

Evaluation of the Scale, Causes and Costs of Waste Medicines

Final Report





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Throughout this report references are made to the work of Primary Care Trusts in areas such as medicines management and further reducing medicines wastage. With the publication In July 2010 of *Equity and Excellence: Liberating the NHS* it is apparent that by 2013 responsibility for such tasks will in England have moved on to GP Commissioning Consortia and/or the NHS Commissioning Board. However, the authors believe that the data and findings offered here should remain relevant.

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Readers seeking further information about the work reported here are invited to contact either Professor Paul Trueman at Paul.Trueman@Brunel.ac.uk or Professor David Taylor at David.Taylor@Pharmacy.ac.uk

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Executive Summary

Previous estimates have suggested that each year between £100-£800 million worth of dispensed NHS medicines go unused and are ultimately discarded. Subject to some continuing uncertainties, the findings presented in this Report of research undertaken in 2009 by the York Health Economics Consortium and the School of Pharmacy, University of London, indicate that the gross annual cost of NHS primary and community care prescription medicines wastage in England is currently in the order of £300 million per year.

This sum represents approximately £1 in every £25 spent on primary care and community pharmaceutical and allied products use, and 0.3 per cent of total NHS outlays. It includes an estimated £90 million worth of unused prescription medicines that are retained in individuals' homes at any one time, £110 million returned to community pharmacies over the course of a year, and £50 million worth of NHS supplied medicines that are disposed of unused by care homes.

Allowances should also be made for the possible under-reporting of waste because of the survey methodology used, the volume and cost of medicines disposed of informally via domestic waste and the drains, and the value of returns made to dispensing GPs. PCTs in addition incur returned medicine disposal costs, which can reasonably be factored into estimates of pharmaceutical wastage. Given these factors, we conclude that for the NHS in England a gross annual prescribed medicines wastage sum of £300 million represents a robust central estimate.

Prescribed medicines wastage deserves both managerial and professional attention. However, not all of it is avoidable, or the result of poor practice. This study estimates that less than 50 per cent of medicines waste is likely to be cost effectively preventable. Allowing for this and factors such as the additional costs of further enhancing existing control measures, the average English PCT seeking further medicines waste reductions will be unlikely to be able to realise more than £0.5 million net per annum. That is, between £1 and £2 per head of population served.

There is evidence of considerable public and professional concern about NHS medicines wastage. Reductions in its scale and costs would not only be financially desirable, but might also be politically popular. Yet the research presented in Section

5 of this Report indicates that in welfare terms significantly greater returns could be generated by better medicines use, as opposed to waste reduction *per se*. Improving adherence in medicine taking can improve health outcomes. The estimated opportunity cost of the health gains foregone because of incorrect or inadequate medicines taking in just five therapeutic contexts is in excess of £500 million per annum, albeit that realising such gains would – to the extent that effective interventions exist – involve additional costs.

Future policies should be based on an informed awareness of the relative scale of these opportunities. The research findings described here do not indicate that the National Health Service in England faces a greater risk of wasting medicines as compared with other countries' health care systems. Overall primary care and care home medicines usage in England – expressed in prescription item volume terms – has risen by about 50 per cent in the last 15 years. Yet our research did not find evidence that the problem of medicines waste has increased over this period.

Nor – despite frequently expressed beliefs to the contrary amongst both professionals and a proportion of the public – is there evidence that introducing more extensive charges for prescription medicines would be likely significantly to reduce current levels of NHS medicines waste. The available research suggests that it might rather discourage medicine taking in some sections of the community.

The array of policies developed by the NHS in areas such as providing GP and pharmacist medication/ medicines use reviews, coupled with interventions in areas such as repeat dispensing management by pharmacists and PCT staff support for improving prescribing and medicines use processes, appears to be at least as extensive as the action identified elsewhere. Managers and clinicians interviewed during the research reported here believe that the health service is now addressing drug waste related problems more effectively than at any previous time.

This Report concludes that primary and community care medicines waste in the English NHS should not be regarded as a serious systemic problem. It is better seen as a normal challenge to be tackled via the continued development of existing strategies and care quality improvement initiatives.

Root causes of medicine wastage

Failures to take medicines to optimum effect are in many instances attributable to either intentional or accidental non-adherence on the part of their users. But patients should not be blamed for the problems they experience in medicines taking, or for medicines wastage. As defined in this Report, most drug wastage is not primarily the result of deliberate patient actions. Its root causes encompass:

- ▶ patients recovering before their dispensed medicines have all been taken;
- ▶ therapies being stopped or changed because, for example, of ineffectiveness and/or unwanted side effects;
- ▶ patients' conditions progressing, so that new treatments are needed;
- ▶ patients' deaths, which as well as serving to reveal previously unused medicines may involve drugs being changed or dispensed on a precautionary basis during the final stages of palliative care;
- ▶ factors relating to repeat prescribing and dispensing processes, which may independently of any patient action cause excessive volumes of medicines to be supplied; and
- ▶ care system failures to support adequately medicines taking by vulnerable individuals living in the community, who cannot independently adhere fully to their treatment regimens.

A significant amount of prescribed drug wastage is therefore inevitable. Reducing further the volume and cost of avoidable waste will require multiple complementary measures aimed at enhancing health and pharmaceutical care quality.

Opportunities for financial savings and better health outcomes

We offer qualitative evidence indicating that in order to motivate clinicians and service users to use medicines as cost effectively as possible, decision makers and managers should place emphasis on improving health outcomes rather than waste cost reduction alone. Health care improvement involves continuously encouraging good communication and more open relationships between service users and health professionals, aimed at enabling as many patients as possible to reveal and resolve medication related concerns. It is recommended that more effort should be focused on applying psychological and related medicines taking research findings to the development of practical interventions capable of cost effectively improving drug use, and where possible reducing waste in day-to-day settings.

Positive opportunities for the further reduction of medicines waste include:

- ▶ providing targeted support for patients starting new therapies, and those on unusually costly and/or difficult to take treatments. There is good quality evidence that extending nationally or locally funded services of this type could reduce waste and contribute other benefits;
- ▶ supporting high quality prescribing, and ensuring that medication and associated treatment regimens are effectively reviewed by doctors, pharmacists and, when desirable, other professionals;
- ▶ incentivising closer professional management of medicines supply at the point of dispensing. Supporting the further development of pharmacist managed repeat dispensing may have a significant future role to play in reducing waste, although many GPs are not yet in favour of greater use of the scheme currently in place for facilitating this. Broadly, medicines wastage would be reduced if every time a repeat prescription is dispensed the pharmacist or dispenser involved was able to check with the patient concerned that each medicine is required. Such service providers should be motivated to prevent unnecessary supply. The systems of repeat dispensing presently commonly in place do not consistently assure this;
- ▶ encouraging the flexible and informed use of 28 day and – where it benefits patients – either longer or shorter prescribing periods. There is evidence that in some circumstances limiting prescription durations to 28 days reduces wastage. But in others it can cause inconvenience to medicine takers and drive up supply side costs;
- ▶ caring better for 'treatment resistant' patients, who may not be taking their medicines correctly;
- ▶ providing better quality pharmaceutical care for isolated patients and other vulnerable people at raised risk of experiencing unobserved problems in medicine taking. This may involve the introduction of new forms of targeted medication and care review, and providing better training in medicines taking support for (social) care workers;
- ▶ undertaking audits of the supply and use of MDS (monitored dosage system) medicines taking aids. The inappropriate use of such aids can waste resources and leave some at risk patients inadequately supported;
- ▶ further enhancing hospital and primary care liaison in contexts such as improving the quality of care at around the time of hospital discharge;
- ▶ delivering better integrated terminal care in home settings, aimed at ensuring good access to all forms of beneficial treatment and support while simultaneously reducing drug wastage; and
- ▶ developing more effective national or local waste medicines return and related public information campaigns.

Our evidence indicates that these last should seek to deliver unambiguous messages about the positive value of appropriate medicines taking, and when and why residual medicines should be returned to pharmacies or dispensing doctors' dispensaries. Environmental protection and personal and community safety may offer salient arguments for avoiding drug wastage whenever possible, and returning unwanted medicine stocks for NHS disposal when necessary.

Minimising wastage of all types is a desirable goal. But in the context of residual medicines there is a danger that a 'zero tolerance' approach could undermine awareness that the core purpose of health care is to increase as cost effectively as possible health and wellbeing, rather than to make savings to 'stand alone' budgets like those for community pharmacy and/or primary care pharmaceuticals. It is concluded that the greatest social and economic returns are to be gained when reducing medicines waste can be effectively linked to improving care quality and health outcomes.

1 Introduction

1.1 Introduction

The cost of NHS medicines and appliances supplied by community pharmacists and dispensing doctors in England in the year ending March 2009 was in excess of £7.5 billion (NHS Prescription Services 2009). The majority of the items dispensed by community practitioners are used by the patients for whom they were prescribed and – depending in part on how they are taken – confer positive benefits. However, it is inevitable that some degree of waste is associated with medicines supply (Jesson *et al.* 2005).

Over and above problems such as inappropriate prescribing, not all drugs that are dispensed are taken by those for whom they were prescribed. Medicines waste as defined in this report refers to drugs that are dispensed but are ultimately physically discarded.¹ That is, they are put into domestic waste or the drains, or returned to pharmacists or dispensing doctors for incineration.

In its publication *Prescribing Costs in Primary Care* (NAO 2007) the National Audit Office noted that the direct financial cost of NHS medicines wastage in England as defined in this manner (calculated in list price terms, and including not only unused drugs but also items such as surplus dressings, appliances and prescribed nutritional supplements like ‘sip feeds’) has been estimated at £100 million annually. But the NAO added that this figure is almost certainly a significant under-estimate and that the true value of NHS waste medicines (also sometimes referred to as residual medicines) may be as much as 10 per cent of the overall health service pharmaceutical and allied product ‘bill’ incurred in the community. That is, approaching £800 million in today’s terms.

1 The European Waste Framework Directive (2008) defines ‘waste’ as being ‘any substance or object the holder discards, intends to discard or is required to discard’. As such, waste in respect to medicines refers to items which have been dispensed but are unused or partly used by patients and eventually need to be disposed of, either because they are no longer needed or because they have passed their ‘sell by’ date. Waste medicines may remain stored in patients’ homes, be informally disposed of as undifferentiated household waste or returned to a community pharmacy or a dispensing GP practice. It should be noted that the survey approach employed in this study utilised a broader definition of waste medicines than that employed in the previous 1995 OPCS study on residual medicines – see subsequent sections.

Other observers have stressed that not taking medicines as prescribed can, depending on the reasons underlying such behaviour, result in avoidable illness. The value of the forgone therapeutic gains associated with medicines being taken sub-optimally (either because they are not consumed at all, or because they are taken incorrectly) may well be significantly in excess of the acquisition cost of all wasted medicines that have to be physically disposed of (see, for instance, Elliott 2009.)

This report is concerned with the current scale, causes and where possible prevention of NHS medicines wastage in primary care and community care settings such as care homes. It summarises the findings of qualitative and quantitative research on medicines wastage in the English NHS that was commissioned by the Department of Health and undertaken by the York Health Economics Consortium and the School of Pharmacy, University of London. On the basis of the evidence gathered it offers recommendations as to how medicines waste might in future be further reduced.

During the course of this research, attempts were made to identify the components of medicines wastage that are potentially avoidable, as opposed to wastage that should be regarded as an inevitable aspect of appropriate, high quality, pharmaceutical care. An illustration of the latter would be a partly used medicine that is disposed of because the user’s condition did not respond as the prescriber had anticipated. Within the potentially avoidable total, further attempts were made to distinguish between the volume and monetary value of waste that is cost effectively avoidable and that which is not, albeit that there are considerable uncertainties involved in making such a differentiation.

Even in contexts where effective interventions are known to exist, extensive efforts on the part of healthcare professionals may be required to reduce levels of pharmaceutical and allied product waste. In other instances there is little or no firm evidence that any presently available intervention is likely in practice to impact significantly on wastage levels. The conclusions and recommendations offered towards the end of this report reflect an awareness of the fact that the costs of seeking to prevent the physical volume of medicines wastage may exceed the benefits of such action, either because of the labour expenditures involved or because of unintended consequences of intervention.

For example, in some instances well intentioned efforts to prevent wastage may paradoxically result in patients ceasing to have their prescribed medicines dispensed. Apparently simple ‘solutions’ to the medicines waste problem, such as charging more patients for treatment (Senior 2001) or reducing prescription durations may at face value promise easy, low cost, remedies. However, the possible impacts of such actions should be carefully considered. There is robust evidence that where they discourage appropriate medicines use they can negatively effect health outcomes and ultimately increase costs to health service providers and funders (Lexchin *et al.* 2004).

Failure to appreciate that much, probably most, NHS medicines wastage is not cost effectively avoidable can sometimes lead to exaggerated and potentially counter-productive criticisms of health service performance. It is therefore relevant to stress here that the research detailed in subsequent Sections of this Report found no evidence that the problem of medicines wastage is greater in this country than in other comparable nations, including – for instance – Sweden. The latter is an example of a community with low levels of disadvantage and good health outcomes, which might reasonably be expected to have relatively low levels of residual pharmaceuticals.

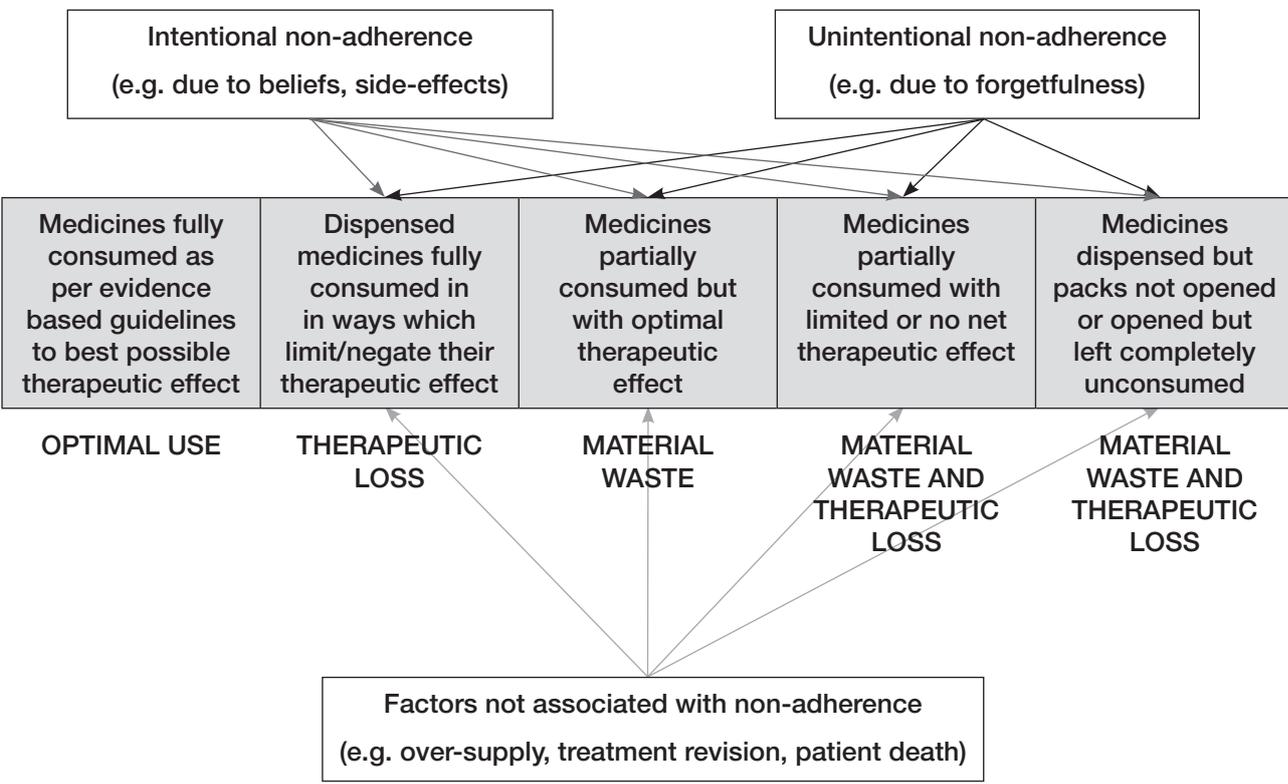
1.2 Distinguishing between medicines wastage and non-compliance and non-adherence in medicine taking

Medicines wastage as defined in this report and by agencies such as the NAO differs from concepts such as non-adherence in medicines taking (failing or choosing not to take medicines in a way agreed with a health care professional) or non-compliance (failing to take treatments in a manner consistent with professional instruction). Both non-adherence and non-compliance may (or may not) result in medicines waste, but neither is necessarily its main cause.

For example, in some cases ‘adherent’ individuals will stop taking medicines as their condition changes, even if this means that their current drugs have to be discarded. In others ‘non-compliers’ may create no waste, but have nevertheless consumed their prescribed medicines in a sub-optimal or actively hazardous manner. An individual might be deemed non-adherent even if they take all their prescribed drugs within a given time span, but have not done so at the correct times and in the correct doses.

There is a robust body of literature (see, for example, Horne *et al.* 2005) showing that non-adherence can stem not only from deliberate action on behalf of ‘the

Figure 1.1
The causes of medicines wastage and lost therapeutic value



Source: the authors

patient' (intentional non-adherence, which is typically related to individuals' beliefs about the necessity and value as opposed to the personal costs of medicines taking) but also from factors outside the conscious control of the medicine user. Such unintentional non-adherence may occur because of, for example, forgetfulness and/or a lack of ordered life style.

Figure 1.1 outlines the relationships between non-adherence and medicines wastage. Prescribed medicines taking exists on a spectrum from fully optimal use through to total non-consumption, with varying degrees of material/financial and therapeutic loss at each stage between these two poles. In addition to the two main types of non-adherence, system level factors such as provider side driven over-supply of medicines also cause wastage. This can occur, for instance, when service users do not require additional amounts of 'PRN' (*pro re nata*, or take as required by the patient) medicines such as pain killers, but are nevertheless supplied them because of repeat dispensing process failures. The latter may on occasions be associated with perverse economic incentives to dispense.

Understanding the inter-relationships between such variables is relevant to both minimising medicines wastage and maximising the positive benefits of appropriate medicines taking. It is also important to differentiate between non-adherence associated with a lack of persistence in longer term medicine taking – which if prescriptions are not requested or dispensed does not lead to material waste – and that characterised by variability in ongoing medicinal drug taking.

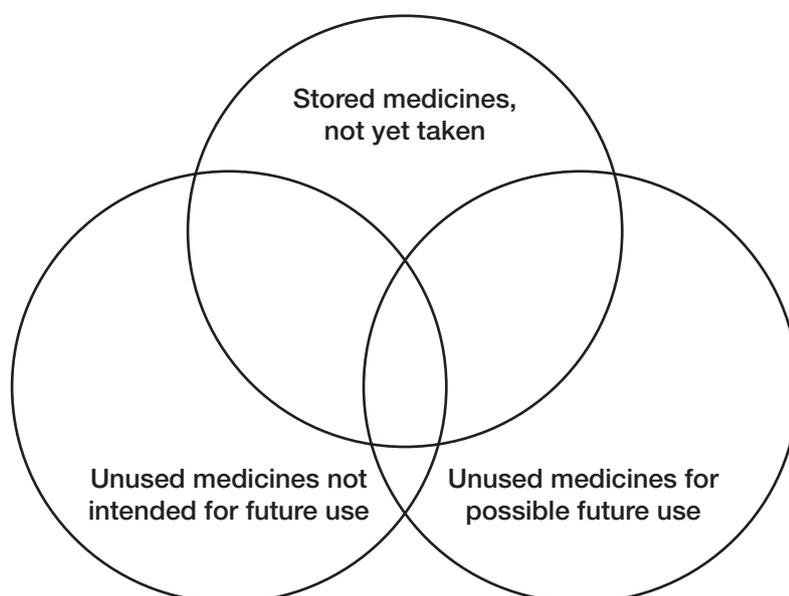
However, this report is primarily focused on medicines waste and its management, rather than the related but separate topic of minimising the therapeutic losses associated with medicines being consumed sub-optimally.

The specific objectives of the research undertaken and the structure of this report are detailed below. But before that, four more general introductory points should briefly be highlighted. They are as follows:

- ▶ It is often difficult clearly to distinguish between those medicines being stored in people's homes that are waste yet to be disposed of and those which could (and will in reality) be used again at some future point. Figure 1.2 illustrates some relevant terminological and categorical overlaps. It also serves as a reminder that (especially if appropriate safety precautions are taken) storing partly used medicines for possible future use may be rational and economic from a consumer perspective, even if some professionals regard it as inherently undesirable. On occasions concerns about the volume of 'waste' medicines found in domestic settings by observers such as pharmacists could be seen as exaggerated from a wider public interest perspective.
- ▶ Evidence presented in the body of this Report suggests that for many health professionals (and members of the public) the most serious aspects of medicinal waste lie in failures to achieve therapeutic benefit, as opposed to the financial losses involved. A key starting point to draw from this is that while seeking to cut the cost of medicines wastage is not the same thing as improving medicines taking, motivating clinicians and patients to act in ways that will further reduce drugs wastage is nevertheless likely to require health gain related issues to be placed centre stage in communications aimed at such groups.
- ▶ The volume of medicines disposed of informally by health service users and patients' carers is not known, but it might in England amount to several hundred tonnes per annum. (For comparison, approaching 600 tonnes of unused medicines

Figure 1.2.

The overlapping boundaries between waste, stored and in-use medicines



Source: the authors

were destroyed in England by the Disposal of Old Pharmaceuticals service in 2004 – Department of Health 2005). The extent of the overall environmental impact of this is again not known. Yet some drugs can remain in groundwater for long periods of time and may cause harm to plants, animals and/or in some instances people. The environmental aspects of medicines wastage therefore require attention.

- ▶ In the order of 70 per cent of all primary and community care medicines are supplied via repeat prescriptions to people with long term health problems. The great majority of these individuals are near or over retirement age. The processes by which such prescriptions are requested by service users, written and verified by GPs and their staff, issued to NHS users or collected and held by pharmacists and ultimately checked and dispensed by them are varied, complex and changing (see, for example, National Prescribing Centre 2004). There are also a number of ways via which patients can receive their dispensed medicines, ranging from self collection to home delivery. These may in turn influence the way they subsequently re-order repeat prescriptions.

Although the evidence presented in later Sections of this report suggests that drugs issued on an *ad hoc* basis for acute health problems are more likely to end up wholly or partly unused than those issued on a repeat basis, the scale of repeat medicines supply is so great that it plays a dominant role. Understanding, monitoring and managing this process and making sure that all the stakeholders involved in it – including medicine users and their carers – are appropriately incentivised to seek optimal patterns of drug use is therefore central to the efficient and effective management of not only medicines waste in the NHS, but primary and community health care improvement more widely.

1.3 Objectives and the structure of this report

This study builds on previous work on the issue of waste medicines, most notably the report *Residual Medicines* (Woolf 1995). This presented the findings of research conducted under the auspices of the Office of Population and Census Statistics (OPCS) in 1994, fifteen years before the fieldwork undertaken for the current study. The OPCS' survey involved home visits to a random sample of households. It sought to identify partially or completely unused medicine packs remaining in households after the individuals for whom they had been dispensed considered their treatment to be completed. This definition was adopted in order to help to distinguish such 'waste' drugs from those which respondents indicated might ultimately be taken.

The OPCS found that 11 per cent of the households surveyed were in possession of residual medicines, and that of all the medicine packs found 8 per cent were partially or completely unused. The research reported here sought to provide updated estimates of the scale of waste medicines. As outlined below, a number of methods were used, although it was not possible to undertake visits to individual households within the time and resources available. Much of the quantitative data presented below were derived from self-reports from a national telephone based survey of medicine users.

This may to a degree limit the reliability of our findings. Problems relating to the correct classification of sub-groups of unused medicines also exist, as indicated in Figure 1.2 above. If anything, our research tended to include medicines in its unused totals that Woolf would not have regarded as confirmed residuals. However, it can be said with some confidence that the scale of medicines wastage identified in respondents' homes during this research was broadly consistent with that identified by the OPCS, despite a 50 per cent increase in the number of NHS primary care prescription items dispensed per head of population (that is, an increase from 10 to over 15 items per capita per annum) in the period 1994-2009.

Specifically, the research reported here aimed to address four key questions:

- ▶ What is the volume of waste medicines prescribed and dispensed in primary and community care?
- ▶ What are the total and avoidable costs of such medicines wastage to the NHS?
- ▶ What are the causes of NHS medicines waste?
- ▶ What does the available evidence indicate could desirably be done to reduce the volume and cost of NHS supplied medicines wastage in England in the primary care context, including in care homes as well as conventional domestic settings?

Multiple research methods were utilised during our investigations of the above questions. The work undertaken included a nationwide public survey, an audit of medicines returned to a sample of over 100 community pharmacies throughout England and in-depth qualitative research conducted with medicines users and healthcare professionals in primary care and care homes. This Report synthesises the findings of these diverse but linked activities, together with evidence and conceptual constructs derived from literature reviews.

This document should not be seen as an attempt to produce a Health Technology Assessment (HTA) report in a standardised format, of the type designed to provide an evaluation of a single therapy or group of closely related interventions. This is not least because of the diverse nature of the phenomena being addressed and the lack of high quality evidence

available on the efficacy and effectiveness of many of the approaches to medicines waste reduction currently being employed in the NHS and elsewhere. Rather, it seeks to offer a clear picture of the current situation which, despite significant levels of remaining uncertainty in a number of important areas, offers policy makers with as robust a basis as possible for deciding how best to continue minimise medicines wastage in English NHS primary and allied care settings.

The main content of the report is structured as follows:

Section 2: An abbreviated report of our literature reviews on medicines wastage. These were designed to inform subsequent research approaches, contextualise our research findings and where possible provide an externally validated evidence basis to support of our conclusions and recommendations

Section 3: A summary of findings on the scale of medicines waste in primary and community care.

Section 4: A summary of findings on the cost of waste medicines to the NHS.

Section 5: Summary of case studies intended to capture the financial value of health benefits foregone which result from sub-optimal medicines taking.

Section 6: A report on the extent of medicines wastage in care homes

Section 7: Summary of qualitative and allied postal survey research findings on public, professional and PCT staff experiences, beliefs and attitudes relating to prescribed medicines wastage and its reduction

Section 8: Implications of the research findings.

Reducing waste of all types is, wherever and whenever it occurs, a potentially high profile priority, especially in times of financial stringency. But despite the fact that our results confirm that there is considerable public and professional concern about medicines wastage in the NHS, our concluding analysis finds that its scale and nature is not such that it should be regarded as a major systemic failing of this country's publicly funded system of care.

More could and in some areas should be done to limit avoidable drug and allied product wastage. Yet our research found no substantive evidence that this problem is significantly greater in the UK than in other developed countries. At the same time it reveals many instances of NHS users, clinicians and managers seeking to provide and use medicines responsibly and efficiently. We recommend that the findings of this report be read against this starting point.

2 Structured Literature Reviews on Medicines Wastage

2.1 Background

To support the design of the survey instruments used in this study and the interpretation of the data generated we first summarised the findings of previous research on the scale and causes of medicines waste, and identifying ways of reducing its volume and costs. This was done via by a structured rather than fully systematic review, designed efficiently to meet the functional requirements of this research.

In contrast with the available literature on adherence in medicines taking, there has been relatively little high quality research on drug and allied product wastage *per se*. This is perhaps because it has often been regarded as a purely managerial and financial problem, as opposed to a clinical concern. Where possible, quantitative data relating to not only the scale of medicines wastage in given settings but also the (cost) effectiveness of interventions designed to prevent its occurrence was collected. However, given the limitations of the work identified the majority of the findings reported here provide contextual information, of primary value in relation to concept building and hypothesis generation. For that reason the review below includes some elements of preliminary discussion, offered as narrative prior to the overall discussion and recommendations contained in Section 8.

2.2 Method

A search strategy was agreed by the York and London teams, as outlined in Box 2.1. The database interrogation undertaken was supplemented by additional hand-searching of sources. The main restriction applied was that the search was confined to English language only. Articles selected for inclusion were mostly published after 2000. However, some flexibility was exercised where significant contributions published before this date had been identified through hand searches or bibliographic reviews.

A list of in excess of 4,000 candidate article titles was generated, which was initially reviewed and reduced to 573 papers for which abstracts were obtained and read. These were in the School of Pharmacy context reviewed by JN and DGT during August 2008 to assess their relevance to medicines wastage and the objectives of the research reported here. The criteria they applied related to whether or not the abstracts:

- ▶ provided information on the extent, costs and causes of medicines wastage in the UK or internationally;
- ▶ evaluated lost therapeutic opportunities associated with waste and linked non-adherence in medicines taking;
- ▶ reported good quality reviews and meta-analyses on the causes of medicine wastage or the effectiveness of interventions to reduce it;
- ▶ provided information about how other countries tackle pharmaceutical waste related challenges;
- ▶ addressed wastage relating to 'tracer' conditions such as asthma, hypertension, type 2 diabetes and depression; and
- ▶ considered environmental costs and problems associated with medicines wastage.

In total 212 articles and reports were selected for full review of which 200 were finally included in the School of Pharmacy literature review process. The parallel YHEC process selected a total of 226 references selected for full review, of which 117 were classified as being primarily on the scale and/or cost of medicines waste and the remainder primarily on its causes (the latter were all included in the School of Pharmacy review).

2.3 Findings

The scale of medicines wastage and associated phenomena

Much of the literature reviewed was, despite the design of the search process, focused more on adherence and/or compliance in medicine taking than on wastage defined as unused dispensed pharmaceutical products that are ultimately discarded. Studies of the latter (Anonymous 2003c and 2004b, Boivin 1997, Bronder and Klimpel 2001, Cameron 1996, Coma and Modamio 2008, Craig 2001, Ekedahl and Wergemeian 2003, Garey *et al.* 2004, Hawksworth 2004, Khurana 2003, Langley and Marriott 2005, Mackridge and Marriott 2007) commonly quote DUMP (Dispose of Unwanted Medicines Properly/Disposal of Unused Medicinal Products) campaign outcomes or the results of pharmacy audits, usually conducted at a regional level. Several good quality audits were identified from

UK settings (e.g. Hawksworth 2004, Mackridge 2007) in addition to similar studies from other countries.

Such publications typically present figures on the volume of unwanted medicines collected over periods of varying numbers of weeks or months, costed in average pack price terms (see Table 2.1). In some cases, these were then extrapolated to produce a national estimate of the scale and cost of waste medicines to the NHS. A number of other sources quoted high-level estimates of the national cost of waste medicines although their derivation was not always clear and in some cases appeared to be derived from 'top-down' calculations based on the assumptions about the percentage of total prescribing costs that can be regarded as waste.

Box 2.1.

Literature search scope and terms

A range of databases was searched to identify reports and articles published in English related to medicines wastage, including:

- ▶ MEDLINE
- ▶ EMBASE
- ▶ CINAHL
- ▶ Health Management Information Consortium (HMIC)
- ▶ Cochrane Library (CDSR, DARE, CENTRAL, HTA database, NHS EED)
- ▶ PsycINFO
- ▶ NHS EED
- ▶ HEED
- ▶ Scrip World Pharmaceutical News
- ▶ Clinica World Medical Technology News
- ▶ International Pharmaceutical Abstracts
- ▶ Pharm-line

Unpublished (grey literature) and 'in process' research was identified through searches of additional sources, including:

- ▶ ZETOC (conference proceedings)
- ▶ UK Clinical Research Network: Portfolio Database (research projects)
- ▶ OpenSIGLE (grey literature, <http://opensigle.inist.fr/>)
- ▶ CRISP (US research projects)

Audit reports and other documents produced by NHS organisations were identified via:

- ▶ Email request to health librarians via the lis-medical email list
- ▶ Searching the websites of relevant organisations, such as the Prescribing Support Unit (PSU), the Audit Commission and the Royal Pharmaceutical Society.
- ▶ A Google search.

The search terms used included words such as waste, wasted, unused, residual, unwanted, discarded and returned coupled with medicines, drugs, prescriptions or pharmaceuticals. In addition terms like environmental pollution, refuse disposal and medical waste disposal were also employed. The School of Pharmacy team also conducted manual citation searches and interviews with expert advisors in order to ensure that a wide range of relevant sources was accessed during the preparatory stages of the qualitative research programme. The York 'side' of the search process was aimed mainly at identifying quantitative findings on the scale of medicines wastage in the UK and internationally, and previous work on topics like the numbers of waste prescription items returned to community pharmacies and dispensing GPs. Additional searches for relevant economic evidence were also conducted by the York team.

Table 2.1 summarises some of the key references identified which are of relevance to the current research.

A number of the reviewed articles erroneously regarded estimates of the cost of 'waste' as indicative of the burden imposed by non-adherence in medicine taking. Such confusions are potentially misleading in that, as already noted in Section 1, not all non-adherence in medicines taking leads to material waste and not all of the latter is a result of intentional or non-intentional non-adherence on the part of medicine users. Little if any of the pharmaceutical (as opposed to economics) based literature reviewed attempted to differentiate between lost therapeutic gain valued in terms of Quality Adjusted Life Years (QALYs) foregone and medicine waste costed in terms of unused products' purchase prices.² (See Horne *et al.* 2005, Hughes 2002, Hughes *et al.* 2007)

However, the difficulties of accurately measuring levels of medicines wastage as a proportion of total prescribing costs, and also of assessing the true degree of non-adherence and/or non-compliance in medicines taking, were acknowledged in some of the included articles, such as Walker and Usher (2003) and Osterberg and Blaschke (2005). The literature reviewed offered substantive evidence that 'patient to professional' reports of non-adherence typically understate the true levels of this common form of health related behaviour (Garber and Nau 2004). This raises some questions as to the likely accuracy of self reports of waste levels.

In some studies which referred to and/or attempted to define the scale and causes of medicines wastage, 'adherence' was primarily defined in terms of taking the correct medicine doses at the correct times. In others it was defined more in terms of persistence/therapy continuation (in US phraseology this may also be termed 'refill adherence' – Gazmararian *et al.* 2006) and whether or not repeat prescriptions were being collected at the correct intervals (Hughes 2002). It is worth emphasising that if repeat medicines are not dispensed then there cannot be material waste, and that even if they are supplied at the recommended intervals 'refill adherence' is not a guarantee of appropriate use.

In international terms, the figures quoted for both medicine wastage and adherence in medicines taking in the UK countries appear broadly similar to, or perhaps 'better than', those recorded in other countries. For example, in the case of antibiotic use there is self report based evidence that British patients are more likely to complete their prescribed courses of treatment and less likely to store residual

2 There was also no discussion of the marginal as opposed to average costs of waste medicines. The significance of this issue relates, for example, to whether or not in a pack of 30 pills in which say 2 are unused the cost of waste should be calculated as 2/30 (or circa 7 per cent) or alternatively as close to zero, because in reality a pack of 28 pills would cost virtually the same to supply.

Table 2.1**Volumes of returned pharmaceutical waste identified in various audits**

Estimates of volume/cost of waste derived from UK based audits		
Hawksworth	UK	30 community pharmacies in Kirklees collected returns over a 1 month period. A total of 1,091 items were returned at an estimated value of £7,762. Extrapolated cost to NHS = £37.6M (1996 prices).
Langley	UK	8 community pharmacists and 5 GP practices in East Birmingham collected over a 4 week period. 340 items returned, 42 to GPs and 298 to pharmacies. Value of returned items estimated to be £3986. Mean cost of items returned was £11.72 to GPs and £12.59 to pharmacies. No attempt to extrapolate findings to a national level. (2005 prices).
Mackridge	UK	51 community pharmacies & 42 GP surgeries over an 8 week period. Identified 934 return events, comprising 3765 items, at an estimated value of £33,608. Mean value was £8.93 (range £0.00 to £358.20). Extrapolated to the NHS, the findings suggest c2million return events, c8million returned items at an annual cost of £75M. (2007 prices)
Estimates of volume/cost of waste from other UK sources		
Bellingham	UK	Quote DH waste accounts for £300-£600M (NB definition of waste as unnecessary prescribing).
Cheeseman	UK	Quote House of Commons Pharmacy Group – medicines returned to pharmacies have value of £230M per annum.
Mackridge	UK	Estimates have placed financial value of medicine that are not used in the UK at between £30 – £90M per annum' (unreferenced). Authors state as these estimates only deal with community pharmacy likely to be a 'gross underestimate'.
NAO	UK	Estimates based on earlier analyses conducted by the Department of Health of at least £100M and as much as 10% of the prescribing budget (c£800M). (2007 prices).
Selected international evidence on the volume/cost of waste		
Boivin	Canada	29 pharmacies with 4 accepting returned drugs. Total value of drugs returned was \$67,000. Extrapolated to Canada this is estimated to be \$113M. It is not clear whether this is per year or waste medicines stored at home by Canadians at any one time.
Bronder	Germany	1 pharmacy in Berlin – 12 months. The value of medicines returned was DM 232,920. Extrapolation to Germany as a whole suggested waste returned to pharmacies was DM 1.5 to 2.0 BN. (1997 prices).
Cameron	Canada	58 pharmacies in Alberta – 8 weeks. Estimated cost of returned drugs was \$60,350, extrapolated to \$716,400 for the whole state for a year (1996).
Coma et al.	Spain	38 pharmacies – 7 working days. Total cost of returned drugs was 8,539 Euros. Over 75% of the total cost was borne by the Spanish Health System. The mean drug price was 10.20 Euros, with 90% of returns having a price lower than 25.90 Euros. Extrapolating this figure to Spain as a whole suggests a cost of returned medications of 129.8M Euros, or 1% of the Spanish Health System budget for pharmacy in 2003.
Ekedahl	Sweden	2 community pharmacies in Malmo – 6 weeks. 1077 packs were returned by 191 patients (mean 5, median 3, range 1-101). 50% of patients returned one or two packs with 10% of patients (19) returning just over 50% of all packs returned. Unused drugs returned to pharmacists correspond to about 4-5% of sales (65 million Euros 1999).

drugs for possible future use than people in countries such as France, Italy and Spain (Branthwaite and Pechere 1996).

The review reported here found no evidence that pharmaceutical wastage in the NHS is greater than that in other comparable health care systems. Nor did it reveal approaches to medicines waste reduction in other settings which appear to be significantly in advance of those being pursued within the NHS.

There is observational evidence regarding the issue of lost therapeutic gain associated with either variability or non-persistence in medicines taking, care systems which impose – as compared with the NHS – more charges for medicines are relatively inefficient in terms of sustaining treatment provision (Atella *et al.* 2006, Lexchin and Grootendorst 2004). There is also limited research based evidence that medicines wastage in the UK may be higher amongst patients who pay prescription charges than those who do not (Woolf 1995).

As indicated above, there is also extensive work showing that non-adherence in medicine taking is a complex, multi-dimensional, phenomenon which is driven by factors ranging from the balance of individuals' beliefs about the costs and benefits of taking medicines to the existence or not of physical, economic and social barriers to their being used appropriately (Horne *et al.* 2005, Elliott 2009).³ But the extent of the available research on

3 Other researchers who have made important contributions to understanding adherence in medicines taking include Joyce Cramer, John Urquhart and Bernard Vrijens – see, for example, Cramer 2004, Vrijens and Urquhart 2005, Vrijens *et al.* 2008. Urquhart uses the term pharmionics to describe the discipline concerned with understanding how patients use prescription drugs. But this review was intended to provide a robust overview of current knowledge of the scale, causes and prevention of medicines wastage, rather than a comprehensive analysis of the extensive literature on adherence and compliance in medicine taking.

medicines wastage as a discrete phenomenon is in comparison relatively disappointing. For example, this review found no robust, high quality, examples of investigations into why some individuals are at special risk of building up large stocks of unused prescribed medicines in their homes.

