible to reduce unused medicines resulting from over ordering.

5.3.7.2 Patient expectations and experiences of prescribing of medicines

There is an increasing amount of data indicating that patient pressure can lead to doctors issuing prescriptions where they would not have otherwise done so^{19,20}. Additionally, Cockburn and Pitt have demonstrated a connection between the prescribing of a medicine and the prescriber's belief that the patient is expecting a prescriptions.¹⁷ Furthermore, a study by Britten and Ukoumunne reported that a fifth of prescriptions issued by the GPs surveyed were not strictly clinically indicated²¹.

In the present study, the expectation of receiving a prescription is shown to reduce the likelihood of the respondent having recent unused medicines. Since these patients

reported that they usually expected to receive a prescription each time they had a consultation with their GP, it is likely that when they would usually consult their doctor only when they wished to obtain medicines. Additionally, where patients were not offered a prescription, those that would usually request one also showed a lower likelihood of having recent unused medicines. In both of the situations outlined above, the patient has actively sought out medicines and therefore, the consultations would be expected to be concordant with the patient playing an active role in the choice of therapy. In such situation, it would be reasonable to expect that the patient, having been involved in the decision process, would be more likely to take the medicines as prescribed and therefore less unused medicines would be generated.

In situations where the patient attends their GP and is not expecting a prescription the unexpected supply of a medicine may result in the patient being less likely to become involved in the choice of therapy, resulting in a discordant consultation. In such scenarios, the patient has not fully engaged in the decision making process and it would be expected that they would be less likely to follow the prescribed therapy, with a resulting increased likelihood of generating unused medicines as indicated by the data in the present study.

Where a patient is offered a prescription for a medicine that they do not wish to take, those that indicated they would usually follow the advice of the doctor – assuming a more submissive role in the doctor-patient relationship – are considerably less likely to have recently unused medicines than those who indicated they would take alternative action. This indicates that the traditional relationship of a dominant general practitioner reduces the incidence of unused medicines. Indeed, it is likely that certain patients respond well to the fully engaged concordant relationship, while others respond better

to the more traditional dominant prescriber model of consultations. It is therefore important that the roles of the prescriber and patient are developed appropriately on an individually tailored basis and the patient feels able to refuse a prescription where they do not wish to take the medicine.

The increased likelihood of recent unused medicines seen among patients that usually purchase OTC medicines where no prescription is offered is likely to be a result of the nature of the packaging of OTC medicines, with seemingly arbitrary pack sizes that do not correspond to any standard course of treatment. Indeed, patients that reported that they would usually purchase OTC medicines where no prescription was offered being almost twice as likely to have recent unused medicines than those patients that follow the advice of the prescriber.

Anecdotal evidence has long suggested that patients that do not want to take a prescribed medicine may still have the prescription dispensed, with one possible explanation being that they believe the prescriber will be informed if they do not have the prescription filled. The dispensing of these prescriptions is confirmed by data from the present study, where 11 respondents indicated that they would have a prescription dispensed even when they had no intention of taking the medicine. Unsurprisingly, these patients were over six times more likely to have unused medicines than those patients that followed the prescribers advice and over three times more likely than those patients who would accept the prescription but not have it dispensed. Further work is needed to determine the reasons why patients would chose to collect a medicine that they have no intention of taking it, in order that this activity, and the unused medicines generated as a result, minimised.

5.3.7.3 The influence of medication reviews

Medication reviews have become an increasingly common intervention and they are recommended in many government guidelines, such as the national service framework for older people¹⁴⁸. Advocates of medication review highlight that they would be likely to reduce the presence of unused medicines¹⁴⁷, yet prior to the present study, no published research has directly reviewed the effect of medication reviews on the incidence of unused medicines in primary care. The present study highlights the benefits of medication reviews, with a significant reduction in the presence of unused medicines in the homes of patients who have recently had their medicines reviewed.

5.3.7.4 The information provided with prescribed medicines

Anecdotal evidence suggests that patients may be frightened or confused by some information provided with medicines and may simply not take the medicine. This is supported by the findings of the group interview (section 4.2.4) where participants indicated that information provided with prescribed medicines could result in patients being afraid of taking their medicines for fear of adverse reactions or as a result of confusion about the medicine. The data gathered from the postal questionnaire suggest that those patients that read all of the printed information provided with their medicines are no more or less likely to have recent unused medicines than those that do not. However, this finding may be misleading, since it is possible that those indicating that they read all the information may be polarised in two disparate groups. In one of these groups, the information has a positive effect and leads to improved use of medicines, while in the other group, patients would be frightened and confused, leading to poor use of medicines. It is not possible to differentiate between these groups in the present study

and further work is needed to fully assess the impact of information on the use of medicines.

5.3.7.5 The financial aspects of obtaining medicines

There are two elements to the financial aspects of obtaining medicines; the cost of the medicine to the patient and the cost borne by the NHS. It is interesting to note that those patients that pay for their medicines appear to have a marginally higher likelihood of having recent unused medicines than patients that are exempt from prescription charges. This indicates that patients who pay for medicines may be more likely to ascribe a higher value to them and therefore minimise their use in order to achieve maximal benefit from minimal outlay. This behaviour has been described in a survey undertaken by Harris Interactive among American patients paying a proportion of the cost of their medicines¹⁵⁶. Since the sums paid for medicines by patients in the UK are relatively small and those that are less able to afford their medicines are generally exempt from charges, it would be expected that the payments for prescriptions would have a limited influence and this is borne out in the data of the present study. However, the indication that medicines non-use is influenced by prescription charges is important to any future review of the charging schemes currently in place and further work may be needed in this area.

The other financial element, the costs met by the NHS, are also of interest. Patients' perceived value of medicines appears to influence their likelihood of having recent unused medicines and four groups can be seen in the data; those that undervalue NHS medicines, those that overvalue the medicines, those that were unsure of the cost of medicines and those that estimated the value correctly. The data indicate that overvaluing or substantially undervaluing (<£5) of medicines significantly increases the

likelihood of having unused medicines. While those respondents that were unsure of the value of medicines to the NHS were considerably less likely to have unused medicines. These data indicate that patient perceptions of the value of medicines are inaccurate and also that these perceptions influence the likelihood of having recent unused medicines. However, more work is needed to understand the specific influences that this information would have on the use of medicines.

5.3.7.6 The age, sex household income and ethnicity of patients receiving medicines

The findings of the collection study reported in sections 3.2.3.1 and 3.3.3.2 indicate that the demographics of patients may influence the likelihood of medicines being returned to community pharmacies and general practice surgeries. However, it is not clear from these data whether it is simply the return of medicines that is altered, or whether these groups have more unused medicines.

The age of respondents appears to influence the likelihood of having recent unused medicines. However, in direct contrast to the findings of the collection study (section 3.3.3.1) recent unused medicines were reported by a substantially greater proportion of younger respondents than older respondents. This appears to indicate that older patients are more likely to dispose of unused medicines by returning them to a GP surgery or community pharmacy and that clearance of medicines is performed more regularly in this age group. This is likely to be a result of younger patients visiting community pharmacies and general practice surgeries less often since they are generally more healthy. Additionally, patients that were seriously ill or had recently died would be unlikely to be included in the questionnaire data and it is also possible that the older age groups are skewed, with only the more healthy individuals in these groups responding.

Indeed, in light of the proportionately greater use of medicines in the elderly¹²⁸ it is somewhat unlikely that the results obtained are a direct consequence of poor compliance in the young. However, this does remain a possibility since the majority of medicines prescribed for younger patients being used to treat acute and often self limiting conditions and further work is needed to clarify the influence of age on medicines use.

Medicines collected from community pharmacies and general practice surgeries indicated that female patients were more likely to return unused medicines than male patients and this was thought to be related to a more pro-active approach to disposal in females. However, the responses to the postal questionnaire indicate that female patients are also more likely to have recent unused medicines than male patients, making this assumption unlikely. Therefore, the data appear to suggest the female patients generally have unused medicines in greater proportions than male patients.

The ethnicity of the respondent also appeared to contribute to their likelihood of having recent unused medicines, with Asian respondents being significantly more likely to report recent unused medicines than White or Afro-Caribbean respondents. It is possible that this is a result of cultural differences in the use of medicines, with traditional therapies such as Ayurvedic medicine still being common in some communities. Unfortunately, the rate of response from ethnic minority groups was low and the generalisability of these findings are unclear, further work would be needed to clarify this point.

