Title

An Analysis of Returned Medicines in Primary Care.

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Abstract

Objective - The number of pharmaceutical items issued on prescription is continually rising and contributing to spiralling healthcare costs. Although there is some data highlighting the quantity, in terms of weight of medicines returned specifically to community pharmacies, little is known about the specific details of such returns or other destinations for wasted medications. This pilot study has been designed to investigate the types and amounts of medicines returned to both general practices (GPs) and associated local community pharmacies determining the reasons why these medicines have been returned.

Method - The study was conducted in eight community pharmacies and five GP surgeries within East Birmingham over a four-week period.

Main outcome measure – Reason for return and details of returned medication.

Results - A total of 114 returns were made during the study: 24 (21.1%) to GP surgeries and 90 (78.9%) to community pharmacies. The total returns comprised 340 items, of which 42 (12.4%) were returned to GPs and 298 (87.6%) to pharmacies, with the mean number of items per return being 1.8 and 3.3 respectively.

Half of the returns in the study were attributed to the doctor changing or stopping the medicine; 23.7% of returns were recorded as excess supplies or clearout often associated with patients' death and 3.5% of returns were related to adverse drug reactions. Cardiovascular drugs were most commonly returned, amounting to 28.5% of the total drugs returned during the study.

Conclusions - The results from this pilot study indicate that unused medicines impose a significant financial burden on the National Health Service as well as a social burden on

the United Kingdom population. Further studies are examining the precise nature of returned medicines and possible solutions to these issues.

An Analysis of Returned Medicines in Primary Care

Introduction

The patient of today is better informed about healthcare and treatments than those of previous generations. The regular appearance of articles on health and medicine in the national media, increased access to the internet and patient empowerment in the modern National Health Service (NHS) have all contributed to this rise in consciousness over recent years. There are indications that patients are becoming more proactive during medical consultations, asking for drugs by name and pressuring doctors to prescribe where it may not be clinically necessary (1). These factors in addition to national guidelines promoting the use of prophylactic drugs such as statins and anti-platelet agents (2, 3) are leading to increased prescription numbers every year with a consequential rise in drug expenditure. During 2001, over 587 million prescriptions were dispensed in England with a total ingredient cost of £6.1bn (€9.2 bn), constituting a 6.4% increase in prescription numbers and a real terms expenditure rise of 6.9% from 2000 (4).

In the year ending March 2001, 584.6 tonnes of unwanted medicines were returned to community pharmacies in England for destruction under the DOOP (Disposal Of Old Pharmaceuticals) scheme. This represented an increase in returned medicines of 65% over the preceding four years (5) compared with a rise of only 14% in prescription numbers during the same period (4) indicating that the proportion of prescribed medicines which go unused is increasing. There are many anecdotes of extreme non-use of medicines in community pharmacy, such as the incident reported in a letter to the Pharmaceutical Journal (6) which details the return of four waste sacks full of medicines

following a patient death and another case concerning the return of 14 unopened and in-date salbutamol metered dose inhalers from one patient on a single occasion.

In the United Kingdom (UK), in excess of 90,000 cases of poisoning associated with pharmaceutical products are treated in hospitals each year (7). The availability of unused medicines in the home may unfortunately constitute a source of material for intentional or accidental poisonings. Moreover, in the social context, it is unclear how much unused medicines are disposed of through normal household refuse and domestic sewerage systems. The environmental impact of inappropriate medicines disposal by patients has not been studied in the UK in depth, however, a recent examination of inland water in the USA detected significant levels of pharmaceuticals in large numbers of tested streams (8), indicating this may be a serious environmental issue.

While there have been a number of large and detailed studies undertaken in countries such as USA, Canada and Sweden that have considered the specific nature of unused medicines in the community (9-11), there is a paucity of published research examining unused medicines in the uniquely funded UK NHS model. Previous attempts at tackling medicines waste in the UK have mostly been based around publicity campaigns calling for the return of unwanted medicines to community pharmacies such as the Disposal of Unwanted Medicines and Pharmaceuticals (DUMP) campaigns of the 1970s (12, 13). While these initiatives theoretically, reduce the risk of poisoning and environmental damage, they do not address issues of wasted resource, therapeutic failure and poor compliance. The few UK studies which examine the nature of returned medicines (14-16) are of limited scope and none have considered the disposal of unused medicines through avenues other than community pharmacy.