This may be indicative of a research funding bias capable of future correction. Nevertheless, there is firm evidence that in international terms the per capita cost (and volume use) of prescription medicines supplied by the NHS is relatively modest as compared to that in countries such as, say, France (OECD 2008). As already noted there is also baseline data for England provided by the OPCS study commissioned by the Department of Health in the early 1990s, which sampled just over 2000 households (Woolf 1995). They were surveyed for the presence of unused or partly used prescribed medicine packs, which the OPCS categorised as residual rather than waste medicines.

Eleven per cent of households were found to have unused (residual) medicines classifiable as waste (ie that respondents had no intention of using again at a later date) compared with 25 per cent that had no prescribed medicines whatsoever. Less than a tenth of all the waste prescribed medicine packs found in respondents' homes were completely unused. Some 40 per cent of the 'waste' packs found were half used and 3 per cent almost all used.

By contrast 92 per cent of all medicine packs identified were either currently in use (78 per cent of the overall total) or part used and being stored for future use (14 per cent). Two thirds of all householders said that they had not disposed of any unwanted medicines in the past year and approaching 90 per cent of the medicine packs identified had been dispensed within a year of the survey date.

Taken together, the OPCS's figures indicate that about 1 per cent by value of all medicines dispensed in England in 1994 were being stored as waste in people's homes in that year.⁴ The amount of medicine informally disposed of by householders as waste rather than returned to pharmacies or dispensing GPs cannot be accurately estimated, but it appears very unlikely to exceed the total volume of residual medicines identified in people's homes.

The most commonly wasted medicines found by the OPCS researchers included (apart from residual antibiotics) analgesics and others supplied on a PRN (as required by the patient) basis. Products used to

prevent rather than treat the symptoms of conditions such as asthma or heart disease were also relatively commonly classified as waste prescribed drugs. Yet overall this important survey found that medicines prescribed for acute episodes were more likely to be unused than those supplied on a repeat basis.

Data from DUMP and related studies (Anonymous 2003c and 2004b, Boivin 1997, Bronder and Klimpel 2001, Cameron 1996, Coma and Modamio 2008, Craig 2001, Langley and Marriott 2005, Mackridge and Marriott 2007) can be difficult to interpret. This is because of problems associated with estimating the periods of time over which returned items have been accumulated and the total size of the population being served. Relatively little reflective analysis has been published on the (cost) effectiveness of DUMP campaigns and their impacts on reducing waste, increasing adherence and/or preventing accidents associated with residual medicines left in homes.

Although Woolf (like subsequent investigators, such as Bound *et al.* 2006) found that only about one person in five in the UK says that they usually return unwanted medicines to a pharmacy, the average volume of each pharmacy return is likely to be significantly greater than that that involved in other forms of waste disposal. One reason for believing this to be the case is that the literature reviewed suggests that a third or more of all return events to pharmacies involve medicines found when people die or enter a care home. Such returns may include not only products accumulated in the terminal care period itself (Zeppetella 1999) but also in previous years of illness and/or increasing disability.

Notwithstanding the uncertainties referred to above, sources such as Hawksworth *et al.* (1996) and Mackridge and Marriott (2007) indicate that in England in the 1990s and early 2000s around 1 per cent of all medicines annually dispensed (by value) were returned to pharmacies. However, work in Sweden – where there is a health care environment comparable to that in the UK, but perhaps a greater society wide awareness of environmental issues – suggests a figure in the 4-5 per cent range (Ekedahl *et al.* 2003). Ekedahl has in various publications on medicines waste as defined in this study (Ekedahl 2003, Ekedahl and Mansson 2004, Ekedahl 2006) drawn attention to the high proportion (50 per cent plus) of unused medicines returned by or on behalf of the 10 per cent most 'at risk' patients. The latter are typically aged over 65 years.

This author also found that in Sweden two 'reasons' appear to account for some 70 per cent of all medicine returns, namely patient deaths (45 per cent) and therapy changes (26 per cent). His analyses have also drawn attention to the possibility that attempts to reduce levels of medicine waste may require expenditures greater than the cost of the unused products involved. From an economic perspective such outlays could only be justified if additional therapeutic gains were also generated.

4 Woolf found 2.6 medicines per household in 1994, of which just under 10 per cent were classified as residual. That is, each English household (with an average size of 2.5 people in that year) was on average holding 0.25 of a waste item, which was equivalent to 0.1 of an item per person. This compares with an average of 9.4 NHS prescription items per capita dispensed in England in 1994. The survey reported later in this Report used a wider definition of waste, which included unused medicines being stored for possible future use.

Similar preliminary conclusions can be derived from the literature reviewed here. Sources ranging from the RPSGB to the WHO (2003) have concluded that between 30 and 50 per cent of all medicine taking in the UK and elsewhere may be considered 'non-adherent'. Although the extent of the lost benefit associated with this is unknown, it is realistic to estimate that about third of all medicine taking confers (to varying degrees) sub-optimal clinical benefits due to adherence related problems (Elliott 2009). This implies that significant volumes of potential welfare gain are lost.

Yet against this the evidence reported here suggests medicine wastage *per se* represents a relatively modest – albeit ideally avoidable – cost to the health service. Further, of the total waste recorded only a proportion will be cost effectively avoidable. Appropriate policy formation will require an informed awareness of these contrasting facts, coupled with insight into the extent to which suggested interventions will in practice reduce wastage and/or productively enhance adherence in medicine amongst individuals and populations.

Causes of medicines wastage

It has been estimated that up to 50 per cent of non-adherence (as distinct from waste) in medicine taking is intentional (Horne *et al.* 1995), while the remainder is unintentional and linked to factors such as forgetfulness or a lack of routinised behaviour (Barber 2002, Ryan 2003, Horne *et al.* 2005). Even if reality the boundaries between cognitively directed and genuinely unintentional behaviour are on occasions blurred (perhaps in because people are reluctant to openly disagree with their doctor or other professionals) it is nevertheless useful to differentiate between these two basic forms of adherence related behaviour

A similar divide exists in relation to some of the causes of medicines waste at the individual user level. Yet there is also evidence that health care system and other external factors are more important in the waste context than they are in that of adherence (Jesson *et al.* 2005). These range from prescribing patterns which do not take sufficient account of service user preferences and requirements (Bellingham 2001) to changes in patients' conditions which require alterations in their treatment regimens. Prescription re-ordering processes which can serve to promote excessive repeat medicine supply are another possible system level cause of waste.

Examples of what might broadly be classified as *individual level* or '*motivational*' risk factors that have the potential to cause medicines wastage include:

- ▶ **A lack of knowledge relevant to why taking a medicine in the recommended way is beneficial.** A number of the reviewed articles considered the relationship between knowledge

and medicines taking (see, for example Alm-Roijer *et al.* 2006, Dowell and Hudson 1997, Ownby 2005, Williams 2007, Wu *et al.* 2008). As in the wider area of health promotion, the available evidence shows that improving knowledge levels has little or no consistent relationship with behaviours such as adherence (Horne 1998). However, there are clearly occasions when having relevant knowledge is a necessary if not a determining factor in achieving appropriate medicine taking and avoiding waste. For instance, an informed awareness of the underlying chronicity of asthma (as opposed to it being seen as a 'serial acute' condition) may be needed to support the correct use of 'preventer' inhalers (Bennett *et al.* 1998, Farber *et al.* 2003). It is also the case that appropriate, accurate, knowledge is needed by health care professionals seeking to advise patients on effective medicine taking and waste minimisation (Byrne and Deane 2005).

- ▶ **Previous experience of and/or anticipation of unpleasant side effects.** There is extensive evidence that past negative experiences of medicine taking (and a perceived probability of future unwanted effects) increase the chance of prescribed treatments not being taken as recommended, and hence in some instances of material waste occurring (Elliott *et al.* 2007, Elliott 2009, Goethe 2007, Hugtenburg 2006, Jokisalo *et al.* 2002). As noted above, such risks may be exacerbated when medicines are for preventive purposes and do not offer symptomatic relief (Piette *et al.* 2006).

The control of hypertension provides an example of one such field (Benson and Britten 2003, Vrijens *et al.* 2008). There is good quality trial based research evidence that in contexts where there is a risk of patients stopping medicines taking because of factors such as a fear of side effects providing support services in the first weeks of intended long term treatment is likely to be more cost effective than offering such support at a later stage (Clifford *et al.* 2006).

- ▶ **Medicines taking experienced as otherwise inconvenient, painful or stigmatising.** Treatments such as those for conditions like Type 1 diabetes in younger people typify this type of risk (Carter *et al.* 2005). Similarly, some medicines waste is likely to be incurred in contexts like HIV and epilepsy care because of stigma related fears and/or individuals denying their condition (Adam *et al.* 2003, Eatock and Baker 2007). The reviewed literature indicates that relatively impersonal approaches involving, for instance, monitored medicine taking are unlikely alone to resolve such essentially social and psychological problems.
- ▶ **Beliefs that medicines are ineffective or that alternative interventions are more effective.** In adherence research considerable importance has been attached to quantifying factors that

determine the psychological balance between the perceived necessity of medicines taking and individuals' beliefs that it may be unnecessary or harmful. However, this will only lead on to cost effective reductions in medicines waste and/or lost therapeutic gain if appropriately affordable interventions for changing medicines taking at a general population level are available. Further, the literature identified shows that in many cases material medicinal waste is not primarily driven by the volitional choices of patients (see, for instance, Jesson *et al.* 2005).

► **Depression.** There is substantive evidence linking depression with non-adherence in medicine taking (Bambauer *et al.* 2007, Bane *et al.* 2006, Gordillo *et al.* 1999, Soule Oldegard and Capoccia 2007.) This to an uncertain degree leads on to the potentially avoidable wastage of medicines. It is therefore a risk factor for the purposes of this study, not only in the context of treating depression itself (Bultman and Svarstad 2000, Goethe *et al.* 2007) but across all therapeutic areas. Other forms of mental distress and functional loss, such as the lack of 'insight' that may be associated with schizophrenia (Ascher-Svanum 2006, Buckley *et al.* 2007, Frangou *et al.* 2005) or early dementia, can co-exist with depression and may have additional impacts on medicines wastage.

► **Low 'self efficacy'.** There is evidence that relatively high levels of self efficacy in relation to medicine taking (defined by the American psychologist Albert Bandura as an individual's belief that he or she can succeed in a specific situation) are related to above average levels of adherence (see, for instance, Godin *et al.* 2005). It is therefore possible that promoting self efficacy in areas like repeat medicine ordering could reduce wastage.

Interventions such as Expert Patients Programme (EPP) courses seek to raise self efficacy levels and may therefore help reduce drug wastage. However, no firm evidence relating to the likely scale of any such effect was found. It is also of note that individuals who are confident that they can control conditions such as hypertension through personal action may be less likely than others to use medicines as recommended (Patel and Taylor 2002). This points to a need for rigour regarding the delivery of programmes that, to achieve better use of medicines, need to foster a critical and reflective sense of self efficacy.

► **A lack of high quality professional support for appropriate medicine use.** There is some evidence that professionals who communicate in inclusive, open and supportive ways are more likely to help patients take medicines in recommended ways than those who are less able to form supportive relationships (Bultman and Svarstad 2000, Di Matteo 1995). There is also some research linking reported patients' satisfaction

with health professionals' services to adherence to therapeutic recommendations (Blenkinsop 2000, Godin *et al.* 2005). But the strength of such associations is limited, and it is important not to misinterpret the underlying causal relationships involved.

These may, for instance, link back to the balance between necessity and concern related beliefs (Pound *et al.* 2005, Labig *et al.* 2005). There is also some evidence that including negative information like side effect warnings in messages about medicines taking reduces adherence levels, and so in some instances cause waste (Berry *et al.* 1997). However, ethical imperatives normally require risk disclosures.

► **A lack of appropriate support for medicine use.** Family and employed carers' attitudes and behaviours directly impact on medicine taking in a variety of ways. For example, there is evidence that parents who are anxious about their children's medicine taking can undermine adherence, even when trying to promote it (Carter *et al.* 2005, Conn *et al.* 2005, and Gerson *et al.* 2004). Reviewed articles argued that the abilities of children to understand and control their medicines use should not be under-estimated (Sanz 2003). Neither should the competencies of disabled adults.

But against this there is evidence that, for example, people living with partners are more likely than those living alone to take medicines as recommended (Godin *et al.* 2005). Such observations suggest that a lack of support for isolated people living in their own homes with declining physical and cognitive skills may appropriately be regarded as an example of a service quality related barrier to improved medicine taking in an ageing population. The occurrence of avoidable medicines wastage might in such circumstances be regarded as an indicator of additional serious problems, rather than a centrally important issue in its own right.

► **Financial cost related barriers to medicines taking.** The available literature shows that in the US in particular medicine costs that have to be met directly by patients have a highly significant impact on usage rates (Elliott *et al.* 2007, Ersek 1999, Hirth *et al.* 2008, Kirking *et al.* 2006, Lexchin and Grootendorst 2004.) Such factors probably explain the greater strength of observations relating to the number of medicines prescribed and levels of non-adherence (primarily defined in persistence/continuation related terms) in US as opposed to UK populations.

In the case of the build up of unused medicine stocks in the home, additional possibilities include individuals deciding to stop using PRN and other medicines (either as part of a recovery process, or on occasions as part of their coming to terms with

the ending of life) but continuing to collect or have collected repeat prescriptions. Such phenomena might in part explain the finding that analgesics are amongst the most commonly wasted medicines, even though patients in pain might be expected to use their drugs. (See Bellingham 2001, Ersek *et al.* 1999, Jesson *et al.* 2005, Zeppetella *et al.* 1999.)

People may accept prescriptions for treatment(s) they do not intend to take because they wish to remain on good terms with their doctor or other health care professionals (HCPs). Some might alternatively think that refusing medication will be interpreted as recovery from a disorder which offers some form of advantage such as, for example, entitlement to social security payments (see Section 7). However, this literature review did not identify evidence relating to such possibilities.

In other instances patients may be afraid of running out of their treatments. They require the assurance provided by the availability of a reserve stock of medicine(s). Hence they may deliberately over-order, and so might in time become 'medicine hoarders'. Hoarding and linked stockpiling behaviours account for a proportion of waste (Ekedahl 2006, Ruhoy and Daughton 2007). Relevant risk factors identified via this review include a lack of supportive human relationships, social isolation and physical disabilities which impair individuals' capacities to move outside the home and/or with confidence access local services.

Process and system causes

Looking beyond personal motivations to take or keep medicines, events such as the inappropriate repeat dispensing of medicines which are not required by the patient can be regarded as a form of accident. The psychologist James Reason hypothesised that most accidents can be traced to one or more of four levels of failure. He categorised these as 1) organisational factors 2) inadequate supervision 3) the existence of preconditions for accidental actions and 4) the unsafe/accidental acts themselves (Reason 1990, Reason 2000). No papers describing medicines waste in terms of avoidable health and pharmaceutical care system related accidents were identified as a result of this review, and it would be beyond the scope of this work to attempt to construct a comprehensive model *de novo*. But examples of *specific treatment process and systemic factors* which may serve as medicines waste promoters include:

- ▶ **Complex treatment regimens.** The literature reviewed here reported a large volume of evidence indicating that adherence in medicine taking is relatively high (and implicitly that wastage will be relatively low) when medicines have to be taken only once or twice a day rather than several times, and also when the overall number of different medicines being taken is low as opposed

to high (Billups *et al.* 2000, Cheesman 2006, Diamantorous 2005, Dezii 2000, Eatock and Baker 2007, Gazmararian *et al.* 2006, Kripalani *et al.* 2007, Osterberg and Blaschke 2005, Schroeder *et al.* 2004, Soule Oldegard and Capoccia 2007).

It is intuitively reasonable to argue that treatment regimens should be as simple as possible. Yet this issue is not as straightforward as is sometimes assumed. It has already been noted that charging patients for medicines can be a complicating factor which can amplify the statistical association between regimen plurality (i.e. the number of items used) and persistence in medicine taking in some groups (Elliott and Ross-Degnan 2007).

A number of the reviewed articles provided evidence that questions the extent to which regimen complexity should be taken to be responsible for non-adherence amongst, for example, mentally competent older people (see Godin *et al.* 2005, Herrier and Boyce 1995). At the same time one (US) study found that older people with limited cognitive abilities on a large number of medicines were at relatively high risk of 'over-adherence': that is, of taking their prescribed medicines too frequently (Gray *et al.* 2001). The implication for the NHS is that where complex patterns of medical treatment offer significant health gain the likelihood of material medicines wastage should not be over-stated. There may well be a greater danger that a lack of support in daily living will lead to lost therapeutic and wider welfare benefits.

- ▶ **Treatment changes.** There is robust evidence that changing therapies is a significant cause of medicines wastage (Cameron 1996, Coma *et al.* 1996, Ekedahl 2006, Jesson *et al.* 2005, Khurana 2003, Hawkesworth *et al.* 1996, Morgan 2001). Such costs are in many instances an unavoidable price of providing good quality care. But to the extent that unnecessary switching between treatments occurs this will cause avoidable wastage.
- ▶ **Unduly long prescription durations.** Following on from the above, it has been reported that limiting prescription durations to a period of four weeks can reduce medicines wastage. Perhaps most importantly, Hawkesworth *et al.* (1996) calculated that (in the UK) had all NHS prescription periods been limited to 28 days then the cost of medicines dispensed and later returned to the community pharmacies involved in their study would have been reduced by a third, or about £50 million in current cost terms. However, this paper did not contain full details regarding the assumptions upon which this conclusion was predicated. It is possible, for instance, that not all the offsetting costs of increasing prescription numbers were fully appreciated.

It is again intuitively reasonable to believe that if prescription periods are limited then material waste – and possibly the overall costs of medicines supply – will be reduced. But a number of the articles reviewed for this study challenge this assumption. In the American prescribing and dispensing context, Domino *et al.* (2004) simulated the impact of moving to a 34 – as opposed to 100 – day Medicaid supply period in six medication fields. They found that up to 14 per cent of total (Medicaid) medicines wastage would be saved. But even this would not justify the resultant increase in dispensing outlays. In addition, some consumers would incur increased personal (e.g. transport) costs.

Similarly, in Italy Atella *et al.* (2006) observed that a shortening of prescription duration for patients being treated for hypertension reduced adherence rates amongst people who had previously been taking their medicines appropriately. This was because of the increased transaction costs involved, which led some patients to stop or reduce their medicines taking. Although this in itself may not cause increased material medicines wastage, it is indicative of a potential price to be paid in terms of lost therapeutic gain as a result of pursuing drug waste reductions a manner inconsistent with service user preferences and total system interests.

The research reviewed here also indicates that introducing small (less than 28 day) medicine packs for people starting new treatments, or who may make a relatively rapid recovery from transient illness episodes, would not necessarily save money (Ekedahl 2006). This is for dispensing as well as manufacturing and allied (marginal) cost related reasons. The conclusion to draw in this context appears to be that policies such as 28 day prescribing should be applied with rational flexibility if they are in practice to reduce medicines wastage and improve the quality of patient care. In the related area of 28 as opposed to 31 day medicine pack sizes our review identified no new evidence relating to waste caused by medicine pack size differences, and the (questionable) possibility that greater standardisation of pack sizes might lead to significant monetary as well as material waste savings.

► **Repeat treatment prescribing and dispensing processes/systems which lead to over-supply.** This area was highlighted in several of the reviewed articles, including Jesson *et al.* (2005) and Mackridge and Marriott (2007). It provides a strong example of a cause of medicines wastage for which patients may on occasions be 'blamed' but which might more appropriately be attributed to system failings such as perverse provider side incentives and/or poor working practices. Nevertheless, no studies comparing the detailed costs and benefits of alternative

approaches to managing repeat pharmaceutical supply systems were identified via this review. This may perhaps be an area which has not attracted research funding proportionate to its importance.

► **Lack of appropriate medicine use support in home settings.** Examples of interventions in this category range from the supply of MDS/medicine taking support devices or calendar blister packs and telephone or text reminder systems to training social care assistants to help with medicines taking. Pharmacist led medicine use reviews in patients' homes could also be included in this category. Issues relating to the capacity of such interventions to reduce the occurrence of medicines waste are discussed later in this review. Here is appropriate to note that failures to provide such services and aids could where there is evidence of their effectiveness be regarded as a cause of avoidable medicines wastage, although several of the included articles emphasised the need to ensure that their cost does not outweigh the benefits generated (Das Gupta and Guest 2003, Hughes *et al.* 2001, Muszbek *et al.* 2008, Pacini *et al.* 2007).

► **Lifestyles and events which prevent or disrupt the routinisation of medicine taking.** As previously observed, there is evidence that individuals who have a well ordered, systemised, approach to medicine taking are more 'adherent' than is on average the case, and are so less likely materially to waste medicines than people with less ordered approaches (Ryan and Wagner 2003, Ulrik *et al.* 2006). There is also evidence that events which can break routines such as going on holiday (or being admitted to hospital) can contribute to wastage in the community setting (Adam *et al.* 2003, Bell 2007).

To the extent that activities such as illicit drug taking are indicative of non-routinised or chaotic life styles, this may explain observations linking such behaviours to (implicitly at least) an increased risk of drug waste (Ascher-Svanum *et al.* 2006, Gordillo *et al.* 1999). Similarly, the underlying reasons for factors such as being a non-smoker being in certain instances positively associated with adherence (Maurice *et al.* 2006) may be linked to having a 'healthy behaviour compliant' life-style and personality. However, this is not to say that illicit drug use or smoking cause medicines wastage.

Additional factors that some mainly American research evidence suggests may be related to problems with medicines use and wastage include race/ethnicity, (low) income and (low) socio-economic status (Adam *et al.* 2003, Balkrishnan 1998, Chisholm 2004, Elliott 2009, Falagas 2008, Gazmararian *et al.* 2006, Gregg *et al.* 2001). Yet any such positive or negative relationships are complex and likely to be linked with many or all of the other potentially causal variables discussed above. The interpretation

offered here is that the available evidence does not show particular ethnic or other social groups to be inherently more or less likely to be 'treatment adherers' or 'medicine wasters' than others. Rather, it indicates a need to understand how generally variations in opportunity and living standards impact on health related behaviours in given social contexts.

A second preliminary conclusion drawn here in relation to DUMP campaigns is that uncritically publicising the costs of undifferentiated (avoidable and unavoidable) medicines waste may not be useful. It could itself be an active cause of avoidable harm, were it to exaggerate the scale of the 'medicines waste problem' as an isolated issue and distort public and political understanding of the value of appropriate medicines taking and the services needed to support it.

Finally, it is also appropriate to observe that medicines recognition by health service users can help promote adherence and reduce wastage (Mason 2009). None of the literature discovered by the formal search process employed in this study investigated this issue in any detail. But it is logical to conclude that if people on long term treatment are supplied with constantly varying drug presentations this will impair their ability to recognise dispensing errors. It might on occasions lead them to discard medicines they are unable to identify, or stop taking their prescribed treatments altogether. Similar possibilities exist with regard to, say, packaging which consumers feel does not adequately identify products, once medicine 'strips' have been taken from their original pack boxes. Such concerns again underline the importance of genuinely respecting patients' requirements and of designing policies, services and products to meet them.

Condition and patient group specific variations

Many of the articles reviewed in this Section offer not only insights into the general nature and causes of medicines wastage, but more specific information about its occurrence and management in particular disease and patient group contexts. For the purposes of this Report the most fundamental finding to confirm here is that medicine waste related risks vary in relation factors such as whether or not the condition being treated is acute or chronic, and whether or not the drug being used offers immediate symptomatic relief. But wastage occurs across all therapeutic areas, and in some cases the linkages between condition characteristics and behaviours such as medicines hoarding may, superficially at least, appear paradoxical. Where fear drives behaviour valued medicines may be stored rather than used.

In general, the more expensive individual medicines are the more it is worth investing in efforts to cut wastage levels. At the same time the more beneficial drugs and related products are provided they are used in a precise manner, the more it is worth

investing in assuring their appropriate use. By contrast a limited degree of wastage and sub-optimal use may be judged acceptable (or at least not cost effectively avoidable) in relation to treatments that are obtainable very cheaply, especially if their capacity to deliver health gain is not critically dependent on tightly defined patterns of consumption.

Examples of the areas covered in the condition specific element of the review summarised here include:

Antibiotic use (Dowse and Ehlers 2005, Kardas *et al.* 2005, Segador *et al.* 2005, Vrijens and Urquhart 2005.)

Asthma treatment (Bender and Rand 2004, Bennett *et al.* 1998, Cohn 2003, Conn *et al.* 2005, Corsico *et al.* 2007, Hansson Scherman and Lowhagen 2004, Horne 2006, Jones *et al.* 2003, Ulrik *et al.* 2006).

Cancer care, including end-stage cancer treatment (Atkins and Fallowfield 2006, Dediu *et al.* 2006, Maurice *et al.* 2006 Ersek *et al.* 1999).

Diabetes care (Cramer 2003, 2004, Grant *et al.* 2007, Soule Oldegarde and Capoccia 2007, Walker and Usher 2003, Williams 2007, Lee *et al.* 2006).

HIV treatment (Adam *et al.* 2003, Bangsberg *et al.* 2002, Beals *et al.* 2006, Collier *et al.* 2005, Falagas *et al.* 2008, Godin *et al.* 2005, Goldie *et al.* 2006, Gordillo *et al.* 2006, Horne 2007, Kalichman *et al.* 2005, Lamiraud and Moatti 2006, Mills and Cooper 2007, Ryan and Wagner 2003, Vrijens and Urquhart 2005).

Hypertension and hyperlipidaemia control (Hyre *et al.* 2007, Schedlbauer *et al.* 2004, 2007 and Schroeder *et al.* 2004a, 2004b, Vrijens *et al.* 2008);

Medicines use by the young and by older adults (Carter *et al.* 2005, Conn *et al.* 2005, Gerson *et al.* 2004, Sanz 2003, Fuller and Edmundson 1996, George *et al.* 2008);

Mental ill health and the use of medicines (Buckley *et al.* 2007, Ascher-Svanum *et al.* 2006, Claassen *et al.* 2007, Frangou *et al.* 2005, Bastiaens *et al.* 2000).

Organ Transplantation (Chisholm 2004, Chisholm *et al.* 2005, Dew *et al.* 2007, Dobbels *et al.* 2004).

The effectiveness and costs of interventions to reduce medicines wastage

The available literature on the effectiveness of interventions to reduce medicines waste is largely dominated by studies of interventions designed to reduce one potential cause of waste, namely intentional non-adherence. Enhancing adherence in medicines taking has the potential to reduce waste, and to improve individual and population health (WHO 2003). Yet the research reviewed here also

shows that interventions to date employed to improve adherence in medicines taking typically have modest effect sizes, and that no one approach has any marked advantage over others (Dodds *et al.* 2000, Haynes *et al.* 2005, Higgins and Regan 2004, NICE 2009, Peterson *et al.* 2003, Roter *et al.* 1998).

This finding has direct implications regarding wastage reduction. As has been observed in other multi-dimensional areas such as health promotion, those interventions most likely to be effective are complex, involving a mix of educational, environmental and behavioural components (McDonald *et al.* 2002, 2003).

Some reports, such as those relating to the Federal Study of Adherence of Medications (FAME – Taylor and Block 2007, Lee *et al.* 2006) indicate an adherence improvement impact significantly greater than the 5-15 per cent most typically reported in the literature reviewed here, at least for the duration of the intervention. Yet care should be taken fully to understand the significance of such results. In the FAME case this initiative involved not only supplying medicines to older people in blister packs, but a pharmacy care programme delivered via the Walter Reed Army Medical Center. It is possible that the structured nature of this setting and the relatively controlled way in which this research was undertaken means that in practice its findings are unlikely to be reproducible in the normal NHS primary and community care environment.

Such observations may question the likely cost effectiveness of presently available and possible future adherence improvement interventions, at least from a tightly defined medicines waste reduction and monetary saving perspective. This is particularly so now that many widely used NHS medicines are available as low cost generic presentations.

However, studies such as Horne *et al.* (2005) suggest that if research investment continues a progressively better understanding of how economically to change factors such as necessity/concern related beliefs will be gained. It can also be argued that even if the savings likely to be derived from medicines waste reduction alone would not justify the additional costs of providing services designed to reduce intentional non-adherence, the welfare gains attendant on improved health outcomes should also be taken into account. This could well allow an increased proportion of medicines waste to become cost effectively avoidable as a result of adherence support provisions, albeit that the scale and value of such benefits is not currently quantifiable in either financial or health terms.

Dosage and regimen simplification

Evidence summarised previously shows an association between multiple daily dosing, regimen complexity and reduced adherence and increased waste in medicines taking. Although such linkages

are weaker than may often be assumed (Horne 1998, Jesson *et al.* 2005, Shalansky and Levy 2002) the literature reviewed here confirms that minimising the number of medicines and medicine doses to be taken is likely to result in limited reductions in waste as well as (given good prescribing) improvements in health outcomes (Claxton *et al.* 2001, Dezii 2000, Diamantorous 2005, Frishman 2007, Gray *et al.* 2001, Kripalani *et al.* 2007, Osterberg and Blashke 2005).

One possible way forward in this context may be via an increased use of fixed dose combination products in fields such as vascular disease prevention and treatment (Bangalore *et al.* 2007, Connor *et al.* 2004, Wald and Wald 2009). The use of such products could offer a range of benefits, including a reduction in medicines wastage.

MDS (monitored dosage systems) and other medicine taking aids

There is evidence that a significant number of older (and other) patients taking medicines for long term conditions experience either physical or organisational difficulties that act as barriers to consistent medicine taking. These can contribute to wastage (Beckman *et al.* 2005, Fuller and Edmundson 1996, Ryan and Wagner 2003). In such circumstances the use of aids such as monitored dosing systems (sometimes also referred to as 'multi-compartment medication devices') and related forms of medicine user support (including where appropriate written aids) may improve medicine taking (Kalichman *et al.* 2005, Ryan-Woolley and Rees 2005, Taylor and Block 2007).

Yet not all medicines can be put into MDS devices, and their effectiveness amongst individuals who have a poor adherence record related to cognitive or other factors is very limited (Brunenberg *et al.* 2007). There is no evidence that dispensing complicated medication regimens in devices such as Dosette boxes to, for example, mentally confused people living alone is a cost effective substitute for providing direct care and support in day to day medicine taking. Nor will it automatically prevent other more able service users from using medicines in other than recommended ways (Elliott and Ross-Degnan 2007).

Such dispensing is relatively time consuming for pharmacists, and so costly for care funders. It may also on occasions lead to otherwise avoidable waste, not least because of all items already supplied in multi-compartment medication support devices have to be thrown away when a prescription is changed. The evidence reviewed here indicates that a well targeted use of such aids is needed to achieve enhanced cost effectiveness. Employing them on a 'blanket' basis could in itself be regarded as a form of waste.

Twenty eight day dispensing

There is intermediate quality evidence that limiting repeat prescribing and dispensing periods to 28 days can contribute significantly to NHS medicines waste reduction (Hawksworth *et al.* 1996). Yet this interpretation is questioned by other European and US research findings, as illustrated in this review by the work of Domino *et al.* (2004) and Atella *et al.* (2006). Short prescription 'refill' durations on occasions inconvenience medicine consumers and raise dispensing costs, perhaps diverting pharmacists away from other more useful activities. Such findings underline the fact that simple 'one size fits all' rule based approaches to medicines waste reduction and the complex needs and behaviours which determine productive medicine taking cannot be universally successful. The available literature indicates that achieving optimum economy in areas such as prescribing and dispensing must involve informed health professionals being enabled to practice in an intelligently flexible manner, which is responsive to individual service user requirements.

A new system of pharmacist managed repeat dispensing has recently been introduced in England.⁵ To date this has been employed on only a limited scale, although some sources believe that the Electronic Prescription Services Release 2 introduction process will lead to a significantly greater uptake of the pharmacist repeat dispensing option by GPs. However, the review reported here identified no substantive evidence on the extent to which repeat dispensing on this basis causes primary and community care medicines wastage to be reduced in a cost effective manner.

Telephone based and related reminder interventions

There is good quality evidence that telephone interventions by pharmacists directed at older (and other) people starting on new medicine courses for chronic conditions can cost effectively decrease non-adherence rates. They can also decrease the physical wastage of medicines, in part via cutting the number of avoidable prescribing switches between one medicine and another (Clifford *et al.* 2006, Elliott *et al.* 2008). Targeted interventions by telephone can also impact on medicines taking adherence rates in other contexts, such as HIV and cardiovascular care (Collier *et al.* 2005, Schedlbauer *et al.* 2007), especially when combined with other forms of support.

Medication reviews

The term 'medication review' covers a wide variety of differing interventions by health care practitioners, including not only pharmacists but also doctors

and nurses. Depending on the extent to which the interventions involved are effective in identifying and helping to resolve problems in medicine taking, they have a potential to reduce wastage (Anonymous 2004b, Nathan 1999, Richman and Castensson 2008) and to create savings by, for example, stopping the supply of unnecessary treatments that are being taken. But much commentary in this area fails to identify specifically the types of intervention used, or to demonstrate causal relationships between the latter and the more sophisticated outcomes desired.

There is also to date a lack of data relating to the cost effectiveness of Medicine Use Reviews (MURs) currently (in 2009/10) being conducted by community pharmacists working to NHS contracts in England. Such a lack of evidence may on occasions be taken to show that pharmacist conducted MURs are not an effective and efficient use of NHS resources, although this is not necessarily the case (Taylor and Newbould 2009). Expert opinion suggests that the value of community pharmacy provided MURs should and could in future be improved by better targeting of such interventions to those most likely to benefit.

The provision of NHS funded MURs and/or other medication reviews in patients' homes, where waste medicines most typically accumulate, has also been advocated. However, some studies have cast doubt on the value of this option (Jenkins 2006, Pacini *et al.* 2007). Holland *et al.* (2005) found that amongst patients aged 80 and over an intervention they described as 'home based medication review' delivered by a pharmacist increased rather than decreased hospital emergency admission rates.

The authors of this study suggested that attempts to improve medicine taking adherence could have increased rates of iatrogenic illness, or have promoted hospital admissions through the identification of real or perceived health problems which would otherwise have either passed unnoticed or received normal GP care. But the view taken here is that such possibilities are not relevant to whether or not the delivery by pharmacists or others of well specified MURs/medication reviews in appropriately selected patients' homes could affordably reduce medicine wastage rates. This might well be the case, although this review did not find firm evidence to this effect.

Enhanced professional care

Some observers appear to blame either patients' demands or 'over-prescribing' by doctors for the problem of medicines wastage (Bellingham 2001). But this could be counter-productive (Britten *et al.* 2003, Jesson *et al.* 2005, NICE 2009). Good medical, pharmaceutical and other professional skills may to a degree help improve adherence in medicine taking, especially when these are used to address service users' highest priority concerns. Yet there is evidence that it can often be very difficult for doctors to identify

⁵ This involves pharmacists re-supplying patients, normally on a 28 day basis, for periods of up to a year.

patients who are not taking their medicines as recommended (Pound *et al.* 2005).

One possible reason for this is that the implicit contracts between doctors and their patients are often both complex and delicate. They sometimes involve medical practitioners deciding not to probe the latter's medicine taking too deeply. It may on occasions be easier for pharmacists to address such questions. But even here many community pharmacists may be unwilling to risk undermining their relationships with people who choose to use their pharmacies.

In the medium and longer terms enhanced professional education and training might help to improve performance in this area, albeit that claims about the value of such investments should not be uncritically accepted. This review found no clear evidence that current levels of material waste of NHS prescribed medicines could be cost effectively reduced via further spending on any particular form of professional education or training.

It has been estimated that in the order of 15 per cent of the overall total of people receiving a medicine for an acute or a long term condition take few if any doses (see Osterberg and Blaschke, 2005). To the extent that such figures are accurate, this must generate potentially avoidable waste. 'Non-responders' with seemingly 'treatment resistant' disorders may on occasions be prescribed increased doses or new drugs, when in fact they are not taking them. Such treatment escalation and switching promotes increased waste. Hence one possible professional approach to limiting the latter could be to audit the treatment of 'treatment resistant' patients.

The literature reviewed for this study provides a range of examples of pharmacist provided interventions designed to facilitate improved medicines usage and better health outcomes (Blenkinsop *et al.* 2000, Bellingham 2001, Clifford *et al.* 2006, George *et al.* 2008, Goodyear *et al.* 1995, Murray *et al.* 2007, Taylor and Block 2007). The cost effectiveness of such interventions is in many instances uncertain,⁶ although they indicate a capacity to influence medicine taking behaviour. This might in future be further developed. Interventions by nurses have a similar positive potential (Reddy 2006), just as poor knowledge and negative attitudes towards medicinal drug use on the part of any professional can also impair medicine taking (Byrne *et al.* 2005).

The EPP and other self management programmes

As already described, the Expert Patients Programme (EPP) and other self management support programmes like those available in the area

of diabetes care seek (at least in part) to promote a balanced sense of context specific self confidence amongst participants. They in can addition impart particular skills in areas such as drug administration or diet management. There is evidence that this can be (cost) effective. (See, for instance, Newman *et al.* 2004, Kennedy *et al.* 2007.)

It is likely that the provision of such services by either health professionals or others will on occasions reduce medicine wastage. But the review process reported here did not find evidence demonstrating this in a quantifiable manner.

Extended charges for receiving prescription medicines and/or making payments for taking them

The evidence found via this review indicates that although it may be believed that having to pay more extensive prescription charges would 'make' NHS patients value their medicines more and so decrease wastage this may not be the case, especially when the loss of therapeutic and implied economic benefit associated with discontinuing medicines taking is factored in to relevant calculations. Extended charging would be relatively unlikely to influence the behaviour of more affluent medicine users, but could cause financially hard pressed individuals to cease taking some or all of their prescribed treatments. This might in time cause an increase in overall health service costs.

An alternative policy option might be to introduce direct payments (or some parallel form of benefit) for adherence to individuals known to be at high risk of not taking medicines to their best advantage. The findings of Claasen *et al.* (2007) suggest that in the case of people being treated for schizophrenia such an approach could help encourage enhanced medication use. But they also reported high levels of ethical concern regarding such strategies amongst mental health service providers. It is therefore uncertain how widely such a scheme could be applied in the UK setting.

It may also be worth pointing out that if individuals are financially incentivised into behaving in a way that they are not otherwise persuaded to accept, they could well revert were the payment to be withdrawn. This is relevant to evaluating the long term costs and benefits of such options.

Waste medicines and the environment

This review included approaching twenty articles that explicitly address environmental issues linked with medicines wastage. They range from those relating to the safe disposal of toxic medications through to concerns about the avoidable use of energy in wasted drug production. This causes potentially

6 If public expectations of pharmacists to provide clinically relevant advice increase, the impact and cost effectiveness of pharmacy led interventions may also rise.

reducible gas releases into the atmosphere and other forms of pollution.

About half the papers identified were concerned with the situation in the United States, which in many regions lacks developed systems for returning unwanted medicines to pharmacies or other safe disposal points (Daughton 2003, Koshland *et al.* 2008, Kuspis and Krenzelok 1996, Musson *et al.* 2007, Nidel 2003, Ruhoy and Daughton 2007, Seehusen and Edwards 2006). This contrasts with the typical situation in Europe, where either health care systems, pharmaceutical companies or wholesalers are required to support pharmacy collection services for controlled and other drugs (Ahmed and Majeed 2007, Bound *et al.* 2006, Mackridge and Marriott 2004, Richman and Castensson 2008, Wennmalm and Gunnarsson 2005, Zuccato *et al.* 2006).