Responses to the postal questionnaire also indicate that household income is a significant factor influencing the presence of unused medicines. Respondents in lower income brackets were half as likely to report recent unused medicines than those in

higher income brackets. While it is unlikely that the household income itself is the cause of non-use of medicines, it is a surrogate marker for different social backgrounds. In this respect, those patients on low income may be more likely to use their medicines, perhaps as a result of attaining lower educational standards and adopting a more subservient attitude in relation to the prescriber. It is not clear whether this factor is a useful marker since it is closely linked to a considerable number of other factors such as educational attainment and employment status and it is possibly more informative to focus directly on these factors individually.

5.3.7.7 The geographic distribution of patients

The data in the present study showed no significant geographic influence on the presence of recent unused medicines. This is expected since the PCT does not differ considerably in community services across the wards. However, geographic patterns may be seen if the study were to be repeated in a PCO with more rural areas.

5.3.8 Patient experience and requirements regarding information on their medicines

Over the past few years, there has been a shift in healthcare provision in the UK towards greater self management by patients. Schemes such as the Expert Patient¹⁵⁷ and moves to increase the availability of information to patients, along with greater involvement of patients in all aspects of healthcare such as adverse drug reaction reporting¹⁵⁸ are all leading to greater responsibility being placed on the patient. In order for these patients to accept this role, it is important that they are well informed on the various aspects of their medicines and to this end, the types of information being provided to patients is increasing each year.

Anecdotally, some patients are resistant to this change, preferring to maintain the hierarchical model of healthcare with the general practitioner as the dominant power and directing the patient in the best way to manage their condition. The data from the present study highlights this to some extent in the number of respondents that felt they were being given too much information, particularly on adverse drug reactions. However, in general respondents to this questionnaire appear to be interested in information on their medicines, including elements that would not usually be supplied, such as how the medicine works. Interestingly, there was only moderate support amongst the respondents for this information to be available from pharmacies, with many wishing the information to be available in written form, such as in a patient information leaflet, and the majority desiring the information from their doctor.

5.4 Summary

This postal, self-completion questionnaire has considerably added to the available data on unused medicines in primary care, with this being the only collection of this type of data for over a decade. Unfortunately, the significance of a number of factors that appear to be of importance could not be demonstrated owing to a low response rate and more focused work would be required in these areas to further understand the full extent of the influence of these factors. However, the responses that were received did permit the identification of a number of important influences and potential action points and these are discussed further in the following chapter.

CHAPTER 6 : Unused medicines in primary care

6.1 Introduction

The present study was conducted over a period of three years in a predominantly urban PCT which has a population of approximately 200,000 people with diverse social, ethnic and cultural backgrounds. The data collected in this study represent the most complete assessment of unused medicines ever conducted in the United Kingdom or worldwide. It incorporates both an assessment of unused medicines returned to community pharmacies and GP surgeries for destruction and an assessment of attitudes and actions towards unused medicines among a sample of patients drawn from the same population.

6.2 Study design and limitations

The present study aimed to expand the knowledge base on unused medicines in primary care in the UK through gathering the most complete data possible on unused medicines. In order to achieve this, three distinct research techniques have been used in conjunction within a single population and the resulting data combined. Detailed quantitative data were obtained by use of medicines returned to community pharmacies and general practice surgeries as a surrogate marker of the nature of all unused medicines. Other quantitative data on the medicines that are unused in primary care and the causative factors that influence their generation were collected through a postal self-completion questionnaire, which also gathered quantitative data on the usual methods of disposal employed by patients. In order that the majority of relevant factors that may affect unused medicines were considered in the postal questionnaire, qualitative data on these

were assembled by use of a group interview. The application of these different methodologies in the same primary care trust enabled the findings from each element of the study to be combined, facilitating the development of a more comprehensive knowledge base on unused medicines.

6.2.1 The assessment of medicines returned to community pharmacies and general practice surgeries.

A number of previous studies in the UK and throughout the world have used the nature and quantities of unused medicines that have been returned to community pharmacies as a surrogate marker of unused medicines.^{2,3,38,39,42,43,45,53,55,56,60,121,159-162} Additionally, one study has assessed unused medicines returned to general practice surgeries in this way⁴⁷ and has demonstrated that patients dispose of a substantial quantity of medicines by this route. The use of returned medicines as a surrogate marker for the true nature and volume of unused medicines in primary care is necessary since it is extremely difficult to measure unused medicines directly in patient's homes owing to ethical issues. In this element of the present study, medicines that had been returned to either a general practice surgery or community pharmacy for destruction were collected and detailed information recorded for each item returned. This collection was purely observational and no campaigns promoting either the study or the DOOP service were undertaken with all returned items being unsolicited. This assessment is the largest and most detailed of returned medicines ever to be undertaken in the UK and one of the most comprehensive studies performed in the world to date. The quantity of medicines that were assessed were sufficient to allowed the identification of a number of significant differences in medicines usage and return. However, since returned medicines are only

a surrogate marker of true nature of unused medicines in primary care, the generalisability of these findings is not guaranteed.

6.2.2 A group interview considering unused medicines

In order that the questions posed in the postal self-completion questionnaire element of the present study be appropriate in eliciting the potential causes of unused medicines, it was necessary to first gather qualitative data on these issues. To date, the majority of studies that have assessed aspects of unused medicines have not explored the factors that may influence the incidence of unused medicines in any great depth. A study performed in Norway has used in depth interviews of patients returning unused medicines to community pharmacies¹⁶³. However, this technique of interviewing patients returning medicines would not have been appropriate in the present study since more than half of return events are made by persons other than the patient (section 3.3.2.2). Qualitative research is an established methodology used in pharmacy healthcare research to inform quantitative research frameworks^{139,164,165} and the participant interaction that takes place facilitates the collection of more detailed data on the factors that influence patient actions. However, since participants of group interviews are required to commit a substantial amount of time, it is important for the individual to regard the subject being discussed as important and they would ideally have some strong views¹⁶⁶. Unfortunately, despite the various methods used in attempting to recruit patients (section 2.6.3), very little interest was shown and sufficient participants for only a single interview were recruited. This limited the diversity of opinion within the data gathered and may have resulted in some of the factors that lead to unused medicines not being identified. This is particularly true where ethnic groups are concerned, since all of the seven participants in the group

interview were of white ethnicity. As a result of this limited diversity in age, sex and ethnicity, the external validity of the data gathered could be questioned. However, it was clear from the responses given that the participants had previously or currently been involved in the care of medicines in the home for their husbands and children as well to their own medicines. Therefore it is likely that the issues identified would include those affecting men and younger people in addition to the factors influencing the elderly women interviewed. Unfortunately, a significant limitation of this element of the study is the omission of ethnic groups and therefore the issues identified are likely to include the majority of issues that influence the generation of unused medicines in primary care with the exception of those that are exclusively related to minority ethnic groups.

Owing to the poor recruitment experienced, both the time frame allowed and the location were not under the control of the author. As a result of this, some of the questions used in the interview may have been excessively closed in order to permit the coverage of more issues. The responses to these closed questions are therefore more limited in scope and the benefits provided by the qualitative research methodology somewhat lost.

The reasons for poor recruitment were not directly assessed, however, it is possible that potential participants may have not responded to the recruitment processes as they were concerned that in discussing medicines non-use they would be admitting non-compliance and previous studies indicate that patients may be secretive about this³.