The aims of the present study embraced the investigation of the types and amounts of medicines returned to general practices and their local community pharmacies and to determine the reasons why these medicines had not been used.

Methods

The present study was conducted in eight community pharmacies and five General Practitioner (GP) surgeries within the boundaries of Hodgehill and Greater Yardley Primary Care Organisation in East Birmingham. Collective agreement was gained from the medical practitioners responsible for all patients included in this study before data collection commenced. Data were initially gathered over a four-week period from community pharmacies during August 2001. It subsequently became apparent that significant quantities of medicines might be returned to general practitioners directly and thus data was collected from GP surgeries for a four-week period during March 2002. No data concerning unused medicines was collected from the patients' home directly, residential care homes or nursing homes. The latter are subject to continuing studies. Returned medicines were collected and data concerning the return (age and sex of patient, reason for return and relationship of the returner to the patient) compiled by the community pharmacist or practice manager according to a simple menu driven form distributed to the practices. Further information was obtained from the patients' notes or the pharmacy patient medication records (PMRs) as appropriate.

A fee of £50 was paid to the participating pharmacies and a £50 gift voucher to the pharmacist involved in recognition of the staff time and inconvenience.

The study was purely observational and all returns were unsolicited. No return campaign was conducted and no attempt was made to encourage patients or carers into returning medicines.

Assembled data were entered into a statistical database programme (Statistical Package for Social Sciences, v11) (17) comprising variables including, the person making the return, age of the patient to whom the medicine belonged, reason for return, British National Formulary (BNF) therapeutic category and number of dose units returned. One dose unit was defined as 1 tablet or capsule, 5 millilitres of oral liquid, 1 gram of cream or ointment and a single spray of a metered dose device. The ingredient cost for the medicine was calculated by multiplying the price per pack by the fraction of a pack returned.

Results

A total of 114 returns were made during the study: 24 (21.1%) to GP surgeries and 90 (78.9%) to community pharmacies. The total returns comprised 340 items, of which 42 (12.4%) were returned to GPs and 298 (87.6%) to pharmacies, with the mean number of items per return being 1.8 and 3.3 respectively.

Over 86.0% of returns were made by either the patients themselves or the patient's friends and relatives. Only 7.0% of returns were made by a healthcare professional. Just under a further 7.0% had no recorded indication of who returned the medicine.

Older patients (60 years and over) returned 61.4% of items with 24.6% of returns coming from patients aged 30 to 59 years and 5.3% of returns originating from patients under 30. Ages were not recorded for 8.7% of returns.

Half of the returns in the study were attributed to the doctor changing or stopping the medicine [Figure 1]; 23.7% of returns were recorded as excess supplies, clearout or patient death and 3.5% of returns were related to adverse drug reactions.

Insert Figure 1 here.

Medicines were returned from most therapeutic areas [Figure 2], however, no dressings were returned to either GP surgeries or community pharmacies.

Insert Figure 2 here.

The number of dose units per item ranged from 1 to 1000 with the majority of returns comprising less than 56 dose units.

The total cost of returned items was £3986 (€6041) (£235 (€356) to GPs and £3751 (€5685) to pharmacies) and the mean item cost of returns was £11.72 (€17.76) (£5.60 (€8.49) to GPs and £12.59 (€19.08) to pharmacies).

Discussion

Reasons why drugs were returned

The most commonly cited reason for medicines return was alteration to the medication regime made by the prescriber. This could result from a number of situations including adverse drug reactions, patient led discontinuation, lack of clinical need and the tailoring of new and existing therapies to individual patients needs. These circumstances may arise at any point during the treatment of a patient but are likely to be more

common on treatment initiation. A number of different approaches can be used to minimise the quantity of drugs that are wasted because of these problems. For instance, the supply of smaller quantities throughout therapy, the supply of test quantities during therapy changes and initiation and the implementation of regular, timely medication review may all be of use in reducing this wastage. The advent of non-medical supplementary prescribing in the UK also provides an excellent opportunity for pharmacists and nurses to help address these issues through a more thorough prescribing review process.