In countries such as the UK and Sweden public awareness of problems such as the feminisation of male fish due to the presence of sex hormones in the water (which is for the most part a function of their excretion by women who have used relevant products, rather than inappropriate disposal of unused drugs) seems to be relatively extensive (Richman and Castensson 2008).

The proportion of all NHS primary and community care supplied waste prescription medicines eventually returned to pharmacies and dispensing GP surgeries or via other collection points is unknown. The estimates derived earlier in this literature review from the OPCS data collected in 1994 suggest that well over of 50 per cent all such pharmaceutical waste by volume is eventually returned,⁷ but even so such data indicates means that relatively large volumes of in some cases toxic products may be being disposed of in household waste or into drains. The harm this does may be small in comparison with that caused by the total amount of noxious material entering the modern environment, but even so it should not be ignored.

Prioritising safe disposal of environmentally hazardous medicines

From a climate change prevention and similar perspectives avoiding all unnecessary drug

⁷ Ekedahl's work in Sweden suggests that the volume of unused medicines returned to pharmacies there is higher as compared to the total volume dispensed than is the case in England. Unless overall wastage rates are also higher in Sweden than in this country, this may indicate that proportionately more waste medicines are disposed of informally in the UK. One report from this author showed that just 10 per cent of return events account for over 50 per cent of residual medicines by volume (Ekedahl 2003). This in implies a high number of small volume pharmacy returns which could indicative of an environmentally aware, or alternatively highly compliant, society.

purchasing, distribution and disposal activities represents a limited but nevertheless tangible way in which organisations like the NHS can contribute to global environmental protection. Within that overall goal seeking to raise the proportion of residual medicines that are returned to pharmacies and then disposed of by incineration is a secondary way of minimising environmental harm.

Logically, cost effective harm reduction should also focus on where possible stopping the inappropriate disposal of those medicines which have the most environmentally toxic effects (Wennmalm and Gunnarsson 2005). In Sweden the Stockholm County Council has introduced a classification of drugs which allows health professionals and members of the public to gain an improved understanding of the differing potentials of medicines to accumulate in surface water and interfere with aquatic life. For example, this shows that the anti-viral drug Ribavirin persists in the environment, is moderately 'eco-toxic', and has a significant bio-accumulation potential (Wennmalm and Gunnarsson 2005). It may be that a similar guide to environmentally hazardous medicines and allied forms of waste would be valuable for NHS users and practitioners.

Some European countries, including France, have waste medicines recycling schemes. Unused packs of drugs with suitable expiry dates are collected and later supplied to populations in need elsewhere in the world (Macarthur 2000, Mackridge and Marriott 2004). This approach can have popular appeal (Crumplin 2000). Yet international agencies such as the WHO do not support waste medicines 'recycling' because of questions relating not only to safety but also appropriateness and cost effectiveness.

Focusing on the importance of returning medicines to pharmacies for safety and environmental protection reasons may therefore be judged desirable. One reason for encouraging such returns in the context of the NHS is that fuller reporting of wastage could support more effective management and care interventions, and efforts to improve the support available to those people most at risk of not taking their medicines effectively.

In a number of European countries pharmaceutical companies also have an extended role in pharmaceutical waste disposal, over and beyond their responsibilities related to tasks such as recalling withdrawn items. However, this review found no evidence that this approach is likely to generate enhanced public benefit as compared to the current arrangements in England. Nor did it identify any robust research relating to whether or not in England PCT commissioned waste medicine collection schemes in England are presently contracted for in an optimally cost effective and environmentally protective manner.

2.4 Summary

The causes of material medicines wastage in the community setting range from people choosing not to start (or finish) taking courses of medicines such as analgesics or – potentially more seriously – antibiotics for acute conditions (Kardas *et al.* 2005), through to individuals on long term treatments regularly collecting prescribed drugs but not taking them all and so building up unused stocks. The reviewed papers show that the reasons for such behaviour range from individuals valuing their relationship with their doctor but not feeling able to communicate fully with him or her through to mental confusion and social isolation, and/or fears of running out of a medicine perceived as being vital.

Problems with repeat medicine re-ordering systems can also cause medicines over-supply. Waste may in addition happen as a result of factors like, for example, variations in the appearances of generic and imported brand medicines which make it difficult for patients to recognise their treatments and can undermine their willingness to take them. However, the available evidence does not allow the proportions of avoidable and unavoidable medicines wastage that occur in the NHS or elsewhere to be attributed with any degree of accuracy to one cause as opposed to another. Nor at this stage does it in the main permit the cost effectiveness of interventions that may further reduce residual medicine volumes to be assessed.

A significant proportion of – and probably most – NHS medicines wastage is either unavoidable (as is often the case when regimens need to be changed) or only likely to be avoidable at a cost greater than that of the medicines that go unused. As with non-adherence in medicines taking, medicines wastage is an international problem, common to all developed societies. There is no evidence that it is greater in this country than in other similar countries, or that other health care systems are seeking to reduce it in significantly more effective ways.

There is limited published evidence on the value of prescribed medicines which are wasted in the NHS. The OPCS from the mid-1990's made a robust attempt to quantify the volume of residual medicines whilst a number of audit based studies have extrapolated their findings to produce estimates

of the scale of the problem nationally. However, there remains considerable uncertainty about the precise proportion of health care expenditure wasted on prescription medicines. The included articles suggest that gross (community supplied) medicines wastage is probably under five per cent of total NHS medicines outlays, and that the figure for avoidable drug wastage is a fraction of that figure. Efforts should of course be made to further reduce avoidable medicines wastage. But exaggerations of the extent to which it is caused by avoidable failures or irresponsible behaviour on the part of NHS professionals or members of the public are likely to be counter-productive.

Decreasing medicines wastage is in part likely to require increased investments of health service staff time and effort. Jesson *et al.* (2005) concluded that '*closer professional management at the point of dispensing and an understanding of patient experiences can help reduce the amount of unwanted medication collected by patients*'. This is consistent with the preliminary conclusions offered in this review, although the research available also indicates that prescribers and patients may also be able to play useful roles before and after the dispensing point.

In order to be optimally effective, integrated approaches to medicines waste reduction should visibly focus on enhancing health outcomes, rather than simply seeking to make limited (and possibly illusory) financial savings. Measures that could contribute to minimising medicine wastage and the harm that it and related phenomena like non-adherence in medicines taking cause range from encouraging more open, fear free, communication between doctors, patients and other health professionals to enabling social carers to help more effectively with medicines taking.

From a waste minimisation perspective there is relatively robust evidence that supporting medicine users at around the time they start a new long term treatment is likely to be a more cost effective approach than later stage intervention. Other goals, like limiting prescription durations and supporting new repeat dispensing systems, should be pursued with flexibility and with a genuine regard for both professionals' and service users' values, preferences and requirements.

3 Estimating the Volume of Waste Medicines in the National Health Service in England

3.1 Background

There have been few rigorous attempts to identify the degree to which medicines supplied by the NHS are wasted. The most notable study to date is the OPCS Omnibus Survey report published in 1995 (Woolf 1995). This survey involved visits to over 2000 homes to identify medicines retained by their users. It categorised medicines depending on whether they were being currently used, retained for future use, or were residual (i.e. not in current use, and the individual had no intention of taking the medicine). The findings suggested that 11 per cent of households in England had at least one medicine in their possession which was being retained but not intended for future use.

This categorisation is important in defining what constitutes wasted medicines and the degree to which the OPCS findings can be compared with the current research. The latter considered waste medicines to be medicines which are not currently being used, and as such includes medicines which may be being retained for future use.

When individuals have medicines stored in their homes for possible future use, this could be seen as rational and may indeed be in line with prescribing guidance (e.g. for PRN medicines). However, in some cases this may raise safety issues in relation to individuals making judgments about when and how to self-medicate. Furthermore, there may be concerns relating to whether the medicine remains within its expiry date and whether retaining unnecessary medicines in a household increases the risk of inappropriate use by others, particularly children.

Within the current study, two separate initiatives were undertaken to estimate the scale of waste medicines in primary and community care. The first was a national public (telephone) survey and the second was an audit of medicines returned to community pharmacies. The National Survey was intended to capture information from individuals about what kinds and amounts of medicine they have retained but are not currently using.

The second element was a community pharmacy audit which provided complementary evidence relating to medicines returned to pharmacies for disposal. These medicines are wasted in the true sense of the term. Together, these investigations

offer a picture of medicines waste in primary and community care settings other than care homes in 2009/10. A summary of the methods employed and the findings from each of the two exercises is provided below.

3.2 National public survey

Methods

This survey focused on identifying medicines that are retained by individuals but are not currently in use. A telephone survey was chosen as the preferred means of conducting this analysis. Telephone surveys inevitably rely on the accuracy of self-reporting: it was recognised that there was potential for participants to under-report the number or volume of medicines that they have in their homes, particularly if the interviewer were to give a negative impression about unused medicines. But the telephone survey was adopted as the preferred means on the basis that it would yield a greater response rate than a postal survey and be less costly, time-consuming and difficult to administer than home visits.

Sample

Given the nature of the survey, no prior attempt was made to define a statistically meaningful sample size. An arbitrary target of 1,000 responses was established. A stratified sampling framework was used to maximise the value of the survey. The group primarily of relevance to the research was medicines users. Whilst the opinions of non-users of prescription medicines were of some importance, a general population sampling framework would have resulted in a significant number of responses from non-users of prescription medicines, who would by definition only be able to provide limited information on their wastage.

The age and gender of current medicines users, as identified from national prescribing statistics, were used as the basis for stratification. This resulted in a sampling framework with a greater number of individuals in older age groups compared to the general population. Similarly, national prescribing data suggest that females consume more medicines than males. The sample taken was therefore skewed towards females. In addition to this, attempts were

made to ensure that individuals invited to participate in the survey were drawn from different socio-economic groups as well as different geographical regions, as defined by the Strategic Health Authority of residence.

Children (under 18 years of age) were included. However, it was judged that it would be inappropriate to recruit children directly. As such, a decision was made to ask participants in the survey whether or not they had children living at home. Where this was the case, the participants were asked whether they would be willing to respond on behalf of themselves, and also as a proxy for their child.

Recruitment

Participants were recruited through a market research company (QA Research) with extensive experience of conducting large scale surveys in health and social care. Potential participants were identified through existing databases developed for market research purposes. This approach was adopted over more general methods, such as recruitment from electoral rolls. Using an existing database of individuals who had already contributed to surveys was expected to lead to a better response rate than a general recruitment method. It also avoided the need for new consent procedures, as these individuals had previously agreed to be contacted for the purposes of market research. Further, the database included information on age, sex, area of residence and socio-economic status, allowing for prior stratification. Finally, this approach allowed for a large number of individuals to be contacted and interviewed over a short period of time. Its main disadvantage was that individuals who agree to be included in market research databases may be atypical, as compared with the general population.

Potential participants were contacted by letter. It was explained who the research was being conducted by, and its purpose. These letters included a blank form on which individuals who wished to participate could write down information about medicines that they had in their possession but were not currently taking prior to the interview. They also provided clear information on how recipients could participate in the research if they chose to do so, as well as their right to decline should they wish to do so.

A pilot study was conducted in December 2008 to ensure that the recruitment and data capture systems were working correctly. Interviews were then carried out between January and February of 2009. Following this, it was found that the number of respondents from black and minority ethnic groups was smaller than expected. Attempts were therefore made to correct for their under-representation. Although the ethnicity of participants was not known in advance, additional sampling from areas with relatively large BME populations was conducted to increase the involvement of individuals from these groups.

Interviewing

An interview guide was developed. This built on the content of the original OPCS research, although some additional questions were also included. It covered the following areas:

- ▶ individual characteristics;
- ▶ recording of medicines not currently being used in the individuals' home; and
- ▶ perceptions about unused medicines and their disposal.

The content of the interview guide was developed by the research team, based on the findings of the literature reviews and previous surveys. The wording of questions attempted to be non-judgemental, in order to promote self-reporting of unused medicines. It was made clear that the focus of the research was on medicines prescribed by a doctor or other healthcare professional and that medicines bought over the counter should not be reported. Whilst the objective of the survey was to identify waste, as defined for the purposes of this study, a decision was made to avoid the use of the term 'waste' medicines during interviews. Use of the latter term could have negative connotations, and involve implied value judgements, and so lead to an increased likelihood of under-reporting. Instead, participants were asked about medicines that were in their possession but which they were not currently taking.

The interview included questions to be answered by all participants, regardless of whether they had any medicines in their possession. Additional questions were included for those individuals with medicines. It was recognised that people with multiple morbidities may have many medicines in their possession. In order to ensure that the interviews were of a manageable length, a decision was made to capture detailed information on a maximum of 10 reported medicines not currently in use per individual respondent.

The questionnaire was piloted with 50 individuals to check its content and feasibility. There were no concerns raised by participants with regard to the content and it was deemed to be understandable to a general audience. No participants raised any concerns about the degree to which they were asked for personal information. On this basis, no significant changes were made to the questionnaire used in the full survey and the responses to the pilot were included in the final analysis.

Interviews were conducted by three individuals with significant experience of market and social research. These interviewers were provided with training prior to recruitment to ensure that they understood the principles of the research and any relevant terminology. As previously noted, they were asked to emphasise that the focus of the research was prescription medicines prescribed for participants by

a healthcare professional, in order to avoid collecting information on over-the-counter medicines.

Data Capture

Information was captured from participants in real time using a computer aided telephone interview (CATI) system. The questionnaire included closed ended questions as well as open ended questions. Open ended responses were transcribed during the interviews.

Information was transferred from the CATI system into Microsoft Excel and subsequently converted into SPSS 16.0 to permit further analysis.

Data Analysis

Closed ended and categorical responses were analysed using simple statistical methods (e.g. frequency counts, means etc).

Responses to open-ended questions were categorised wherever possible to facilitate data analysis. Categories for closed ended questions were developed by reviewing responses and identifying appropriate themes into which responses could be categorised.

The data set was transferred to SPSS 16.0 for further analysis. Data were initially analysed at an aggregated level and subsequently sub-group analyses were considered for specific groups of responders (e.g. by ethnicity, age etc). In many cases, sub-group analyses should be treated with caution due to the low number of respondents in each category.

Findings

A total of 1185 respondents took part in the research. Of these, 133 did so on behalf of themselves and a child in their household. This yielded a total of 1318 useable returns.

The characteristics of the respondents involved are presented in the table below.

Table 3.1:
Demographic details of respondents

Group	Survey	Population
Female	50.8%	40.3%
Male	39.1%	38.1%
Children (sex unknown)	10.1%	21.6%
'White British'	84%	83.6%

Fifty one per cent of respondents were female, 39% male and 10% children (sex not known). Compared with the general population statistics, there was a bias towards female respondents. The majority of

participants reported their ethnicity as White British (84%) which is broadly in line with the population statistics. Almost 80 per cent of respondents stated that they did not pay any contribution to the cost of their medicines.

Table 3.2 summarises the number of respondents with waste medicines, according to the definition applied above. The majority of waste medicines were reported by women although these also made up the majority of respondents. In total, approximately 20% of respondents reported having waste medicines, with no significant differences according to gender. Approximately 19% of responses made on behalf of children reported having waste medicines.

Table 3.2:
Gender breakdown (total and total with waste medicines)

	Total number of respondents	N with waste medicines	% of group	% of waste
Female	670	135	20.1	50.9
Male	515	105	20.4	39.6
Children	133	25	18.8	9.4
Total	1318	265		

Table 3.3 presents the proportion of respondents in each age group reporting having waste medicines. Although there is some variation between age groups, the differences are not statistically significant from the mean. However, this may be due to small sample sizes in certain age groups. These data do not indicate higher rates of waste medicines in the elderly population. Rather, above average rates were reported by people in the 18-24 and 35-44 age groups.

Table 3.3:
Age breakdown of responses (total and total with waste medicines)

Age	Total respondents (%)	Have waste medicines?		% with waste medicines
		No	Yes	
< 18	133 (10.1%)	108	25	18.8
18-24	20 (1.5%)	12	8	40.0
25-34	81 (6.1%)	68	13	16.0
35-44	81 (6.1%)	58	23	28.3
45-54	102 (7.7%)	83	19	18.6
55-64	203 (15.4%)	166	37	18.2
65-74	633 (48.0%)	502	131	20.6
74+	65 (4.9%)	56	9	13.8
Total	1318	1053	265	20.1

Although almost 200 respondents reported their ethnicity as other than ‘White British’, the number in each ethnic group sub-category was too small to provide any meaningful indication of an impact on reported medicine waste levels.

In Table 3.4, the median number of waste medicine items reported was zero, whilst the median number amongst those participants reporting waste medicines was one. Almost 10 per cent of the total number of respondents reported having 2 or more waste medicines in their homes, with the maximum number reported being 8. The total number of waste medicines reported by the sample was 466.

Table 3.4:
Number of waste medicines per respondent (adults and children)

Number of waste medicines	N	Percent of total responders	N as a % of responders with waste meds
0	1053	79.9%	
1	158	11.9%	59.6%
2	59	4.5%	22.3%
3	23	1.7%	8.7%
4	13	1.1%	4.9%
5	7	0.5%	2.6%
6	3	0.2%	1.1%
7	0	0%	0%
8	2	0.1%	0.8%
Total number of responses	1318		

Respondents were asked to identify the types of waste medicine they reported, which were subsequently coded into categories as defined by the British National Formulary (see Table 3.5). A total of 466 medicines were identified as waste items in the survey. In 16 per cent of cases, respondents were unable to provide sufficient information to allow the medicine to be coded. They are hence reported as ‘Other’ in the table below). The most frequently reported indications were medicines for gastrointestinal and skin problems, followed by pain and cardiovascular disease.

Table 3.5:
Types of waste medication

Category of unused medication	Frequency	Percent	% Excluding “other”
Other*	75	16.1%	
Gastrointestinal	58	12.4%	14.8%
Skin	52	11.2%	13.3%
Pain	49	10.5%	12.5%
Cardiovascular	48	10.3%	12.3%
Central nervous system	41	8.8%	10.5%
Respiratory	34	7.3%	8.7%
Infections	29	6.2%	7.4%
Eye / ear / nose / throat	28	6.0%	7.2%
Nutrition / blood	20	4.3%	5.1%
Endocrine	13	2.8%	3.3%
Mental Health	10	2.1%	2.6%
I can’t remember	9	1.9%	2.3%
Total	466	100.0%	100.0%

* Insufficient information provided to allow for coding

Of the waste medicines recorded, 52% were reported to be generic drugs. Thirty six per cent were branded and in the remaining cases it was impossible to determine whether the drugs were generic or branded, based on the information provided by the interviewee. In over 60% of the cases, the waste medicines found had been prescribed within the last year. But there were some notable cases of medicines having been prescribed more than 5 years ago and retained in the household, as shown in Table 3.6.

Table 3.6:
When was the waste medicine prescribed?

	Frequency	Percent
In the last month	31	6.7%
In the last 3 months	54	11.6%
In the last 6 months	86	18.5%
Last Year	124	26.6%
Two years	71	15.2%
3 years	40	8.6%
5 years	21	4.5%
More than 5 years	30	6.4%
D/K	9	1.9%
Total	466	100.0%

Interviewees were also asked to estimate how much of their medicine(s) they had remaining. The findings are presented Table 3.7 below.

Table 3.7:
How much of the medicine remains unused?

	Frequency	Percent
Can't estimate / no answer	17	3.6%
Almost gone	87	18.7%
Half remaining	139	29.8%
Three quarters remaining	137	29.4%
Never used	86	18.5%
Total	466	100.0%

Of the 466 medicines identified as unused in this survey, only 86 (18.5%) were considered completely unused. The most commonly reported medicines that were completely unused were for central nervous system conditions, cardiovascular disease and infections. However, the definition of waste adopted herein included PRN and other medicines not currently in use, but which the patient might perhaps take in the future.

As can be seen from Table 3.8, more than 40% of waste medicines were discontinued because the participants' symptoms had disappeared. Other key reasons for waste included a change of medication from the GP (16.3% of the sample) and discontinuation due to side-effects or problems with the medication itself (combining to 22% of participants). Some 7% of participants stated that they had not taken their medication as they did not want to, suggesting that they had not been fully engaged in prescribing and dispensing decisions with healthcare professionals. In only 4 per cent of cases did respondents say that they took their medicines on a 'take as needed' basis. These items were amongst those identified as 'unused' in the survey, but could be seen as being available for possible re-use at a later date. (See also Table 10 below.)

Table 3.8:
Reasons for not completing the course of medication

Code	Reason	Frequency	Percent
1	Symptoms disappeared	198	42.5%
2	GP / Consultant changed medication	76	16.3%
3	Side-effects of medication	65	13.9%
4	Didn't want to take the medicine	32	6.9%
5	Found it didn't help (no perceived effects)	28	6.0%
6	Take as needed	20	4.3%
7	Over prescription	8	1.7%
8	Forgot to finish the course	5	1.1%
9	Found it difficult to take the medication	6	1.2%
10	Other	28	6.0%
	Total	466	100.0%

The reasons for not completing a course of medication varied substantially according to the type of drug involved. Table 3.9 shows that for the majority of indications, particularly those categorised by intermittent symptoms such as GI, skin and infections, the disappearance of symptoms was the main reason for stopping therapy. However, in the case of products used in the cardiovascular disease and endocrinology contexts, switching the medication by a GP or consultant was reported as the most common reason for discontinuation.

Table 3.9:*Reasons for discontinuation of medicines by BNF Chapter*

BNF Chapter	Reason for Discontinuation										
	Didn't want to take the medicine	Forgot to finish the course	Found it didn't help	Found it difficult to take the medication	GP / consultant changed medication	Over prescription	Side-effects of medication	Symptoms disappeared	Take as needed	Other	
1 Gastro-intestinal system	2%	0%	7%	0%	13%	4%	17%	48%	4%	4%	
2 Cardiovascular system	2%	2%	0%	4%	43%	4%	26%	11%	7%	2%	
3 Respiratory system	9%	3%	9%	0%	12%	0%	3%	59%	3%	3%	
4 Central nervous system	8%	0%	4%	0%	9%	1%	17%	48%	5%	8%	
5 Infections	0%	3%	9%	0%	14%	3%	9%	43%	6%	14%	
6 Endocrine system	0%	0%	6%	6%	39%	6%	22%	11%	0%	11%	
7 Obstetrics, gynaecology and urinary-tract disorders	0%	0%	20%	0%	0%	0%	20%	60%	0%	0%	
8 Malignant disease and immunosuppression	0%	0%	0%	0%	100%	0%	0%	0%	0%	0%	
9 Nutrition and blood	17%	0%	0%	0%	0%	17%	33%	17%	17%	0%	
10 Musculoskeletal and joint disease	13%	0%	6%	0%	13%	0%	17%	44%	6%	2%	
11 Eye	14%	0%	0%	0%	14%	0%	0%	71%	0%	0%	
12 Ear, nose and oropharynx	0%	0%	0%	0%	17%	0%	0%	83%	0%	0%	
13 Skin	10%	0%	15%	3%	3%	0%	0%	59%	3%	8%	
Unknown	0%	0%	0%	0%	100%	0%	0%	0%	0%	0%	

Table 3.10:*Reasons for keeping the waste medication*

Reason	Frequency	Percent
Use again	273	58.6
Forgot to throw out	100	21.5
Don't know what to do with it	47	10.1
Intends to dispose of it	28	6.0
Other	18	3.9
Total	466	100.0

Table 3.10 shows that in total almost 60% of the medicines were being retained with a view to using them again, despite only 4% of respondents stating that they took their medicines on a 'take as needed' basis. No attempt was made to determine whether self-medication was appropriate in these cases. But cross-tabulations suggest that there are higher rates of intended re-use of medicines in conditions which might be characterised by intermittent symptoms, as shown in table 3.11. Medicines for GI disorders, the central nervous system, musculoskeletal disease and skin disorders make up over 50% of all medicines intended for re-use. Medicines for indications categorised as chronic conditions (such as endocrine disorders) were less frequently reported as being retained for future use.

Table 3.11:
Medicines retained for future use by BNF Chapter

BNFChapter	Frequency	Percent
Gastro-intestinal system	28	10.3
Cardiovascular system	21	7.7
Respiratory system	27	9.9
Central nervous system	63	23.1
Infections	21	7.7
Endocrine system	9	3.3
Obstetrics, Gynaecology and urinary tract disorders	1	0.4
Nutrition and blood	3	1.1
Musculo-Skeletal and joint disease	28	10.3
Eye	5	1.8
Ear, nose and oropharynx	4	1.5
Skin	29	10.6
Unknown	34	12.5
Total	273	100

In a significant number of cases, intention to re-use was the main reason for retaining the medicine. For example, 61 per cent of GI drugs, 74% of skin drugs and 79% of respiratory drugs identified in the study were said to be being retained for future use. By contrast, only 39% of cardiovascular drugs were being retained for future use.

When respondents were asked what they normally do with waste medicines, some 40% stated that they usually return them to a pharmacist or GP (see Table 3.11). This is higher than the figures found in the literature reviews. But it nevertheless contrasts markedly with the overall proportion of 75% of adult respondents claiming to be aware that unused medicines can be returned to a pharmacist or GP.

Table 3.12:
What do you normally do with unused medicines?

Reason	Frequency	Percent
Return to Chemist	422	35.6
Don't Know	307	25.9
Throw into bin	171	14.4
Throw into toilet	78	6.6
Return to GP	55	4.6
Keep for later use	46	3.9
Keep for intermediate period	43	3.6
Always complete the course	31	2.6
Forgot to dispose of	15	1.3
Never have medicines	11	0.9
Throw into fire	6	0.5
Total	1185	100

3.3 Audit of community pharmacies

Methods

An audit of community pharmacies was undertaken to establish the volume and types of medicine (and appliance) returned to pharmacies by patients for disposal. This was intended to be an adjunct to the public survey, which was designed to quantify and characterise unused medicines in the home.

An audit tool was developed for the purposes of the study. This captured information on the type of medicines returned, the volume and the reasons for return. It was based on guidance from the Royal Pharmaceutical Society of Great Britain.⁸ Pharmacists in each of the pharmacies were responsible for collating returned medicines and appliances over a one month period. These were retained on the premises and coded using the audit tool so that consistent information was recorded from each pharmacy that participated.

Sample

The audit was intended as a data capture exercise with no prior hypothesis being tested. As such, it was inappropriate to undertake any formal sample size calculation. An arbitrary target of 100 pharmacies was set as the preferred sample size. This was chosen mainly on pragmatic grounds that it would be difficult to recruit and analyse data from a greater number within the time and resources available.

8 Drug Wastage Audit template available at <http://www.rpsgb.org.uk/registrationandsupport/audit/#temp>

Recruitment of pharmacies

Pharmacies were recruited to take part in the audit through Primary Care Trusts. This approach was preferred to direct recruitment by the research team for two reasons. Firstly, recruiting pharmacies through PCTs was expected to elicit a higher response rate than recruitment by a research team. Secondly, by selecting PCT areas with differing characteristics, with regards to the socio-economic status of their populations and their geography, it was possible to recruit a sample of pharmacies that may be more representative of the national picture than would have been the case if we had attempted to recruit at random.

Two of the Primary Care Trusts approached to participate were already mid-way through conducting a waste audit. Both agreed to provide full details of their audits for the purposes of this study and both were found to be using a similar data collection tool. This facilitated aggregation of their findings. Five further PCTs were asked to participate, and three agreed to do so. Attempts were made to recruit Trusts which were geographically diverse, were predominantly rural or urban and included areas of affluence and deprivation. Furthermore, attempts were made to stratify them according to their prescribing volumes, so that those with low, medium and high levels (per capita) of dispensing were included.

The participating Primary Care Trusts were asked to distribute invitations to all pharmacies in their areas, asking them to participate. Participation was voluntary, although PCTs emphasised the importance of the audit and followed up with non-responders to encourage them to participate. A small monetary incentive was offered to each participating pharmacy to cover the time involved in collating data on returned medicines.

Data collection

Participating Trusts were provided with all the necessary information required to conduct the audit, including an introductory letter for pharmacies, guidance on data collection and data collection tools. Pharmacists were asked to collect data over a one month period. This involved recording information on returned medicines, appliances, devices and other items, including wherever possible the reason for the return.

Findings were passed on to the research team for input and analysis. In the majority of cases, pharmacies returned their data in hard copy, using the templates provided by the research team. In a small number of cases, data were captured electronically, also using tools provided by the research team.

Data analysis

The details of medicines returned to pharmacies were collated and analysed at individual PCT level and at an aggregate level for all participating pharmacies. Individual reports were provided to the participating Primary Care Trusts. Aggregated analysis was conducted on the total sample and is presented here.

Findings

A total of 114 pharmacies from 5 primary care trusts were included in the analysis. The number from each PCT is reported in Table 3.13.

Table 3.13:
Characteristics of pharmacies included in the audit

PCT identifier	Characteristics	SHA location	Number of pharmacies included
PCT 1	Urban	London	51
PCT 2	Rural	North-West	16
PCT 3	Urban	North-West	16
PCT 4	Rural	West Midlands	7
PCT 5	Urban/Rural	Yorkshire and Humber	24

All pharmacies provided information on medicines and appliances returned over a one month period. In total, 8626 items were reported as returned. An outline summary by PCT is reported below.

Table 3.14:
Mean number of items returned per pharmacy

PCT identifier	Mean number of items returned per pharmacy/month*
PCT 1	61
PCT 2	57
PCT 3	69
PCT 4	143
PCT 5	91
Total	76

*Rounded to nearest whole number

The mean number of items returned per pharmacy per month varied from 57 to 143. The higher number is explained by a significant volume of returns to a single pharmacy (395 in a single month). Once this outlier is removed, then there is no obvious trend for more items being returned to pharmacies in predominantly rural areas compared to urban areas.

For almost 7,500 of the returned items it was possible to identify what the items were and code them for analysis. In the case of approximately 1200 items this was not possible. A summary of the items

returned, coded by BNF chapter, is presented in Table 3.15.

Table 3.15:
Items returned to community pharmacies participating in the audit

BNF Chapter	Frequency	Percent	Percent (exc missing data)
GI System	828	9.60%	11.18%
Cardiovascular system	1950	22.61%	26.33%
Respiratory system	528	6.12%	7.13%
Central nervous system	1907	22.11%	25.75%
Infections	444	5.15%	6.00%
Endocrine system	518	6.01%	7.00%
Obstetrics, gynaecology, urinary tract infections	107	1.24%	1.44%
Malignant disease and immuno-suppression	53	0.61%	0.72%
Nutrition/Blood	249	2.89%	3.36%
Musculoskeletal, joint disease	364	4.22%	4.92%
Eye	129	1.50%	1.74%
Ear, nose, oropharynx	68	0.79%	0.92%
Skin	192	2.23%	2.59%
Anaesthesia	9	0.10%	0.12%
Borderline substances	25	0.29%	0.34%
Wound management	34	0.39%	0.46%
Total	7405	85.85%	100.00%
Missing	1221	14.15%	
Total (inc missing)	8626	100.00%	

Pharmacists were asked to code the reason for the medicine being returned. A list of possibilities was supplied to facilitate this, although pharmacies were free to provide additional information. Coding was based on guidance provided by the Royal Pharmaceutical Society of Great Britain.⁹ A summary of the main reasons for returns is provided below.

Table 3.16:
Reasons for waste being returned to pharmacies

Reason for return	Frequency	Percent
Death (D)	2247	26.50%
Compliance (C)	412	4.78%
Inequivalence (I)	91	1.05%
Drug Stopped (S)	2223	25.77%
Unknown (U)	1793	20.79%
Other (O)/Missing	1860	21.56%

Inequivalence refers to different items on the same prescription being prescribed for differing periods of time. The result is that patients do not need to re-order all medicines on each prescription (for example, where a prescription includes medicines prescribed on both a two-weekly and a monthly basis, the monthly medicine does not need to be prescribed on each occasion). However, in some cases this is not fully understood, so that patients build up a stock-pile of unnecessary medicines. The other reasons for returns are death, compliance resulting in unused medicines and stopping taking the drug, either due to professional guidance or cessation of symptoms. It should be noted that there may be some uncertainty as to how to record returned items using these definitions. For example, large volumes of medicines are often returned when an individual dies. Whilst the cause of these returns is expected to be coded as death, these medicines have been stockpiled presumably because of inequivalence (resulting in over-prescribing) or poor compliance (resulting in unused medicines). As such, there is some degree of interpretation required.

The main reported reasons for waste being returned were as a result of death or due to the drug being stopped. Together, these are the 'cause' of over 50% of all medicine returns. Inequivalence and (non) compliance are, by contrast, relatively infrequent reported causes of returns. The low level of inequivalence, as defined above, is an encouraging result, suggesting that where prescriptions include multiple items, checks are being put in place to determine whether these are dispensed on each occasion. However, in over 40% of cases the reason for the medicine being returned was either unknown or missing from the record.

3.4 Discussion

The findings of the public survey, coupled with the audit of medicines returned to community pharmacies, provide an insight into the scale of unused prescription medicines in the community. A summary of some of the key issues identified, along with an interpretation of our core findings, is reported below.

⁹ Further details available at http://www.rpsgb.org.uk/pdfs/drug_was.pdf.

Estimating the scale of waste medicines

Our data may be taken to indicate is that there is not a systemic problem of NHS supplied prescription medicines being wilfully unused and retained by individuals. Such cases do, of course, occur. Yet the majority of respondents claimed to have no waste prescribed medicines, despite being prompted to check prior to interview. Of those who reported having unused medicines (circa 20%), the median number of medicines was 1, although approaching 10 per cent of respondents had 2 or more unused prescription medicines in their home. Based on this evidence, there does not appear to be a widespread problem of stock-piling of medicines by individuals.

Attempts were made to 'scale' the findings of the survey to the English population, in order to allow for comparisons with earlier studies. The survey findings were subsequently transformed, by taking estimates of waste stratified by age, sex and ethnicity and applying these to census data from the Office of National Statistics.

We estimate that just over 20 per cent of individuals living in private dwellings in England have waste medicines in their homes, according to our definition. This was, as previously described, broader than that adopted by the OPCS in its face-to-face 1994/5 study. The latter estimated that just over 11 per cent of households in England contained residual medicines. This is equivalent to our finding of one individual in five having a waste medicine, given that over half the items identified in our study might at some point in the future be re-used (see Table 10 above).¹⁰

In the current study, we adopted a telephone survey based methodology. This may have resulted in some under-reporting of the volume of waste if, for example, participants considered admitting to not using prescribed drugs to be a negative reflection on their behaviour, or those with unusually high numbers of waste medicines were for whatever reason excluded. However, any such bias is likely to have been more than counterbalanced by our relatively wide definition of waste. Our findings therefore indicate that there has not been any significant worsening of the problem of NHS medicines wastage

¹⁰ Calculating a precise figure for the number of waste items retained per household is complicated by variables such as the extent to which older individuals taking multiple medicines are more likely to live alone or in two person households than are younger adults and children. However, whereas Woolf (1995) found approximately 0.1 of a waste item per average household member, our data indicate a figure of 0.3. Due to differences in the definition of waste, we recommend that the latter should be adjusted to reflect the proportion of medicines that were intended for future use (64 per cent) (see page 12 of *Residual Medicines*), making it almost identical with the OPCS waste volume per capita estimate

in the 15 years since the publication of Woolf's OPCS study. Indeed, both the absolute and relative volumes of prescribed NHS medicines wastage may have decreased during this period.

We also found via our community pharmacy audit that the number of items returned per pharmacy per month averages around 76. National prescribing data show that in 2009 there were around 75 million items prescribed in primary care each month. On the basis that there are just over 10,000 pharmacies in England, this equates to around one returned item for every 100 items prescribed. Clearly, the evidence from the National Survey reported above indicates that the remaining 99 items are not always used in compliance with prescriber intentions. However, a 1 per cent pharmacy return rate offers a degree assurance that medicines are, in the majority of instances, being used appropriately.

We explored attitudes to disposal and identified that while there was a high degree of reported awareness that unused medicines should be returned to a pharmacist or other healthcare professional (c75%), only a minority of individuals surveyed said that they actually did this (c40%). In around 20 per cent of cases individuals stated that they would typically throw away any unused medicines through household waste. This might suggest that the actual volume of waste in the community is greater than that indicated in this Report. However, we caution against adjusting the figures presented herein to account for this on the basis that it could lead to double-counting.

Previous studies of a similar nature have found varying rates of returns. Hawksworth *et al.* (1996) found 1,091 items were returned to 30 pharmacies over a one month period. This equates to a rate of return approximately half of that reported here. Grant (2001) reported 3,099 items returned to a single pharmacy over a 36 month period, which generates an estimate of the total number of prescription items returned per month similar to the current research (86 vs 76). Mackridge *et al.* (2007) reported that 3765 items were returned to 91 pharmacies and GP practices over a two month period, equating to approximately 20 items per pharmacy/GP practice per month.

The differences between findings like these may to a degree reflect regional variations in prescribing and dispensing patterns coupled with other factors, such as whether or not in some instances studies were designed to evaluate interventions aimed at increasing return rates. It should be emphasised that high rates of return are not necessarily an indication of poor prescribing and dispensing practices. As with the DUMP campaigns referred to elsewhere in this report, relatively high rates of return may simply be indicative of higher than average (or a temporally increased) awareness of the undesirability of disposing of unwanted drugs via other routes.

Characteristics of waste medicines

The most frequently reported returned medicines in our National Survey were for gastro-intestinal disorders, skin disorders and pain. In many instances, these appeared to be medicines that had been prescribed for short-term or intermittent disorders. This is consistent with participants reporting that they had ceased taking their medicines due to the disappearance of symptoms.

In this context there are both similarities with and differences from the findings of the OPCS's 1995 report. Skin, GI and CNS medicines were all frequently reported as residual in this last, mirroring the findings reported below. Similarly, previous studies reported in the literature review identify that drugs for these indications have commonly been reported elsewhere as partially or completely unused medicines. However, relatively low numbers of medicines for infections and ENT (ear, nose and throat) problems were reported in the current survey, as compared to the OPCS report. These changes could reflect changes in prescribing practices over time and/or changes in policy which have impacted on the volume of prescribing in these categories. Most notably, perhaps, there have been attempts to reduce unnecessary antibiotic prescribing.

In over 75 per cent of cases where unused medicines were reported, respondents said that a half or more of the latter remained unused, although it should be acknowledged that some PRN medicines will have been included in this figure. This is a higher figure than reported by the OPCS report (c 60%). Some 18 per cent of the waste medicines reported in our survey were said to be completely unused. Cross tabulations identified that of the 86 medicines included in this category, 42 were being kept with the intention of their being used in the future. The majority of these were in BNF Chapters 4 (CNS, which includes some pain medications) and 5 (infections). Therefore, while almost a fifth of the waste medicines identified were reported as being completely unused, only half of these were said to be completely unused with no intention of future use.

Over 40 per cent of the waste medicines that respondents identified were dispensed via a repeat prescription. This is to a degree encouraging, in that overall in excess of 70 per cent of all NHS prescription items are supplied on a repeat basis. However, the possibility that some prescriptions may be filled repeatedly and left unused (or partially used) warrants investigation (see also Section 7). Although the number of cases is likely to be relatively small, inadequately managed repeat dispensing can lead to stock piling. This may only become apparent when isolated and poorly supported patients die, have a medical crisis, or are admitted to a care home.