6.2.3 A postal questionnaire on unused medicines

A number of methodologies have been used previously to gather data that is generalisable to unused medicines and medicines non-use in primary care. These have included the direct assessment of unused medicines in patients' homes^{63,64}, self completion surveys of people returning medicines for destruction¹⁶³, structured interviews of people returning medicines or contacting information services^{49,65} and postal questionnaires of local populations^{48-50,167}. The direct assessment of unused medicines in patients' homes would be very difficult in the UK since agreement to participate could substantially influence the findings, with those patients having very large quantities of unused medicines in their home refusing to allow access, thereby leading to data that underestimated the problem. This phenomenon of secrecy towards non-compliance has been reported in a number of studies and it would not be ethical to demand access to the patients home to inspect their unused medicines.^{3,126} Additionally, any results gained through interviewing or surveying of people returning medicines to pharmacies or whilst using some other service such as a poisons information service could be equally misleading since the inherent sample selection process may result in bias. A postal self-completion questionnaire, administered to 1,000 randomly selected residents of EBPCT, was therefore used in the present study to gather quantitative data on the factors that influence the generation of unused medicines. Recipients were selected by random sampling of the edited electoral roll as detailed in section 2.7.2. While this ensures that all the recipients were over 18 years of age and therefore more able to complete the questionnaire, no data were gathered on the use of medicines in children and the factors that influence unused medicines in this patient sub-group. Some self-selection bias is inevitable with this research technique through non-response and the use of the edited electoral roll means that some individuals will have already

removed themselves from the sampling pool. However, owing to data protection restrictions, no realistic alternative to the edited electoral roll exists as a source of resident names and addresses aside from the postcode address file and the mailing of anonymous questionnaires is likely to result in lower completion rates than those mailed to specific individuals¹⁴⁰. Although the response rate for the present study was maximised by use of two follow-up mailings to non-responders, it was poor in comparison with other postal questionnaires administered to the general public^{139,141,142}. Therefore the data collected in this element of the present study was not sufficient to demonstrate the significance of differences identified in the data, limiting the opportunity to demonstrate the factors that influence the generation of unused medicines. Additionally, since returns were only received from 47% of the recipients, the generalisability of the results to the population of the PCT may be limited.

In devising any self-completion questionnaire, the specific wording of the questions, in addition to the response options given and the structure and order of the questions are all important in ensuring validity and eliminating bias. In order to minimise the risks of bias and invalid questioning, the questionnaire was piloted in its final form to test the specific wording was understood and that the research tool itself was valid. Owing to time constraints, the pilot was conducted in a convenience sample of ten post graduate students and did not highlight any substantial changes that were required. However, this pilot was limited in a number of ways and the outcomes were therefore of only limited value in assessing the validity of the questions. The number of people used to pilot the questions was small and as such is less likely to identify anything but the more obvious issues. Additionally, the pilot volunteers were all graduates and studying for PhDs, as such they all had advanced educational status and were of moderate income. Therefore the understanding of questions and the manner in which they were answered in this

group might be somewhat different to that of the same questions in the population group being studied. This was seen clearly in the responses to question 23 of the questionnaire, which covered the education status of the respondent. In the pilot, all respondents answered this appropriately, however, the responses from the study sample were unclear and a number of people appear to have misunderstood the question. Additionally, the need for a '*no qualifications*' option was not identified during the pilot as all respondents were well educated, whereas the questionnaires returned in the study often had no response to question 23, but it was not clear whether the question had not been answered or the respondent did not have any qualifications. As a result, this question was considered flawed and omitted from data analysis.

6.2.4 The population sample that was studied

The population in which the present study was performed contained substantial diversity in terms of affluence, ethnicity and age demographics (section 2.3). Owing to this diversity, the factors that influence the generation of unused medicines and the nature of these medicines in EBPCCT are likely to be broadly representative of those in other PCOs elsewhere in the UK. However, since EBPCCT is predominantly urban, it is possible that the population do not fully represent the residents of PCOs that are predominantly rural, where other factors may influence the usual actions of the population, such as travel limitations. In addition, the change to the boundaries of the PCT during the course of the present study, while small, may have influenced the findings in some unknown way and the generalisability of the data to the whole UK population is limited. Therefore, only general estimates have been made when extrapolating some data to the population of the UK.

6.2.5 The influence of the author on outcomes

In any research, it is essential that the researcher remains objective throughout and their influence is minimised to an acceptable level in order that the data be a true reflection of the problem being studied. In research involving non-sentient subjects, controlling the researcher's influence is relatively easy and forms part of the research methodology. However, in studies involving humans, the researcher's influence can become very pronounced unless steps are taken to minimise it. This is particularly true of qualitative research where the researcher interacts directly with the subject such as in a group interview. Any preconceptions or prejudices of the researcher can influence the design and facilitation of the research as well as subconsciously influencing the responses to the interview.

In the present study, the experiences gained by the author during practice as a pharmacist and through discussion with other healthcare professionals may have influenced the data collection. This is particularly true where leading questions have been used in the group interview and the questionnaire. Such questions arise from a desire for the researcher to demonstrate some fact that is based on preconceived ideas and the subject is led to give an answer that may not be a true reflection of their actual actions or opinion.

In the present study, researcher bias, while evident in some aspects of the work, is unlikely to have substantially influenced the outcomes and general findings and the data gathered where bias may have been present have been used cautiously in analysis and in drawing conclusions.

6.3 Major findings of the present study

The present study gathered data on the nature of unused medicines, including the quantities, types and financial value of medicines that were returned to community pharmacies and general practice surgeries and the therapeutic classes of medicines that were present in the domiciliary setting. Data were also collected on the usual methods employed by patients for disposal of unused medicines in addition to the factors that influence medicines non-use and the incidence of unused medicines in the home. Incidental data were also collected on a number of other aspects of medicines use including patient attitudes towards medication reviews, the provision of medicines information and the potential re-use of unused medicines that have previously been supplied to patients. Data are discussed in detail in Chapters 3, 4 and 5 above and a summary of the salient findings of these discussions follows.

6.3.1 The nature of unused medicines in primary care

In the collection element of the present study, over £33,000 worth of unused medicines were returned to surgeries and pharmacies in just eight weeks (section 3.2). These data indicate that approximately £75 million worth of unused medicines are disposed of by this manner each year in the UK. Further data on usual disposal methods that were uncovered by the postal questionnaire indicate that only one in three patients usually dispose of unused medicines by return to a GP surgery or pharmacy (section 5.2.6.4). This indicates that the total quantity of unused medicines generated each year in the UK would have a financial value of approximately £225 million. This is the most robust estimate to date of the financial value of unused medicines in the UK and is equivalent to approximately 3% of the annual NHS expenditure on medicines⁹¹.

The data gathered in the present study indicate that medicines non-use and unused medicines are ubiquitous in primary care with over two fifths of respondents to the postal questionnaire indicating that they currently had or had recently disposed of unused medicines. Additionally, the data indicate that around 3% of the population of the PCT return unused medicines to surgeries and pharmacies each year. The most commonly reported unused medicines were those used in the treatment of cardiovascular disease, respiratory diseases, diabetes and pain. Psychoactive medicines were also found to be unused in substantial quantities in primary care, sufficient to be a cause for concern.

6.3.1.1 Medicines used in the treatment of cardiovascular disease

Cardiovascular medicines comprised a substantial proportion of the items returned for destruction (27%) in the collection element of the present study and were returned from 40% of the patients. However, the survey element showed that just 17% of respondents had unused cardiovascular medicines in their home. These findings are comparable to a number of similar studies conducted between 1994 and 2001 in the UK^{2,3,45,50} and indicate that cardiovascular medicines are commonly unused in primary care and are also more likely to be returned to a pharmacy or surgery for destruction than medicines from other therapeutic classes.

6.3.1.2 Medicines used in the treatment of respiratory diseases

Respiratory diseases such as asthma are common in the UK population^{133,134} and NHS spending on inhaled corticosteroids and bronchodilators has risen considerably over previous years^{7,8,168-171}. The data gathered in the present study indicate that medicines employed in the treatment of these conditions are unused in substantial quantities in

primary care and they also represent a notable proportion of the total financial value of all unused medicines. Additionally, a number of previous studies performed in the UK have demonstrated the presence of unused respiratory medicines in primary care, particularly those used in the treatment of respiratory diseases^{2,3,45,48-50}. Anecdotal evidence of unused medicines returned to community pharmacies also indicates that individual patients may return inhaler devices with no doses having been removed and in the present study over two thirds of the inhaler devices returned were completely full. These data suggest that there is a problem of oversupply among inhaled medicines used in the treatment of respiratory diseases, with patients obtaining more devices than are necessary.

6.3.1.3 Medicines and devices used in the treatment of diabetes

In the present study appreciable quantities of insulins and oral anti-diabetic agents were found to be unused and patients also returned a large number of unused blood glucose test strips for destruction. The unused insulins returned in the present study were of considerable financial value, indicating that this drug may place a significant financial burden on health services where it is unused. Previous studies have shown unused endocrine medicines to account for only a small proportion of the total unused medicines. However the trend indicates an increase in the incidence of unused medicines in this therapeutic class, suggesting that the non-use of these medicines may become more significant over time^{2,3,45,48-50}.