The second most prevalent reason for medicines return was the periodic clearance of unwanted items in the home. Factors leading to accumulation of unused medicines in the home include, uncompleted courses of treatment, acquisition of unnecessary over the counter (OTC) medicines, redundant 'as required' medication and over-ordering or supply of prescription medicines. Medicines waste resulting from simple over-supply can easily be reduced through the synchronisation of prescription quantities and the deletion of inappropriate items from the repeat order form, whereas other mechanisms of medicines waste are more difficult to regulate. As such, it is important that all health professionals are proactive in ensuring the appropriate and timely disposal of these surplus medicines to minimise the risk of poisoning or environmental damage.

Types of drugs returned

Cardiovascular drugs were the most commonly returned, amounting to 28.5% of the total drugs returned during the study. This group of drugs comprise approximately 20% of all the drugs prescribed in the UK (18) and thus drug non use appears to mirror prescribing patterns. The prevalence of cardiovascular drug wastage highlighted in this study may be related to changes in prescribing practice in response to the National

Service Framework (NSF) for Coronary Heart Disease (2) which was in the initial stages of implementation at the time of the study. The local delivery of this NSF has led to the development of a variety of different formularies and guidelines geared toward the optimisation of drug choice. Changes in drugs and doses according to the application of guidelines may have resulted in higher degree of drug wastage than would normally occur. It is therefore imperative that medicines wastage is monitored following the implementation of new national and local guidelines in order to fully appreciate the economic impact of such initiatives. Other types of drugs returned in significant proportions included, opioid analgesics and drugs active in the central nervous system. Since many patients prescribed drugs acting on the central nervous system have potential for deliberate self-harm, access to large quantities of these types of medicines may increase the risk of both intentional and accidental suicide.

The illicit use and diversion of controlled drugs into the black market might also be fuelled from unused medication obtained through prescription, for example, when large supplies are provided for terminally ill patients. The illegal and inappropriate use of controlled drugs has unfortunately been highlighted recently in the UK by the actions of Dr Harold Shipman, who used unrecorded supplies of controlled drugs from dead patients in order to murder other patients in his care over a protracted period. A documented system to manage unused controlled drugs would help to reduce the likelihood of misuse of such agents. Furthermore, electronic prescribing systems might facilitate recording of patients' usage patterns and thus curtail stockpiling of large quantities of medicines by patients.

This study has highlighted that within the population investigated, an alteration or stopping of a medicine accounted for half of all unused medicines returned. The most

common type of medicines to be returned to either a GP surgery or community pharmacy were medicines used to treat cardiovascular complaints. Coupled with central nervous system agents and drugs used to treat respiratory disorders, these returns accounted for over 60.0% of all medicines returns in the study.

Considering the size of this study, the quantity and value of drugs returned have highlighted a worrying level of medicines non-use. Owing to the scale of this study, it is not wise to extrapolate this data to the whole of the UK. In addition, the apparent high drug wastage identified is likely to be an underestimate of the whole problem since the results include only those medicines returned to primary care sites. No data is as yet available for medicines non-use in the domiciliary environment or nursing/residential care homes and tertiary specialist hospitals. Irrespective of these limitations, the results indicate that unused medicines impose a significant financial burden on the NHS, moreover, the presence of unused medications in the domiciliary environment may present a public health risk in terms of the potential for accidental poisoning or misuse. This poor resource use is not limited to the cost of the drug that has been wasted, but also the time taken prescribing and dispensing these medicines and the time and money spent dealing with the consequences of their non-use and misuse. Unused medicines in primary care in the UK appear to be both widespread and varied, and minimisation of this problem would ensure reduction in the waste of scarce funds and the potential for environmental damage and poisoning.

Despite the increased emphasis placed on good prescribing in recent years, the problem of medicines non-use has changed little since it was highlighted by the DUMP campaigns of the 1970s. Indeed, it appears to be continuously increasing significantly year on year.

Following the results of this pilot study, Aston University Pharmacy Practice Research Group are currently undertaking a comprehensive review of medicines non-use in the UK, developing medicines management strategies to reduce this waste of NHS resource and promote maximal cost-benefit through best practice.

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