In contrast to the above findings relating to medicines in the home, the medicines most frequently returned to pharmacies were for cardiovascular disease and

CNS conditions. Whilst patient death was frequently reported as the reason for returns, this 'cause' accounted for only a quarter of all returns.

The differences in the types of waste medicines identified in the National Survey and the pharmacy audit raise questions about why individuals may perceive that it is safe and/or desirable to retain certain drugs, whilst thinking that others should be returned to pharmacies. It was impossible to explore in any depth attitudes towards different medicines via this quantitative research. But our findings overall suggest that significant attitudinal variations exist, which warrant further exploration.

Reasons for waste

As noted above, the most commonly identified reason for medicines wastage identified in the National Survey was the disappearance of symptoms. In total this 'cause' accounted for over 40 per cent of reported cases, although it was responsible for as much as 80 per cent of waste in some contexts. Cessation of symptoms is frequently a sign that treatment has been successful, and is no longer necessary. However, having residual medicines may be taken to imply that the volume prescribed was too large, or that the patient failed to adhere to the full course of therapy.

The latter can in some contexts result in avoidable harm. But this is by no means always the case. It is also important to note that recovery times from, for example, painful injuries are often difficult to predict, and that in such circumstances providing longer rather than shorter 'once off' treatment courses can be the most cost effective option. Hence unqualified generalisations relating to these data should be avoided.

With regard to the occurrence of unexpected side effects, this too is by definition largely unpredictable. Hence the waste associated with this cause can reasonably be considered to be unavoidable, where it occurs due to factors other than known intolerances or contra-indicated interactions between medications.

Of the drugs returned to community pharmacies, the most common reasons were patient death and the drug being stopped, although this may also capture a degree of voluntary stopping – i.e. intentional non-compliance. Analysis by BNF category (that is, drug class) showed in some cases a systematic relationship between the reported reason for waste and the intended therapeutic effect. For example, over 60 per cent of strong analgesic and approaching 80 per cent of wound dressing returns were reportedly as a result of patient death. This is to a degree to be expected, in that when patients are in receipt of end of life care they may be prescribed significant volumes of medicines such as pain relief to be used on an as needed basis. This apparent over-supply is largely unavoidable, although possible ways

or reducing the material waste involved are discussed in later Sections.

Similarly, wound management products are often prescribed in large quantities to patients for use on an as needed basis, although in this instance better supply management may be more easily achieved. Patients with chronic wounds are subject to regular healthcare professional visits which could include monitoring supplies to prevent stockpiling.

By contrast, drugs for infections and musculo-skeletal disorders were most frequently returned to pharmacies due to the drug being stopped by the doctor or patient. In many cases, these medicines are prescribed to manage intermittent symptoms (like back pain) or short-term infections. These findings broadly correlate with previous research. For instance, the study by Mackridge *et al.* (2007) identified death as being the cause of 35 per cent of all medicine returns. These authors found 'clear outs of old or expired medicines' as being responsible for an additional 28 per cent of returns and prescription changes as the cause of a further 17 per cent. In line with the findings presented here, adverse reactions were reportedly responsible for a relatively small number of returns, albeit that they may also be involved in other categories.

Estimating the avoidable element of waste

It is of course important to consider the degree to which prescribed medicine wastage is avoidable through appropriate interventions. This issue is more fully addressed later in this document, but in relation to the data presented here it is of note that in approaching a fifth of all instances respondents indicated that they had chosen not to take their medication. This was either because they did not want to, did not feel that the medicine had any effect, had found it difficult to take, or had decided to use their medicine on an as needed basis. Perhaps not surprisingly, only a small proportion of responses indicated unintentional non-compliance, with just one per cent of respondents saying that they had forgotten to finish their medicine.

System factors can be argued to account for around a further 18% of cases who reported waste medicines as a result of changes in medication from their GP/consultant or over prescribing/dispensing. Combined, these factors account for around 37% of the waste reported in the survey. Waste as a result of disappearance of symptoms could, in some cases, also be as a result of over prescribing or intentional non-compliance and could so increase this figure even further.

Based on such assumptions we estimate that the level of waste that could realistically be considered to be avoidable is likely to be less than 50 per cent of the total identified in this Report. However, it is

acknowledged that this is an interpretation of the findings and is subject to some uncertainty.

Further consideration needs to be given to the degree to which avoidable waste can be reduced in a cost effective manner. Many of the drugs identified were of relatively modest cost (see Section 4). In many instances failing to use them is also unlikely to result in a lasting detrimental effect on patient health. For example, medications such as penicillin and co-codamol are given for the management of short-term infections or pain. Depending on the precise circumstances, the financial and therapeutic losses resulting from failures to take such drugs as recommended are unlikely to justify intensive interventions to monitor and/or enhance usage.

However, there were other cases where such interventions might be justified. Responses identified a number of individuals with asthma inhalers, branded anti-epileptics and cardiovascular drugs (e.g. warfarin, plavix, rosuvastatin) all of which have a greater acquisition cost and may be associated with greater therapeutic losses when patients fail to follow prescribing advice. In these instances, it may be cost effective to put in place interventions to improve compliance, monitor usage and where necessary change prescribing. This is explored in more detail in Section 6.

The pharmacy audit offers similar insights into the degree to which medicines returned to pharmacies are avoidable. Returns due to death can be regarded as largely unavoidable, even if in some instance amassing stocks of medicines prior to death is an indication of over-prescribing. Returns due to stopping therapy, either due to patient preference or due to professional guidance, inequivalence and compliance could be argued to represent avoidable waste, which together account for almost a third of the known reasons for returns. Also, the reason for a significant number of returns was unknown. Assuming that at least some of these can be attributed to 'avoidable' categories, then the overall level of avoidable waste in pharmacy returns might approach 50 per cent.

In contrast with the public survey, many of the drugs returned to pharmacies were for chronic conditions (cardiovascular disease, central nervous system) and were relatively costly (see Section 4). On this basis, a larger proportion of the waste found in this context may warrant interventions to promote appropriate use, and be cost effectively avoidable.

3.5 Limitations of this research

It is appropriate to point out the limitations of both the National Survey and the pharmacy audit reported this Section. The national survey relied on self-reporting. This may lead to some under-reporting, and also some inaccuracies. For instance, these could have

occurred in coding the responses although every effort was made to ensure that participants provided an accurate description, including a spelling, where there was any uncertainty about the medicines that they identified.

The degree to which the findings are generalisable to the overall population also needs to be considered. Participants in the research were selected from existing market research databases. Whilst robust attempts were made to select a cross-section of the population, there was inevitably a degree of selection bias. On the basis that participants were able to volunteer to participate or not, it might be assumed that our sample included relatively high numbers of individuals with an above average interest in the subject and who might be comparatively careful medicines users. Also, to the extent that medicine wastage is linked to phenomena such as individuals' having multiple morbidities and/or complex and challenging conditions (e.g. mental health problems) then such subjects were unlikely to be fully represented in the current study. On this basis, it is probably fair to say that our findings on the scale of waste in individuals' homes may err on the conservative side.

As discussed earlier in this Section, it was not possible within the current survey to identify the volume of medicines discarded through household waste. A significant number of respondents reported that they typically dispose of medicines by flushing them down their lavatory or sink, or throwing them into the bin. The scale of this problem has not been fully addressed in the current research, although we would caution against inflating the figures presented herein to take this into account on the basis that it may lead to double-counting.

The degree to which the findings are directly comparable with earlier estimates, in particular Woolf's 1994/95 OPCS study, needs to be considered carefully. Throughout the reporting of our findings we have acknowledged that the differing study designs and definitions of waste adopted mean that the findings are not directly comparable. However, we believe that the evidence generated

is sufficiently robust to confirm that the scale of the problem has not significantly increased in the last fifteen years, and that it is now being better managed than in the past.

Similarly, the pharmacy audit cannot claim to offer a definitively representative insight into national practice, given the fact that it included only 1 per cent of pharmacies in England and that there are variations in prescribing and dispensing practices across the country. Whilst the number of community pharmacies included in our sample is believed to be larger than in any previous study of this topic in England, they were drawn from only five areas. Attempts were made to ensure appropriate diversity, but some degree of caution needs to be taken in generalising the findings presented.

3.6 Summary

The National Survey and community pharmacy audit reported here provide data on the extent to which prescribed medicines dispensed via the NHS are being wasted, and the reasons for this. Overall, our findings do not indicate that there is a widespread intentional waste. The national survey findings suggest that around 20 per cent of individuals have one or more unused medicines in their possession that are not presently being taken, although in over half of these instances respondents indicated that the drugs involved might at some future come into use again. The pharmacy audit found that on average community pharmacies receive around 75 returned items per month. Assuming that this finding can be generalised, this means that nationally around 1 in every 100 dispensed items is eventually returned to a pharmacy or dispensing practice unused, or only partially used.

Looking at the totality of the data generated, we predict that in the order of 50 per cent of the waste identified across both settings is likely to be avoidable, although a rather smaller proportion is estimated to be cost effectively avoidable.

4 Estimating the Cost of Waste Medicines in the National Health Service

4.1 Background

A number of previous studies have attempted to estimate the cost of waste medicines at a regional and a national level. At a national level, the figure of £100 million per year is widely quoted (National Audit Office, 2007) although this is widely regarded as a conservative estimate. Local audits of waste medicines returned to pharmacies have generated estimates which in some cases have been inflated to national levels. For example, Mackridge *et al.* (2007) estimate that the value of medicines returned to pharmacies could be in the region of £75 million per year, although this takes no account of the value of medicines which are not returned to pharmacies. There remains considerable uncertainty about the cost of medicines which are wasted in community settings.

The previous Section summarises research which attempted to determine the scale of waste medicines in the community. This one attempts to build on that evidence by estimating the cost to the NHS associated with these waste medicines.

Details of the methods and findings are reported below.

4.2 Public survey

Methods

Information on the types of medicines reported as unused in individual interviews was collated and analysed. List prices for each medicine were derived primarily from the Drug Tariff available at the time of the analysis (December 2008). Where products were not listed in the Drug Tariff, list prices were derived from the British National Formulary.

Medicines and appliances were costed according to the information provided by survey participants. However, in some cases, responses included missing data relating to:

- ▶ drug name (a small number of responses simply provided a class name, such as a statin with no information on whether it was branded or generic);

- ▶ drug dose; and
- ▶ pack size.

Methods were used to impute values to correct for missing data wherever possible. Where there was uncertainty about the formulation, dose or pack size, a weighted average cost of all medicines in the class was derived based on the proportion of each medicine prescribed in the class and the relative pack price, as derived from the Prescription Cost Analysis prepared by the NHS Information Centre. Unless otherwise stated in their response, we have assumed that individuals had a single pack of the medicine identified in the survey. It could be argued that this may over-state the cost of the waste medicines identified as the survey indicated that in almost 80 per cent of cases respondents reported having used a quarter or more of their medicines. However, the corollary to this is that some individuals may have had multiple packs of medicines and/or may have under-reported their waste. On this basis, we believe that this handling rule will provide a reasonable estimate of the value of the wasted medicines reported.

In a small number of responses, the information provided by participants was insufficient to allow for a cost to be derived. For example, the drug or appliance name and formulation were not listed in either the Drug Tariff or the British National Formulary. In these cases, the drugs reported had to be excluded from the analysis. In all other cases, it was possible to estimate the cost of each medicine reported as well as aggregated costs for all responses.

Findings

In total, 403 of the 466 items identified in the public survey were able to be costed using the methods described above. Costs were identified at the level of an individual item and then aggregated to BNF chapter. The cost of waste medicines reported in the public survey is presented in the Table 4.1.

Table 4.1:

Cost of waste medicines identified in the public survey reported by BNF chapter (note, figures rounded to two decimal places, rounding errors may occur throughout)

BNF Chapter	N	Mean £	Sum £
1	45	6.78	305.16
2	52	6.51	338.28
3	33	8.11	267.7
4	107	6.00	641.47
5	33	4.92	162.5
6	18	6.95	125.07
7	5	20.82	104.11
8	1	10.29	10.29
9	6	9.48	56.86
10	47	4.86	228.25
11	7	2.46	17.23
12	6	6.11	36.68
13	39	4.54	177.23
99	1	3.09	3.09
Other	3		
Total	403	5.33	2473.92

The total cost of all medicines reported as unused in the public survey is estimated to be £2,474. The mean cost of items identified and costed in the survey was £5.33.

The cost according to BNF chapter is largely influenced by the volume of drugs returned in each chapter. The greatest contributors to the reported cost are medications for CNS, CVS, GI and musculoskeletal diseases which are also the most frequently reported waste medicines. However, there are some chapters which are associated with relatively low volumes but relatively high cost unused medicines resulting in a disproportionate contribution to the overall cost. When ranked by the mean cost per chapter medicines for obstetrics, malignant disease, nutrition and respiratory disease were the most expensive items identified.

The cost of medicines identified in the analysis was summarised by cost bands and is reported in the table below. The majority of medicines identified were relatively inexpensive, with a unit cost below £10 per pack. Relatively few expensive medications with a cost in excess of £50 per pack were identified in the survey.

Table 4.2:

Frequency of waste medicines identified stratified by cost

Cost of medicine	Frequency	Percent
£0 < £10	340	72.96%
£10 < £25	44	9.44%
£25 < £50	16	3.43%
£50 < £100	2	0.43%
£100+	1	0.21%
Total	403	86.48%
Missing	63	13.52%
Total	466	100.00%

Costs according to age group are reported in the following table. The 65-74 age groups contributed the highest proportion of the total cost of unused medicines reported. However, this age group also contributed the greatest volume of responses to the survey due to the sampling framework adopted. Those aged 18-24 and 45-54 were associated with the most expensive medicines identified in the survey.

Table 4.3:

Costs of unused medicines reported in the public survey by age group

	Mean cost per item £	Count	Sum £
Under 18	2.78	32	55.69
18-24	7.24	11	50.68
25-34	6.55	17	78.66
35-44	7.06	34	197.68
45-54	7.57	41	272.38
55-64	6.90	57	351.71
65-74	5.82	258	1355.75
75+	7.16	16	114.50

* NB. Rounding errors may occur.

The mean cost of unused medicines per responder was estimated to be £1.88. The mean cost per responder reporting unused medicines was £9.34.

The cost of unused NHS medicines in the home in England

Attempts were made to scale up the cost of unused medicines reported by participants in the survey to the national level. To enhance accuracy, the sampling framework was stratified to maximise the representation of responders likely to be medicines users. The findings were scaled up to a national level by adjusting responders according to age, sex and ethnicity to reflect the English population.

The findings are presented in the table below, stratified by age, sex and ethnicity.

Table 4.4:
Extrapolated costs by age, ethnicity and gender (£1000s)

	Male		Female		Total
	White British	BME	White British	BME	
Children					£4,611
18-34	£5,839	£349	£6,582	£1,872	£14,642
35-54	£14,501	£438	£23,564	£1,876	£40,379
55-64	£11,129	£41	£1,583	£1,145	£13,898
65+	£4,612	£1,940	£9,755	£1,096	£17,403
Total	£36,081	£2,768	£41,484	£5,989	£90,933

The resultant data indicate that at any one time the total cost of unused medicines in English homes other than those providing institutional care is £91 million. However, it should in this context be noted that it was not possible to establish the volume of medicines which are thrown away via drains or household waste. Around 20 per cent of respondents said that this was their typical means of unused drug disposal.

This is relevant to the overall estimate of wastage costs given elsewhere in this report, albeit that the £91 million component figure presented here will include some medicines that will ultimately be discarded in this manner. In addition, our qualitative evidence indicates that the volume of each informal disposal is likely to be small relative to that of the typical pharmacy return. We estimate that the total value of prescribed NHS primary care medicines disposed of informally via household rubbish is under £50 million per annum.

4.3 Survey of community pharmacies

Methods

In addition to estimating the cost of unused medicines reported in the public survey, attempts were made to capture the costs of medicines returned to pharmacies. In all cases, participating pharmacies were responsible for ensuring that data on the drug (or appliance), brand name, formulation and amount returned were accurate. Clarification was sought on some items for example, where exceptionally large volumes were reported of very high costs drugs and in some cases corrections were made. However, for the most part, it was accepted that the pharmacies were providing accurate information.

Pharmacies from two of the participating PCTs provided data electronically. The remaining pharmacies provided data in hard copy which were subsequently entered into databases by the research team. Data entries were verified by a different member of the research team and double data entry was conducted on a sample of responses to check for accuracy.

Costs were applied to medicines and appliances returns reported by the pharmacies contributing to this work, in line with the methods described for the national survey. They were analysed at the pharmacy level, and average data were subsequently scaled up in order to derive the national estimate.

Findings

The total cost of medicines identified in the 114 pharmacies over a one month period was approximately £107,000 (see Table 4.5). The most costly individual items were treatments for malignant disease, borderline substances, wound management dressings and treatments for respiratory illness. Medication for CNS disease was the BNF chapter that contributed the most to the overall cost.

Table 4.5:
Costs of medicines returned in the community pharmacy audit

BNF chapter	Mean cost per item £	Number of items reported	Sum £
Gastro-intestinal system	6.33	772	4886
Cardiovascular system	8.27	1908	15777
Respiratory system	31.16	598	18633
Central nervous system	16.07	1966	31600
Infections	8.36	465	3888
Endocrine system	18.95	525	9950
Obstetrics, gynaecology, and urinary-tract disorders	20.28	138	2798
Malignant disease and immunosuppression	115.85	50	5793
Nutrition and blood	7.30	248	1810
Musculoskeletal and joint diseases	8.52	366	3118
Eye	19.91	175	3484
Ear, nose, and oropharynx	11.25	83	933
Skin	8.93	216	1930
Anaesthesia	7.81	11	86
Borderline Substances	35.89	27	969
Wound Management	32.93	30	988
Total	14.07	7578	106642

Based on the above findings, the mean cost of medicines returned per pharmacy was approximately £935 per month. The mean cost per item was £14.07, compared to £5.33 in the public survey. Items identified in the survey were put into bands, according to their unit cost (see table 4.6).

Table 4.6:
Frequency of waste medicines returned stratified by unit cost

Unit cost of item	Frequency	Percent
£0 < £10	6313	73.2
£10 < £25	949	11
£25 < £50	452	5.2
£50 < £100	223	2.6
£100+	188	2.2
Total	8125	94.2
Missing	501	5.8
Total	8626	100

In line with the findings of the public survey, the majority of items returned were of relatively low unit cost, as can be seen in the above table. However, the community audit identified 10% of medicines which were valued at more than £25, which is greater than the public survey.

Interpretation for the NHS

The findings from the sample of pharmacies included in the research were scaled up to provide an estimate of the implications for the NHS as a whole. Assuming that return patterns do not differ significantly over the course of a year, then the findings suggest that the average cost of medicines returned to a pharmacy over the course of one year will be in the region of £11,225 (that is £935 per pharmacy per month, as derived above). The number of pharmacy contracts in the United Kingdom is estimated to be approximately 10,000.¹¹ Based on this estimate, the total value of medicines returned to community pharmacies in a year is estimated to be approximately £112 million per year.

4.4 Discussion

The findings reported here mean that the cost of unused medicines in individuals' homes is approximately £91 million. This estimate is based on the findings of the national survey of waste medicines reported in Section 3. Unit costs were applied to medicines identified in the survey and the findings subsequently scaled up to a national level.

¹¹ NHS Information Centre states that there were 10,475 pharmacy contracts in March 2009.

In addition to this, the cost of medicines returned to pharmacies is estimated to be in the region of £112 million per year. This is derived by costing the items identified in the pharmacy survey reported above and scaling it up to a national level based on the number of pharmacies operating in England.

The figure should be considered in the context of previous studies of a similar nature. An audit of 33 pharmacies conducted in 1995 (Hawksworth), estimated the annual cost of medicines returned to pharmacies throughout England to be around £38 million. This is lower than the figure presented herein, even taking into account inflation. Mackridge *et al.* (2007) estimated that the value of medicines and appliances returned to pharmacies and GPs to be in the region of £75 million.

International comparisons are fraught with difficulties due to differences in populations, prescribing practices and currency fluctuations. However, the estimates generated in this research are of a similar magnitude to those produced by studies of a similar nature in Sweden (Ekedahl *et al.* 2003), Canada (Boivin 1997) and Spain (Coma *et al.* 2008) and significantly below estimates from Germany (Bronder and Klimpel 2001).

Based on this, we estimate the total cost of waste medicines (as defined for the purposes of this study) in primary and community care settings to be approximately £200 million, excluding that incurred in care homes and without making allowance for possibilities such as sampling bias or the informal disposal of unused medicines via undifferentiated household waste.

4.5 Limitations of the research

It is important to acknowledge the limitations of the research methods and ensure that the figures presented here are communicated with appropriate caveats. With regard to the costs of medicines in individual's homes, there were a number of limitations in the analysis undertaken, mainly as a result of missing data or a lack of detail in the responses to the survey. Where this was the case, handling rules, described above, were adopted. These were deemed to be an appropriate way of correcting for missing data although it is acknowledged that they cannot correct for the complexities that characterise the pricing and reimbursement of pharmaceuticals and appliances in practice.

For example, it was not possible to consider whether pharmaceuticals were dispensed in broken bulk form, or whether there was any form of brand equalisation in the reimbursement of the medicine at the time it was supplied. Given that we were reliant on information provided by the survey respondent, it was not possible to access these details during telephone

interviews. Similarly, no attempts were made to correct list prices to take into account any discounts or other mechanisms that operate nationally or locally to adjust list prices or the prescribing and dispensing costs that may be associated with the item. The approach to costing considers the list prices of the medications and appliances reported in the survey and as such is in line with previous studies (Mackridge *et al.* 2007).

A more fundamental issue is whether the sample of participants included in the survey form a suitable basis for generating national estimates. This has been discussed in the previous Section.

In considering the costs derived from the pharmacy audit, there was some significant variation in the number of items returned to pharmacies in the community pharmacy audit. Whilst attempts were made to recruit pharmacies from a number of Strategic Health Authority regions with differing characteristics, the sample of 114 pharmacies remains relatively small in the context of the total number of pharmacies in England (approximately 1%). As such, it is difficult to determine whether the findings from this sample are truly generalisable to all pharmacy practitioners in England and the degree to which returns in a single month are representative of activities over the course of the year. However, this is believed to be the largest audit of its kind to date and adds to existing literature on this topic.

4.6 Summary

From a policy perspective, interest will undoubtedly focus on the cost of waste that is potentially avoidable. As discussed in the previous Section, the findings of the public survey suggest that up to 50 per cent of waste identified in individual's homes is likely to be avoidable (c£45 million), although only a proportion of this is likely to be avoidable in a cost effective manner. This is highlighted by the relatively low average cost of the medicines identified in this survey.

The findings of the community pharmacy audit suggest that between 50-70 per cent of medicines returned might be considered to be avoidable (between £56-78 million per year). These medicines had a higher unit cost than those identified in the public survey and, as such, there may be a stronger economic case for intervention.

Based on these figures we estimate that £100-£150 million of the waste identified in this section is likely to be avoidable. This represents just under £1 million for the average PCT.

However, consideration should be given to the proportion of avoidable waste that can be addressed in a cost effective manner that is, those drugs where the financial and therapeutic savings would outweigh the costs of any intervention. The findings above indicate that many of the drugs identified in the survey and the audit are relatively inexpensive. The public survey identified just under 15 per cent of unused medicines with a unit cost in excess of £10, whilst in the community pharmacy audit around 20 per cent of returns were in this price range. The vast majority of medicines identified in both parts of the research had a unit cost less than £10.

Interventions may be better targeted to higher cost drug wastage, at least in the first instance. However, the lower cost medicines should not be ignored. In many cases these are medicines used in very high volumes so their total cost to the NHS may be significant and there may be large therapeutic losses associated with them. In such cases, there may be a case for less intensive, high-level interventions aimed at raising awareness of the importance of compliance with common medications for chronic conditions where the per patient cost of the intervention is relatively modest.

However, the cost effectiveness of such interventions needs to be explored. Overall we estimate that any further effort to reduce NHS primary and community medicines waste is unlikely to produce net savings of more than £0.5 million per average PCT.

At a national level much has already been done to ensure that medicines are used appropriately. Any attempts to promote improved medicines usage need to acknowledge this, and recognise that the remaining waste in the system may be unusually hard to address. As such, there may be diminishing returns associated with significant further investment in interventions to further reduce NHS primary and community care pharmaceutical waste. But this takes no account of the therapeutic losses which are associated with waste, which are explored in the following Section.

5 The Economic Impact of Poor Compliance

5.1 Background

The public survey and community pharmacy audit were both intended to provide some insights into the scale of waste medicines in primary and community care settings. These were conducted to generate estimates of the volume of waste medicines and the associated cost.

However, it was recognised at the outset of the project that the acquisition costs associated with wasted medicines are probably insignificant in comparison with the lost therapeutic benefit that might result from inappropriate use of medicines. Whilst waste medicines resulting from poor compliance represent a discrete component of waste, as defined in our research, their impact on patient health and the use of healthcare resources in the longer term are important and believed to be significant. (See Hughes 2002 and Urquhart 1996 for a fuller discussion of the issue). Previous attempts have been made to quantify the impact of poor compliance in particular indications or particular patient groups, such as hypertensives (Rizzo 1997) and people with schizophrenia (Thieda 2003). However, the studies are few in number, heterogeneous and largely from non-UK settings, meaning that further research is warranted (Horne 2005).

In order to provide a rounded picture of the economic impact of waste medicines in the NHS, it was felt to be necessary to explore the value of health benefits foregone as a result of poor-compliance. This stage of the research considers a number of case studies (mainly long-term conditions) and the impact of non-compliance with medication on patient outcomes. The case studies attempt to identify whether non-compliance has a material impact on patient health in the short-term, capturing any effect in the form of quality adjusted life years (QALYs). Monetary values are then attributed to the health effects to provide an estimate of the financial implications of non-compliance.

This part of the research is an adjunct to the investigations of waste medicines. It considers one specific cause of waste, namely non-compliance. However, the interest is not in the degree to which non-compliance results in waste medicines but rather the degree to which non-compliance results in foregone therapeutic benefits and the value of these benefits. As such, the findings presented below

should be considered to provide further context to the debate about the costs of waste medicines but the costs should be considered to be separate from the analyses presented in Sections 3 and 4.

5.2 Methods

A total of 6 case studies were developed to explore how to capture the costs and benefits of non-compliance. Selection of case studies was largely pragmatic based on a rapid review of the available literature on each indication to determine whether the development of a simple economic model would be feasible.

Based on these considerations, the following case studies were selected for evaluation:

- ▶ asthma;
- ▶ type 2 diabetes;
- ▶ high cholesterol/coronary heart disease;
- ▶ statins for primary prevention and secondary prevention;
- ▶ hypertension; and
- ▶ schizophrenia.

These are believed to provide a cross-section of long-term conditions, many of which are high priorities for the NHS (e.g. diabetes, hypertension and high-cholesterol) whilst others are recognised as being associated with significant non-compliance (e.g. schizophrenia).

Development of the economic models

For each of the case studies an economic model was developed that was intended to reflect a simplified representation of the treatment pathways and resulting patient outcomes. Due to the resources available for this stage of the research, some degree of simplification was inevitable and a decision was made to consider only major and easily quantifiable events associated with the condition, for example, hospitalisations or deaths. In all cases, simple deterministic, decision analytic approaches were applied to the case studies.

It is acknowledged that in some cases, patient level models may be more applicable to the decision

problem, as they can take into account changes in variables over time and the interaction between events associated with a condition. This is particularly important when considering the issue of persistence with medication over time and the risk of events which are associated with age, co-morbidities or other variables. However, given the resources available it was only possible to undertake rapid assessments of each case study. In light of this, the findings presented should be considered with caution and illustrative to some extent. It is hoped that the approach developed in this report can be further developed to undertake more rigorous analyses to provide accurate estimates of the impact of non-compliance on outcomes.

Event rates

For each case study, data were identified, typically from trial settings, which reported event rates for patients with the given condition. Event rates from trials were assumed to apply to a 'compliant' population, given that patients are assumed to be more compliant when tightly monitored in trial settings than in practice.

Further data were then identified to estimate the impact of partial compliance on event rates. Data were typically presented in the form of relative risks comparing event rates in partially compliant populations to those of a compliant population.

It was not possible to undertake a systematic approach to identifying evidence on event rates within the remit of this research. As such, event rates were derived from known, large, pivotal trials in a particular condition. Additional data were derived purposively to populate the models, with a preference for UK specific data wherever possible.

Measurement of compliance

In most cases compliance was measured with the medication possession ratio (MPR) that is defined by the number of days of treatment dispensed divided by the number of days between prescription refills (excluding the last prescription). Patients were stratified into categories based on their compliance scores (%).

In general, the following classification was used in the analyses:

- ▶ compliant refers to compliance of 80% or more;
- ▶ partially compliant refers to compliance of 50-80%; and
- ▶ non-compliant refers to compliance of 50% or less.

These three categories were used in the hypertension and cholesterol models where it was assumed that patients could be less than 50% compliant with medications without developing acute, life-threatening events. For asthma, diabetes and schizophrenia

only two categories were considered (compliant and partially compliant), since in these cases the notion of non-compliance was deemed to be medically unfeasible as it would result in health states that are unsustainable and possibly life-threatening (e.g. hyperglycaemia, acute asthmatic events).

The compliance rate for each treatment was assumed to be the independent of gender and age. It was also assumed that the compliance rate stays stable over time. Both of these are recognised as simplifying assumptions.

Costs

For each event considered in the models, a cost was derived from the literature or other widely used sources of cost data (e.g. NHS Reference Costs or Unit Costs of Personal and Social Services from www.pssru.ac.uk).

Average treatment costs were derived using unit costs derived from the Drug Tariff or British National Formulary. Where there were multiple possible treatment options, the treatment cost was based on the most widely used intervention, as determined through expert opinion.

Patient outcomes

Quality of life data, in the form of utility values, for patients who experience each event were also derived from published literature. The compliance level, per se, was not assumed to affect quality of life. However, poor compliance is assumed to be associated with higher event rates which, in turn, impact on quality of life.

Time horizon

The models consider the costs and events occurring over a one year period. No effort was made to extrapolate beyond this time period. This was mainly due to concerns about the quality of the long-term evidence on the relationships between compliance. In addition to this, simple decision analysis is unlikely to be an appropriate solution to the longer-term problem.

Perspective

The models are based on a NHS perspective that is they take no account of indirect costs which might be associated with partial compliance.

Findings

Summary findings for each of the case studies are presented in the tables overleaf. The tables are intended to provide the key findings at a patient

level, summarising the expected annual treatment costs according to whether a patient is compliant or partially compliant along with the expected annual QALYs accrued. Estimates of the net benefit associated with being compliant are also presented. The net benefit figure is an estimate of the total monetary benefit associated with being compliant and is calculated by summing any savings in treatment costs with the monetary value of any QALY gains. Costs and benefits at a national level are also derived, by applying estimates of the prevalence of each condition to the patient level outputs.

For the purposes of this analysis, QALYs are valued at £20,000, which is towards the more conservative end of the range accepted by the National Institute for Health and Clinical Excellence (NICE). As such, the net benefit estimates should be regarded as conservative. The net benefit figure is thought to be particularly useful as this gives an indication of how much could be spent per patient to improve compliance. Interventions to improve compliance are justified where they do not exceed the net benefit.

5.3 Asthma findings

Development of the economic model

A decision analytic model was developed to illustrate a simplified version of the treatment pathway and potential outcomes associated with asthma treatment. The model considers a cohort of individuals presenting for treatment with asthma. Individuals are categorised as:

- ▶ compliant with treatment, defined as taking 80-100% of the prescribed dose of treatment; and
- ▶ partially compliant with treatment, defined as taking less than 80% of their prescribed dose.

No attempt was made to include a non-compliant arm in the model, for reasons outlined above.

The outcomes associated with treatment include:

- ▶ uncontrolled asthma resulting in a severe exacerbation of symptoms that requires an emergency hospital admission;
- ▶ uncontrolled asthma resulting in a moderate exacerbation of symptoms requiring an additional GP visit; and
- ▶ controlled asthma.

The probability of experiencing an outcome is determined by the degree to which the individual is compliant with their medication.

Event Rates

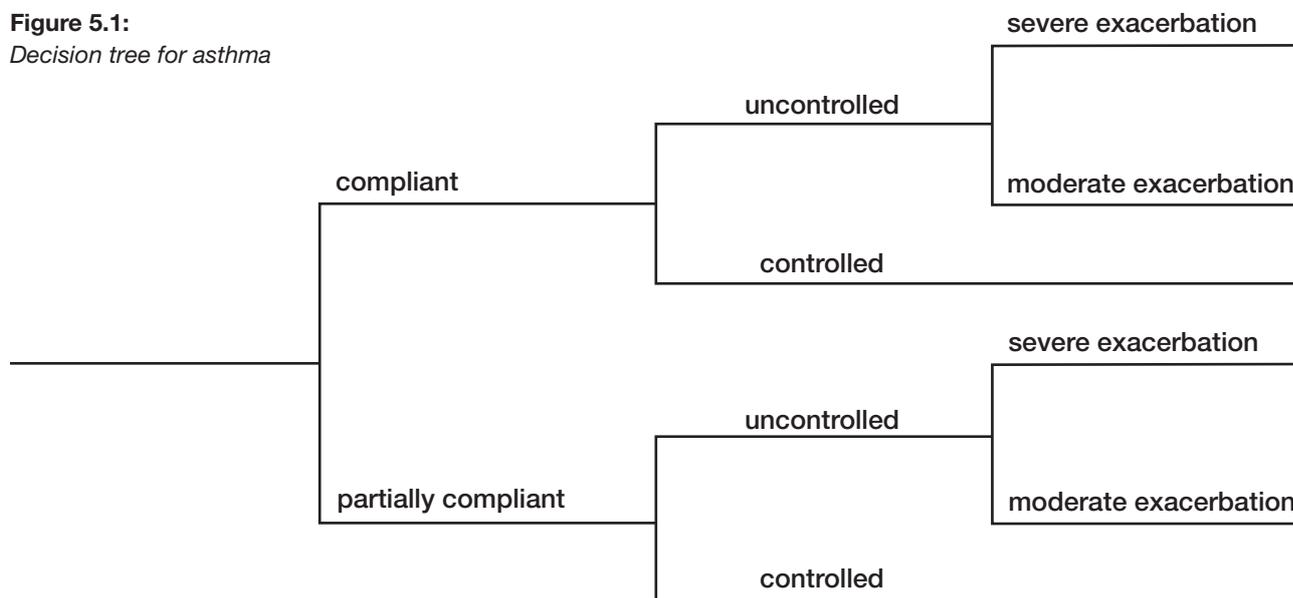
Gillissen (2004) reports that 82% of patients who are compliant with their medication are assumed to be controlled with only 18% being uncontrolled. For patients who are partially compliant, the rates are 72% controlled and 28% uncontrolled.

Exacerbation rates were taken from the standard care group from a published study assessing the cost effectiveness of a novel treatment for asthma (omalizumab) in general practice compared to standard asthma treatment (Brown *et al.* 2007). Based on these data, the risk of a severe exacerbation in an individual who is uncontrolled is estimated to be 58%. The remaining 42% of uncontrolled patients are assumed to have moderate exacerbations which require an additional GP visit.

Compliance rates

Compliance rates were derived from Gupta *et al.* (2003), which considered what factors influence the management costs of asthma in the UK. The findings report that 41% of patients are compliant and consequently, 59% of patients are deemed to be partially compliant.

Figure 5.1:
Decision tree for asthma



Costs

Costs for each of the events considered in the model were compiled from published sources. A summary of the costs data used is presented in the table below.

Table 5.1:
Unit costs

	Cost per year/ event
GP surgery visit 2 per year	£73.30
Nurse surgery visit (15.5 min) 6 per year	£47.34
Annual treatment cost	£180.64
Cost of an acute asthma attack needing an urgent GP appointment	£425.23
Non-elective inpatient asthma with and without complication	£918.23

It was assumed that patients make two GP visits and 6 practice based nurse visits per year for the routine management of their asthma. The total cost of medication was derived from the asthma audit studies (National Asthma Campaign, Asthma UK 2002). A moderate exacerbation resulting in an asthma attack is assumed to lead to an emergency GP consultation to stabilise the patient. The cost is based on audit data (National Asthma Campaign, Asthma UK 2001). Where a patient experiences a severe exacerbation they are admitted to an emergency ward and their episode is costed according to the National Tariff.

Costs were inflated to 2008 prices where necessary.

Utilities

Utilities were derived from two previous economic evaluations of asthma (Brown *et al.* 2007, Price *et al.*, 2002).

Table 5.2.
Utilities used in the analysis

State	Utility
Controlled – Compliant	0.922
Controlled – Partially compliant	0.893
Moderate exacerbation	0.572
Severe exacerbation	0.326

Individuals are assumed to remain in a health state for one year. However, it is recognised that in some instances outcomes may be temporary or short lived and as such, this may overstate the impact of an outcome on quality of life.

Number of patients with asthma

The number of patients with asthma in the England, according to the Quality and Outcomes Framework primary care asthma register data compiled by the NHS Information Centre 2006/2007 is 3,099,526 (unadjusted prevalence 5.8%).

Outputs

The summary findings from the asthma case study are presented in Table 5.3 below. Compliance is associated with a reduction in expected annual treatment costs of approximately £75 per patient per year and incremental QALYs of 0.11 per patient.

Table 5.3:
Summary findings from asthma case study

	Expected annual cost per patient	QALYs
Compliant	£435.61	0.833
Partially compliant	£510.23	0.725

The resulting net benefit associated with compliance is estimated to be £2,250 per patient. Based on the point prevalence reported above, the findings suggest that there are almost 1.8 million asthmatics in England who are non-compliant. If interventions were available to change the behaviour of all partially compliant medicines users so that they were to become 80 per cent or more compliant in their medicines taking, then we estimate that over £130 million in treatment cost savings could be realised. A more modest target, of doubling current compliance rates so that 80% of individuals with asthma are compliant (as defined above) would result in savings of approximately £90 million per year. This takes no account of the additional improvements that might be achieved in health outcomes.

5.4 Diabetes findings

Development of the economic model

A decision analytic model was developed to illustrate a simplified version of the treatment pathway and potential outcomes of diabetes treatment. The model considers a cohort of individuals presenting for treatment with Type 2 diabetes. Individuals were categorised as:

- ▶ compliant with treatment, defined as taking 80-100% of the prescribed dose of treatment; and
- ▶ partially compliant with treatment, defined as taking less than 80% of their prescribed dose.

Outcomes associated with treatment considered in the model included:

- ▶ Uncontrolled diabetes resulting in complications leading to death;

- ▶ uncontrolled diabetes resulting in complications leading to hospitalisation; and
- ▶ controlled diabetes.

An illustration of the model is provided below.

The probability of experiencing each event was determined by the degree to which the individual was compliant with their medication.

Event rates

Evidence on events rates were sourced from published references. Evidence on the relationship between compliance and mortality and hospitalisation was derived from two studies (Ho *et al.*, 2006, Sokol *et al.* 2006).

Compliance rates

The probabilities of being compliant and partially compliant were also derived from the Sokol study, with 55% of individuals assumed to be compliant and 45% partially compliant.

Costs

Costs for each of the events in the model were compiled from published sources.