6.3.1.4 Analgesics

A substantial quantity of analgesic medicines were recorded in the present study and individual patients returned in excess of 1000 tablets of paracetamol containing

medicines for disposal in a single return event. Analgesics such as tramadol and opiates were also returned in substantial quantities and this is of concern in light of the potential for these medicines to be used in self poisoning attempts^{100,172} or to cause harm through accidental poisonings⁹³. Indeed, access to paracetamol containing products was restricted by legislation in 1997 for this reason and this has been shown to have reduced the number of successful self poisonings using this agent¹⁷³. Other evidence also indicates that patients suffering from pain are at an increased risk of suicide¹⁰⁴ and extra care is needed to ensure their safety when supplying analgesic medicines. These data indicate that there is overestimation of the analgesic needs of patients in primary care, leading to accumulation of these potentially dangerous agents in patients homes.

In addition, the unused opiates found in the present study highlight the failings of current legislation in controlling the availability of these drugs. Indeed, the data suggest that possibly up to 18 kg of diamorphine, with a street value of up to £36 million, may be diverted onto illicit markets each year in the UK^{74,174-176}. This illustrates the need for care in prescribing of opiates in primary care to ensure that patients are supplied with sufficient for their healthcare needs without excessive quantities being issued. Also, the safe use and disposal of these medicines once in the care of the patient should be guided and facilitated by all healthcare professionals. This is partly being formalised through the legislative changes being instigated following the heinous actions of Harold Shipman,⁷¹ which introduce controls on record of administration and disposal of controlled drugs.

6.3.1.5 Psychoactive medicines

The quantity of unused psychoactive medicines recorded in the present study is of concern owing to their potential to cause accidental⁹³ or deliberate harm¹⁰³ or to be

diverted to illicit markets¹⁷⁴⁻¹⁷⁶. Additionally, many of the patients in possession of these medicines may be suffering from a mental illness such as depression, which may affect their predisposition to suicide¹⁰⁶. The national suicide prevention strategy for England highlights the availability of a means to attempt suicide as one of the factors that influences a patient taking their own life⁹⁶ and the presence of CNS medicines in the home is therefore extremely undesirable.

6.3.1.6 Anti infective agents

Evidence suggests that anti-infective agents are often not used as directed by the prescriber¹⁷⁷, with many patients failing to complete the prescribed course. Previous studies in the UK have also shown between 5% and 10% of unused items to be anti-infective medicines but that the proportion of unused medicines in this therapeutic class appears to be declining^{2,3,45,48-50}. Additionally, the collection element of the present study reported just 4% of the returned items being from this group further supporting this declining trend. However, 1 in 5 respondents to the postal questionnaire that had unused medicines reported the presence of anti-infective agents, indicating that while the return of these medicines appears to be declining, their non-use does not. It is possible that patients are selectively retaining these medicines to be re-used should the infection recur. Alternatively since only a small number of dose units of these medicines are usually supplied, patients may be routinely disposing of these medicines by grey and black water or domestic refuse with potentially harmful environmental effects.

6.3.2 The causes of unused medicines in primary care

The factors that influence medicines non-use and the incidence of unused medicines were identified in the present study by triangulation of three different research techniques. Patients returning medicines to community pharmacies and GP surgeries were asked to give the reason which had led to the need for disposal of unused medicines and participants in a group interview were asked to suggest possible causes of unused medicines. In addition, patients completing a postal questionnaire were asked the reasons for the presence of unused medicines in their home. Correlations were also identified between possible causative factors and the return of medicines or the presence of unused medicines in the home. A number of factors that may influence the generation of unused medicines were identified and their effects are shown in Table 6.1.

Table 6.1: The impact of various factors on the incidence of unused medicines in primary care

Factor	Influence on unused medicines
<i>Changes in the need and perceived need for a medicine</i>	<ul style="list-style-type: none">• Changes in the patient's condition or prescribed therapy leads to substantial quantities of unused medicines being generated in primary care
<i>Over ordering of medicines on repeat prescription</i>	<ul style="list-style-type: none">• Over ordering of prescribed medicines occurs in primary care and this increases the incidence of unused medicines in the home
<i>Patient death</i>	<ul style="list-style-type: none">• The death of a patient leads to substantial quantities of medicines being unused in many instances
<i>Medication reviews</i>	<ul style="list-style-type: none">• Patients on regular medicines who have received a medication review in the previous 12 months have a substantially lower incidence of unused medicines that those who have received no medication review

Factor	Influence on unused medicines
<i>Concordancy of GP consultation</i>	<ul style="list-style-type: none"> • The issuing of a prescription where the patient was not expecting to receive one appears to increase the incidence of unused medicines • Patients who expect a prescription each time they visit their GP or request a prescription where one is not offered are less likely to have unused medicines • If a prescription is offered for an unwanted medicine, patients that request an alternative have an increased propensity towards medicines non-use • Patients that are issued with a prescription for an unwanted medicines may have it dispensed and not take any of the medicine supplied, leading to increased unused medicines
<i>Patient non-compliance</i>	<ul style="list-style-type: none"> • When patients chose to not take a prescribed medicine as directed unused medicines appear to be generated
<i>Patient affluence</i>	<ul style="list-style-type: none"> • Patients with household incomes below £20,000 pa are less likely to have unused medicines in comparison with those with incomes in excess of £20,000 pa
<i>The financial burden on the patient</i>	<ul style="list-style-type: none"> • The payment of prescription levies by the patient increases the likelihood of unused medicines in the home
<i>Patient sex</i>	<ul style="list-style-type: none"> • Female patients are more likely to have unused medicines and also to return them to pharmacies or GP surgeries for destruction • Medicines that are unused by male patients are more likely to contain larger quantities of dose units and be of higher value
<i>Patient age</i>	<ul style="list-style-type: none"> • The number of patients with unused medicines increases with age • The unused medicines possessed by each patient increases as the patient's age increases

Factor	Influence on unused medicines
<i>Patient perception of medicines value</i>	<ul style="list-style-type: none"> • Medicines non-use is more common where the patient under- or over-values prescribed medicines • Patients who were able to accurately indicate the value of prescribed medicines were less likely to have unused medicines • Medicines non-use is lower among patients who do not know the financial value of prescribed medicines
<i>Patient ethnicity</i>	<ul style="list-style-type: none"> • The ethnicity of the patient appears to influence the presence of unused medicines in the home, with patients of Asian descent being more likely to possess unused medicines
<i>Adverse drug reactions</i>	<ul style="list-style-type: none"> • Where patients suffer adverse drug reactions unused medicines are generated
<i>Errors in supply process</i>	<ul style="list-style-type: none"> • Clerical errors in the prescribing process such as selection of the wrong agent when producing a prescription, or errors in the dispensing process such as selection of the wrong product, lead to the generation of a small amount of unused medicines
<i>Difficulties with using medicines</i>	<ul style="list-style-type: none"> • Patients with dexterity difficulties may be more likely to generate unused medicines • Patient confusion regarding dosing instructions may lead to the generation of unused medicines
<i>Information provision</i>	<ul style="list-style-type: none"> • Different types of information may increase or decrease the generation of unused medicines among different patient groups, however the specific influences this information has on medicine use are unclear
<i>Method of ordering medicines on repeat prescription</i>	<ul style="list-style-type: none"> • The method of ordering medicines on repeat prescription does not appear to influence the generation of unused medicines

6.3.3 The usual methods used for of disposal of unused medicines and the DOOP scheme

Previous UK studies that have considered unused medicines have reported a number of ways in which patients usually dispose of unused medicines⁴⁸⁻⁵⁰. These are based

around two core themes; return to a medical or pharmaceutical establishment, such as a GP surgery, community pharmacy or hospital, and disposal in domestic refuse or grey- and black-water. The former of these ensures the safe destruction of unused medicines, while the latter has implications for both the environment and public health. Furthermore, in addition to these disposal methods, patients have also indicated that they may store medicines for re-use⁵⁰ and there is evidence to suggest that a certain quantity are diverted to illicit markets^{176,178}. In the present study, disposal by return to medical establishments appears to be more common than reported in studies undertaken in previous years. In the early 1990s, between 1 in 6 and 1 in 10 patients disposed of unused medicines by return to a pharmacy or surgery⁴⁸⁻⁵⁰ compared to 1 in 3 in the present study. While this demonstrates a substantial improvement in the disposal activities of patients in the UK, it does not compare favourably with the residents of Sweden, where 8 in 10 patients return their unused medicines to pharmacies for safe disposal¹⁵⁵.

The present study also identified that the DOOP scheme for safe collection of unused medicines through pharmacies was not well known amongst patients and the majority indicated that they would use this service now that they were aware of it. However, a small minority indicated that they would continue to use their normal method of disposal despite availability and knowledge of the DOOP scheme. A knowledge of the outcomes that result from poor disposal of unused medicines appeared to influence the disposal method chosen by an individual. For example, patients that indicated an awareness of the potential for medicines to leach from landfill sites tended to dispose of medicines by means other than domestic refuse while those aware that sewerage treatment processes do not eliminate medicines appeared to avoid their disposal in grey and black water. These data indicate that a tailored campaign promoting the DOOP

service and the effects of poor disposal would substantially increase the safe destruction of unused medicines.

6.3.4 Other principal findings

6.3.4.1 The weight of unused medicines as a surrogate marker

The data from the present study indicate that the use of the weight of unused medicines as a surrogate marker is grossly flawed and there is no relationship between weight and either the financial value of the unused medicines or any clinical factor. Additionally, the data on the weight of medicines that pass through the DOOP scheme each year is of little value aside from estimation of the workload in the processing of these medicines by community pharmacies.

6.3.4.2 Health and safety

The present study has also uncovered some potential health and safety issues in the provision of disposal services from community pharmacies and GP surgeries. Items returned included highly oxidising chemicals and unidentified medicines and liquids. Additionally, anecdotal evidence also indicates that poisons may also be returned to community pharmacies for disposal. The community pharmacies that currently provide DOOP services do not have appropriate facilities to dispose of these chemicals or poisons and unlabelled medicines represent an unknown risk to the pharmacy staff. Additionally, there are no formal disposal schemes for unused medicines that are returned to general practice surgeries. However, the data indicate that this is an important means of disposal of unused medicines for some patients with one in five of the return events in the collection element of the study involving GP surgeries and 2%

of respondents to the postal questionnaire indicating that this was their usual method of disposal. It is likely that patients may use this method in conjunction with their usual method of disposal. Further work is needed to determine the extent of medicines that are disposed of through general practice surgeries and the manner in which the surgeries deal with them. Additionally, the implications of provision of these collection services need to be assessed in terms of the Control of Substances Hazardous to Health (COSHH) regulations.¹⁷⁹

6.3.4.3 Prescription charging schemes

The respondents to the patient questionnaire were largely in favour of some form of prescription charging scheme, with many suggesting a fixed fee of £1 to £5 or that patients should pay a proportion of the cost of their medicines. However, the majority of patients were unsure of the financial value of prescribed medicines and estimates of average item cost were generally lower than the true value.

The influence on the use of medicines and the generation of unused medicines of prescription charging schemes and informing patients of the financial value of medicines is not clear and further work is needed.

6.3.4.4 Re-use of previously dispensed medicines

A study in the Puy-de-Dôme region of France during 1998 reported that 20% of the unused medicines returned to community pharmacies could be re-used for humanitarian purposes¹⁶¹ and that 43% of these were listed on the WHO list of essential drugs. The present study found that 28% of the packs returned to community pharmacies and general practice surgeries could have been re-used for humanitarian purposes and 43% of these packs were listed on the WHO list of essential drugs¹²⁵. These data indicate that

although only a proportion of unused medicines would be suitable for re-use, almost half are essential drugs and would be of considerable benefit if deployed in less developed countries. However, three quarters of respondents to the postal questionnaire in the present study indicated that they stored their medicines predominantly in their bathroom or bedroom, where higher temperatures and humidities would be experienced. Therefore the potential for re-use of these medicines remains unclear as their stability in these environments has not yet been fully assessed.

6.4 The implications of these findings to current practice

The findings of the present study, along with the data available from previous research performed in the UK and the rest of the world, have a number of implications for the practice of pharmacy and the use of medicines in general. These implications are based around two core aims; the reduced presence of unused medicines in primary care and the maximisation of the safe and timely disposal of any unused medicines that are produced.

6.4.1 Reducing the presence of unused medicines in primary care

Since medicines incur a cost through both the action of supply and the inherent cost of the medicine itself, when they are unused and have brought no benefit to the patient they are highly undesirable in a cost efficient system. While it would be impossible in present circumstances to totally eliminate unused medicines from primary care, there are a number of opportunities to minimise their generation. Many of these opportunities have been identified in the present study, and have been placed in context with the available findings from other studies. In many cases, the changes that are highlighted below would have cost implications. However through their application to practice, it is

possible to both minimise unnecessary expenditure on medicines and improve patient care. Therefore, in certain cases the proposed changes may be cost neutral or even reduce expenditure.

The potential changes to practice that have been identified are outlined below, along with the possible barriers to their implementation.

6.4.1.1 Pharmacist intervention

Pharmacists are well placed to intervene in patient use of medicines, promoting appropriate use and minimising the incidence of unused medicines and a number of opportunities have been highlighted by the study findings.

- Identification of patients with large quantities of unused medicines and assessment of the medicines being returned to identify the most appropriate action
- Use of data gained from returned medicines to inform decisions made on the repeat dispensing of items for the patient concerned
- Undertaking of medicines use reviews under the advanced services element of the new contractual framework
- Locally negotiated provision of full clinical review of patients identified through return of unused medicines under the enhanced services element of the new contractual framework

These opportunities may bring a number of benefits to patients and could result in considerable cost savings. However, the extent of any benefits achieved may be limited by a number of barriers to the implementation of these changes such as those outlined below.

- The provision of appropriate staff may cause difficulty with the recruitment and training already proving difficult in some areas and incurring substantial investment
- Resources for provision of enhanced services must be locally negotiated and in some areas funding may not be available. Additionally, since pharmacies benefit financially from each item dispensed, alternative funding streams are needed to allow pharmacists to discourage patients from having items dispensed that may otherwise be unused
- Respondents to the postal questionnaire were not generally in support of clinical reviews being performed by pharmacists or provided in pharmacies and this would need to be overcome if pharmacists are to move into this area

6.4.1.2 General practitioners

General practitioners and other prescribers are also important in the minimisation of unused medicines and the findings of the present study highlight a number of implications for their practice.

- Greater concordance in consultations is required, in order to more accurately establish the expectations of patients
- More prudent prescribing with supply of trial and post-dated prescriptions, particularly where new or altered therapies are being prescribed and changes are more likely to occur, may substantially reduce the generation of unused medicines

These changes could be implemented with little difficulty, utilising existing processes and procedures; for example, trial prescriptions could be issued as a repeat dispensing batch of two 14 day supplies, removing the need for further consultations if the patient

does not experience any difficulties. However some barriers do exist that may limit the full implementation of these changes to practice.

- Training on methods to improve consultation concordancy may be required, particularly among more experienced practitioners that are more familiar with the traditional dominant prescriber model
- Time pressures on general practitioners limit their opportunities to fully engage the patient in a discussion of the best treatment options available and these would need to be addressed if fully concordant consultations are to be achieved

6.4.1.3 Primary Care Trusts and the National Health Service

Primary Care Trusts and the NHS as a whole are also important in tackling the generation of unused medicines. Opportunities for these organisations to influence this problem are as follows.

- Targeting of resources to patients in disease groups where the greatest benefits can be achieved and cost savings are largest. The diseases groups implicated in the present and previous studies as most likely to lead to unused medicines were
 - Diabetes
 - Respiratory diseases
 - Coronary heart disease
- Education campaigns targeted towards patients with higher household incomes and ethnic minority groups may result in a substantial reduction in unnecessary expenditure
- Careful review of the prescription charging system may help to reduce the generation of unused medicines in primary care

6.4.2 Optimisation of the safe and timely disposal of unused medicines in primary care

While it would be desirable to entirely eradicate unused medicines from primary care, this is not possible under current conditions and it is important to ensure that those medicines that are unused are disposed of in a safe and timely manner. The data gathered in the present study allow the identification of a number of opportunities for healthcare professionals and organisations to facilitate this in primary care.

While the DOOP scheme allows patients to dispose of unused medicines easily, the data indicate that many patients are not aware of it. Additionally, the data indicate that information on the effects of poor disposal is likely to promote the use of appropriate methods and through concerted information campaigns on the disposal services offered, along with information about their purpose, it is possible to minimise the quantities of medicines that are disposed of in domestic refuse and grey and black water. The targeting of this information to younger, male patients may also improve the return of medicines further since these groups appear to be least likely to dispose of medicines appropriately. Additionally, specific reference should be made to the dangers of analgesic and psychoactive medicines being allowed to accumulate in the home and the need for safe disposal of these medicines should be highlighted.