Table 5.4:
Unit costs

	Cost per event/year
GP surgery visit unit cost	£73.30
Nurse surgery visit (15.5 min)	£47.34
Average non-elective inpatient diabetes care cost	£1,135.58
Medication cost	£710.70
Cost of death	£0.00

It was assumed that patients with diabetes make two GP visits and 6 nurse visits per year to routine monitoring and management of their condition. The total cost of medication was derived from a previous study that explored the financial costs of managing diabetes (Currie *et al.*, 2007). The cost of a non-elective in-patient admission was derived from the National Tariff. Death was assumed to be cost-free.

Where necessary costs were inflated to the price level of 2008.

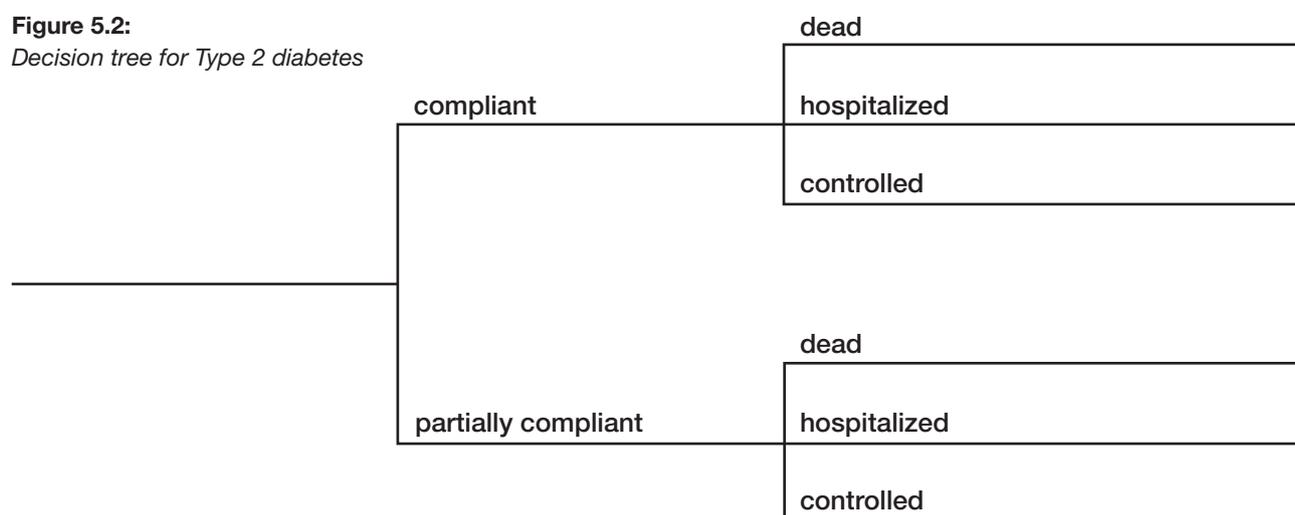
Utilities

Utility values were derived from the UK PDS study which reported health related quality of life scores for patients with and without macro/micro vascular complications using the EQ5D. The utility for hospitalization (0.744) was calculated as the weighted average of utilities for macrovascular and microvascular complications. The utility of the patient group with no complications (0.8) was used for the controlled state. Death was associated with a 0.0 utility score. Individuals are assumed to remain in a given health state for the one year duration of the model, although it is recognised that in some instances the effect of an outcome on quality of life may be temporary (e.g. hospitalisation).

Number of patients with diabetes

The number of patients with diabetes in England, according to the diabetes QOF register 2006/2007 is 1,961,976 (unadjusted prevalence 3.7%). Diabetes UK reports that approximately 90% of people with diabetes have Type 2 diabetes. Therefore, it was assumed that there are 1,782,784 patients with Type 2 diabetes.

Figure 5.2:
Decision tree for Type 2 diabetes



Outputs

The summary findings from the diabetes case study are presented in the table below. Compliance results in a reduction in the expected annual cost per patient of approximately £128 and incremental QALYs of 0.02.

Table 5.5:
Summary findings from diabetes case study

	Expected annual cost per patient	QALYs
Compliant	£950.47	0.761
Partially compliant	£1078.66	0.739

The resulting net benefit associated with compliance is estimated to be £440 per patient.

Assuming that the non-compliance rates reported above are applicable to the English population, over 800,000 individuals with type 2 diabetes are non-compliant with their medication. Applying the costs derived above, these individuals are estimated to cost the health service over £100 million in avoidable treatment costs per year.

5.5 Hypertension

Development of the economic model

A decision analytic model was developed to illustrate a simplified version of the treatment pathway and potential outcomes associated with the management of hypertension. The model considered a cohort of individuals presenting for treatment with hypertension. Individuals were either categorised as:

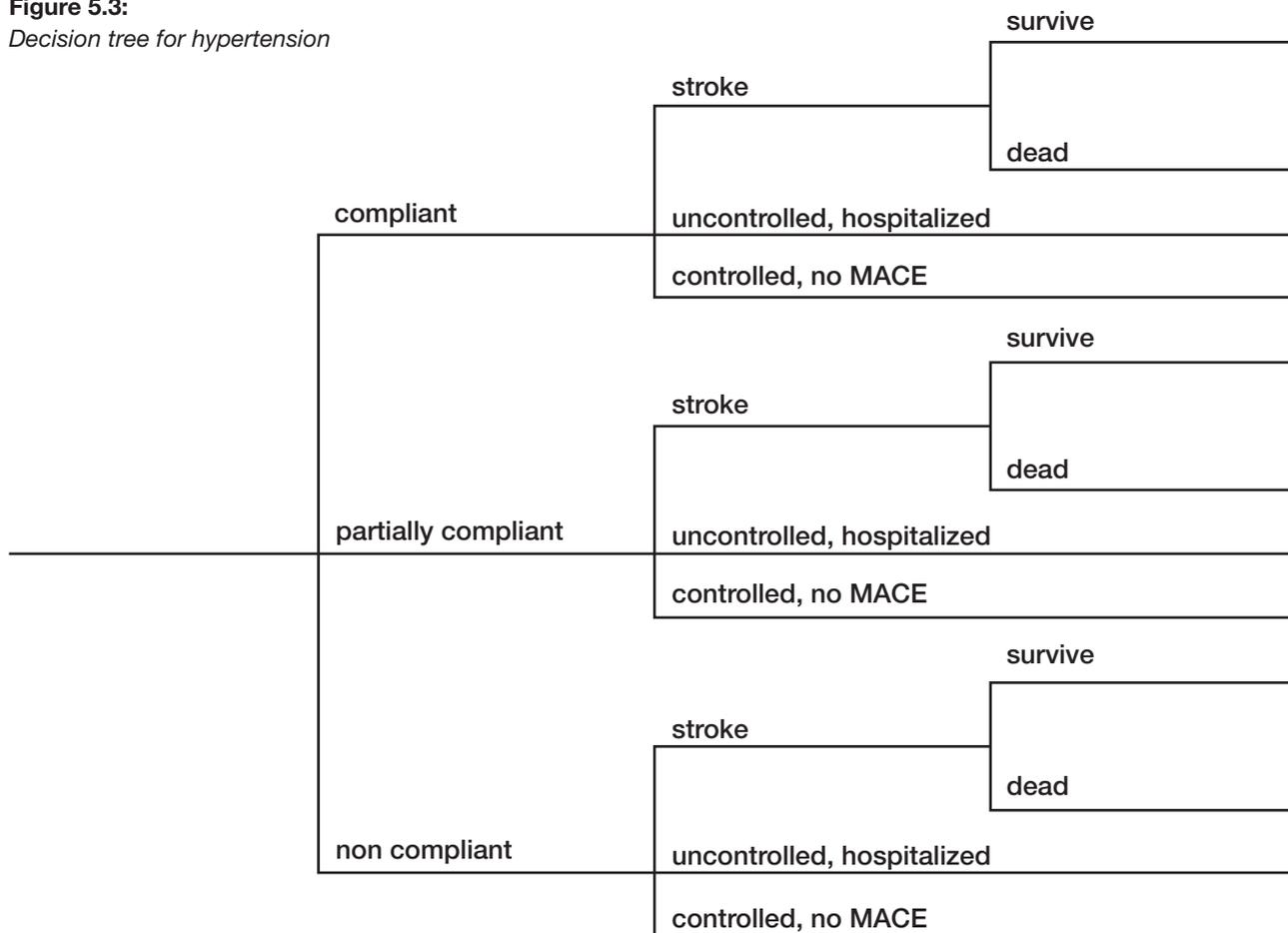
- ▶ compliant with treatment, defined as taking more than 80% of the prescribed dose of treatment;
- ▶ partially compliant with treatment, defined as taking between 50-80% of their prescribed dose; and
- ▶ non compliant if taking less than 50% of their prescribed medication.

Outcomes associated with treatment considered in the model included:

- ▶ stroke (fatal and non fatal) resulting from poor control;
- ▶ uncontrolled hypertension leading to hospitalisation; and
- ▶ controlled hypertension, resulting in no major adverse cardiac events (MACE) or hospitalisations.

An illustration of the model is provided in the figure below.

Figure 5.3:
Decision tree for hypertension



Probabilities and event rates according to each level of compliance were derived from published sources. Further details are provided below.

Event rates

Event rates were derived from published sources (Progress Collaborative Group, 2001). The risk of stroke was derived from a large clinical study of the risk of stroke in individuals with a prior history of stroke or TIA and as such, may be slightly elevated compared to a more general population with hypertension. The risk of stroke in the placebo arm of the study was adopted to represent the non-compliant population. The risk of stroke in the compliant and partially compliant arms of the study were assumed to be reduced by 70% and 35% respectively, compared to the placebo arm. Assuming linearity of the relationship between compliance and risk is acknowledged to be a simplifying assumption.

Risks of hospitalisation were derived from a previous study which examined the relationship between compliance and resource use in a range of chronic conditions. (Sokol *et al.* 2006).

Compliance rates

Compliance rates were derived from a previous study. Based on these we assume that 73% of patients are compliant, 15% are partially compliant and 12% are non-compliant.

Costs

Costs for each event considered in the model were compiled from published sources. Routine care for individuals with hypertension was taken to comprise two GP visits and 6 nurse visits per year. Where individuals experienced a stroke it was assumed that they would be hospitalised and make an additional GP visit following discharge. In-patient episodes were costed according to the National Tariff. The cost of uncontrolled hypertension leading to hospitalisation was also based on the National Tariff.

Medication was costed according to the average one year cost of the maximal daily dose (10 mg) of ramipril according to the British National Formulary 56.

Where necessary, costs were inflated to 2008 prices where necessary.

Table 5.6:
Unit costs

	Cost per event/year
GP surgery visit unit cost	£73.30
Nurse surgery visit (15.5 min)	£47.34
Treatment cost; average cost of max daily dose of ramipril	£164.58
Average non-elective inpatient care cost for hypertension	£1,096.69
Average non-elective inpatient care cost of stroke	£2,428.49
Cost of death	£0.00

Utilities

Utilities were derived from a study which examined the cost effectiveness of interventions to improve adherence in hypertension (Brunenburg *et al.* 2007). The intervention arm was taken to be representative of the compliant population, generating an estimated utility of 0.88.

Utilities for stroke were calculated as the weighted average of utilities from patient recovered / dependent / and being independent after a stroke (0.61) based on the study by Dorman *et al.*

Since there were no data available in the literature on utilities of hospitalized hypertensive patients it was assumed that a hospitalization reduced utility by 10% compared to the controlled state.

All individuals are assumed to remain in a health state for the one year duration of the model.

Number of patients with hypertension

The number of patients with reported hypertension in the QOF register 2006/2007 England is 6,705,899 (unadjusted prevalence 12.5%).

Outputs

The summary findings for the hypertension case study are presented below. Compliance is associated with a saving in expected annual treatment costs of approximately £119 compared to partial compliance and £339 compared to non-compliance. The respective QALY gains are 0.032 and 0.070. The net benefit of moving from being non-compliant to fully compliant is approximately £1413 whilst the net benefit associated with moving from partial compliance to compliance is £651.

Table 5.7:
Summary findings from hypertension case study

	Expected annual cost per patient	QALYs
Compliant	£573.80	0.786
Partially compliant	£693.03	0.754
Non-compliant	£912.64	0.716

Shifting all patients to a position where they are compliant with their medication would result in treatment savings in excess of £390 million per year. However, it is recognised that the asymptomatic nature of hypertension means that this is unlikely to be feasible. A more realistic target of increasing compliance to 80% of hypertensives would result in savings of just over £100 million per year.

5.6 Statins for primary prevention of cardiovascular disease

Development of the economic model

A decision analytic model was developed to illustrate a simplified version of the treatment pathway and potential outcomes associated with primary prevention of cardiovascular disease.

The model considered a cohort of individuals with no coronary heart disease history presenting for treatment with statins for primary prevention. Individuals are categorised as:

- ▶ compliant, defined as taking more than 80% of the prescribed dose of treatment;
- ▶ partially compliant, defined as taking between 50-80% of their prescribed dose; and
- ▶ non compliant, defined as taking less than 50% of their prescribed medication.

Outcomes associated with treatment include the following events:

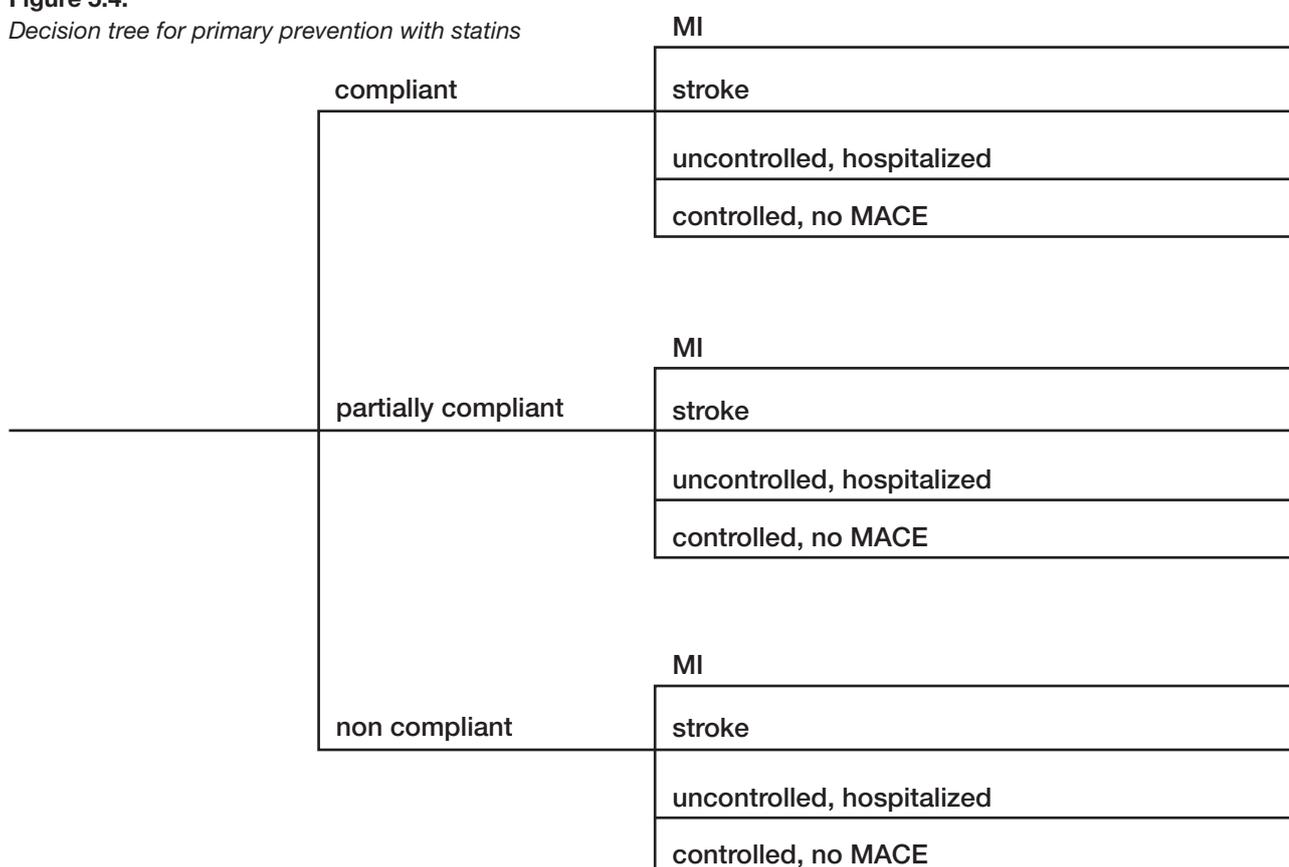
- ▶ a stroke (assumed to be non-fatal);
- ▶ a myocardial infarction (assumed to be non-fatal);
- ▶ uncontrolled high cholesterol resulting in a hospitalization; and
- ▶ controlled cholesterol, resulting in no acute events.

The probability of experiencing any of the events discussed above was determined by the degree to which the individual was compliant with their medication.

Event rates

Event rates for both stroke and myocardial infarction (MI) were based on published meta analyses (Thavendiranathan, 2006). Event rates from the

Figure 5.4:
Decision tree for primary prevention with statins



intervention groups were applied to the compliant population whilst event rates in the placebo group were assumed to be applicable to the non-compliant arm. A linear relationship was assumed between compliance and the LDL cholesterol level reduction, thus events for partial compliance were calculated as the average of the intervention and controlled group.

Rates for hospitalisation in the different compliance categories were derived from the study by Sokol (2006).

Compliance rates

Rates of compliance, partial compliance and non-compliance were also derived from Sokol with 59% of patients reported to be compliant, 23% partially compliant and 18% non-compliant.

Costs

Costs for each of the events considered in the model were compiled from published sources. It was assumed that patients with high cholesterol make two GP visits and 6 nurse visits a year. Following discharge for treatment of an MI or stroke it was assumed that patients make an additional GP visit following discharge. Average treatment costs were calculated based on the cost of the maximal daily dose of atorvastatin, fluvastatin, pravastatin, rosuvastatin and simvastatin; drug prices were derived from BNF56.

Where necessary costs were inflated to the price level of 2008. A summary of the costs is presented in the table below.

Table 5.8:
Unit costs

	Cost per event/ year
GP surgery visit unit cost	£73.30
Nurse surgery visit (15.5 min)	£47.34
Treatment cost; average cost of statins	£605.46
Average non-elective inpatient care cost for MI	£1,397.81
Average non-elective inpatient care cost of stroke	£2,316.07
Hospital cost (ischaemic heart disease)	£958.39
Cost of death	£0.00

Utilities

Utilities were derived from multiple sources. Controlled patients were expected to have a similar quality of life to population norms, derived from the Health Survey for England. Utilities associated with other states were derived from trial sources or previous economic analyses. All utility decrements associated with an event were assumed to apply

for the one year duration of the model. These are summarised in the table below.

Table 5.9
Utilities used in the analysis

State	Utility	Source
Controlled	0.850	Health Survey for England
Uncontrolled – hospitalisation due to angina	0.714	Kim <i>et al.</i> 2005
Myocardial infarction	0.800	Granz <i>et al.</i> 2000
Stroke	0.520	Shin <i>et al.</i> 1997, Thomson <i>et al.</i> 2000

Number of patients treated with statins for primary prevention

It is difficult to estimate with any precision the number of patients who should take statins as primary prevention. According to the British National Heart Foundation 57% of men and 61% of women in England have cholesterol levels in excess of recommended levels. However, not all of these individuals are expected to have sought treatment and medication [BHF statistics 2008].

In the absence of a definitive estimate of the number of individuals who are currently prescribed statins, the analysis considers a population of 1 million people suitable for treatment. This is believed to underestimate the eligible population.

Outputs

The summary findings for the primary prevention of cardiovascular disease case study is presented below. Compliance is associated with a reduction in expected annual treatment costs per patient of approximately £38 compared with a partially compliant population and £48 compared with a non-compliant population. The incremental QALYs resulting from compliance are estimated to be 0.05. The net benefit associated with moving an individual from the non-compliant state to the fully compliant state is approximately £90.

Table 5.10:
Summary findings from statins (primary prevention) case study

	Expected annual cost per patient	QALYs
Compliant	£345.90	0.825
Partially compliant	£383.89	0.820
Non-compliant	£393.10	0.820

Introducing interventions to allow all patients comply with their recommended medication would lead

to treatment savings of approximately £17 million per year. A more modest target, of 80% of patients complying with 80% of their medicines, would realise savings of just under £9 million per year. These figures are based on an eligible population of 1 million patients, which is believed to be an under-estimate.

5.7 Statins for secondary prevention of cardiovascular disease

Development of the economic model

The model developed to examine statins in primary prevention was adapted to consider their use in secondary prevention of cardiovascular disease. The main change was an assumption that MI and stroke may have a great risk of death in individuals taking statins for secondary prevention. The decision tree developed for the model is presented overleaf.

The probability of each event occurring was determined by the degree to which the individual was compliant with their medication.

Event rates

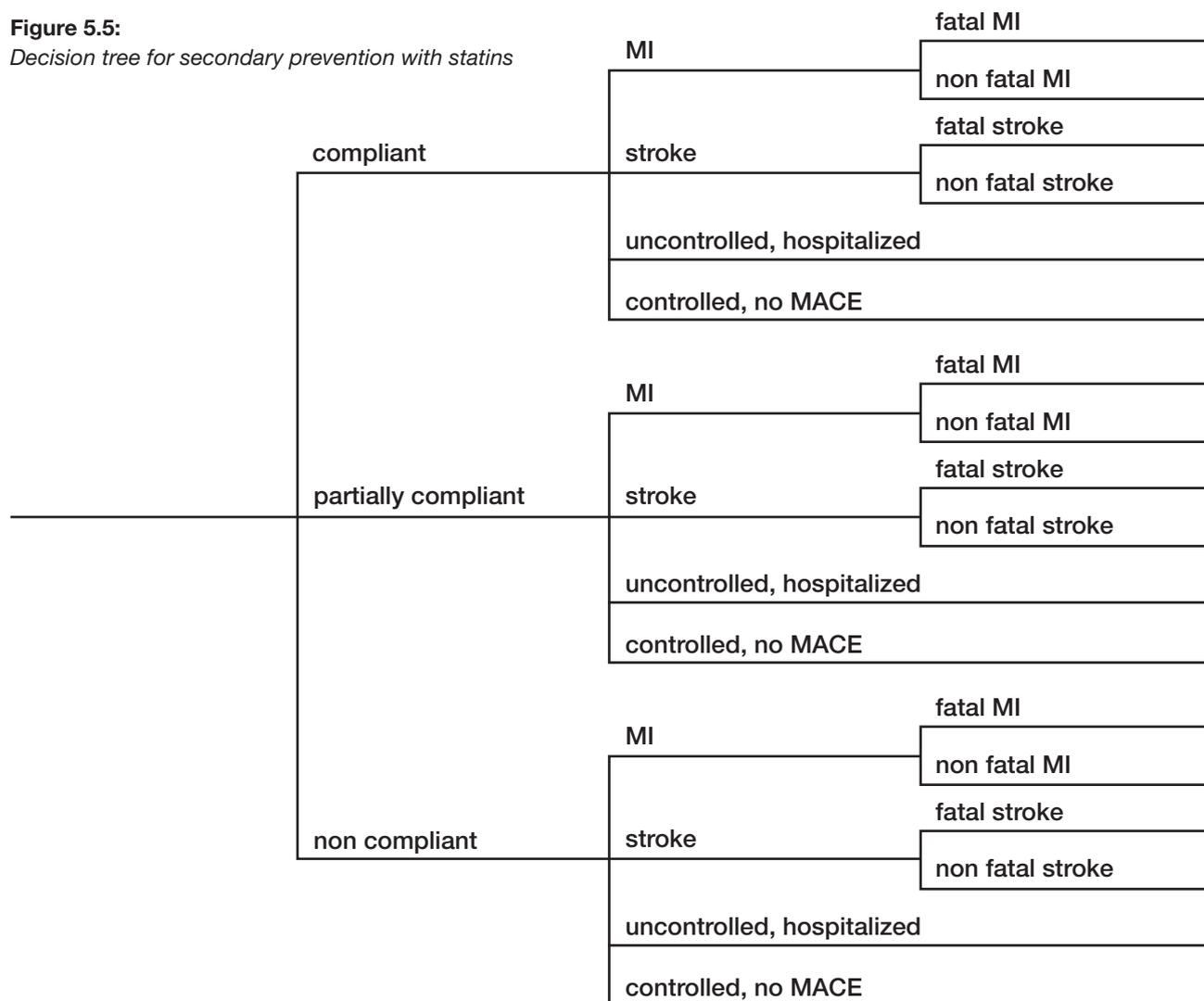
Rates of an MI and stroke were derived from two meta-analyses of intensive statin therapy which reported the effects of high-dose versus low dose statin therapy relative to placebo (Josan 2008, Afilalo *et al.* 2008). Rates from the high-dose statin arm in the meta-analysis were applied to the compliant cohort. Rates from the placebo arm were applied to the non-compliant arm whilst the low dose statin population was used as a proxy for partial compliance.

Rates of hospitalisation, according to compliance level, were based on the study of Sokol (2006) evaluating the impact of compliance on health care utilization costs and risk of hospitalization in various conditions, including high cholesterol.

Costs

Costs for each of the events considered in the model were compiled from published sources. It was assumed that patients make two GP visits and 6 nurse visits a year; after an MI and stroke it was assumed that patients make an additional GP visit. Average treatment costs were calculated based on

Figure 5.5:
Decision tree for secondary prevention with statins



the cost of the maximal daily dose of atorvastatin, fluvastatin, pravastatin, rosuvastatin and simvastatin; drug prices were derived from BNF56.

Where necessary, costs were inflated to the price level of 2008. A summary of the costs is presented in the table below.

Table 5.11:
Unit costs

	Cost for a year
GP surgery visit unit cost	£73.30
Nurse surgery visit (15.5 min)	£47.34
Treatment cost; average cost of statins	£605.46
Average non-elective inpatient care cost for MI	£1,397.81
Average non-elective inpatient care cost of stroke	£2,316.07
Hospital cost (ischaemic heart disease)	£958.39
Cost of death	£0.00

Utilities

Utility values associated with each health state/event occurring in the model were derived from published sources. Utility decrements associated with each event are assumed to apply for the one year duration of the model. These are summarised below and discussed in more detail in the analysis of primary prevention above.

Table 5.12:
Utilities used in the analysis

State	Utility	Source
Controlled	0.850	Health Survey for England
Uncontrolled – hospitalisation due to angina	0.714	Kim <i>et al.</i> 2005
Myocardial infarction	0.800	Granz <i>et al.</i> 2000
Stroke	0.520	Shin <i>et al.</i> 1997, Thomson <i>et al.</i> 2000

Number of patients treated with statins for secondary prevention

The number of patients with coronary heart disease in England reported on the QOF register in 2006/2007 was 1,898,565 (unadjusted prevalence 3.5%).

Outputs

The summary findings for the secondary prevention of cardiovascular disease case study are presented below. Compliance is associated with a reduction in expected annual treatment costs per patient of approximately £154 compared with a partially

compliant population and £182 compared with a non-compliant population. The incremental QALYs resulting from compliance are estimated to be 0.35. The net benefit associated with moving an individual from the non-compliant state to the fully compliant state is approximately £730 per patient.

Table 5.13:
Summary findings from statins (secondary prevention) case study

	Expected annual cost per patient	QALYs
Compliant	£246.64	0.830
Partially compliant	£400.00	0.795
Non-compliant	£428.32	0.794

Increasing the proportion of individuals who are compliant to 80% would lead to over £66 million in treatment cost savings per year. If this could be increased further so that 100% of individuals were compliant with 80% of their medication, then treatment costs could be reduced by over £120 million per year.

5.8 Schizophrenia

Development of the economic model

A decision analytic model was developed to illustrate a simplified version of the treatment pathway and potential outcomes of schizophrenia treatment. The model considered a cohort of individuals presenting for treatment with schizophrenia.

Individuals are either categorised as:

- ▶ compliant, defined as taking 80-100% of the prescribed dose of treatment; and
- ▶ partially compliant, defined as taking less than 80% of their prescribed dose.

Outcomes associated with treatment considered in the model include:

- ▶ uncontrolled schizophrenia, resulting in a severe relapse that requires hospitalisation;
- ▶ uncontrolled schizophrenia, resulting in suicide; and
- ▶ controlled schizophrenia.

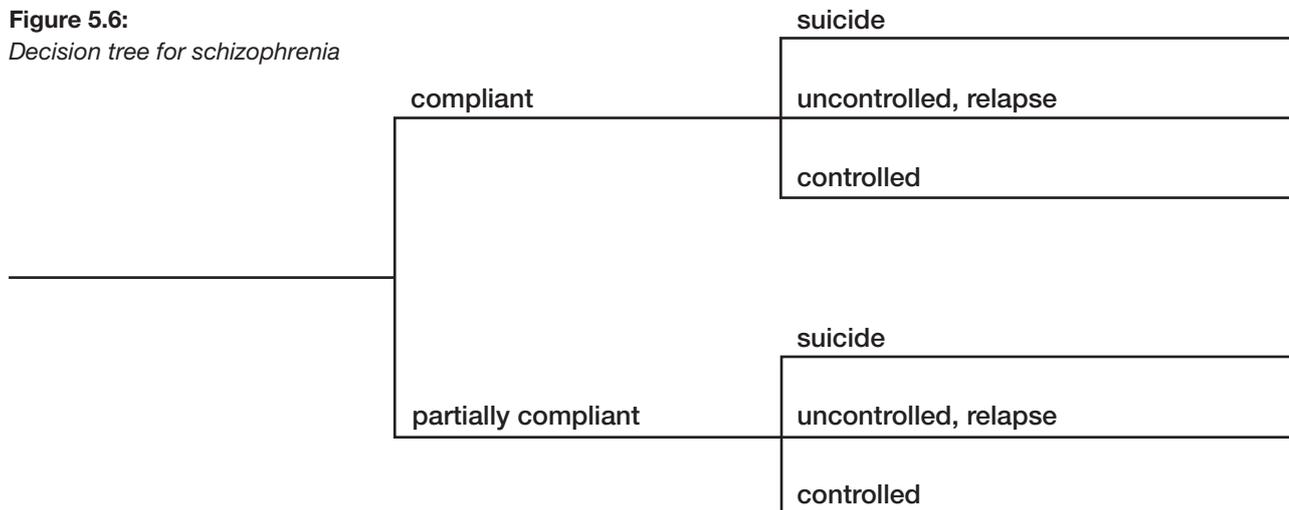
An illustration of the decision tree is presented below.

The probability of each outcome considered in the model was determined by the degree to which the individual was compliant with their medication.

Event rates

Rates of suicide were derived from a previous economic study that reported the annual risk of

Figure 5.6:
Decision tree for schizophrenia



suicide associated three antipsychotics (olanzapine, risperidone, and haloperidol) based on a UK population (Almond *et al.* 2000). A second study (Llorca 2008) was used to estimate suicide rates in non-compliant individuals, suggesting that the relative risk of suicide is four times higher if patients are not compliant with therapy.

Relapse rates were based on an observational study examining the relationship between costs and adherence (Gilmer *et al.*, 2004) while rates for hospitalization according to the level of compliance were derived from a previous economic evaluation (Briggs *et al.* 2008).

Compliance rates

Compliance rates were derived from the same study that reported rates of suicide according to compliance (Llorca 2008). Based on this, we estimate that 52% of patients are compliant with medication and 48% partially compliant.

Costs

Costs for each of the events considered in the model were compiled from published sources. Annual costs of hospital care, community care and the cost of antipsychotic drugs were derived from an economic study conducted alongside a trial in the UK (Davies *et al.* 2007).

Where necessary costs were inflated to 2008. The table below summarises the costs used in the analysis.

Table 5.14
Unit costs

	Cost per event/year
Community care cost	£907.33
Cost of antipsychotics	£631.48
Hospital annual cost	£18,748.00
Cost of suicide	£0.00

Utilities

Utilities for the controlled state were derived from the same studies that also provided much of the cost data (Davies *et al.* 2007, Briggs *et al.* 2008). Some adjustment was made to derive appropriate utilities. Utilities are assumed to apply for the one year duration of the model. These are summarised below.

Table 5.15:
Utilities used in the analysis

State	Utility
Partially compliant controlled	0.641
Compliant controlled	0.766
Uncontrolled – relapse	0.604

Number of patients with schizophrenia

A previously published literature review (Goldner *et al.* 2002) examined the evidence on prevalence and incidence of schizophrenia published between 1980 and 2000. The average life time prevalence of schizophrenia is 0.55/ 100. The English population aged over 45 in 2001 was 25,160,300, so the prevalence of schizophrenia in individuals aged over 45 is estimated at 138,382. For the purposes of the analysis a cohort of 140,000 was used.

Outputs

The summary findings from the schizophrenia case study are presented overleaf. The findings suggest that compliance is associated with a reduced annual treatment cost per patient of approximately £3,350 compared to the partially compliant arm and an incremental QALY of 0.12. The resulting net benefit is approximately £5,700.

Table 5.16:
Summary findings from schizophrenia case study

	Expected annual cost per patient	QALYs
Compliant	£4,066.71	0.743
Partially compliant	£7,421.98	0.625

Increasing the proportion of patients who are compliant with their medication to 80% would lead to a saving of over £113 million per year. It is unlikely that all patients in this indication could be made to comply with their medication. However, if we were to assume that 100% compliance is possible, then savings of over £190 million would be realised.

5.9 Summary

These case studies are intended to provide an insight into the value of the health benefits foregone that result from sub-optimal compliance in a number of long-term conditions. Our findings are to be considered as an adjunct to those findings presented earlier in the report on the cost of wasted medicines, albeit that non-compliance and material drug wastage are discrete phenomena.

Given limited resources, the approach adopted is knowingly simplistic and the findings should be considered to be indicative of the true scale of therapeutic losses associated with non-compliance. The authors would also wish to acknowledge that the population of the models was undertaken without recourse to a systematic review for each of the case studies due to the limited time available for the research. In some instances, the potential QALY gains may be overstated as utilities associated with transient events (e.g. hospitalisation, relapse etc) were assumed to apply for the entire one year duration of the model. Furthermore, it is recognised that simple decision analytic approaches are not necessarily the most appropriate means of addressing the issue of compliance and that in some cases Markov models or patient level simulation models may be more appropriate, particularly where there are complex interactions between behaviours and medicines (Hughes, 2007).

However, the findings remain quite striking. Sub-optimal compliance is associated with both an increased treatment cost and a deterioration in patient outcomes. In several of the case studies, the treatment costs alone associated with non-compliance are estimated to be in excess of £100 million per year. In some cases this is driven by the high prevalence of the condition (hypertension) whilst in others it arises because of the significant incremental cost that is associated with non-compliance (schizophrenia). The findings support the belief that the value of losses to the health service

and individual medicines users associated with lost therapeutic outcomes significantly outweigh the value of material losses associated with wasted medicines. This issue has been previously explored (Horne 2005) with commentators pointing out that there is a gap in the evidence base on the costs associated with non-compliance but also acknowledging some of the difficulties inherent in attempting to undertake such studies. Others have sought to evaluate the cost effectiveness of interventions designed to improve compliance (Elliott 2008) which ultimately helped to inform national policy on the issue from NICE in 2009.

The findings provide useful insights into where investment to improve compliance might be best targeted. For example, by providing estimates of the net benefit associated with compliance, policy makers can determine whether the potential benefits associated with compliance are likely to outweigh the costs of any interventions designed to improve compliance.

In the above case studies, there would appear to be a strong case for investment to improve compliance in asthma and schizophrenia where the net benefits associated with moving from partial compliance to full compliance are significant. This is largely due to the potential QALY gains that might result from compliance, which in turn arise due to a reduction in serious adverse outcomes. In these cases, it may be possible to justify intensive, personalised interventions designed to support compliance at a patient level.

Whilst it is difficult to object to any attempts to improve compliance, the economic case for intervention in other indications, such as statins for primary prevention of cardiovascular disease, appears less strong. The net monetary benefit associated with improving compliance in this indication is relatively modest. Similarly, the gain in QALYs is modest as patients are asymptomatic at the time of intervention. As such, it would be more difficult to build an economic case for intensive interventions designed to improve compliance in this indication. However, there may be a case for less costly but more far-reaching interventions, such as general awareness campaigns, to promote the concept of compliance given the high prevalence of these conditions.

A further consideration might be the degree to which the relationship between compliance and outcomes is understood. In the above case studies we have adopted arbitrary cut-off points for what constitutes compliance. For example, our simplistic analysis assumes that achieving 80% compliance with medicines produces the same benefit as 100% compliance. Clearly, this relationship is likely to differ across different compounds and different populations and any more robust attempts to account for compliance should seek to address this. Whilst this may be true in some cases, it is unlikely to be the case for all medicines. In addition to compliance at any given time, the issue of persistence also needs to be taken into account when considering medicines

for chronic conditions. Further consideration of this relationship may also help to inform which conditions might be the best candidates for a more detailed study.

However, it is acknowledged that it is unfeasible to shift all patients with a particular condition into a compliant state and there may be diminishing returns associated with interventions intended to improve compliance. Therefore, policy makers are urged to consider the realisable savings that might be possible, rather than the potential savings.

These analyses are acknowledged as being simplifications of reality and the degree to which evidence has been synthesised from multiple sources to produce the estimates of costs and QALYs means that they are open to significant uncertainty. However, it was our intention to explore the feasibility of conducting such analyses rapidly and develop a methodology that might be further explored by future research. The findings also support the hypothesis that the value of healthcare losses foregone as a result of non-compliance significantly outweigh the acquisition costs associated with waste medicines.

6 Waste Medicines in Care Home Settings

6.1 Background

Anecdotal feedback often identifies prescribing and medicines management in care homes as a potential source of medicines wastage. This issue is explored in the following Section of this Report. To some extent such beliefs result from the high usage of medicines associated with the complex needs of many residents, who may have multiple progressive illnesses and be taking multiple medicines. A recent study of 256 randomly selected residents in a purposive sample of 55 care homes in three different areas of the country found that residents took an average of seven medicines each (Barber *et al.* 2009). This can result in frequent changes in medication and difficulties in adhering to complex polypharmacy regimens, which in turn engender waste.

Because of the elevated risks associated with prescribing in care homes the Care Quality Commission (CQC) has established detailed processes for medicines management and audit. They require clear documentation of all the medicines received into a care home, administered (or wasted at point of administration) and returned for disposal. Additional steps have also been put in place in individual homes. Most have their medicines dispensed to them in monitored dosage systems (MDS): these involve a pharmacy repackaging medicines into systems that some commentators believe reduce error and wastage.

However, MDS is only suitable for solid dosage forms. In the homes that used MDS in the above study 40 per cent of the doses administered were not obtained from the MDS system because, for example, they were liquids or inhalers. Typically, each home would be supplied from one main pharmacy but may get additional supplies for acute treatment from a second pharmacy. Community pharmacists receive no special item of payment for MDS dispensing.

High levels of prescribing, coupled with tight regulations surrounding the management of stocks and disposal of unused medicines, mean that waste emanating from care homes is very visible. This helps to account for the widespread perception that this setting is associated with high levels of waste.

In recognition of the complexity of prescribing and dispensing in the care home context, specific investigations were undertaken with regard to

the scale of medicines waste in this setting and initiatives put in place to address this problem. This Section reports the findings of both qualitative and quantitative research undertaken in a sample of homes.

6.2 Objectives

The aim of the research reported in this Section was to study the causes, nature and extent of waste medicines from care homes. The objectives were to:

- ▶ understand the nature of waste associated with medicines used in care homes;
- ▶ understand the reasons for the waste produced in care homes;
- ▶ estimate the extent of waste medicines in monetary terms; and
- ▶ suggest methods to reduce waste medicines.