The data indicate that if the DOOP service was appropriately promoted, it would be likely that the vast majority of patients with unused medicines would use this service. However there is a small minority who indicated that they would not use the service, stating that it was inconvenient or that they were not able to visit their pharmacy and a substantial quantity of medicines were returned to general practice surgeries indicating that this is a favoured route of disposal by some patients. It may therefore be necessary

to review the current provision of medicines disposal services to facilitate appropriate disposal.

Safe disposal of unused medicines may also be promoted through pharmacists and their proxies collecting unused medicines while making deliveries of prescription medicines to patients' homes. Medicines may also be removed for disposal by nurses and doctors making home visits. However, the transportation of unused medicines by unregistered health professionals is currently prohibited by the Hazardous Waste Regulations and therefore appropriate registration or exemptions from the legislation would be required. Additionally, medicines remain the property of the patient, and pass to their estate on their death, making it difficult to remove them from patients homes, even where they are not being used appropriately. Legislative changes that ensure NHS prescribed items remain the property of the NHS would overcome this boundary and allow health professionals to remove them for safe disposal. Unfortunately, the actions of Harold Shipman have clouded this issue somewhat and called into question the integrity of health professionals and their trustworthiness to undertake such tasks. However, this should not be a barrier to ensuring the safety of the general public and individual patients and a review of the current practices in this area and the impact of changes being imposed in the wake of the Shipman Report is needed prior to implementation of any legislative changes.

6.5 Further work

Unused medicines and medicines non-use have been studied little in the UK and the data gathered during the present study have highlighted a number of issues where further work may be necessary in order to fully understand the factors that influence the

generation and incidence of unused medicines. The principal areas that have been identified as requiring further consideration are as follows.

- Assessment of the influence of ethnicity on medicines non-use and the generation of unused medicines, including the patients' preferred method of disposal
- Review of the impact of the additional roles of pharmacists including repeat dispensing and medication use reviews on the generation of unused medicines and the impact on the safe disposal of these
- Assessment of the extent of diversion of unused medicines into illicit markets and the effect of new legislation on this
- Assessment of how information provided with prescribed medicines affects the incidence of unused medicines
- Development and implementation of targeted information on safe medicines use and disposal, with assessment of the impact of such information
- Further assessment of the stability of blister packed medicines stored in artificial environments that simulate the temperature and humidity of a domestic kitchen or bathroom with a view to the potential for re-use
- Exploration of the potential for re-use of unused medicines collected in primary care in terms of the implications on humanitarian aid
- Assessment of the influence of payments for prescribed medicines has on the incidence of unused medicines and medicines non-use
- Examination of the COSHH implications on provision of the DOOP scheme in community pharmacies

6.6 Conclusion

The present study has considerably expanded the current knowledge on unused medicines in primary care and provides the most complete assessment of this issue to date. The study has identified a number of factors that lead to the generation of unused medicines and has considered the possible changes to practice that may limit this waste of vital resources. Over the course of the study, a number of changes have occurred in the provision of healthcare within the NHS in the spheres of Pharmacy and General Practice. There are now non-medical supplementary and independent prescribers working in many different roles in primary care and the introduction of the new pharmacy contractual framework for England and Wales has resulted in pharmacists performing many new roles. The introduction of repeat dispensing and medication use reviews as well as enhanced pharmacy services is likely to considerably change this role in the future. Further changes have yet to be fully implemented, such as the National Programme for Information Technology, central spine records and electronic prescription transfer. The specifics of these have yet to be finalised and the impact on pharmacists working in primary care is not yet known. These changes will ultimately alter the ways in which patients access and use their medicines and the influences of these changes on unused medicines and medicines non-use has yet to be determined.

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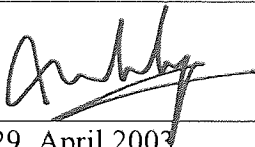
Appendix I : Risk assessments

RISK ASSESSMENT

Task	Receipt of unused medicines from the public
Location	Community pharmacies & GP surgeries in Eastern Birmingham PCT
Responsible person	Adam John Mackridge MRPharmS

Hazard [Harm]	Risk	Action
Sharps contaminants [Extremely harmful]	Very Low	Medicines are to be placed into clear plastic bags and sealed with minimal handling. If any risks are identified, they should be dealt with in the normal manner as detailed in the location's risk assessment document
Mercury [Harmful]	Very Low	
Crushed tablet [Slightly to moderately harmful]	Low	
Broken glass from broken bottles [moderately harmful]	Low	


Other action	Normal care and attention should be exercised at all times
---------------------	--

Assessor	Adam Mackridge
Signed	
Date	29, April 2003

RISK ASSESSMENT

Task	Collection of waste medicines from research sites
Location	Community pharmacies & GP surgeries in Eastern Birmingham PCT
Responsible person	Adam John Mackridge MRPharmS

Hazard [Harm]	Risk	Action
Injury from lifting and carrying [Slightly harmful]	Low	Exercise normal care and attention and employ normal lifting and carrying techniques

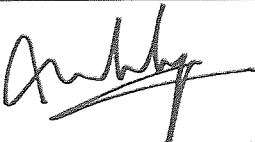
Assessor	Adam Mackridge
Signed	
Date	29, April 2003

RISK ASSESSMENT

Task	Waste Medicines Analysis
Location	
Responsible person	Adam John Mackridge MRPharmS

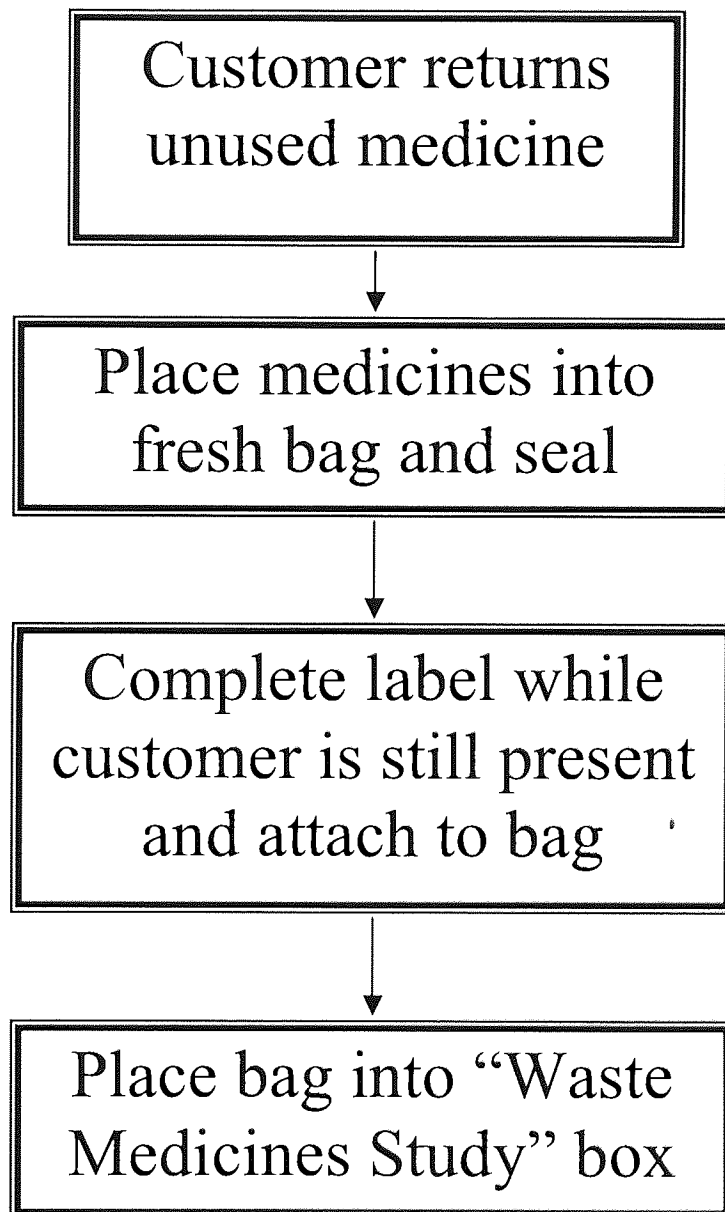
Hazard [Harm]	Risk	Action
Sharps contaminants [Extremely harmful]	Very Low	Operator wears double gloves. (incinerate following cleanup) Place sharps into sharps bin and incinerate
Mercury [Harmful]	Very Low	Operator wears mask and gloves. Use mercury clean-up kit
Crushed tablet [Slightly to moderately harmful]	Low	Operator wears mask, eye glasses and double gloves. (incinerate following cleanup) Sweep up tablet with designated dustpan and brush and double bag.
Broken glass from broken bottles [moderately harmful]	Low	Operator wears double gloves. (incinerate following cleanup) Place glass into sharps bin and incinerate.

Other action	All risks reduced through emptying bag into white plastic tray for visual assessment prior to any physical handling
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Assessor	Adam Mackridge
Signed	
Date	29, April 2003

Appendix II : Standard operating procedures

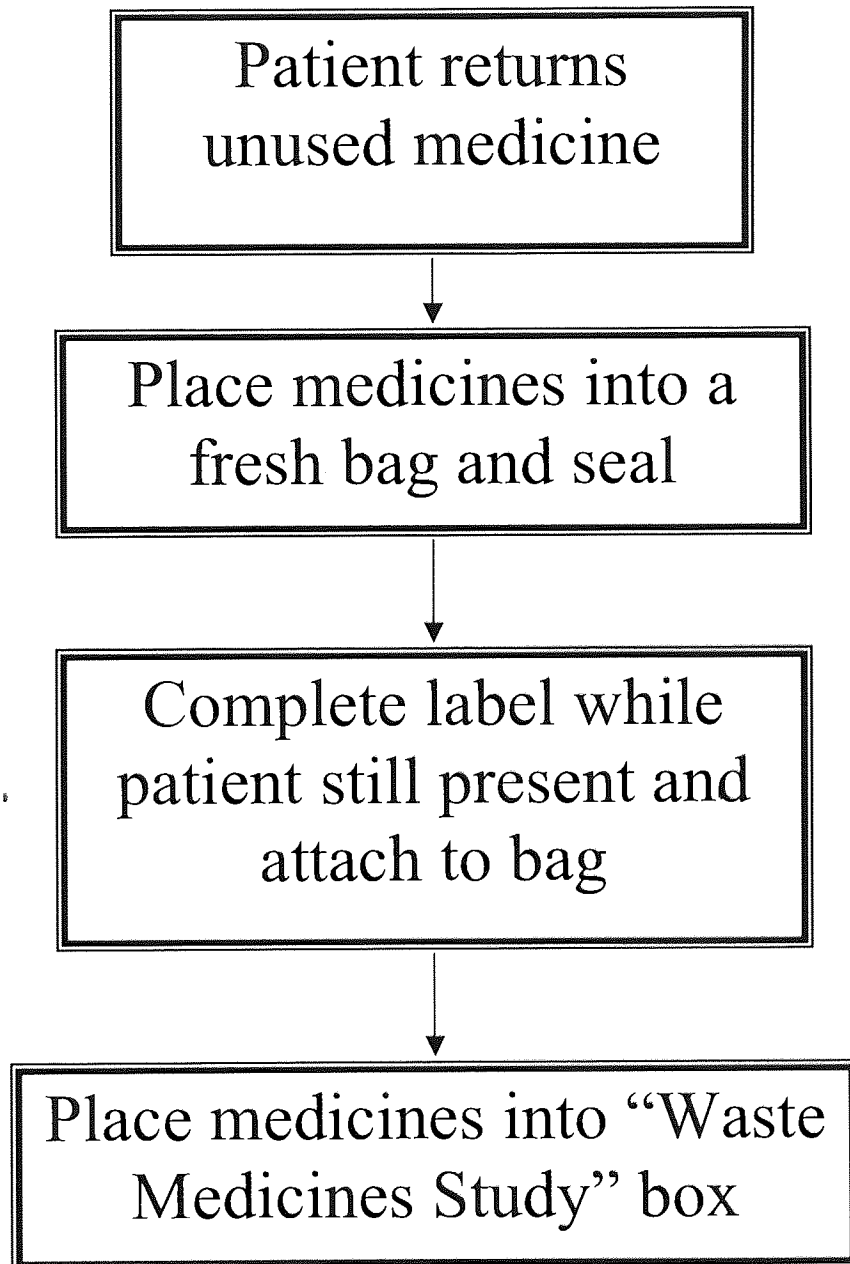
Waste Medicines in Primary Care



If patient returns medicines in a non-disposable dosette or nomad tray, empty the contents into the bag and write the patient's name at the top of the label.

Any problems or queries regarding the study, call Adam

Waste Medicines in Primary Care



If you have any problems or queries regarding this study, please contact [redacted]

Appendix III : Group interview recruitment flyer

Waste Medicines in the Community

Aston University and Eastern Birmingham PCT are trying to find out about unwanted medicines in your community.

In this important part of the project, we are asking patients from this area to tell us about how they use their medicines, what problems they have with taking them and what they do with their old medicines.

If you can spare an afternoon or evening, we would like you to come to a group discussion and **tell us what you think.**

If you are interested in taking part or would like more information, please contact Adam on:

Appendix IV : Postal Questionnaire

Medicines in Eastern Birmingham Patient Questionnaire

The Pharmacy Practice Group at Aston University are working with Eastern Birmingham Primary Care Trust to find out about medicines waste in this area and help to reduce it.

Why are we doing this questionnaire?

We are trying to find out the reasons why some medicines are not always taken exactly as the doctor prescribes them and what problems this causes for patients.

What are we going to do with the answers?

We hope to use any information that you give us, to help you and other people to get the best possible treatment from the NHS, to improve the way people use medicines and to help people to deal with unwanted medicines properly.

What would we like you to do?

This questionnaire is designed for you to fill in yourself.

Example question

1. *Do you own a car?*

- Yes
 No

Simply place a tick or a cross in the box next to the answer that you think applies to you best.

Please try to complete all the questions and fill in the information about yourself. When you have filled everything in, put the questionnaire into the envelope provided and post it. **YOU DO NOT NEED TO PUT ANY STAMPS ON THE ENVELOPE.**

How long will it take:

The questionnaire should only take you about **10 minutes** to complete.

What to do if you have a problem with the questionnaire:

This whole research project has been looked at and approved by the local ethics and research committee, if you have any problem with the way the questionnaire has been done, you can telephone the secretary of the Ethics Committee and they will arrange for your problem to be looked at.

If you want to know more about the study, or ask any other questions, please call

~~your GP or the study in any way.~~ not affect your medical care.

If you don't take part in the study, your medical care will not be affected.

By returning the questionnaire, you are agreeing to your answers to be used in this research

Section 1 - Your Medicines

1. *Have you used any medicines in the last 12 months? Including inhalers, ointments, creams and liquids. (Tick **all** that apply)*
 - Medicines prescribed by your doctor
 - Medicines bought from a pharmacy (chemist)
 - Herbal medicines
 - Vitamins or mineral supplements
 - Homeopathic medicines
 - Not taken any medicines

2. *Where do you normally keep your medicines at home? (Tick where you keep **most** of your medicines)*
 - Kitchen
 - Bathroom
 - Bedroom
 - Somewhere else _____ (please write here)

3. (a) *Are any of your medicines on repeat prescription?*
 - Yes – please go to Question 3(b)
 - No – please go to Question 4

- (b) *Do you find the repeat medicines order system at your doctor's surgery easy to use?*
 - Yes
 - No _____ (please write any problems)

- (c) *When you order your medicines do you:*
 - Order all the items available, just in case you need them / to save making more trips
 - Order only the items you have run out of at that time

- (d) *How do order your repeat medicines at the moment? (Tick **one**)*
 - Over the Internet
 - By Telephone
 - In the Pharmacy
 - By post
 - In Person at the surgery
 - Other _____

- (e) *How would you like to order your repeat medicines? (Tick **all** that apply)*
 - Over the Internet
 - By Telephone
 - In the Pharmacy
 - By post
 - As you do now
 - Other _____

Appendix IV: Postal Questionnaire

4. *How many months of treatment would you like to get at a time when you get your repeat medicines? (Tick one)*
- Less than a month
 - One month
 - Two Months
 - Three Months
 - More than three months

Section 2 - Old Medicines

When people get medicines from their doctor, they sometimes don't take all the medicines given. People do this for a number of reasons and we are interested why people have leftover medicines and what they do with them.