6.3 Methods

We used a mixture of qualitative and quantitative techniques. A purposive sample of care homes from four Primary Care Trusts (PCTs) in London was selected. Their areas were socially diverse and the care homes involved were of varied sizes and included organisations with nursing and residential beds from both the private and voluntary sectors. We had originally intended to include homes that did not use MDS: however, there had been a recent trend by homes to convert to MDS and non-MDS homes were a rarity.

The study had Ethics Committee approval and each site and individual taking part gave consent. To determine the causes of medicines wastage, care home managers and a PCT pharmacist were interviewed in person or over the telephone to obtain their accounts and views of where and why they thought medicines were wasted. (Pharmacists were interviewed more extensively in other parts of the study.) The interviews were semi-structured and the questions explored reasons for the occurrence of waste medicines, factors affecting the extent of wastage and ways of reducing waste medicines. Most interviews were taped with the participants' consent.

In addition to the interviews an audit of waste medicines was conducted in the homes that were visited, the data being drawn from the home's waste medication record forms. These provided detailed information on medicines used in the home, including medicines identified as unused that were to be sent for disposal. These data were analysed, grouped accordingly and costed to provide insights into the monetary value associated with medicines waste in care homes.

6.4 Findings

A total of 90 care homes were invited to participate in the study, of which 32 agreed to be involved within the time frame of the study. Twenty one homes eventually took part and all their managers were interviewed – three were accompanied by their medicines manager or senior nurse. Sixteen homes were visited and data collected from the waste registers in 14. In addition three Primary Care Trust pharmacists were also approached for interview, although only one agreed to participate within the time available. Interviews lasted 10-90 minutes and were transcribed and analysed using constant comparative analysis: a second researcher reviewed categorisation of the emergent themes.

Below, we first set the scene by describing the common processes related to medicines ordering and management in care homes. We subsequently review the quantitative waste findings, then the causes of waste, and finally we synthesise some suggestions to ameliorate waste. For the purposes of this Section the term 'waste medicines' includes medicines for disposal/return as well as dropped or spilled medicines.

Medicines ordering and management

The findings reported here were derived from the interviews conducted for this research and are consistent with our previous work in 55 care homes (Allred *et al.* 2008, Barber *et al.* 2009). Most homes prefer to obtain medication from one pharmacy. More than one GP practice may serve the patients in a care home, although in a few homes all the patients were registered with one practice. Patients who move from their own home to a care home may wish to maintain the same GP practice, which is one of the causes of multiple practices being associated with care homes. Also, some have short term or respite patients, who remain with their existing GPs and obtain medicines from their usual pharmacy.

A record is required to be kept for all prescription requests, receipts, medication administration or wastage and returns of medicines, accounting for each dose unit. This audit trail is a CQC requirement. It is a time consuming exercise that may involve the staff responsible in considerable work, depending on the size and type of the care home.

Increasingly, care homes have moved away from receiving original pack dispensing (the way medicines are dispensed to patients visiting a pharmacy) to monitored dosage systems (MDS), except for medicines where the medication regimen, dose form or formulation is not suitable for MDS dispensing. Non-solid dose forms (liquids, sachets, and topical preparations), large tablets (Calcium supplements), variable and PRN (as required) doses (e.g. analgesics) are not dispensed in MDS. The move away from conventional dispensing had, in the homes we encountered in this study, been encouraged and advised by pharmacists and/ or the CQC following inspections, in order to manage and help maintain the audit trail required by the CQC. However, some PCT pharmacists discourage MDS use.

For most homes, prescription ordering is on a monthly cycle, with lead times ranging from 1-3 weeks. In smaller homes, one individual is responsible for medication ordering and record keeping. In larger homes, a team of individuals may be involved, with one person taking the lead. In most nursing homes, medicines are generally managed by nurses, whereas in residential homes, the manager takes greater responsibility for ordering, record keeping and returns.

Quantitative waste study

The records of medicines wasted at the end of each month were documented in 14 homes: a total of 1892 items were reported. The size of the homes from which records were taken varied from 9-93 beds and the recorded items seen by the researcher ranged from 2 to 326 items per home. They represented from one to six months data per home. Table 6.1 shows the number of times each medicine (or group of medicines) was recorded as waste.

Table 6.1:
Frequency with which medicines were identified as waste

Product	Frequency	Percent
Laxatives	293	15.5%
Paracetamol (or paracetamol containing analgesics)	273	14.4%
Calcium supplements	116	6.1%
Aspirin	68	3.6%
Omeprazole	57	3.0%
Furosemide	35	1.9%
Ferrous sulphate	31	1.6%
Warfarin	26	1.4%
Salbutamol	25	1.3%
Ramipril	21	1.1%
Digoxin	21	1.1%
Simvastatin	18	1.0%
Lansoprazole	18	1.0%
Amlodipine	18	1.0%
Gaviscon	17	0.9%
Folic acid	16	0.9%
Codeine phosphate	16	0.9%
Vitamin B Compound	15	0.8%
Tiotropium	15	0.8%
Prednisolone	15	0.8%
Hypromellose	14	0.7%
Clonazepam	14	0.7%
Bendroflumethiazide	14	0.7%
Metoclopramide	13	0.7%
Levothyroxine	13	0.7%
Co-amilofruse	13	0.7%
Quetiapine	12	0.6%
Metformin	11	0.6%
Haloperidol	11	0.6%
Citalopram	11	0.6%
Alendronic acid	11	0.6%
Co-careldopa	10	0.5%

The number of medicines returned each month varied from home to home. For instance, 36 items were returned over a six month period in a 19 bedded care home, whereas there were approximately 350 items over 5 months from a 93 bedded care home that had nursing care beds. There seemed to be more drugs recorded in the nursing care homes: interviewees thought this was because more drugs were prescribed and there were more 'as required'

medicines used in nursing care. No other pattern was noted. On average the number of medicines wasted ranged between 0.51 to 1.25 per bed per month for a sub-group of seven homes that kept sufficiently detailed records to permit this calculation.

Reasons for medicines being wasted were documented (to any extent between comprehensively and hardly at all), in 10 of the 15 homes, and are shown in Table 6.2. These give indications of the recorded reasons, but might be skewed because, for example, a home with a large number of dementia patients might have a greater proportion of patient refusals. This data, while limited, broadly agrees with interviews in other parts of this study, and experience with care homes in another study (Alldred *et al.* 2008)

Table 6.2:
Reasons for medicines being wasted

Reason	Frequency	%
Reason not recorded	1505	79.6%
Death	122	6.4%
Patient refused	59	3.1%
Remnant (pack size related)	48	2.5%
Wasted to synchronise ordering cycle	46	2.4%
Patient admitted to hospital	42	2.2%
Change in therapy (drug, dose or formulation)	25	1.3%
Discontinued	17	0.9%
Expired	12	0.6%
Homely remedy	6	0.3%
Duplicate or extra supply	3	0.2%
End of course or no longer indicated	3	0.2%
Transferred	2	0.1%

Costs were attributed to the medicines and supplies reported as being wasted in the care homes. Costs were allocated on a similar basis to that used in the analysis of the public survey, as described in Section 4. The total cost associated with the medicines identified as waste in the care homes was £11,667.

Qualitative findings

The following paragraphs reflect the analysis of interviews with 24 care home staff in 21 homes and one PCT pharmacist. In some cases more than one person was in the interview, for example the manager and senior nurse would be interviewed together.

Handling of waste medicines

The majority of interviewees did not feel that waste medicines were a concern as they felt that the amount was small. Most of the care homes

managers considered waste of medicines to mean those that were wasted at the point of administration due to patient refusal, dropping medicines or spillage. Medicines that remained at the end of each month were 'returns' which had to be recorded and set aside for disposal either by a waste management company or the community pharmacy (some community pharmacies also had a waste management licence). The managers were unaware of the financial details for waste management contracts, though returns to community pharmacies were thought to be free of charge. Some community pharmacies arranged for a company to remove waste medicines for the home as part of their MDS service.

For medicines wasted at the point of administration the usual method of disposal was reported as domestic bins or flushing down the sink. One site had a jar for collecting dropped tablets, which once full was sent for disposal with the usual returns. Routine waste was stored in the original dispensing packaging if being returned to the community pharmacist, or in specially provided waste bins if being handled by waste contractors. Controlled drug disposal was always recorded in the controlled drug register. Then such drugs were returned to a pharmacy or denatured before disposal into the allocated waste bins.

Senior staff or team leaders were responsible for co-ordinating the disposal of excess, unused or unwanted medication at the end of each month. In accordance with the CQC (formerly Commission for Social Care Inspection, CSCI) guidelines, a record comprising the patient's name, drug name and quantity of waste medicines was kept by all the homes visited. In addition to the medicines listed as being returned in Table 6.1 there were sometimes related, non-medicinal, items returned: of these the most commonly mentioned were dressings and sip feeds.

"... people treat dressings as a repeat medicine ... it could be huge sizes, it could be inappropriate dressings ... they would still be ordering the old one ... You end up with a whole load of sip feeds in storage ... they just expire and get thrown away."

PCT pharmacist

Reasons for wastage

Reasons for medicines waste fell into three groups. First, those which nothing could be done about; second, those that could theoretically be a problem but which the homes felt they managed well or had little chance to influence; and finally those which could be managed differently to reduce waste. Interviewees spent most time on the last of these groups.

Death and change in therapy because of a change in the patient's clinical condition were considered

uncontrollable reasons for waste of medicines. Inappropriate prescribing and failure to review medication on a regular basis were also cited, but these were presented as theoretical reasons, perhaps because nearly all of the homes studied had a system of at least annual review by a GP surgery (and occasionally by a PCT pharmacist) and additionally when requested by the care home manager. Some homes had input from community pharmacists as well. An inadequate ordering and review process was a related factor, as was the expiry date for dispensed items such as eye drops and liquids. Admission to hospital was another commonly quoted cause of medicine wastage, due to failure to use patients' own supplies on admission as well as lack of communication at point of discharge.

The most frequent reason given in interviews for the wastage of medicines was the variable use (or lack of use) of 'as required' (also called PRN) medication for the management of pain or constipation. This finding confirmed by the most common medicines cited in Table 6.1, which were laxatives and paracetamol based analgesics. Patient need and demand for these medicines is likely to vary depending on symptoms, thus making it difficult to predict usage and hence the quantities to be ordered.

"... things like constipation just crops up from nowhere. I always tell the staff, there's prune juice, use that, don't let them write prescriptions, it's just a waste. But the residents are not happy with that. Psychologically they feel better if they receive something from the doctor ... that goes to waste, two days they use it and the third day, I'm ok now, and I'm fine now. Not thinking they were already fine ..."

Residential home 1, Manager

In most of the larger homes any excess PRN medicines remaining at the end of the month were returned and a new supply reordered. In smaller homes where one individual was responsible for medication ordering 'as required' medicines were only ordered at the end of the month if there were insufficient supplies to last the next month.

Patient refusal (which could be considered intentional non-adherence) was another reason for wastage. For example, homes with mental health patients reported that willingness to take medication often depended on the patient's mood and mental status.

Factors affecting the extent of waste

The total volume of waste medicines was, as would be expected, affected by the size and type of home. Not surprisingly, larger homes were believed to generate a greater volume of waste compared to smaller ones, predominantly because of the number of residents: most residents would have 'as required' prescriptions which may not be used. Care homes

that provided nursing care were also seen as more liable to generate waste as there was likely to be a greater use of medication compared to residential care homes.

The prescribing and ordering system was frequently mentioned. Ordering was on a cyclical basis. Most homes tried to synchronise the cycle so that all residents received a new supply on the same day. Repeat prescribing systems were usually set to order 28 days supply. As the home could not order less than a 28 day supply to get new patients or those returned from hospital in line with their normal ordering cycle, this meant wasting any existing supplies. Repeat prescriptions were often issued by staff other than the prescriber and this was seen as sometimes resulting in discontinued and unwanted items being issued.

"It's on the computer, the doctor's prescription ... because once somebody's on medication, even if they discontinue it ... the whole prescription will come."

Nursing home 3, Manager

"... which I will cross it out and say discontinued or I won't order it, it's just from the one surgery ... you don't order it, but they tend to send it, issue the prescription for everything."

Residential home 13, Manager

Care homes managing their own ordering process have more control and reported better efficiency in the process rather than direct prescription collection and delivery by the pharmacy.

"Because at the moment, the prescriptions go from the Doctor's surgery to the Chemist. We don't intervene on them, when it's reordering, we don't actually say what we want. It's the whole prescription is reordered monthly ... We get mountains that we don't need of some things, and not enough of other things, because we don't prompt the prescription generation. The Chemist does it. He lets us know when he needs a new prescription. So we have to say they need a prescription, and then they go and pick it up. We don't actually see the prescription for reordering."

Residential home 12, Manager

This was seen as particularly important in the case of 'as required' items.

"That can cause problems, like with the paracetamol. You know because it's been a repeat thing that the chemist sorts out, it comes automatically. You know, I don't want these anymore. So that's the only problem, when there's something that's not needed anymore, you're gonna receive it regardless until you

get down to the doctors. Whereas if it was us getting prescriptions, I could phone up and get it stopped."

Residential home 3, Manager

Failure to check actual quantities of stock remaining at the point of reordering also affected the amount of waste.

"The whole repeat process, you need someone to sit down and order the medicines and they need to do it where medicines are stored, and that doesn't happen. The chart is taken away and the nurse is sat at a desk. They order from the MAR sheet rather than ordering, things like lactulose you sometimes find about 10 bottles of lactulose for the one patient because nobody's bothered to check whether they've run out or not."

PCT Pharmacist

In addition, for most homes, reordering from repeat prescribing was at least three weeks in advance, so it could be difficult to anticipate the need at the end of the month. Any changes during the order cycle could lead to waste and/ or repeat dispensing. Monitored dosage systems, such as cassettes and blister packs, were considered to minimise the extent of waste, whereas dispensing in boxes and bottles was seen as more wasteful.

"Before I came here they were using the packets, now we have moved to blister pack, so there is not much waste at the moment."

Nursing home 2, Manager

Medicines for 'as required' usage were not usually included in monitored dosage systems, whereas those prescribed for regular use were, unless the nature of the drug prevented it. For example, calcium supplements were dispensed in the original packs and were amongst the top three drugs involved in wastage.

Pharmaceutical packaging could be an influence. For drugs that are not dispensed in MDS, original packs are dispensed, some of which are 30 days rather than 28. Therefore there is regular excess at the end of each month.

"We have Movicol sachets. They come in boxes of 30, but cycles are 28 days so those two will be returned."

Residential home 10, Medication lead

Other pharmaceutical factors related to changed expiry dates once packs were opened or re-dispensed. Liquid medicines have a shortened expiry once opened and therefore large pack sizes (e.g. lactulose 500ml, used for constipation) may result in wastage. Dispensing part packs also reduces the time till expiry of the medicines.

“There is a limit when you open the bottle or if you get a medicine in a brown bottle, not from the original packs, they’ve got a certain time and then you have to return them.”

Residential Home 13, Manager

Homes which had residents with dementia or other mental health problems were said to be more likely to have waste due to refusal/non-adherence and expiry of liquid medicines. Homes which had terminally ill patients were more likely to have unused PRNs (ordered for symptom control in terminal care) and discontinuations of previous regular medication. Having unused PRN medicines was considered preferable to not having the required medication for end of life care.

Official guidance and recommendations were seen by some as another cause of waste. Homes are discouraged from retaining excess supplies at the end of each month. Most homes reported they would be ‘in trouble’ if inspected and found to have supplies of regular medication dispensed earlier than the previous month.

“You don’t want use the packs from hospital, they are already been used, every time you know when people come to us we have to count each tablet and write it in the entry book. Then somebody comes doing an inspection and they get a hump because it shouldn’t be done like this. They want you to have a clean sort of label.”

Residential home 13, Manager

Ways of reducing medicines waste

The key to reducing waste of prescribed medicines was seen as maintaining and improving communication between healthcare professionals in the community as well as across the primary and secondary care interface. In primary care, to manage medication supply in sequence with the ordering cycle it was important to have good communication relating to changes in therapy. For patients admitted to hospital, better interaction between the care home and the hospital around patient’s existing medication supply and arrangements was seen as a useful way of preventing duplicate and unnecessary dispensing on discharge.

“... when clients are discharged or when they are admitted into hospital for treatment and they come back. So during that time the medication will not be taken here and we have to return that. And hospital will repeat it again, so there will be duplicate of what we already have at times.”

Nursing home 1, Deputy Manager

Tighter control within the ordering process, especially for ‘as required’ medication could further minimise waste of these types of medicines. Many of the respondents felt that being able to order bulk or stock of these items rather than individual dispensing would be better. Others reported they requested smaller pack sizes of ‘as required’ items and reordered only when supplies were depleted.

“... if a way could be devised that only one supply of paracetamol comes each month, instead of each one getting their own. For generic use, instead of supplying individually, maybe that can be done.”

Nursing home 1, Senior Nurse

Regular review of medication was deemed necessary to ensure appropriateness of prescribing and to minimise waste which resulted from patient refusal or non-adherence. Several respondents remarked that 6 monthly or annual reviews, with the additional ability to request *ad hoc* reviews, was the best way of achieving this. Some felt that unused, unopened medications should be reusable to minimise wastage.

Education and training for those involved in medication administration and reordering would also help minimise wastage. Some examples of situations where education and training may help were given by the respondents and included:

- ▶ learning to deal with patient refusal at the point of administration by returning after a short interval or considering whether a liquid may be more suitable;
- ▶ following up/highlighting cases of persistent refusal to the doctor so that medication may be reviewed; and
- ▶ checking the amount of unused medicines (particularly PRN), before initiating reordering, rather than relying on the repeat prescription order form or medication administration chart.

“... check what you do actually have left from last month before you order again for this month, rather than just ticking the box.”

Residential home 5, Manager

One pharmacist from a primary care trust suggested that if managing the waste of medicines was incentivised or part of the contract between primary care trusts, community pharmacies and care homes, then this was more likely to happen.

“We are going to give you a pharmacist, the PCT will pay for a pharmacist to organise supply, help you with the ordering process, but you need to be committed to reducing waste. I think within that they can’t say no.”

PCT pharmacist

6.5 Discussion

Our findings suggest that the wastage of medicines in care homes is relatively small in terms of both cost and volume, and is perceived as such by care home staff. There are present a little over 400,000 people in care homes in England (Laing W. personal communication). If as this research indicates each resident is associated with the 'waste' of one full prescription item per month valued at £10 (the true NIC mean figure will be a little lower) then the total cost of this would be in the order of £50 million per year. Much more conservatively, we might assume that half of the item was wasted and that, given that most of the items were low cost generic items, the full ingredient cost would have been £2, then the total value of the wasted medicines would be in the order of £5m per year.

The upper limit medicines waste figure of £50 million is used elsewhere in this Report. However, we have been able to get some verification of the range of estimates shown above in a personal communication from Mr Tariq Muhammad, Chief Executive and founder of Pharmacy Plus. This company provides a medicines management and administration system to around 10,000 care home residents. They analysed their returns for one month, using the returns forms supplied by the homes. Their total value came to £48,907. Assuming 400,000 residents this equates to £23,799,026 per annum for England, which equates to roughly the mid-point of the range identified above.

In addition to the sort of waste mentioned previously, this sample had two additional high cost groups which, particularly when combined, could significantly shift the total cost. The first is the prescribing of three months' supply of a drug, so any change would yield greater wastage. The second issue is 'specials' (formulations that have to be individually made by a specialist manufacturer) which start at £150 each. In one month specials represented only 0.3% of the volume issued and yet 8% of the value, at an average cost of £288 each. Not all of these specials are needed. For instance, 500mg of paracetamol 500mg/5ml is a special that can cost £250: 1000ml of paracetamol 250mg/ml costs £7.32.

The most commonly wasted medicines are laxatives and paracetamol containing analgesics. That is medicines which are not in the main required in identical doses, day in, day out, but are needed sporadically. Other causes of waste relate to the patient having some significant event which changes their need for regular medicines – death, a change in clinical condition or an admission to or discharge from hospital.

The supply of medicines to care homes runs as a large engine at constant revolutions, supplying the same amount of medicines at the same rate. Wastage occurs when the rate of consumption of medicines falls below the rate of supply. Given that

the supply process consists of monthly batches of medicines, the mismatch between the rates of supply and consumption has, broadly, two causes. The first is the occurrence of a significant event within the month: death; admission to or discharge from hospital; discontinuation of a medicine or a significant change in a patient's condition. The second cause is the lack, or insensitivity, of the feedback process by which information on consumption is incorporated into the process by which the repeat prescription order is generated. The first cause has little potential for amelioration, the second more so, albeit that if reducing the limited costs of waste identified here were to require significantly increased amounts of either NHS or care home staff time it would be unlikely to be cost effective.

As has been found in other Sections of this Report relating to care delivered in patients own homes, medicine taking in the period approaching death may become erratic. Yet in this context there is a clear moral duty to err towards over supply rather than under supply, so that the patient does not suffer unnecessarily from a lack of medicine.

In the case of hospital admission, or discharge from hospital back into the home, there will be remnants of the month's supply left, or a part supply required until the patients medicines are synchronised with the monthly ordering requirements. It may be thought that there is potential for the drugs dispensed pre admission to be retained and continued post admission. However, medicines are frequently changed while in hospital – the inadequacy of previously prescribed medicines is often the cause of admission. An undue focus on saving limited amounts of medicines waste could create a significant risk that patients, on their return home, would be continued on inappropriate medication.

On discharge from hospital patients will usually have been provided with 2-4 weeks supply of medicines, although not dispensed in an MDS. These medicines would, more often than not, take the patient through to the next 28 day supply cycle for the home, and so it would be less wasteful to use them. There is, however, a risk associated with this course of action. In care homes that use MDS the whole medicines administration process is structured around MDS trolleys and processes. In order to mix hospital dispensed medicines with this process then the home would have to have suitable procedures and suitably trained staff to cope with such occasional deviations from normal practice.

There is potential to reduce waste by improving the sensitivity of feedback into the repeat prescribing process. First, it has been suggested that ordering repeat prescribing should be directly from the care home to the GP surgery. Some homes order repeats via the pharmacy, which may not know which medicines should not be repeated and has a limited economic incentive to keep dispensing

medicines whether they are required or not. Second, there needs to be a process in the care home by which patient medicine taking behaviour is recorded systematically and fed back to the person reordering the medicines and as appropriate to the prescriber as well, so that when necessary repeat prescriptions may be changed.

The latter can not only reduce waste by stopping the reordering of medicines that are being refused, but may also improve patient care – for example, a patient persistently refusing a large tablet may benefit from being changed to a liquid formulation. Yet there is often no direct economic incentive for care homes to take ‘extra trouble’ of this type to reduce medicines wastage, as NHS supplied drugs cost them nothing. From a purely financial perspective care homes should only invest staff time and effort in such activities if they lead to compensatory returns such as reduced labour costs in recording and managing the overage of drugs that need to be returned at the end of each month, or otherwise reduces workloads.

With regard to the use of monitored dosage systems, these are a type of unit dose dispensing system. Unit dosing is used widely in hospitals in the USA to reduce medication administration errors, but is no safer than the UK hospitals’ stock system (Dean 1995). MDS systems are commonly believed to reduce medication errors and waste, and are liked by many care home managers because they can quickly audit their staff’s work by looking at the MDS and seeing if the day’s doses have been given. But the literature to support the benefits of MDS in UK care homes is weak and unidimensional.

Because around 40 per cent of doses are not given from the MDS we do not know whether the medicines administration round, which is usually structured round the MDS device, leads to more errors being made in the medicines that are not contained in the MDS. Nor do we know the consequences of the long ordering lead time often associated with their use, which means that the lag from the date of ordering to the last tablet being administered may be 7 weeks. The increase in dispensing errors that result from the required repackaging of medicines is also unknown. As dispensing into MDS devices for homes attracts no extra funding (notwithstanding any underlying contractual adjustments affecting all pharmacies) it may lead pharmacies to seek economies of scale. This can at worst lead to the establishment impersonal dispensing ‘factories’ many miles from the care homes they serve, which in turn can reduce communication.

MDS dispensing presently has strong proponents and strong detractors. Because of the weaknesses of the current evidence base further research should be commissioned to determine its most appropriate applications.

The ways of reducing the proportion of waste medicines that is reducible relates primarily, as our interviewees stated, to having good feedback and communication between the triad of care home, GP practice and pharmacy actors. If the patients’ needs and wants can be fed into this triad, and if its members are alert to the need to be flexible, then a more sensitive and responsive ordering system should be cost effectively achievable. It is logical to conclude that underpinning this communication there needs to be appropriate training for the staff in care homes, pharmacies and GP practices.

Ordering systems in addition need to be reviewed. Our research findings indicate that care homes should not reorder directly from the pharmacy, but instead directly from the GP practice. However, many homes deal with one pharmacy and more than one GP practice, so the time costs and complexity of this approach needs to be studied. Presumably those who wished to reorder via one pharmacy could continue to do so provided they were provided with a system responsive to their needs. Care homes in our judgment need to systematically record which patients refuse medicines, how frequently and why. The capturing of ‘returns’ at the end of each month, according to CQC regulations, also provides useful information which can be fed into the ordering system.

Some homes would benefit from an agreed approach to dealing with constipation and pain (some analgesics cause constipation), drugs to treat these conditions were the commonest cases of waste. Their staff should work with NHS professionals such as GPs to share understanding of these common conditions, and GP practices should be discouraged from prescribing regular doses of these treatments for what are often acute symptoms. The ability of homes to keep stocks of suitable medicines for any patient who needs them should be further investigated.

6.6 Limitations of the research

The study has its limitations. First, the acceptance rate from care homes was quite low at 35 per cent, compared to our previous study (Barber *et al.* 2009) in which participation was around 75 per cent. This may have in part been due to the short time frame within which a researcher could visit the homes. However, it may also reflect that homes concerned about their performance simply refused to take part. As such, we may have underestimated the extent of wastage. Also, our recording of medicines waste in turn reflected the quality of the waste recording by the homes, and it may be that better managed homes (which implicitly may have had less waste) may be over represented in the sample.

On the other hand, there are several causes of waste likely to be independent of the quality of management of care homes, such as that caused by deaths or patient refusals and/or hospital admissions. The qualitative work, like all such work, needs to be recognised as an analysis of accounts provided for public consumption and may not match reality. Yet there are useful triangulations between the quantitative and qualitative data in this study, and also the quantitative and qualitative findings in other parts of the research conducted by the combined School of Pharmacy, University of London, and York Health Economics Consortium Team.

6.7 Summary

In conclusion, the view taken here is that the reduction of waste should not be seen as a simple end but more as a symptom of the quality of care as a whole. In 'lean thinking' (the efficient management system developed by Toyota, among others), muda (Japanese for waste – in this sense any human activity that absorbs resources but does not create value) is in many ways a marker of the system's overall effectiveness and efficiency (Womack, 2003). By taking a holistic approach we should be able to reduce waste as a by-product of improving quality, rather than a 'lone end' which requires its own policies that may clash with those of designed for other ends such as the reduction of errors.

7 Public, Health Professional and PCT Staff Experience, Attitudes and Beliefs about Medicines Wastage

7.1 Introduction

To augment the findings of the quantitative surveys reported in this document, in-depth qualitative research was conducted to explore perceptions and experiences of medicines wastage, and the ways in which it may be reduced, amongst members of a range of stakeholder groups. The analysis summarised here was undertaken by School of Pharmacy members of the combined team, and informed by the literature reviews described in Section 2. This present Section also draws upon the findings of additional work conducted by both York Health Economics Consortium and School of Pharmacy colleagues.

Studies additional to the main one described here included a series of interviews undertaken with pharmaceutical industry based respondents, and a postal survey of PCT pharmacists and chief pharmacists working in NHS acute and mental health Trusts. The volume of evidence generated was considerable. The findings presented below attempt to bring together the key issues identified, although this Report does not detail all the observations made by the research team.

7.2 Methods

Recruitment of PCTs and interviewees

Six PCTs were purposefully selected and invited to participate. (These were not the same Primary Care Trusts as those which worked with YHEC on the audit of medicine returns to pharmacies.) All six agreed to take part. They possessed a range of contrasting geographical, social and economic, cultural and NHS development linked characteristics. The PCTs involved included organisations serving relatively small inner city areas and limited (circa 200,000) populations with high proportions of ethnic minority community members, through to larger organisations serving communities numbering in excess of 500,000 people living in both rural and urban settings. One was currently involved in delivering a waste return campaign and three others had recent experience of such initiatives. The other two, both of which

happened to be in inner city locations, had not within the past three years conducted such campaigns.¹²

The participating PCTs were guaranteed institutional confidentiality. All the individuals who kindly agreed to take part were similarly promised personal confidentiality. In four of the PCTs staff members helped with the identification of the professionals to be approached for interview. In the two remaining localities GPs, pharmacists and other potential interviewees were approached at random. Letters and emails were sent or telephone calls made, inviting subjects to take part in face to face meetings. These were, with permission, recorded.

When necessary, telephone interviews were conducted. Some professionals participated via focus groups, which were also recorded. This was in part for inconvenience, and also to permit observations of group values. Either JN or DGT were present at all the interviews and focus groups conducted, although neither was present at every occasion.

Via purposive snowballing, a range of voluntary organisations and individuals with an interest in medicines taking (from a number of geographical areas) were invited to take part in this research. Five focus groups involving medicines users were conducted, using a semi-structured interview schedule. (This and the individual semi-structured interview guide employed is included in a detailed report of this work, available from the authors.) As far as is known, the service users interviewed were not patients of any of the participating health professionals. They too were guaranteed personal confidentiality. Participants were also reminded to avoid disclosing personal information that they might wish to keep confidential during focus group discussions.

Similar techniques were used to approach people with a pharmaceutical industry employment background.

Research ethics

A document outlining the work planned was submitted to the chair of the Research Ethics Committee located in one of the six participating PCT areas. The written response from the committee (available for inspection) indicated that the planned

¹² One of these PCTs has since run a new waste medicines return campaign, which has reportedly been 'well received' by local professionals and the wider community.

study should be exempt from ethical approval. Participating PCTs were informed of this decision, and all accepted that no further external ethical approval need be sought.

Sample

In total 61 face to face interviews and 11 focus groups were conducted with medicine users and health professionals – see Table 7.1. Six additional individual interviews and a discussion group were held with pharmaceutical industry employees. Data were collected over a one year period (28th August 2008 to 12th August 2009). In order to support analysis of the data generated within the time available the authors employed a ‘constant comparison’ approach, which involved feeding back findings and developing interpretations on a continuing basis.

Medicines users (n=45) were interviewed in focus groups (n=5). Participants included those on regular repeat and PRN medications; infrequent medicines users; carers of /co-medicine takers with older and less independent medicines users; and parents of children on medication. All five focus groups were audio recorded.

Table 7.1:
Interviewees by role across the 6 participating PCTs

Role	Number of participants (total n=127)
GPs	46
Pharmacists	37
PCT staff	23
Nurses	13
Practice managers/administrative staff	6
Dispensing doctor dispensary manager	2

Analysis

Interviews were partially transcribed. (Verbatim quotes were transcribed when judged valuable: otherwise non verbatim notes were made). Data were coded using thematic headings taken from the semi-structured interview schedule (which was finalised following pilot interviews) together with others which emerged during the data collection and evaluation processes. The abridged survey findings and narrative analysis offered below is divided into three main parts, as follows:

- ▶ The perceived scale and nature of medicines wastage.
- ▶ Respondents’ views on the causes of medicines waste.
- ▶ Opinions on and experiences of how pharmaceutical wastage can be reduced.

7.3 Findings

The perceived scale and nature of medicines wastage

All participants in this research were asked open ended questions as to their view of the extent and significance of medicines wastage in the NHS. The great majority said that they regard it as a very significant issue, the scale of which should not be underestimated. Some said it was a severe concern that they are aware of on a daily basis. Community pharmacists – who constantly see medicines that have been returned, and whose roles are focused on facilitating correct drug use – appeared particularly aware of, and in some instances distressed by, the scale of perceived medicines wastage.

One exemplar comment was:

“We are in an area which is very deprived, people don’t pay for their prescriptions, we don’t get carrier bags back, we get bin bag fulls back.”

IV 11, Pharmacist, PCT area 1

Another pharmacist was immediately able to offer a quantification¹³ of the amount of medication returned to his pharmacy:

“We did an audit here, on a 2 day period we counted the drugs that were returned, it was £624. The company did an audit for the 2 days in their 500 shops, when skewed [sic] for a month in those 500 shops it was over £4.5 million.”

IV 40, Pharmacist, PCT area 3

For GPs, preventing medicines wastage *per se* tends to be less of a ‘front of mind’ issue, although most of the doctors interviewed for this study appeared to be engaged in ensuring that their prescribing is economic as well as therapeutically appropriate. Providing good treatment was typically the doctors’ highest expressed priority.

When addressing medicines wastage most of the health professionals interviewed saw it as being something ‘wrong’, not only in terms of its avoidable financial costs to the NHS but also at a moral/ethical level. Some felt that it was a ‘green issue’, with environmental dimensions relating not only

¹³ This estimate implies that (if the pharmacies involved were of average size) in the order of 10 per cent of all dispensed medicines by value are in total returned to community pharmacies. However, this is an order of magnitude greater than the proportion reported in the YHEC survey conducted as part of this study, and by other research based sources. This may in part reflect the difficulties inherent in translating short term audit findings (which can sometimes influenced by PCT and/or pharmacy staff and/or service user expectations, and related factors) into overall annual wastage cost figures.

to the energy and material costs of unnecessary pharmaceutical production but also those linked to the possibly toxic impacts of inappropriate drug disposal.

Some pharmacists experienced conflict in relation to receiving fees for dispensing prescribed items that they were not sure should have been supplied.¹⁴ GPs, by contrast, were more inclined to feel that medicines were paid for via 'their budgets', albeit that some also said they did not experience the latter as being 'real'. Yet despite cost and other concerns being widely expressed by respondents in all the geographic areas covered in this research, the PCTs participating gave medicines waste reduction varying levels of priority as compared to other issues. One respondent working in a relatively well funded inner city setting said:

"The areas we focus on tend to be those where the management scrutiny lies within the PCT. So we are meeting targets from the PCT on smoking cessation; there is pressure to do that ... There are so many priorities that we are juggling, they are all up in the air and then one issue becomes a hot potato and so you manage that for a bit and can't deal with others."

IV 01, PCT employee, PCT area 2

Service users on several occasions said that they had heard media reports that medicines waste is a widespread problem, or had been told it was by their pharmacists:

I: "Is wastage a problem?"

R1: "Yes, definitely!"

I: "Have you seen examples?"

R1: "I have heard about it."

I: "Personal experience?"

R1: "No, but my brother in law has a lot of left over medicines lying around the house."

R2: "My local pharmacist said they have had £750 worth of unused medicines returned"

FG 01, Medicine users

Such exchanges may be indicative of social pressures to say that medicines waste is a serious problem. (For comparative purposes, the average English community pharmacy currently dispenses approaching 90,000 items a year, with a total ingredient cost of over £800,000). Service users also said that doctors often failed to give sufficient reasons for prescribing. It was argued that pharmacists might do more in this context.

¹⁴ Doctors also effectively receive payments for supplying medicines. Viewed objectively rather than emotionally, salaried pharmacists are arguably personally more distanced from item of service fee related NHS payments than doctors working in income sharing partnerships.

A few individuals, mainly GPs, pointed out that the costs of measures aimed at reducing medicines wastage may exceed those of the waste itself and so not be worth investing in. But the most frequently expressed belief was that avoidable medicines wastage often occurs, and that further action should be taken to reduce it.

A number of respondents said that if the reduction of medicines wastage levels is seen only as an isolated, relatively minor, cost control function it may be less likely to attract medical and high level management attention than it does when presented as an integral part of good quality overall health care provision. If cutting the costs of pharmaceutical waste is presented as a 'silo' financial issue it may attract relatively little clinical interest, except perhaps when it threatens to become a publicly reported 'scandal'.

Medicines waste now compared to in previous decades

A number of experienced pharmacists (including one with a substantive NHS management role) said that in their view the NHS's approach to medicines waste reduction is more informed and better managed today than it was in the 1980s and 1990s. This was evidenced by reference to the virtual elimination of 6 month prescribing, and the widespread adoption of 28 or 56 day periods. References were also made to the introduction of better hospital admission and discharge procedures relating to 'patients' own drugs' (PODs)¹⁵. Such views were reflected in the findings of the University of York postal survey's findings. Respondents to the latter highlighted initiatives such as 'green bag' schemes, which can help prevent the waste of community supplied medicines when people go into hospital.

But some other respondents said that medicines wastage has become a bigger problem in recent years, because more patients are in receipt of 'poly-pharmacy'. For instance, one GP commented:

"I have been here 20 years now and the biggest change: 20 years ago repeat prescriptions were hand written by our reception staff. If anyone was on more than about 3 medicines the PCT [sic] would come round and say this is poly-pharmacy, you must stop doing this straight away. I checked, we have about 300 repeat items a day going out."

IV 44, GP, PCT area 6

The interpretation offered here is that while there is evidence that medicine management approaches have become more robust during the past decade,

¹⁵ In objective terms neither 28 day prescribing (see Section 2) or the quality of medication management after hospital discharge should be accepted uncritically as successful in the context of waste minimisation. See, for instance, Care Quality Commission 2009.

it is also true that the volume of medicines used has increased significantly and that there are many more older people taking complex medication regimens and living in largely unsupported community settings than was the case in past decades. A few respondents questioned the extent to which PCT policies and service providers' practices have sufficiently adjusted to this fundamental shift, despite tangible efforts to reduce waste.

Frequently wasted Items

Some respondents remarked that 'everything' is wasted, referring to the wide variety of medicines returned to pharmacies and GPs. This is consistent with previous research showing that even treatments for severe conditions such as cancer and indications like preventing transplant rejection are not be taken as intended. However, the findings of the reviews and surveys presented earlier in this report suggest that the majority of unused medicines are for intermittent and relatively minor ailments (GI or skin disorders).

During the interviews undertaken for this study, inhalers (containing drugs used to prevent or relieve asthmatic symptoms or COPD, which may be popularly referred to as chronic bronchitis) were, along with painkilling medicines, the items most frequently identified as commonly wasted. Other products often mentioned included statin based and blood pressure reducing medicines, proton pump inhibitors and other drugs for gastro-intestinal distress, sip feeds, blood glucose testing strips and dressings. Devices and appliances were highlighted by a number of respondents, as exemplified by comments from a primary care commissioner:

"[It] tends to be gadgets, testing strips, and inhalers – because every time someone writes a prescription they get a new one. Increasingly you see that pharmaceutical companies are doing that, you used to be able to get rotator inhaler caps for your inhaler, now you have to get them with a new inhaler."

IV 08, PCT employee, PCT area 4

Some professionals expressed concerns about the possibility of oversupplying when private companies deliver appliances directly to patients. This may happen, for instance, with stoma/colostomy bags provision. One GP complained of being 'sent the bill' for such items while having no control over the ordering process.

A number of respondents suggested that some companies deliberately cause waste by, for example, introducing new devices (such as insulin injectors or blood glucose monitors) while taking others off the market. But, as already noted, other respondents also acknowledged that the costs of intervening to remedy waste may actually outweigh the monetary benefits of doing so.

"Many of the medicines we supply as generics cost [little more than] the dispensing fee. You have to remember that when we are talking about reducing the costs of waste."

IV 51, GP, PCT area 6

One implication of remarks like this is that it may on more occasions than is often understood be more economic to over-supply patients with low cost items than it would be to under-supply them and risk the possibility of precipitating an additional home visit, or an emergency hospital admission or outpatient attendance.

Individual level interventions to remedy material waste which involve increased labour costs may not be economically viable in any context where the prices costs of drugs are low. It follows that waste reduction interventions should be targeted towards areas where there is a strong probability that the true marginal savings generated (for example, the actual difference in price between a smaller or larger pack of dressings or tablets) will exceed the total cost of the intervention itself, plus any additionally incurred service costs elsewhere in the health and social care system. Some respondents did not appear to have a strong awareness of this reality. Thinking was more often dominated by the existence of material rather than labour wastage.

Issues relating to waste medicines disposal

Pharmacists and other health care professionals did not feel that they could estimate with any degree of accuracy the extent to which patients dispose of unwanted medication at home rather than returning them to a community pharmacy or a dispensing practice. It was generally assumed that routine medicine disposals would normally be via domestic rubbish or the drains, although some survey participants said that members of the public would be more likely to take larger amounts of residual medicines to pharmacies. This may also be so with items believed to be unusually expensive, especially if it were thought that some form of recycling might be possible.

A few GPs said patients occasionally asked them how to dispose of medication they did not need any more, but this is reportedly a relatively rare occurrence. Some pharmacists commented that it tends to be the same people who return unused medicines. This to a degree reflects the findings of Swedish and other research referred to in Section 2.

Only one of the community pharmacies visited had a clear sign on display relating to waste medicines disposal. The level of effort put into encouraging patients to return unused medicines to pharmacies varies between PCTs. Some interviewees had thought carefully about this area. But in the main respondents had difficulty in describing local or national policy goals relating to, for instance, whether or not all or

just a proportion of waste medicines should ideally be returned to pharmacies. Many expressed some uncertainty about the intended health and/or financial benefits of unwanted medicines return (DUMP) campaigns.

Medicines users said that they often keep unused or partly used medicines for future use, and normally felt justified in doing so. On occasions questions were raised about the motives of professionals who might want all unused medicines returned. (For example, it was suggested that this might increase subsequent sales.) Against this, one patient reported being told by a pharmacist (apparently regardless of contractual obligations) that their pharmacy did not take waste medicines. Some other similar events involving health professionals were mentioned. Both pharmacists and dispensing doctors also spoke of problems with returns which include controlled drugs, as this means having to complete extra paperwork and asking the person returning the medication a series of questions.

In addition to taking unwanted medicines back to pharmacies, people also described *'throwing them in the bin'* or down the lavatory. There were suggestions that medicines may be disposed of at home because the amounts involved are considered trivial, or less often because the individuals involved did not feel they needed to take them but did not want either health professionals or officials outside the NHS to know this. This research provided evidence that on occasions some people receiving social security benefits may feel obliged to go on collecting medicines they do not intend to take because they fear that checks would be made. It is possible that in some cases that such fears might be justified.

However, even in circumstances like this last, medicine users generally showed a concern to behave responsibly and not to harm others. Several respondents reported making special efforts to dispose of drugs in a way they thought safe. Their attitudes were illustrated by one focus group participant who was particularly aware of the environmental damage that might be caused by medicines disposal into water resources:

"Yeah, but you don't know if it pollutes the water though, they were saying that men were getting emasculated by the contraceptive pill going into the water."

Respondent 7, FG 02, medicine user

Even though in reality female sex hormones normally enter water supplies as a result of medicines such as contraceptives being taken correctly rather than being disposed of unused, the existence of such public concerns has policy implications. If it would be desirable for a greater proportion of unused medicines to be returned to pharmacies, this research confirms that it could be useful for relevant communications to emphasise the environmental as well as the family safety related reasons for making

such returns. But the findings of this research also indicate that a proportion of patients will need to be more assured of confidentiality and continuing access to NHS care before changing their current disposal behaviours.

Respondents' views on the causes of medicines waste

A wide range of responses were given as to the causes of medicine wastage. Even though there are overlaps between categories, they naturally divided between those which appeared to interviewees to be mainly unavoidable, and those which seem largely avoidable.

In summary, respondents described (correctly or otherwise) 'unavoidable' causes of waste as including:

- ▶ medicine users getting better, so that their residual medicines are no longer required;
- ▶ patients deciding that they do not need a medication because, for instance, they find it ineffective, even though they still have the condition for which it was prescribed;
- ▶ people starting a new medication and discontinuing it relatively soon, due to – for instance – unwanted/unaccustomed side effects; and
- ▶ patients stopping taking a medicine they have been using for a long time because, for example, of the late appearance of side effects or an emergent belief that the condition being treated no longer presents a risk to them or their family.

In this last context one informant, who was a retired pharmacist, recounted having to return several unused packs of a statin medicine. He had been on this treatment for several years after a heart attack, and had built up a limited reserve 'stock'. But he had recently started to experience side effects from taking this medicine. Other examples of the causes of waste identified in interviews which patient and/or other respondents tended to regard as unavoidable¹⁶ were:

- ▶ patients going into hospital;
- ▶ individuals being provided with MDS (monitored dosing system) devices which it was argued by a number of respondents can sometimes cause rather than prevent waste;

¹⁶ Another category of waste that may or may not reasonably be regarded as unavoidable is that associated with medicines going out of date before being dispensed: that is, pharmacy returned waste. This may not always be separately identified from that associated with the return of unused or partly used dispensed medicines.

- ▶ speculative prescribing, which in essence involves patients being given a drug to see if it works or in case they feel they need it; and
- ▶ ‘unavoidable non-compliance’ associated with forgetfulness or confusion.

Several professional participants, mostly GPs, were overtly sympathetic to patients regarding the difficulties associated with poor adherence in medicines taking. It was suggested that if, for instance, less able medicine takers could be given more help by home care staff they would find it easier consistently to take their treatments as prescribed:

“As patients have chronic conditions people are on more or more medicines, as regimens get more complex people are more likely to genuinely miss medicines at one time of the day or another.”

IV 13, GP, PCT area 1

Additional illustrations of experiences and attitudes relating to what is often regarded as unavoidable medicine wastage are discussed briefly below. Causes of medicine wastage perceived as being avoidable by participants in this qualitative research included:

- ▶ people losing, or saying they have lost, their medicines and wanting replacements;
- ▶ the over-ordering or over-supply of repeat medicines. This can result, respondents indicated, not only from patient ‘laziness’ but from pharmacists ordering repeat medication for patients and having little or no positive incentive to check that every item is needed;
- ▶ deliberate medicines hoarding by individuals;
- ▶ ordering to maintain benefits.

Associated with this last, one respondent said:

“I have now a very good doctor, but the old doctor if you didn’t want something on your prescription they would take it off, so we were ordering stuff even though we didn’t want, we knew we had loads in the cupboard but we didn’t dare not get it. The other thing is that they look at that when you do DLA (Disability Living Allowance) and that as well they check on your medication. So if you are shown at your doctor not to be on that medication it can affect your DLA form. So you have to keep in mind that people are ordering tablets that they are not going to take.”

Participant 6, FG03, medicines user

Further examples of what were regarded as avoidable causes of waste include:

- ▶ GPs ‘over prescribing’ and/or prescribing unnecessarily;¹⁷
- ▶ third parties ordering repeat medication for patients;
- ▶ incorrect storage of medicines leading to their having to be discarded; and
- ▶ ‘media scares’ and disturbing reports relayed by friends that cause patients to stop taking medicines and so waste them.

The issue of incentive mechanisms for stakeholders involved in prescribing and dispensing was highlighted by some participants:

“I also have a great concern when pharmacists and not patients order repeats. I think it’s not a robust system, it should be the patient. Pharmacists have a real incentive to dispense so they get the fee.”

IV 31, PCT employee, PCT area 4

In another instance it was suggested that GPs cause waste by prescribing needlessly large volumes for patients paying prescription charges ‘to give [them] value for money’. Some respondents also said that patients who are exempt from prescription charges use the NHS to obtain medicines such as paracetamol or aspirin inappropriately. A pharmacy assistant interviewed (IV 17) stated that this not only leads to avoidable medicines wastage but also to an unproductive use of professional time.

Some community pharmacists commented that when medicines are returned patients often say ‘the GP changed the medicines which is why I am bringing them back’. At the same time they were aware that although this is true in some cases, in others it was said in order to avoid embarrassment and perhaps to absolve the person concerned from responsibility. Pharmacist respondents noted that people may tear off the labels from returned items so they cannot be identified. One implication of this is that if in future NHS users believe that advances in health service computerisation and medicine pack identification will make it easier for ‘officials’ to trace wasted medicines, this could change disposal behaviours and promote increased secretiveness.

It was mentioned by many interviewees that death or the point of entry into long term care is often the time when waste medicines come to light. Although

17 One GP mentioned a culture in which patients expect a consultation to end with the patient taking away a prescription (IV 37). However, there is sociological research which questions such provider-side perceptions. Similar issues relate to prescribing and dispensing in some mental health care contexts, where a possibly inappropriate fear of legal consequences may drive supply in circumstances where there is a high probability of wastage (IV 09).

'end stage' home care may itself be associated with some supplied medicines being left unused, waste medicines identified at the time of death or admission into residential or nursing home can accumulate over a number of years:

"The reason it is associated with death is that's the only time the house gets cleared, it could have been going on for [say] two years."

IV 06, PCT employee, PCT area 5

Health professional interviewees and family members expressed surprise at the amounts of medicine that sometimes build up in the homes of older individuals. However, there is a risk that the repeated description of a relatively few highly memorable events could lead to an exaggerated perception of the scale of this problem.

Problems with repeat prescribing and dispensing

Interviewees raised a number of issues related to repeat prescribing and dispensing leading to waste, which were summed up by one respondent as follows:

"Systematically, practices are churning out repeat prescriptions with as little fuss and bother as possible. Most patients are exempt from charges so there is no value [cost] for them in the medicines ... you have the system churning out prescriptions, a patient who doesn't pay and a pharmacist who gets paid to fill the prescription. So you have really set yourself up with the perfect system to fill people's houses with medicines."

IV 12, PCT employee, PCT area 1

Another commented:

"Most prescribing is repeat and most [repeat] prescribing is managed by the least trained person in the organisation, the admin staff [receptionists]."

IV 04, PCT employee, PCT area 3

It was stressed that patients often do not know the names of all their drugs, or indeed recognise them if they are supplied in varying presentations. Patients may also fear that if they do not request an item it will disappear off their repeat list, so they will not be able to order it in future without another consultation with their doctor. Although this should not occur, it is unquestionably a perceived risk. Some patients also reported being dispensed items which they had specifically not requested. Illustrative comments included:

"My inhalers run out at different times, I order two more than I do the other one. But then they

are different sizes too, one is 500g and one that you take every day is 200g – I can't think why."

"I crossed it out several times with a big, thick black pen, but do you know? When I collected it, it [the medication the patient did not require] was still in the bag!"

Medicines users in FGs 02 and 04

The level of effort put into the processes of repeat prescribing and dispensing by many community professionals, practice staff and patients, should not be unfairly denigrated. However, significant levels of concern were expressed by a number of interviewees. One relatively pro-active PCT had set up an initiative to provide practice staff with training on repeat prescribing but it was said that high staff turnover had meant that this was only partially successful. It was also suggested that annual therapeutic reviews conducted by GPs are not all of a high standard.

Some GP respondents believed there were safeguards in place in their practices to ensure that the repeat prescribing process did not permit or encourage avoidable wastage. Some also suggested that pharmacists should have more of a role in checking that medication is needed before it is dispensed. Other GPs, however, were frank about problems in the system, but pessimistic about the extent to which it could be improved:

"Our days are so busy that the gold standard of checking every item against the patient record is completely unrealistic. A good proportion go through on the nod because we don't have the time to do anything else."

IV 44, GP, PCT area 6

Several community pharmacists also expressed doubts as to the extent to which they and their colleagues acted appropriately and effectively to reduce the medicines wastage associated with repeat prescribing and dispensing. Some respondents openly described being *"torn over knowing the patient does not need the medication, but knowing there is a fee associated with dispensing it"*. Even in relation to a 'not dispensed' incentive scheme in which local pharmacists receive a modest payment for not supplying repeat items that are prescribed but not needed, one pharmacist felt it to be ethically questionable to be in receipt of fees for not dispensing medicines which GPs should not have prescribed in the first place. Another expressed view was that general practitioners and community pharmacists should be paid to work in the most complementary way possible.

It may be concluded that the repeat prescribing system was identified by both health professionals and medicines users as a significant factor in causing medicines waste, over and above the effects of volitional individual action.

Deliberate stockpiling and hoarding as a cause of waste

It is commonly believed that excessively long prescription durations (resulting in the issue of three or six month supplies, or even greater amounts at one time) have historically been among the most important drivers of medicines waste. If a patient's condition changes, all his or her dispensed items may need to be discarded. But the intentional actions on the part of some service users can also on occasions contribute to such problems.

Interviews with NHS patients indicate that if, for example, people believe that a 28 day prescribing period is uncomfortably short, or they for other reasons feel in danger of not having a 'safe' reserve, some will tell health professionals that they have lost their medicines when this is not actually the case, or take other measures that could be interpreted as deliberate stockpiling.

Several health professionals noted that medicine stockpiling and hoarding appears to be more prevalent among elderly patients than younger people. Professional respondents tended to give examples of 'chaotic' stockpiling or hoarding, in which patients had accidentally acquired amounts of medication in significant excess of their needs. Such stockpiles might go out of date before they can be used.

Medicines users, by contrast, were more like to identify 'deliberate' stockpiling, in which they obtain extra supplies for a specific reason. This difference is potentially significant. It may point to a need for improved professional awareness of service users' motivations and requirements in relation to long term medicines supply.

Further to this, comments on the extent of hoarding should be taken with some caution. In one PCT several participants in separate interviews recalled what was apparently the same incident involving an individual who had amassed a very large number of wasted inhalers. Whilst there is no reason to doubt the veracity of these accounts, such duplications could lead to an exaggerated perception of the frequency of such events.

Patients' relationships with their doctors

The occurrence of avoidable medicines wastage can be seen as an indicator of poor quality patient care. This research revealed high levels of concern about particular products, most notably inhaler waste in relation to both asthma and COPD treatment. In asthma, patients need to balance appropriately the use of preventive as opposed to symptom relieving medications. This requires effective patient education and support. At the same time it appears to be relatively widely believed that medicine wastage often reflects poor – or at least restricted – communication between doctors and their patients.

Some service users who have decided not to take their medicines may well believe that they might upset or annoy their doctors by admitting this:

"[They] don't tell the doctor as they don't want to upset them. People worry the doctor will tell them off, the doctor has a special place in their lives. When I first started [at this pharmacy, and was not known to patients] every mistake was the pharmacist's fault, not the doctor's. Doctors are greatly respected."

IV 18, Pharmacist, PCT area 1

The difficulty of knowing what is actually taking place in relation to day to day medicines taking was emphasised by a PCT based professional, who said:

"The GP knows that they have prescribed – the pharmacist knows what they have dispensed – but none of us knows what happens with the medicines once they get into the home. It's about getting patients to be honest and to say to the doctor when they are not taking them."

IV 07, PCT employee, PCT area 6

Perceptions of patients being dishonest in their relationships with health professionals should be interpreted with caution. But some patients interviewed also expressed a desire for better communication by the medical professionals and others involved in their care:

"Prescribing needs to be taken more seriously. [I am] not happy with the way patients are prescribed medicine without being given an explanation."

Participant 11, FG 01, medicines user

Against this, many service users said they were very satisfied with the care given by both their pharmacists and their GPs, although a number took the development of larger practices to mean that patients often have to see different doctors. Some expressed discomfort with this. They stressed the importance of personal relationships between patients and their GPs, and the value of doctors knowing their patients and their medical (and their medicine taking) histories.

A number of points were raised with regard to prescription items being collected even when they are not going to be taken. Some of the remarks offered suggested that sometimes individuals' inability to accept fully their conditions may be an important cause of non-adherence in medicine taking, and ultimately waste. Seen from this perspective, it should not be assumed that GPs are as naïve as some criticisms suggest.

Several GP respondents described instances in which they were aware that medicines they had prescribed were very probably not being taken as they had recommended. Yet they had judged it inappropriate to confront their patients directly.

This finding reinforces other research suggesting that maintaining good, or at least workable, doctor patient relationships can require compromises that external observers do not always adequately understand. For the purposes of this study it confirms that (in theory at least) it may sometimes be desirable for other health professionals to question patients' about their medicines taking, provided that this can be done in partnership rather than conflict with medical care providers.

Relationships between GPs and community pharmacists

A number of pharmacists and to a lesser extent medically qualified respondents indicated that they believe that more effective working relationships between general practitioners and community pharmacists could improve clinical care standards and outcomes, and minimise medicines wastage. It was apparent that as community pharmacists see returned medicines on a daily basis they are on average more aware than family doctors of such waste as a practical reality. But against this they may be less aware of other patient and public interests.

Some GPs questioned the value of community pharmacists' contributions in contexts such as conducting Medicines Use Reviews. Nevertheless, two of the 46 GPs interviewed mentioned their own limited knowledge of drugs and said that pharmacists should be more directly involved in selecting medicines for patients. A significantly larger number of GPs said they were at the time of interview unwilling to use the relatively new pharmacy repeat dispensing scheme, which allows community pharmacists to manage the repeat prescribing and dispensing process for up to a year.

The main reason given for this was that practitioners feared losing touch with their patients' treatment needs. It also appeared that for many GPs the fact that a community pharmacist has a degree in pharmacy and is a registered practitioner does not necessarily mean that they are clinically competent and should be trusted to care for 'their patients'. The interviews undertaken indicated that many doctors require personal knowledge of a given pharmacist's competencies and reliability before fully accepting them. GPs also described losing confidence in local community pharmacies as they shifted from personal professional control to corporate ownership.¹⁸ It is possible that interviewees' responses in this area were influenced by factors which are difficult to observe or assess accurately, such as underlying personal concerns regarding losing autonomous control over health care working practices.

¹⁸ In reality professional standards and staff training quality may be as high or higher in 'chain' pharmacies as they are in 'independents'.

Monitored dose system (MDS) use as a possible cause of waste

The objective of supplying medicines in monitored dose systems such as Dosette boxes or blister packs is that it should enable individuals at risk of making errors to take complex treatment regimens more safely and effectively. In institutional or supported home care settings MDS dispensing may also reduce the risk of nursing or other less qualified care staff making medicine administration errors. However, interviewees' responses in this area revealed concerns relating to the effectiveness of MDS dispensing relative to its costs and its impact on waste levels.

GPs and other professional respondents noted that if patients have significantly impaired mental self care abilities, MDS dispensing is likely to be of little help to them. It could even be hazardous, in as much as it may give others a false confidence in their being able to care for themselves and/or their partners. Similarly, some professionals expressed concerns that MDS dispensing was being used as a solution to problems such as non-compliance in medicine taking (and so also to waste reduction) when in fact much deeper issues/needs remain to be addressed:

"Often you go into the patient's house and they have started one Nomad (MDS tray), taken a few tablets from another, some from another. They get four from the pharmacy to last the month but open Tuesday in one in one room, move into the next room open another Tuesday and so on."

IV 15, GP, PCT area 1

"One of the chaps I care for in an informal way, he is intelligent in many other ways but when it comes to medicines he just seems to get confused. He has one of these boxes but I go to see him on a Friday and there is still all of Thursday's medicines there."

Participant 3, FG 02, medicines user

One respondent suggested stricter guidelines for defining the suitability of MDS dispensing for particular patients, and that ideally it should be agreed by both the patient's GP and their pharmacist. However, although such systems should not be seen as 'cure alls', almost all respondents saw a significant role for prudent MDS use in appropriate circumstances.

Variations in the way medicines look and are packed

Despite the value of professional interventions, the patient is the last line of defence in any system designed to facilitate the safe and effective use of medicines. But their ability to fulfil this role is impaired if they cannot recognise the drugs that they should be taking. Interviewees reported experiences such

as getting two different 'brands' of a product in one box. Other reported 'split pack' linked difficulties include uncertainty as to how much medicine has been taken, and failures to provide patient information leaflets.

Respondents who were carers also reported problems related to getting patients to accept unfamiliar treatments:

"Generic drugs when they change, it is very confusing. So does the packaging, the brands, they like their packaging. I am colour blind, in one case I got one lot of tablets confused with the other. I think we understand the reason, but sometimes insufficient thought is given to the end user and the problems they will experience with sudden changes to [their] tablets and also the packaging."

Participant 10, FG02, medicines user

Some health professionals also noted similar cautions:

"They (patients) don't look at the box and the name, it's all by colour and shape to them."

FG 08, Nurse, PCT area 4

With regard to pack sizes, both patients and professionals complained about variations (most typically manufacturers' packs contain 28, 30 or 31 days medication). This means that some medicines will be wasted if they are re-ordered every 28 days. Several respondents called for greater standardisation. Some suggested that such variations were deliberately maintained by companies in order to cause wastage.

Yet respondents with pharmaceutical industry roles denied such motivations. It was pointed out that the marginal cost/price of two or three extra pills is in reality low, and far less than the 10 per cent of the pack price some other interviewees appeared to assume. One 'industry respondent' with a pharmacy degree pointed to differing market preferences across Europe, and the fact that if packs are dispensed in calendar as opposed to lunar month volumes a one month saving in dispensing fees could be achieved over the course of a year.

End of life care drug wastage

The return of medicines recorded when an individual dies or enters long term institutional care is the largest single wastage 'cause' highlighted in the available literature, albeit that this in reality is a composite category. It includes medicines accumulated over extended periods of time before the terminal care phase, as well as those left over from the latter. Despite an increasing emphasis on delivering palliative and terminal care in home settings, especially for cancer patients, several professional respondents reported that medicines waste is in this context declining because nursing and

other specialist team members (which may include pharmacists) are becoming more skilled and careful about ordering medicines and other items:

"I think palliative care does cause some wastage but that is sort of inevitable in that area of care. But I think management in the area of palliative care has improved significantly – we are no longer seeing 3 months worth of high strength drugs returned from a palliative care patient, that degree of wastage is long gone."

IV 31, PCT employee, PCT area 4

Nevertheless, some pharmacists commented on the high cost of some medicines prescribed for palliative/terminal care patients, sometimes in what they considered to be excessive amounts:

"If GPs could be persuaded to reduce the length of prescribing (in terminal care), they are still prescribing 2 months worth of medication. But the needs of the patient they change all the time, and the patient we know they will die. They are expensive drugs."

IV18, Pharmacist, PCT area 1

Such concerns are understandable, especially amongst professionals and managers whose primary focus is on financial costs and the 'correct' use of medicines as technical interventions, as distinct from the holistic treatment of patients as people.

By contrast, a number of GPs spoke of the sensitivities involved in changing long term treatment regimens when a patient enters their terminal phase:

"[Perhaps] they should not be on things like statins with only a few months left to live. But it seems a bit cruel to say we are writing you off now so we are only going to give you these drugs to make you pain free and forget about all those drugs we have been banging on about for the last 25 years, they don't matter anymore. That's quite a difficult debate to have. More often than not, you say if the patient is able to swallow OK keep them on all their regular drugs, as that will give them the psychological help that you are not giving up on them."

IV 13, GP, PCT area 1

In one reported instance there was a local problem with the timely supply of medicines for dying patients. This resulted in ordering medicines 'in case', rather than when needed. A GP involved suggested that appropriate stocks of medicines should be obtained and held in the local pharmacy, to be supplied promptly to the patient if and when needed. Elsewhere, other professionals advocated having a system whereby drugs typically required for terminal care are securely stored in home care settings, and can subsequently be re-supplied elsewhere in the event of the patient dying.

Concerns about dispensed NHS medicines being sold or given to others

In some areas interviewees suspected that 'waste' medicines, in the sense of treatments that are never consumed, are a relatively rare problem. This was because they claimed that their intended users are likely to send or sell them on to others who will take them. In one practice there was thought to be a significant problem with patients trying to get medicines for extended family members in parts of South Asia, where medicine quality or accessibility may not be the same as that in the UK.

In other less advantaged settings in England professional respondents linked problematic use of NHS supplied medicines and allied products to illicit drug use:

"[There is] huge leakage onto the street of things like Fortisip [a sip feed] to drug abusers ... as a city centre [practice] we see this. You find this out as the pharmacist rings up and says 'you know you prescribed 28 Fortisip, well him and his three mates have just come into the shop and drunk the lot'."

IV 15, GP, PCT area 1

The extent of such problems should not be overstated, although when primary care professionals are required to face behaviour of this sort it may be very challenging.

Beliefs about recycling waste medicines

This theme was independently raised by a number of the professionals and patients contributing to this research. It evoked strong feelings, both negative and positive. A proportion of both the doctors and pharmacists interviewed argued that re-dispensing should be permitted when unused packs were intact, in good condition and in date. It was claimed that this would reduce material wastage. Some pharmacists spoke of their frustration and distress in seeing items leave the pharmacy and be returned a short time later, and then having to discard them. Some professionals saw the recycling of medication as a logical extension of recycling in other areas of life:

"I think we really need to look at it. Green issues are really important at the moment. The amount of waste we get. When you think back to when the regulations were written, it was before we had blister packs and things like that. We now have re-use for pandemic flu drugs I think there is a case to explore it, looking at re-using some medicines. If they have been in a pack and you can see it has been untouched, you could ask how it has been stored to make sure it has been stored correctly. I think it should be explored."

IV 17, Pharmacist, PCT area 1

"If they are in date and in blister packs, I don't see why they can't be used in the NHS."

FG 10, Nurse, PCT area 4

A number of dispensing GPs and one dispensary manager had looked into the option of sending unused medicines to developing countries, and two practices had actually done so. Some patient interviewees were also in favour of this option (which some pharmaceutical industry respondents noted is practiced in France, where the industry is responsible for waste medicine collections) or of recycling within the NHS. Several medicines users indicated that they do not take back unused medicines to their pharmacies as they now know they are 'only destroyed'. This is a significant observation, if policy makers were to wish to maximise unused medicine return rates.

However, other interviewees, especially pharmacists, were strongly against the idea of recycling dispensed medicines, even in circumstances when they have been returned in unopened packs. This is because of quality and safety concerns, in line with the official view of agencies such as the WHO. Some respondents also thought it offensive to suggest that medicines judged unsuitable for use in this or similar countries could be distributed in poorer parts of the world.

A hospital pharmacist who had worked outside the UK on a medicines recycling project also noted that in practice the returned medicines sorting process was complex, and that often little of that which was sent could in fact be used. Observations of this nature mean that the extent to which any form of community supplied medicines recycling scheme could affordably reduce the local or global costs of NHS medicines wastage is likely to be very small, particularly when it is remembered that only a minority of returned medicines are in unopened, in date, packs.

Medicines wastage in care homes

The issue of medicines wastage in care homes has been separately researched – see Section 6. But the qualitative research reported here, which did not directly involve residential or nursing home based respondents, found that care homes were often regarded by PCT staff, community pharmacists and GP interviewees as being responsible for large amounts of avoidable medicines waste. Such respondents claimed, rightly or not, that care home systems and practices wrongly lead to significant numbers of unused and partially used prescription items being thrown away:

"What we find in a number of homes is whatever's left at the end of the month, so often the PRN medicines or the liquids, what is left at the end of the month they throw away. They think that is normal to do that, and that is how you should practice and then they re-order fresh the following month ... tablets are 60 in

the pack and they only need to give 56 in the month the other four will be thrown away as they think they need to start a new pack, but they could just carry that dose on."

IV 07, PCT employee, PCT area 6

PCT and some other respondents mentioned that the high turnover of staff in care homes made interventions to assist with managing medicines of limited value. Some said that in their view medicines management competency levels are often disappointingly low. Perhaps linked to this, reliance on standardised operating procedures and verifiable audit trails can lead to waste (interviewees claimed) through, for example, discouraging the use of common stock bottles for widely used treatments. Comments were also made to the effect that as residents get NHS medicines free, care home managers have little incentive to avoid ordering unnecessary items. Some annoyance was expressed regarding what were perceived as unduly wasteful care home practices, such as inappropriate repeat medicines ordering.

From what respondents said, care homes appear to attract a significant proportion of PCT staff attention. Some commissioning organisations, for example, had arranged initiatives on topics such as avoiding the unnecessary re-ordering and re-supply of repeat items.

In interpreting these observations it is important to recall that care homes contain relatively large, highly visible, concentrations of people being prescribed above average volumes of medicines. It is also relatively easy to quantify the proportion of drugs unused in such settings.

To individuals such as pharmacists – whose expertise and professional mission is centred on medicines use – it may well appear reprehensible when even relatively limited amounts of inexpensive items are discarded with seeming disregard. If considerable amounts of costly professional time have been invested in MDS dispensing of items that could have been more economically supplied, this must also be very irritating.

But this does not necessarily mean that in reality nursing home practices are cost ineffective, when seen from an overall public interest perspective. Given the findings contained in Section 6, an informed conclusion could be that PCT pharmacy and allied staff time might often be better focused elsewhere in more difficult to manage settings. However, it may be a relatively challenging and costly task to identify and support more effectively isolated or otherwise vulnerable medicine takers living independently in the community.

Medicines waste at the interface with hospital care

As with care homes, the qualitative research described in this Section was not directly aimed at understanding medicines waste and its prevention

within hospitals. Rather, it was concerned with attitudes and beliefs in the community and themes relevant to the passage of patients and medicines across the junctions between primary and secondary care, and in particular the processes of admission to and discharge from hospital. To this end a limited number of hospital and mental health trust pharmacists were interviewed, and YHEC undertook a postal survey. This last was sent to a sample of 379 potential recipients, of whom 115 returned a completed questionnaire.

Many respondents mentioned with approval the Patients Own Drugs (PODs) initiative. This is aimed at reducing wastage by encouraging patients to take the medicines that they are on into hospital, and where appropriate to go on using them during their admission and/or on their return home. The PODs approach may also enable hospital staff to understand more fully than was often previously the case patients' drug histories. But some medicine users reported that their drugs had gone missing or wrongly been thrown away during recent admissions:

"Last time I was in it didn't work very well, one of [my medicines] was lost. I wasn't very satisfied. I would rather they left them with me and said look after it yourself. Some [hospitals] do."

Participant 2, FG03, medicines user

In another illustrative instance a dispensing practice dispensary manager was concerned that a patient had ordered extra medicines before an admission as a result of the local PODs policy, but that they were wasted when their treatment was changed on discharge. Some GPs also mentioned continuing problems relating to discharge processes. They expressed concerns about the accuracy of the information given to them, its readability, and the timeliness with which it arrived. Although interviewees reported that some progress has been made, it appears that further effort is needed to improve medicines supply and reduce medicines wastage after hospital discharges.

It was in addition reported, rightly or wrongly, that the use of limited formularies by hospitals can lead to medicines being supplied in formulations that patients cannot or will not take. They may also be supplied in a form that the patient does not recognise and/or chooses not to accept:

"Yes, they [the hospital] keep changing what the patients are on because it's not on their formulary; they change the type or the brand. They will change a statin say, if a patient is not on a typical one, as they don't have it in their formulary, the patient throws them [their original medicine] away, and then we normally end up changing them back to the statin they were on originally, so the hospital supply is thrown away too."

IV 20, GP, PCT area 1

However, respondents said that in their view the extent to which such incidents contribute to total medicines wastage in primary care or across the NHS as a whole is small, especially as many hospitals now limit discharge prescriptions to only seven or possibly 14 days' worth of treatment. The overall picture derived from the interviews undertaken in this context and the other survey returns analysed was once again that many NHS staff believe that although problems remain, effective steps have been taken to reduce medicines wastage during the last decade.

Opinions on and experiences of how pharmaceutical waste can be reduced

The 2004 pharmacy contract and the 2008 White Paper *Pharmacy in England* contained a number of key provisions and policy innovations aimed at reducing the volume and costs of residual medicines. Respondents' views on these and related issues are discussed below, together with additional themes related to how waste can be avoided.

The value of pharmacist provided Medicines Use Reviews (MURs)

At the time that this research was conducted community pharmacies in England were funded to provide up to 400 MURs per pharmacy per annum, for which a payment of £28 per review was made. Pharmacy MURs as currently (in 2010) specified are intended to identify problems with medicine use, rather than to check the clinical appropriateness of therapy. The latter should be evaluated amongst user groups such as older people via annual medication reviews undertaken by GPs.

Not all pharmacists said they provided MURs, in part because for pharmacies with just one professional staff member this may be difficult to in practice to arrange. Of those that did carry out reviews, some said that they tended to spend longer on MURs than the 10-15 minutes guidelines suggest, and that they often addressed clinical appropriateness issues.

There appeared to be a significant difference between pharmacists' and GPs' perceptions as to the value of MURs. Several medical interviewees questioned their usefulness, although several pharmacists recalled identifying episodes involving medication waste and/or incorrect medication use through an MUR:

"When I do an MUR I look at the repeat slip. I go through each one and they say yes I take that, I don't take that, I haven't been on that for years, I don't know why that's one there and actually they forgot to take this out. So we tidy it up, and once I send that to the GP the person there can tidy up their computer and that way you don't have this picking the wrong one or ordering the wrong one."

IV 29, Pharmacist, PCT area 3

Against this positive finding there was some concern that employed pharmacists feel pressured to undertake MURs. Some appeared to resent the fact that the income generated by this 'extra job' did not go directly to them, but to the pharmacy. A number of respondents also spoke of the limitations of the present MURs, and that they may not be focused on meeting the needs of more vulnerable medicine users.

One individual said:

"You could perhaps have an MUR where you could focus on the PRN [medicines]. What tends to happen is if someone is on a lot of medication, that you take a long time going through the medicines and there is not much time left to go into other things. You are tending to focus on pharmacological things so they tend to be overlooked a little bit."

IV 24, Pharmacist, PCT area 3

Interviewees in all groups suggested that there may be a tendency to select for review patients perceived as being comparatively less likely to have complex difficulties. In addition to experiencing problems with entering pharmacists' MUR reports into their record systems, some GPs warned of unnecessary and unproductive role duplication and suggested that 'chain' (which might broadly be taken as meaning commercially driven) pharmacies may conduct MURs amongst patients with only a limited need for them, rather than with those most likely to benefit:

"My feeling is [that] an MUR is a waste of money – you are paying two people to do the same job. We have to check drugs every year, why pay someone else to do the same job again? We look at MURs and then we shred them, we don't keep copies."

IV 15, GP, PCT area 1

PCT based respondents also tended to question the value of pharmacy MURs as presently provided as an advanced nationally funded pharmacy service, which they said inhibits locally direction. A number expressed frustration because they said they do not feel able to review and evaluate MURs, and are unsure of their benefits:

"I'm spending £2-3 million on MURs [figure not in fact reflective of PCT 3 local spending] but I don't think I'm getting £2-3 million [worth of benefit], I've had no evidence that they are making an impact."

IV 04, PCT employee, PCT area 3

Patients, by contrast, seemed relatively positive about MURs, albeit that most said that they already received good quality support and advice from their pharmacists. A medicines user who had had an MUR commented:

"It is very useful. I am in my 80s. I forget what I am prescribed for, so I look back at my review and it tells me [for example] that tablet is for my blood pressure."

Participant 12, FG 02, medicines user

In three of the participating PCT areas limited numbers of domiciliary MURs were being conducted at the time of the field research, by both community and PCT pharmacists. In PCT 1 home MURs were conducted prior to the commencement of MDS provision. In two other areas PCT respondents said they were hoping to introduce this service.

Several participants commented on the complexities and slow development of the local process:

"We are trying to get them to do domiciliary MURs, they have taken 2 years to decide who is going to pay for the CRB checks."

IV 07, PCT employee, PCT area 6

"We would like to do home MURs because it is the people who are stuck at home who have the problems with their medicines. There are issues about CRB checking and who pays for them. But they are the people that we don't see very often. They are seen at home, but often when something has gone wrong."

IV 22, GP, PCT area 3

Despite the current lack of research based cost effectiveness evidence, it appeared that a majority of the respondents contributing to this research accepted that well conducted pharmacy MURs can be useful in relation to reducing waste and improving care quality.¹⁹ But some GPs do not share this view, and it is not possible for PCTs locally to quantify the benefits that community pharmacy MURs are currently generating. It is also very likely that their productivity would be improved if their provision could be effectively targeted towards those most in need of better pharmaceutical care.

¹⁹ In relation to the financing and value of money of pharmacy MURs, it is relevant to note that they have in effect been resourced to date from money previously earned by community pharmacists via other routes, such as retained medicines discounts. Research not reported here suggests that a short form needs assessment instrument, derived from existing research findings, of a type that that community pharmacists might be used to identify those patients most likely to benefit from pharmacy or home based pharmacist MURs.

Repeat dispensing

The uptake of the (relatively new) pharmacy repeat dispensing service option (which allows GPs to issue a 'master' prescription with a set of additional unsigned 'slave' repeats that pharmacists can subsequently dispense against for periods of up to twelve months) had been slow in all participating PCT areas. The recorded rates varied between two and five per cent of all repeat dispensing in the six areas concerned.

GPs are not incentivised to use this scheme, although practices can benefit from repeat prescribing related work being shifted to community pharmacies (see Holden and Brown, 2009). Participating pharmacies receive an additional payment of £1,500 a year, regardless of the number of items handled or the interventions made.

GP respondents gave a range of reasons for not using this scheme more extensively. It was most frequently said that they wished to sign repeat prescriptions themselves in order to keep in touch with patient needs and check if any QOF related interventions were 'flagged'. It was also reported that it could be difficult to identify suitable patients, who were unlikely to require changes in their treatment for the period of the prescription. One GP said that if an altered dosage or different drug was needed before the prescription is fully dispensed it would demand 'a completely new set of paperwork'.

Pharmacists were typically more positive about adopting this repeat dispensing option, but consistently reported a lack of enthusiasm amongst other stakeholders:

"Not too much around here. One surgery uses it for all their blister pack patients and a few patients in one of our care homes. In terms of members of the public, only about three or four [are using the scheme] but again they don't always understand that. So I've got scripts in there where they have had the first issue and it has been explained to them and they sign up, but they have never come back for the subsequent issues and the GP has issued other scripts to them."

IV 34, Pharmacist, PCT area 5

Encouraging the use of pharmacist repeat dispensing when this can constructively relieve GP workloads and maintain or enhance patient care quality should help to limit medicines waste. But at the same time options for improving 'conventional' repeat dispensing should not be ignored. For example, a respondent working in a dispensing GP practice reported that:

"We have an automatic repeat system, so every 28 days we automatically deliver it to them ... But we don't put on there, all we put on there

is 28 day pack sizes, we don't put on their inhalers, creams, painkillers. We put a label on the bag saying our next delivery will be 3rd August so when they get it in July they will have rung up and said will you put me in an inhaler or some painkillers. So ... they don't order ... every month because they don't have to ring up for everything."

IV 41, dispensing practice dispensary manager,
PCT area 6

Our research also found similar good practices being pioneered in some community pharmacies. The objective of such systems is to help ensure that while medicines that should be taken consistently are always renewed, those which are appropriately used on a variable basis are not automatically re-supplied. They instead require specific re-ordering by the service user. PCTs and other stakeholders with an interest in medicines waste minimisation should be aware of the potential value of this approach.

Twenty eight day prescribing

A general acceptance of the desirability of 28 day prescribing was found amongst commissioners and some but not all prescribers. However, the level of investment and effort devoted to supporting this end varied between PCTs. Some also seemed to have a more flexible approach than others.