5. *(a) Have you got any medicines at home that are not being used or have you disposed of any medicines in the last 6 months? (Tick all that apply)*
- Yes – Currently have unused medicines at home – please go to **5(b)**
 - Yes – Have got rid of unused medicines in the last 6 months – please go to **5(b)**
 - No – All medicines are being used / not taking any medicines – please go to **6**

(b) Why were these medicines leftover? (Tick all that apply)

- Got better
- Side effects
- The doctor changed the medicines
- Didn't want to take the medicine
- The medicine went out of date before it was used
- The doctor/pharmacist gave the wrong medicine
- Other reason _____ (please write here)

(c) What were these medicines for? (Tick all that apply)

- | | |
|--|--|
| <input type="checkbox"/> Stomach problems | <input type="checkbox"/> Thyroid problems |
| <input type="checkbox"/> Heart treatment | <input type="checkbox"/> Diabetes / blood sugar |
| <input type="checkbox"/> Blood pressure | <input type="checkbox"/> Contraceptives |
| <input type="checkbox"/> Cholesterol | <input type="checkbox"/> Bladder problems |
| <input type="checkbox"/> Breathing problems | <input type="checkbox"/> Hormone Replacement Therapy (Menopause) |
| <input type="checkbox"/> Allergies | <input type="checkbox"/> Cancer treatment |
| <input type="checkbox"/> Mood | <input type="checkbox"/> Vitamins / Iron |
| <input type="checkbox"/> Pain | <input type="checkbox"/> Eye problems |
| <input type="checkbox"/> Epilepsy | <input type="checkbox"/> Ear problems |
| <input type="checkbox"/> Dizziness/sickness | <input type="checkbox"/> Skin problems |
| <input type="checkbox"/> Stop Smoking | <input type="checkbox"/> Other _____ |
| <input type="checkbox"/> Infections (bacterial/fungal) | (Write illness here) |

6. *What do you normally do with old medicines? (Tick the one you do most often)*

- Flush down the toilet
- Throw away with normal rubbish
- Take to pharmacy (chemist)
- Take to doctor's surgery
- Take to a hospital
- Other _____ (write what you do here)

Appendix IV: Postal Questionnaire

7. **Most of the pharmacies (chemists) in this area run a scheme that lets you take your medicines to them and they send them off for safe disposal. It is sometimes called the 'DOOP scheme' or the 'Green Bin' scheme**

(a) *Have you ever heard about this scheme?*

- Yes
 No

(b) *If you have not used this scheme before, do you think that you will use it now you know about it?*

- Yes
 No _____ (please give reasons)

8. **Medicines which are put down the toilet are not completely cleaned from the water by the normal sewage treatment process**

(a) *Did you know this already?*

- Yes
 No

9. **Medicines which are thrown away with normal rubbish can leak out of the rubbish tip and end up in rivers and streams damaging the environment and sometimes getting into drinking water**

(a) *Did you know this already?*

- Yes
 No

10. (a) *Do you think that the government should ban people from putting medicines in their toilet or normal rubbish and make them take medicines to their pharmacy?*

- Yes
 No

(b) *Do you think more should be done to make people aware of the problems caused by getting rid of medicines in the toilet or bin?*

- Yes
 No

11. *Who do you think should sort out the problem of medicines waste as a whole? (Tick one)*

- Government
 NHS
 Other _____
 Medicines waste does not need sorting out

Section 3 - You and Your Doctor

12. *When you go to see the doctor, do you expect to get a prescription?*

- Yes
 No

Appendix IV: Postal Questionnaire

13. *If the doctor didn't give you a prescription, what would you usually do? (Tick one)*
- Accept his/her advice and do as they ask
 - Ask for a prescription for the medicine you think is best
 - Go to the chemists and buy something
 - Other _____ (please write here)
 - Never happened
14. *If the doctor prescribed a medicine that you don't want to take, what would you usually do? (Tick one)*
- Accept his/her advice and do as they ask
 - Ask for a prescription for a different medicine that you think is better
 - Take the prescription and not bother to take it to the chemists'
 - Take the prescription to the chemists' but not take the medicine
 - Other _____ (please write here)
 - Never happened
15. *Do you usually read all the written information given with a new medicine before taking it?*
- Yes
 - No

16. When people get their medicines, they might get information from their doctor or pharmacist about the medicines.

(a) *Generally, do you think that the information you normally get about your medicines is?*

	Not enough	Just right	Too much
Side effects	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Why you are taking it	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
How it works	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
How you need to take it	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

(b) *Where would you like information about medicines to be available?*

	Pharmacy	Doctor	Leaflet in pack	Internet	Other
Side effects	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Why you are taking it	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
How it works	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
How you need to take it	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

(c) *Is there any other information you would like about your medicines?*

Section 4 - Medication Reviews

A medication review is where a healthcare professional such as a Doctor, Nurse or Pharmacist goes through all the medicines you take and talks to you about side effects, how you take your medicines and what they are for. They might change the medicines you are on after this review so that you get the best treatment for you and don't take anything you don't need.

17. *When did you last have a Medication Review (Tick one)*
- Last 3 months
 - Last 6 months
 - Last 12 months
 - Never had a medication review
 - Not on any regular medicines
18. (a) *How often would you like to have a medication review? (Tick one)*
- Every 3 months
 - Every 6 months
 - Every 12 months
 - Every 2 years
 - Medication checks are a waste of time
 - Not on any regular medicines
- (b) *Who would you like to do this medication review? (Tick all that apply)*
- Doctor
 - Nurse
 - Pharmacist (chemist)
 - Other _____
- (c) *Where would you like to have this review? (Tick all that apply)*
- In your doctor's surgery
 - In your home
 - At your local pharmacy
 - Other _____

Section 5 - The cost of medicines

When your doctor gives you a prescription, you might pay a charge for each item, or you might get all of it free with the National Health Service paying for the rest of the cost of the medicine.

19. *How much do you think the NHS pay for an item on average? (Tick one)*
- Less than £5
 - £5 to £10
 - £10 to £20
 - £20 to £30
 - More than £30
 - Don't know

Appendix IV: Postal Questionnaire

20. *Do you pay for your NHS prescriptions? (Tick one)*

- Yes
- No – Under 16
- No – 16,17 or 18 and in full time education
- No – Over 60
- No – Maternity exemption
- No – Medical exemption
- No – Receive income support
- No – Receive Working Families' Tax Credit / Working Tax Credit
- No – Receive minimum Income Guarantee / Pension Credit
- No – Receive disabled Person's Tax Credit / Disability working allowance
- No – Have HC2 certificate
- No – Receive income based Jobseekers allowance
- No – Receive war pension
- No – Other _____ (please write here)

21. *How much do you think that people should pay for NHS prescription? (Tick one)*

- Prescriptions should be *free* to **all** patients
- Prescriptions should be *free* to **some** patients
- About £1 per item
- About £5 per item
- Other fixed amount £ _____
- Patients should pay a proportion of the cost of the medicines

Section 6 - About You

22. *How old are you? (Tick one)*

- 19 or under
- 20 to 29
- 30 to 39
- 40 to 49
- 50 to 59
- 60 to 69
- 70 to 79
- 80 to 89
- 90 or over

23. *Which of the following do you have? (Tick all that apply)*

- GCE / GCSE / O Level
- A Level
- BTEC
- NVQ
- University Degree
- Other _____

24. *What is your household income (Tick one)*

- Less than £10,000
- £10,000 to £19,999
- £20,000 to £29,999
- £30,000 to £39,999
- Over £40,000

25. *Are you?*

- Male
- Female

26. *What is your postcode?*

Appendix IV: Postal Questionnaire

27. Which of the following best applies to you? (Tick **one**)

White

- British
- Irish
- Any other White background

Mixed

- White and Black Caribbean
- White and Black African
- White and Asian
- Any other Mixed background

Asian or Asian British

- Indian
- Pakistani
- Bangladeshi
- Any other Asian background

Black or Black British

- Caribbean
- African
- Any other Black background

Chinese

- Chinese

Any other ethnic group

- Other ethnic group

*Ethnic groups are taken from the 2001 census questions for England and Wales

Thank you very much for your time.

Please put the questionnaire into the envelope provided and post back to us.

YOU DO NOT NEED ANY STAMPS