Professional and service user respondents had more mixed views and experiences relating to prescription durations. One pharmacist protested:

"It varies [by branch in a chain of 7 branches], the surgery here typically gives 100 days at a time. The surgery in X [another other branch] often gives a year at a time. People literally walk out with 360 days supply ... We've had people say 'I can't cope with this, will you store it for me', it's madness."

IV 26, Pharmacist, PCT area 3

Against this, a few of the GPs interviewed were articulately critical of PCT advice to change to 28 day prescribing:

"There are also system costs in prescribing for short durations: GP time, patient travel, pharmacy costs. So the knee jerk reaction to say well we should limit it to 28 day prescribing is, in my view, completely wrong headed ... GPs are signing twice as many scripts so have even less time to monitor [whether or not] the prescribing is appropriate."

IV 44, GP, PCT area 6

One such respondent suggested that 28 day prescribing boosts pharmacy earnings rather than saving the NHS money. The extent to which this policy is evidence based with regard to material

waste reduction was also questioned, even within PCTs. One interviewee remarked:

"We also looked at the number of days prescribing and the amount of waste but found no correlation ... We had thought there would be, although it is possibly because we [only] did a one week audit that no correlation was found, you might have to do it over a longer period to see that."

IV 02, PCT employee, PCT area 1

Medicines users also identified issues of cost and convenience in relation to 28 day prescribing. For example, one said:

"There is a cost thing as well, I know my GP used to put two of the same inhaler on the same script and then you only have to pay the one charge. But I know he got fed up with that because at that point I wasn't managing my condition particularly well and he used to say 'You've got through a Ventolin in 2 weeks!' Certainly if you are paying for your prescriptions it's a lot cheaper [to have a longer duration prescription] isn't it?"

Respondent 4, FG03, medicines user

One GP argued that 28 day prescribing should apply to those who do not pay for prescriptions, while those who pay should more often be given longer prescriptions. But this raises equity issues and might in some respects be considered incompatible with NHS values.

Leading on from this, 28 day prescribing was one of the few discussion areas where social class was spontaneously mentioned. A dispensing doctor interviewee described being forcefully confronted by a well educated patient with a second home about the length of prescription this individual needed, and having his arguments in favour of 28 day prescribing effectively challenged. The same GP mentioned other patients who were less assertive, but might also have good reason to want three month or even longer prescriptions.

Interviewees' views on prescription charging to avoid wastage

When asked, many of the professionals and a significant number of medicine users interviewed said that they believe that large numbers of NHS patients (other than themselves) do not think about the cost and extent of medicine wastage, and that the scale of the latter should be more widely publicised. It was commonly assumed that raised awareness of medicine costs would decrease wastage. It was also often said that many patients are not aware that they can return unwanted medicines to a pharmacy, and that there should be more national campaigns.

Yet one pharmacy manager strongly believed that local campaigns to be more effect than a national campaign, while another pharmacist argued that waste campaigns 'get lost in all the PCT campaigns going on'.

One pharmacist said that community pharmacists should seek to have more in depth conversations with customers when medicines are returned. Others were worried this would deter people from bringing back 'residual' drugs. While gathering better management information about the circumstances in which medicines go unused and are ultimately discarded could be helpful, some respondents also felt that a proportion of patients would be 'put off' if they believe that the NHS could track wasted items back to the individuals for whom they were prescribed.

Along with expressing judgments that medicines are often not properly valued by those to whom they have been supplied, a substantial proportion of the primary care professionals and PCT staff interviewed made remarks to the effect that 'when someone is given something free they don't value it'. Several respondents suggested that everyone should be charged something for their medicines, and that even if this was a small amount, wastage would as a result be reduced. It was commented that many patients who get free prescriptions can afford other things, such as mobile telephone or cigarettes:

"What is not paid for is not valued. But I know what will happen; someone will be trotted out who can't afford it! These days I think we overplay this poverty thing a bit. People are quite willing to spend £1 on a lottery ticket or mobile phone texting or whatever. I think the prescribing fee [sic] to the chemist, if we paid that, it would be [the] straightforward solution."

IV 10, PCT employee, PCT area 1

"You wouldn't get someone who pays for their prescription hoarding it would you, not at £7.20? If we charged everyone 50p an item that would get rid of it [waste] overnight. But we'd never get away with that politically would we? But that's what they should do."

IV 11, Pharmacist, PCT area 1

Patients, by contrast, appear more likely to be aware of issues such as perceived injustices in NHS prescription charge exemption rules. Some mentioned the fact that in Wales and Scotland prescription charges have been removed. A number of both professional and service user respondents were concerned that in England the cost of a charged prescription item is sufficiently high to discourage some people from accessing appropriate treatment.

When questioned further about this topic, most interviewees who initially advocated universal charging said it should be set low enough not to

present a barrier to care access, or that people in financial need should continue to be exempted. Inconsistencies like these indicate a need for careful evaluation from a policy formation perspective. The qualitative research undertaken in this context indicates that people are not necessarily fully committed to the opinions they initially express at interview. Further, the literature reviews in Section 2 of this Report show there is little or no evidence that charging a greater proportion of the population for NHS prescription medicines would reduce waste levels in a cost effective manner. It could to a degree limit primary care costs by discouraging medicines use amongst those most sensitive to such price signals, but with potentially detrimental impacts on overall health spending.

Should NHS medicine packs be priced?

Some sources have advocated putting the supply price on every NHS medicine pack in order to raise awareness of costs, and so perhaps to reduce wastage and/or increase consumption. This research sought to understand the views of respondents on this suggested way of reducing the cost and volume of residual medicines supplied by the NHS. It found rather less immediate support for this proposal than there was spontaneous advocacy in favour of increased direct charging. Some interviewees said it would 'make patients realise the cost of medicines'. But in rather more cases, service user respondents and others felt that pack pricing might cause some patients in need of effective treatment to become worried about its cost to the public purse. It might also, it was suggested, in some instances encourage the 'selling on' of some medicines and/or deliberate requests for more costly treatments.

One GP said that the people who he most wanted to target probably would not care about the price of their medicines. Messages that appeal to a sense of responsibility are by definition unlikely to affect the genuinely irresponsible. Interviewees also mentioned the problems that could emerge in situations where (as is the case with approaching a half of the items used in the community) a medicine's ingredient price is lower than the prescription charge:

"Getting into discussions about 'why am I paying £7.20?' is not something we want when we are busy trying to dispense drugs."

IV 43, Practice manager PCT area 6

In conclusion, the interpretation offered here is that even it were possible within the European setting to implement such an idea, relatively few people are on consideration likely to judge the option of printing UK prices on all NHS medicine packs advisable. Most may be more inclined to think that it would cause more problems than it would solve.

Unused medicine return campaigns

All the participating PCTs had run a 'DUMP' or similar campaign since their establishment. But the level of engagement in such activities varied at the time of the research undertaken for this report. Professional and other respondents had mixed views as to the costs and benefits of such efforts to raise awareness of the waste problem. Some questioned whether or not such activities change behaviour sustainably, or simply '*encouraged people to make space for more drugs that end up as waste*'.

On some occasions interviewees suggested that highlighting (and in so doing perhaps exaggerating) the scale of medicines wastage could have harmful effects in that it could reinforce false beliefs that much prescribing is unnecessary and that not taking medicines is normal behaviour. This point links back to the literature review findings reported in Section 2 regarding the unwanted consequences of negative messages.

One pharmacist reported concern that NHS colleagues seemed 'proud' when an audit identified/projected millions pounds worth of waste:

*"I do sometimes think what are we doing?
Saying 'oh well done' we have lots of waste –
surely it's a bad thing, waste!"*

IV 32, Pharmacist, PCT area 5

Other respondents asked if DUMP campaigns might result in medicines which could reasonably be kept for prudent re-use at a later date being returned for destruction at the NHS' expense. One interviewee described home visits which revealed older medicines (either prescribed or self purchased) like pain killers that patients thought were waste, but were in fact still fit for use. This is a possibility which it appears some pharmacists find difficult to consider dispassionately, as noted earlier in this Section. Yet from a public interest perspective it nevertheless demands rational discussion.

In summary, there was considerable underlying uncertainty as to the fundamental goals of 'once-off' unused medicine return campaigns. The extent to which PCTs and the NHS as a whole wishes all unused medicines to be returned to pharmacies or dispensing practices for subsequent disposal at NHS cost is unclear. A significant proportion of those respondents involved in executing DUMP and allied campaigns said that they did not regard them as a major contribution to 'solving' the problem of wastage or non-adherence in medicine taking, despite the pride managers may feel about local newspaper and other media reports highlighting such PCT interventions.

Other opportunities

Some medicine users and professionals said that they thought that waste savings could be generated by giving small 'starter packs' of medicines to patients beginning new treatments. However, the economic viability of this and related 'common sense' suggestions needs critically to be considered. Limited volumes of small starter packs would be relatively costly, both to produce and dispense. Other respondents argued that a better option would be to enhance the care and support given to individuals starting new treatments by pharmacists and/or other health professionals. There is a much more robust case for this option, particularly if from an economic perspective it also led to measurable health gains.

At a more general level a number of medicine users stressed the importance of being able to recognise their medicines. One participant in a focus group pointed out that Warfarin tablets are presented in colours consistently linked to their strength, and that there are no other major variations between differently sourced products. She argued that either this approach should in future be applied to other commonly used medicines, or that NHS patients should be entitled to specify a specific brand or related presentation for each of their medicines. It was also suggested that just because older patients in the UK pay for their medicines via taxation rather than directly, this should not make them any less entitled to choice and control than consumers who pay out of pocket.

7.4 Summary

The findings presented above underpin the discussion and the recommendations in Section 8 below. To avoid repetition, an abbreviated summary is therefore offered here. These qualitative observations provide robust evidence that there is extensive public and professional concern about the scale of medicines wastage in the NHS, particularly amongst pharmacists. There is no doubt that drug waste occurs. However, the extent to which this is so and likely to be avoidable could on occasions be exaggerated as a result of hearsay linked to social pressures not to understate this problem. Waste is a term which has pejorative connotations, even though no system or process can be completely waste free.

When confronted with relatively large volumes of material medicines waste this research found that it may be difficult for actors such as community pharmacists to assess accurately its importance against the overall scale of primary and community health service medicines supplied and the wider costs and benefits of good quality health care. Similarly, it appeared that some interviewees could more easily recognise the lost value of a physically wasted medicine than that of waste associated with

avoidable human labour²⁰ and the opportunity costs of not only sub-optimal pharmaceutical therapy but also impaired holistic health care.

This research also suggests that underlying public and political concerns about medicine hazards and allegedly unnecessary prescribing on occasions to elide with expressed worry about material medicines wastage. Well intended attempts to raise awareness of the later may on occasions contribute to misperceptions. At worst, the perceived importance of preventing drug waste as defined in this Report could outweigh that of delivering better individual and public health. But the extent of this hazard should not be overstated. The majority of interviewees, particularly clinicians, appeared to be committed to prioritising health and welfare gain.

Respondents understood that medicines waste can result from many factors. They range from deliberate choices on the part of patients through to involuntary personal and system related variables. Although there was on occasion some simplistic blaming of 'irresponsible' prescribers and patients, the majority of interviewees displayed a relatively sophisticated awareness of the multiple, sometimes complex, causes of wastage.

Various interventions to reduce medicines wastage were spontaneously identified as desirable by respondents, although not all would necessarily be possible, (cost) effective or otherwise desirable. They included:

- ▶ ensuring that every time a repeat prescription is written and/or dispensed systematic checks are made to ensure that all medicines supplied are genuinely required by the person for whom they were prescribed;
- ▶ reviewing treatment regimens and medicines use more frequently and effectively;
- ▶ providing better practical and psychological support to vulnerable medicine takers and their carers at all stages of the medicines taking cycle, from initiation to long term treatment maintenance;
- ▶ reforming care home and nursing home practices to prevent the unnecessary disposal and re-ordering of prescription items;

20 The average medicine costs about £10 for a month's supply, and the median somewhat less. The cost to the NHS of pharmacist and medical labour is typically between £25 and £100 per hour.

- ▶ improving the quality of the relationships between patients and their doctors and pharmacists, so that medicine users become more willing to tell professionals when they are not taking their drugs;
- ▶ enabling GPs, community pharmacists and other NHS professionals to work together more effectively;
- ▶ stopping inappropriate prescribing, including the supply of unduly large volumes of drugs and allied items;
- ▶ charging all or most patients on every occasion a prescription medicine supplied by the NHS; and
- ▶ 'recycling' dispensed items which are returned unopened and in good condition.

Populist policy decisions based uncritically upon such qualitative data would be unlikely to achieve desirable goals. There is little or no robust evidence to support several of the implicit beliefs expressed above. But the findings contained in this Section nevertheless highlight the importance of appropriately respecting service users' preferences and requirements in contexts like, say, the duration of prescriptions supplied.

Some GPs had thought about the economic prescribing and use of medicines considerably more carefully than others. A few individual doctors appeared to spend much more time than their peers on activities such as checking repeat prescriptions. Some PCTs also appeared, primarily for historical reasons, to have attached rather more priority to reducing medicines waste *per se* than others.

It was not possible via this research to identify which if any individual practitioner and organisational approaches were in overall terms more cost effective than others. There were suggestions that relatively robust attitudes to medicines management issues as a whole may correlate positively with above average performance in other areas, but this possibility could not be demonstrated by this study. However, a majority of experienced respondents in all areas expressed general agreement with the view that – notwithstanding the reality that more members of the population are taking greater volumes of primary care supplied medicines than in the past – the modern NHS is taking more effective action to limit waste and support appropriate medicines use than was the case in previous decades.

8 Implications of the Research Findings

8.1 The scale, costs and root causes of NHS medicines wastage

This Report presents the findings of a series of discrete yet linked investigations into the scale, costs, causes and management of medicines wastage relating to the provision of NHS primary and community health care in England. This final Section discusses the main observations made in order to provide an overview of medicines waste within the NHS primary and community care system and, as far as it is possible, to offer recommendations as to how existing achievements in this area can most effectively be taken forward in order further to limit this problem.

However, the overall strength and nature of the evidence – including our own – on how current policies and service delivery programmes might be improved is in few instances equivalent to that provided by, for example, randomised clinical trials of medical treatments. This is partly because of the complex nature of medicines wastage as a phenomenon with multiple social, organisational and individual level causes. One initial recommendation is that public discussion of medicines waste management should recognise this reality, and be conducted in as prejudice and emotion free a manner as possible. Particular attention should be given to not attributing blame to patients who, whilst the ultimate consumers of medicines, are in many cases not responsible for the root causes of their waste.

The costs and systemic significance of NHS medicines waste

There is evidence from our study of widespread expressed concern amongst health professionals (most notably pharmacists) and many patients about the extent of medicines waste in primary and community care and in care homes. A proportion of dispensed medicines are not consumed by the people for whom they are prescribed, and are eventually discarded. The costs of this problem should not be ignored or trivialised. But neither should they be exaggerated.

Our quantitative findings show that one individual in every five surveyed in 2009 reported having one or more broadly defined ‘waste’ medicine in

their possession, that was not in use at the time of interview. Projected nationally, the present estimated value of unused medicines being retained in private households is approximately £90 million.

An uncertain proportion of these items will in fact be used again at some future point, or in subsequent years returned to community pharmacies or dispensing GPs. But against this a similarly unknown additional volume of medicines is discarded informally by patients and carers. Our public survey findings show that about 20 per cent of respondents said they typically dispose of medicines through household waste, albeit that the volume and cost of each such disposal is likely to be significantly smaller than the average return made to a community pharmacy.

This country’s ageing population is now receiving about 50 per cent more prescriptions items per head for the prevention and treatment of conditions such as heart disease, stroke, diabetes, COPD and asthma than was so in the early 1990s (OHE 2010). Yet our results suggest that the relative scale of the present domestically retained waste medicines problem is of a similar magnitude to that observed when the OPCS investigated this topic some 15 years ago. Given that the inclusion criteria for waste medicines adopted in our survey were broader than those used by the OPCS (as they included items being retained for possible future use) it appears that the true volume of NHS medicines waste has not increased over time.

The value of medicines returned to community pharmacies in England is estimated in Section 4 at just over £110 million per annum. As noted above, our separate estimate of the value of waste medicines retained in households at any one time is about £90 million, and that for care home unused medicine disposals is £50 million annually. If all unused medicines reported in households are eventually disposed of and our point estimate of their value represents the annually accumulated total value of such drugs (this could be an overestimate, but such an assumption is in our view robust for the purposes of this study), these figures indicate that the value of wasted NHS primary and community care prescribed medicines is in the order of £250 million a year.

However, allowances may in addition be made for factors such as the possible under-reporting of waste in our public survey (see the analysis offered in Section 3), the volume and cost of medicines disposed of in domestic waste and via the drains,

and the value of returns made to dispensing GPs. The latter were not included in our community pharmacy audit calculations. It is also of note that PCTs incur returned medicine disposal costs, which might arguably be factored into estimates of pharmaceutical wastage. We therefore conclude that for England as a whole a gross annual NHS primary and community medicines wastage valuation of £300 million represents a realistic central estimate.

This is a significant sum, equivalent to approaching 4 per cent of general pharmaceutical service drug and allied product costs in England and 0.3 per cent of all NHS annual outlays. However, it should be emphasised that the costs associated with any additional intervention to reduce waste levels could in many instances outweigh any savings that might result, particularly as many of the medicines identified in our survey and pharmacy audit were relatively inexpensive.

We estimate that the proportion of the waste identified that might be considered to be cost effectively avoidable is likely to be between 30 and 50 per cent of the total volume identified (ie £100-150 million). This represents approximately £1 in every £50 spent on prescribing in primary and community care and for an average PCT is (given the probable additional cost of the interventions needed to secure wastage reductions) likely to equate to an annual further potential saving of around £0.5M.

National performance

Medicines waste occurs in all health care systems. For example, our literature review indicates that the volume and cost of medicines waste in this country is similar to that recorded in Sweden (Ekedahl *et al.* 2003, Ekedahl 2006 – see Section 2), which has in some important respects a more advantaged population than that of England. Furthermore, studies from Canada and Spain which examined returns to pharmacies generated estimates of a similar magnitude to the pharmacy audit described herein (Boivin 1997, Coma *et al.* 2008).

We found no evidence that medicines waste is significantly greater in this country than other comparable nations, or that NHS organisations are failing to tackle it as robustly as other health care providers and/or purchasers. The array of policies and practices developed by the English NHS in areas such as providing GP medication and pharmacy medicines use reviews, coupled with initiatives in areas such as repeat dispensing by pharmacists and PCT staff support for improving prescribing and medicines use, is at least as extensive as those identified elsewhere.

Some respondents to our surveys said they believed that people receiving 'free' medicines (about 80 per cent of NHS prescriptions do not currently attract prescription charges) are at special risk of wasting

them. It was suggested that even if only limited charges for all prescription items were introduced, this could lead to very significant reductions in medicines waste. This was in essence because it was thought that this would '*make patients more responsible*'.

But more deliberative responses to further questioning provided a more nuanced picture than that suggested above. Further, our literature review did not provide evidence to support the view that NHS medicine waste would be decreased by more extensive and/or higher prescription charges, or increases in population level awareness of NHS medicine costs.

In the associated context of non-adherence in medicine taking, NICE (2009) has warned of the negative effects of 'patient blaming'. It argues that beneficial behaviour changes are more likely to accrue from robust efforts to understand service users' requirements and meet them as effectively as possible. Our research results support this finding, and the related conclusion that increased charging for prescribed medicines would be more likely to reduce persistence in medicines taking than it would be to decrease the ratio of material waste to overall drug use (Atella *et al.* 2006, Elliott *et al.* 2007, Ersek 1999, Hirth *et al.* 2008, Kirking *et al.* 2006, Lexchin *et al.* 2004, Woolf 1995).

Despite continuing challenges in some areas (see Section 7 of this Report, and the Healthcare Quality Commission 2009 in the context of the hospital/community interface) we therefore conclude that primary care related medicines wastage does not represent a serious systemic problem within the NHS. Achieving further improvement in national performance in this and related contexts is in our view likely to require a realistic appreciation of the degree of success already gained, and the complex causes of continuing wastage problems.

We also draw attention to the calculations presented in Section 5. These show that the opportunity cost of the health gains foregone because of inadequate medicines taking in just five therapeutic contexts is likely to be in excess of £500 million. This is over twice the level of the avoidable waste costs identified in this Report. Such data confirm the potential utility of investing in – as and when they can be identified – cost effective methods of reducing non-adherence rates and optimising the appropriate use of medicines.

Although such interventions may have as one of their secondary benefits the effect of reducing certain forms of avoidable waste, this should not be seen as their central value. Many people may be more immediately aware of the observable reality of physical drug waste than they are of theoretically avoidable health gain losses associated with taking medicines inconsistently or otherwise insufficiently, or the costs of inefficient professional activities or

needless expenditures of service user time. But we recommend that this bias should not be allowed to skew service improvement agendas.

Root causes of medicines wastage

Failures to take medicines to optimal effect are, assuming good prescribing and dispensing standards, often attributable to either intentional or accidental non-adherence on the part of their users. But although non-adherence can and does lead to wastage as defined in this Report, our research highlights the fact that the latter's causes also include factors which have nothing to do with patient motivations or actions. The quantitative and qualitative research findings reported here indicate that the root causes of waste additionally encompass:

- ▶ patients recovering before their dispensed medicines have all been taken;
- ▶ therapies being stopped or changed because, for example, of ineffectiveness and/or unwanted side effects;
- ▶ patients' conditions progressing, so that new treatments are needed and others become redundant;
- ▶ patients' deaths, which as well as serving to reveal previously unused medicines may involve drugs being changed or dispensed on a precautionary basis during the final stages of palliative care;
- ▶ factors relating to repeat prescribing and dispensing processes, which may independently of any patient action or inaction cause excessive volumes of medicines to be supplied; and
- ▶ care system failures to support adequately medicines taking by vulnerable individuals living in the community or on occasions in institutions, who cannot independently adhere to their treatment regimens.

Against this background of plural causality, reducing medicines wastage is likely to be facilitated more by multiple measures aimed at improving therapeutic and care quality than it is by any single 'magic bullet' intervention aimed at, say, changing medicine user beliefs about medicine taking or further increasing the proportion of prescriptions written for relatively short periods. Another important conclusion is that cutting medicines wastage should not be portrayed as an isolated task, separate from that of improving health care quality as a whole.

We offer qualitative evidence to the effect that in order to motivate clinicians and service users to use medicines as effectively as possible decision makers and managers should place emphasis on improving health outcomes, rather than waste cost reduction alone.

8.2 Implications for Policy

Ongoing health care improvement is likely (in part at least) to demand progressively more effective prescriber/patient communication, and more equal and supportive therapeutic partnerships between health care professionals and service users (Coulter 2005). Where medication related concerns exist, open relationships based on mutual trust should facilitate informed and meaningfully shared decision-making.

There is also robust evidence that changing the psychological balance between the perceived necessity of medicines taking and individuals' concerns as to why it may be unnecessary or harmful can facilitate greater adherence in medicine taking. This should, if only to a limited degree, reduce wastage. (See, for example, Horne *et al.* 2005, Horne 2009).

The qualitative research findings reported in Section 7 suggest that there would be significant service user and professional support for policies that aim to improve further the quality of medicines related information provision to patients, and/or promote enhanced support for medicines taking in the community. Community pharmacists and GPs are also likely to agree that more effective ways of joint working between them to deliver better targeted support for medicines taking should be possible. Yet they may disagree as to how progress towards this end can best be achieved, and how existing roles and institutional arrangements should be changed. For example, there was some observed conflict over which professionals should lead the management of repeat prescribing and dispensing.

Relatively little robust evidence exists on the correlations between factors such as the quality of patient/doctor and patient/pharmacist relationships and levels of material medicines wastage. Similar cautions apply with regard to the extent to which interventions to change medicine taking related beliefs can effectively be made in the primary care setting, and would in practice improve health outcomes and/or reduce drug wastage. There is as yet little evidence as to the size of the effects achievable in daily practice, or their value for money.

It is not possible, therefore, in the general context of improving communications between GPs and community pharmacists and their shared interactions with patients to offer evidence based policy recommendations. It is, however, reasonable to argue that more effort should be focused on using psychological and related medicines taking research findings to develop practical interventions capable of cost effectively improving drug use, and where possible reducing waste. It appears that adequate investment in such translational activities has yet to be made.

At the service and practice development level the qualitative and quantitative evidence summarised here does allow additional recommendations to be offered. They are as follows:

Providing targeted support for patients starting new therapies and those on selected high cost/high gain treatments

Our research indicates that there are sub-groups of individuals and types of medicines which are associated with an above average risk of waste. For example, the findings of the qualitative research undertaken raise concerns about socially isolated individuals who are on multiple medicines, and our quantitative surveys also highlighted specific difficulties associated with treatments for respiratory disorders such as COPD and asthma. Evidence from our work in care homes indicates particular problems with PRN medicine supply and use, and the special challenges associated with the care of individuals with mental health problems.

There is good quality trial based evidence that providing face-to-face or telephone support to patients starting new treatments can cost effectively improve treatment continuation rates (Clifford *et al.* 2006). This should to a degree reduce wastage. There appear to be significant opportunities for introducing new or extended pharmacy services of this type, on either a locally or nationally funded basis.

There is also a robust case for prioritising the provision of medicines taking support to areas where it can offer the most benefit. Many of the medicines identified as unused in our surveys are relatively inexpensive and associated with only modest health benefits foregone (e.g. medicines for skin conditions). Similarly, participants interviewed in the qualitative research recognised that the costs of intervening may in some cases outweigh the potential benefits associated with improved compliance. As such, intervention for patients taking medicines which are particularly expensive, and/or likely to deliver high levels of health gain only when taken appropriately, should be prioritised. In most instances such treatments are presently delivered in secondary and tertiary settings. Yet in future years an increasing proportion of relevant interventions in areas such as, say, HIV care and cancer treatment may be delivered via community services.

Supporting high quality prescribing and incentivising closer professional management of medicines supply at the point of dispensing

Although our quantitative findings indicate that only a small proportion (circa 2 per cent) of medicines were wasted due to reported over-supply in our sample, several aspects of the research point to the potential for improvements in the management of medicines

at the point at dispensing. Improved monitoring and management of repeat dispensing is a key priority, even though medications given for acute transient conditions have the highest chance of becoming residual. This was, for example, apparent in our research relating to care homes, where automatic dispensing of repeat PRN items was particularly likely to be regarded as unnecessary.

Greater use of the pharmacy managed repeat dispensing arrangements first introduced in England in 2007 has, expert sources suggest, the potential to reduce medicines waste, improve care and relieve doctors' repeat prescribing workloads. Yet respondents' opinions on such schemes were divided. We present evidence that a significant proportion of GPs believe that this scheme currently has disadvantages. However, greater use of pharmacy managed repeat dispensing and closer working between community pharmacists and GPs may follow the 'roll-out' of electronic prescribing.

Medicines wastage would be reduced if every time a repeat prescription is dispensed the pharmacist or other pharmacy or dispensary staff member involved could check with the patient concerned that each medicine is required, and was adequately motivated to prevent unnecessary supply (Jesson *et al.* 2005). Such reviews should allow other reasons for discontinuation to be assessed, including the management of symptoms, side-effects and patients expectations about their medicine.

Our observations indicate that procedures which separate the 'automatic' re-supply of medicines to be taken regularly and that of medicines that are to be used on a discretionary basis promote this end. Such improvements might be particularly beneficial in care home settings, where the process of repeat prescribing and dispensing is often sub-optimal. More attention needs to be paid to the quality of pharmaceutical care in this context, albeit that the extent of cost effectively avoidable medicines wastage in care homes should not be overstated. This is not least because of current safety and allied care quality management requirements.

We also recommend that the effectiveness of local or other 'not dispensed' incentives, via which pharmacists receive modest payments when prescribed items found to be surplus to requirements are not supplied, should be subject to further national investigation. Initial findings from our qualitative research suggest that these may be effective at changing behaviours within individual localities, although larger studies are required.

In addition, our findings suggest that patients using items such as inhalers and nebulisers for conditions like asthma or COPD, or injectable drugs for diabetes, may benefit particularly from better pharmaceutical care at the point of dispensing. The findings of the pharmacy audit identified a number of such devices being returned, as well as cases of

individuals having multiple devices (e.g. inhalers). For those medicine users who wish to attend them, EPP and other courses aimed at helping them manage their conditions confidently and effectively can also be of value. They may, for instance, help combat factors like disease denial and/or the social stigma associated with some forms of medicines taking. (See, for example, Adam *et al.* 2003, Carter *et al.* 2005, Eatock and Baker 2007, Newman *et al.* 2004.)

Service commissioners should be aware of such options, and be prepared to fund such services as and when they are judged likely to be cost effective. However, given the limited evidence base available it is not possible to offer unequivocal recommendations here as to what level of service should be regarded as affordable.

Flexible use of 28 day and other prescribing periods

Our findings indicate a broad acceptance of the principle of 28 day prescribing, particularly amongst PCT staff and community pharmacists. But our qualitative interviews identified questioning of this approach by GPs and patients. Amongst these stakeholders there were some calls for a more pragmatic approach to prescribing periods, and suggestions that it may be more cost effective to prescribe and dispense for longer than 28 days in some instances. The findings from our research in care homes also suggest that automatic 28 day supply, whilst perceived as efficient in this setting, may lead to the excessive provision of some medicines.

There is observationally based UK evidence that 28 day prescribing can facilitate waste reduction (Hawksworth 1996). It limits the volume of medicines held by patients at any one time, and has been widely encouraged throughout England. But there is also international evidence, supported by our literature review and qualitative survey observations, that 28 day prescribing can in some circumstances be associated with increased costs for commissioners, care providers and/or patients (Atella *et al.* 2006, Domino *et al.* 2004), and so promote rather than reduce overall resource waste.

Unduly short prescription durations may inconvenience well stabilised regular medicine takers and drive up dispensing event volumes, and so community pharmacy service costs. They can also divert pharmacist time and effort away from other activities. Emphasis therefore needs to be placed on encouraging a flexible and medicine user centred approach to meeting convenience and care related requirements, as well as wider public interests.

Our findings indicate that some vulnerable individuals living at home will benefit from weekly medicines provision. In other instances prescription durations of 56 days or more may provide better value for the NHS and for patients. It is possible that in some cases extended average supply durations would in

addition allow community pharmacy resources to be used more productively in pharmacy settings or elsewhere. We recommend that such opportunities should be rigorously evaluated.

Caring well for 'treatment resistant' patients

As initially discussed in Section 2, there is evidence that apparently poor responses to drugs that lead on to dosage increases and/or therapy changes can be associated with patients not taking their medicines. Our survey findings indicate that a GP or consultant changing the prescription was the second most common cause of unused medicines in individuals' homes. Similar problems may also exist in care homes, particularly when there is poor communication between staff giving medicines on a daily basis and the professionals responsible for re-ordering, prescribing and dispensing.

If more of these cases could be identified early and effective action taken, reductions in wastage rates should result. Realising these and other improved medicines use linked benefits will in part depend on the further development of competencies and instruments that can identify patients at risk of medicine taking problems in a timely manner. It is recommended that further attention should be paid to developing such aids to good practice.

Eighteen per cent of the waste medicines identified in our survey were completely unused. Our research revealed instances in which people have collected prescription medicines that they do not intend to use because of fears that they will otherwise lose social security payments, or due to allied beliefs relating to taking their medicines. The latter include fears that medicines perceived as vital may at some future point 'run out'. This suggests that strengthening guarantees of medication review confidentiality might reduce the perceived need for such behaviour. However, no trial based or other substantive evidence confirming the scale of such problems or the likely cost effectiveness of possible interventions was found during the course of this research project.

Providing good quality pharmaceutical care for isolated and/or housebound patients and other people at raised risk of experiencing unobserved problems in medicine taking

Evidence from our audit of pharmacies identified death as the most common reason for medicines being returned to a healthcare professional. This 'cause' accounted for around a quarter of all returns. Such observations indicate that the build up of unwanted stocks of pharmaceuticals in patients' homes can be associated with a gradual loss of self care related skills in the final years of independent living, before individuals die or are admitted to care.

The research conducted in care homes also raised concerns about the degree to which medicines use is monitored adequately sufficiently. However, people in these settings are likely to be better cared for than isolated individuals in the community. The findings of our literature review also highlight other groups with an elevated risk of poor compliance, including those on unusually complex treatment regimens and individuals with chaotic lifestyles. These last include some but not all drug users, and individuals with mental health problem.

As indicated above, if patients at elevated risk of medicine taking problems can be identified via the systematic analysis of practice records or via the use of brief questionnaires in settings such as pharmacies this should to a degree reduce medicines wastage, provided that effective medication reviews are then undertaken.

There is limited evidence that if other health or social care needs are revealed during the course of such investigations their impact may, in the short term at least, be cost increasing. (See Section 2 and Holland *et al.* 2005). But this is not in our view sufficient reason for failing to try to further improve the scope and utility of medication and medicines use reviews by community pharmacists and other health professionals.

The qualitative research evidence in Section 7 shows that there are significant doubts in the minds of many GPs and some pharmacists about the value of pharmacist conducted Medicine Use Reviews (MURs) as they are presently (in 2009/10) specified, funded and communicated to prescribers. There are additional questions relating to medication reviews conducted by doctors. We therefore recommend that policy makers should consider current patterns of incentivisation and management relating to all forms of NHS medication review with a view to maximising their (cost) effectiveness in relation to health outcome improvement and, secondarily, medicines waste reduction.

Undertaking MDS use audits and providing tailored care worker training on medicines taking support

Our qualitative evidence reveals significant concerns about MDS (Monitored Dosage System) dispensing on the part of pharmacists, GPs, PCT staff and some patients. Issues associated with the appropriate use of MDS were also identified in our work in care homes, where MDS dispensing is widely adopted in the belief that it may help to reduce administration errors. Well conducted MDS prescribing and dispensing audits could help ensure productive use of such systems and so facilitate efficiency gains. But while some patients could benefit from an extended use of, for instance, seven day MDS dispensing, others with reduced cognitive abilities may be being

put at risk by inappropriate MDS dispensing, which can also promote drug waste.

In the latter context employers' and related (social) care staff fears about issues such as legal liability presently appear to mean that vulnerable people seeking to take complex regimens in their own homes are on occasions denied practical help. Our evidence suggests that providing training and accreditation in medicines administration for domiciliary care workers of all types could alleviate such problems. We therefore recommend that the provision of such training should be evaluated with a view to it becoming nationally available.

Improving hospital and community service liaison aimed at reducing wastage and improving treatment outcomes

Being admitted to hospital can be a disruptive experience, one possible consequence of which is that medicine taking is interrupted. Previous studies identified as part of our literature review have, together with our qualitative research findings, highlighted the interface between care settings as a point at which for poor management of medicines may occur, which might result in waste. Findings from nursing and residential homes also identified waste arising following discharges from hospital.

Many of our respondents said that significant progress has been made to address the problem in recent years. Even so, there is evidence that better communication about patient discharges between not only hospital specialists and GPs but also hospital and community pharmacists could make further contributions to ensuring good quality treatment co-ordination, and permit further medicines wastage reductions.

Delivering better integrated terminal care in home and community settings

The findings of our pharmacy audit, the care homes survey and our qualitative research survey indicate that there is a significant risk of waste occurring during the end-of-life period. This can contribute to the return of large volumes of medicines from a single patient after death, which may also include unused drug stocks accumulated in the last few years of independent life.

Clearly it is difficult to manage the supply of medicines which might be needed on an *ad hoc*, unpredictable, basis to manage problems like intermittent pain. As noted in Section 6 on care homes, there is arguably a moral duty to err towards over-supply to avoid unnecessary suffering towards the end-of-life, meaning that some of the waste that results might reasonably be considered unavoidable. Nevertheless, our findings show that a proportion of health professionals believe that further improvements

in end of life care standards could be made in ways which might also result in pharmaceutical waste savings.

Guidance from agencies such as the WHO indicates that in general attempts to 'recycle' surplus medicines back for use by other patients risk being counter-productive. Yet end of life home care may be a field in which special arrangements could, from a waste reduction and care improvement perspective, desirably be made to permit the return of dispensed but unused medicines for subsequent re-issue. However, any attempts to better manage medicines in this population should ensure that the focus remains firmly on alleviating the symptoms and distress of individuals at the centre of the care process, rather than merely controlling pharmaceutical expenditure.

Reviewing and further developing national or local waste medicines return (DUMP) and related public information campaigns

Our National Survey found that whilst the majority of individuals (75 per cent) participating said that they are aware that unused medicines should be returned to a healthcare professional, only a minority (circa 40 per cent) reported actually doing so. The literature review and qualitative research interviews conducted for this project indicate that while NHS staff members working in settings such as PCTs may with justification be proud of the work they do in areas such as organising DUMP campaigns and generating publicity about medicines wastage, a proportion also question the underlying value of such initiatives.

There is little good quality evidence that such programmes are presently cost effective. Some respondents in our study believed that more effort should be made to design and deliver sustained messages that are unambiguous about the positive value of informed medicines taking, and clear about when and why residual medicines should be returned to pharmacies or dispensing doctors' practices.

If national policy is to maximise medicine return rates or otherwise optimise them, members of the public should be provided with good reasons for taking such action. Given that, as noted above, it is not normally thought desirable to re-dispense unused medicines or to send them abroad for use in poor communities, environmental protection and community and home safety may offer the most salient arguments for avoiding wastage whenever possible, and returning unusable medicine stocks for NHS disposal when necessary. Such environmental messages have resulted in significant behaviour change in other settings, like the re-cycling of household waste. This suggesting that the general public may respond positively to such messages, given evidence based reasons to do so.

8.3 Conclusion

The extent of the avoidable NHS medicines wastage problem in England is, on the basis of the research findings contained in this Report, less extensive than has sometimes been suggested. There is also no evidence that it is worse in this country than the equivalent challenges found in other developed nations, and wastage does not with regard to residual medicines found in people's homes appear to have increased since the early 1990s. From the NHS perspective the challenge of limiting medicines waste is almost certainly being more actively managed today than in the past. As such avoidable drug wastage should not in our judgment be regarded as a serious systemic problem in the NHS.

Nevertheless, our estimates indicate that in gross terms primary care and care home medicines waste costs about £250 – £300 million per annum in England. This sum equates to approximately £1 in every £25 spent on NHS medicines. Even if additional net savings of only £1 per head per community member served could be made as a result of additional efforts to reduce such costs, this would represent a significant – if relatively limited – national benefit.

There is a range of opportunities for working further towards achieving the goal of residual medicines minimisation in the English NHS. They are in large part based on building constructively on existing policies and practices. They include enabling GPs, practice nurses and community pharmacists to help patients become accustomed to taking new medicines as effectively as possible, and promoting greater efficiency and procedural fitness for purpose at every stage of the repeat prescribing and dispensing process.

However, excellence and equity in service commissioning and provision also demands responsiveness to service user requirements, and the constant pursuit of the NHS's highest priority aims. There is a danger that too narrow a 'zero tolerance' type focus on cutting drug waste could undermine awareness of this reality.

In the final analysis the purpose of health care is to increase as cost effectively as possible the overall health and wellbeing of health service users and local communities, rather than to make savings against 'stand alone' budgets headings like those for community pharmacy and pharmaceuticals. It is when reducing medicines waste also directly and effectively contributes to the fundamental task of improving care quality and health outcomes that the greatest returns are to be gained.

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