

## Clinical pharmacy in primary care

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### Introduction

Clinical Pharmacy in the secondary care sector began to develop in the 1970s and has evolved into a service known as pharmaceutical care. The developments of such services in the primary care sector have not occurred at the same pace because of a remuneration structure which, to this day, largely depends on the speed and accuracy of dispensing a prescription. A complete examination and re-arrangement of the dual roles of the professional and trader is required in order to provide a more effective, efficient and easily accessible pharmaceutical care service within primary care.

It has been suggested that up to 11.4% of hospital admissions [1–3] are related to the patient's drug therapy and that if corrected at the dispensing stage would save considerable primary care costs [4]. An analysis of adverse drug reaction (ADRs) rates from 49 hospitals published in 36 articles stated that ADRs were responsible for 0.2–21.7% of hospital admissions [5]. Overall 71.5% of these were related to side effects, 16.8% were excessive effects, 11.3% were hypersensitivity reactions and 0.4% idiosyncratic. In 1989 Neville *et al.* [6], from a General Practitioner (GP) survey, stated that 1.06% of prescriptions had therapeutic errors but this may now be greater due to the inadequate control of a computerised repeat prescribing system [7]. This analysis of the prescribing in 50 GP surgeries revealed that 72% of repeat drugs had not been reviewed by a doctor for 15 months. Harris [8] reported that 75% of all prescribed items were repeats. These accounted for 81% of prescribing costs and 48.4% of patients obtained their next medicine supply by this method. Thus up to three quarters of all prescriptions may be generated by a patient initiating a repeat prescription. There is therefore a need for involvement by a clinical pharmacist at the prescribing and dispensing stages. This paper will focus on the limited reports of pharmaceutical care in the primary healthcare sector during the dispensing process.

### Pharmaceutical care

The term 'pharmaceutical care' to replace clinical pharmacy was introduced by Brodie *et al.* [9] in 1980, when they suggested a complete change in the delivery of pharmaceutical services. Further developments of 'pharmaceutical care' were described by Hepler [10], as a covenantal relationship between a patient and a pharmacist, suggesting that pharmacists should accept more responsibility for drug use control. These concepts were further developed in 1989 by Hepler & Strand [11] who provided the now widely accepted definition of 'pharmaceutical care' as 'the respon-

sible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life'.

In 1986 the Nuffield Report [12] suggested that community pharmacists must be more patient-orientated. It also indicated that Pharmacy Practice (within the primary healthcare system) is an 'area of health services research in which the greatest weaknesses are to be found. There is too little information available, relatively weak structures and very little funding' [12]. The next dozen years have seen little change, and much of the Government funding has been spent on developing pilot services rather than their evaluation. Consequently when the funding has run out many of the services have ceased.

Working party reports between 1986 and 1994 [13–16] have encouraged community pharmacy to assess its level of practice and research. Value for money and health outcomes will play a major role in the future and studies need to highlight the added value of community pharmaceutical services during the dispensing process. These studies should be based on the principles of pharmaceutical care especially the responsible provision of drug therapy, definite outcomes and quality of life issues. They also need to highlight the possible advantages for the development of multi-disciplinary teamwork amongst providers of care.

### Therapeutic drug and biochemical parameter monitoring

The benefits of measuring plasma drug concentrations or biochemical parameters with pharmacodynamic and pharmacokinetic interpretation to derive optimised dosage regimens have been shown [17–20]. The value of this type of service has been reported in hospitals e.g. anticonvulsants [21], digoxin [22], theophylline [23–25], aminoglycosides [26]. These studies, with the exception of the latter, have been carried out using in-patients shortly after admission and thus demonstrate the need for this type of service in the primary care sector. The working party report 'Pharmaceutical care: The future for Community Pharmacy' [13] highlighted the possibility of therapeutic drug monitoring by the Community Pharmacist. At present reports demonstrating the need for this service, within primary care, have focused on theophylline [27–31]. Others have shown how a similar service can be provided when measuring some biochemical concentrations [32].

The value of pharmacokinetic interpretation following measurement of plasma theophylline concentrations was demonstrated by an assessment of 26 (asthma and COPD) patients in a Belfast Community Pharmacy. The number of patients who had a plasma theophylline concentration in the therapeutic range increased together with improvements in peak expiratory flow rates at 3 months and 12 months after dosage optimisation [31]. Lowen *et al.* [29] showed how instant measurement of serum theophylline concentrations followed by Bayesian interpretation [33, 34] provided immediate dosage

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recommendations. Although this was based in an out-patient department it could be extended to a Community Pharmacy. Hawksworth & Chrystyn pursued this and demonstrated that measurements in a Community Pharmacy of carbamazepine, digoxin, phenytoin and theophylline together with creatinine, potassium and urea from the plasma samples of patients, were as accurate as those measured by a hospital biochemistry department [35]. They then used this method to measure plasma concentrations from blood samples taken from patients calling to pick up their prescriptions from a community pharmacy [36]. Instead of classifying the measured values into either above, below or within the therapeutic ranges they interpreted the measurements using Bayesian pharmacokinetic methods [33, 34] and then integrated these results with the pharmacodynamic endpoints, required by each patient, to derive optimised dosages. This showed that of the 19 patients prescribed carbamazepine, 23 digoxin, 13 phenytoin and 51 theophylline, dosage changes were necessary in 63.1% (12 patients), 47.8% (11), 84.6% (11) and 58.6% (30) respectively. Other changes in the therapeutic management were required for 22 out of the 46 patients whose plasma potassium was measured. Of these 13 (28.3% of the total) were hypokalaemic and their medication included a diuretic without potassium supplementation and nine of these were also prescribed digoxin. The other nine (19.6%) were hyperkalaemic and prescribed diuretics with potassium supplementation. Also 33 (70.2%) out of 47 patients whose plasma creatinine concentration was measured had a creatinine clearance which indicated that some change was required to their therapeutic management.

The last two reports [35, 36] and others [37, 38] demonstrate that the technology and assay skills are available within the primary healthcare sector. They also indicate that the General Practitioner needs assistance with all aspects of therapeutic management. It is very unlikely that these measurements will become available in primary care and so the measurements available at local hospitals should, therefore, be used. This will allow more time to be directed towards interpretation of those patients that need monitoring and for detailed pharmacokinetic with pharmacodynamic interpretation of the measured value to recommend optimal dosing. This would be part of a pharmaceutical care service rather than a specific therapeutic drug monitoring service and be extended to many other drugs eg. warfarin, lithium.

#### *Interventions with the prescriber during the dispensing process*

Community pharmacists contact the prescriber on issues of legal prescribing and also on matters relating to the practice of pharmaceutical care. A pilot study (in one UK community pharmacy) has revealed that out of 9000 items dispensed the prescriber was contacted on 10 occasions because of legal omissions and 80 (0.89% of the dispensed items) others to make clinical pharmacy interventions [39]. When the full details of these clinical pharmacy interventions were presented to an independent multi-disciplinary panel it was assessed that 15 (0.17% of the dispensed items) may have resulted in a hospital admission if the intervention had not been made. Applying Local Trust costings to the anticipated length of stay, these prevented hospital admissions amount to a saving, to the primary healthcare budget, of £1.17 for

each of the 9000 items dispensed compared with the £1.21–£1.37 remuneration fee received for dispensing each of the items at the time of the study [39]. In addition the clinical panel also decided that a further 15 (0.17%) of the interventions may have prevented the occurrence of a harmful effect and that it was likely that 31 (0.34%) others could have provided an improved therapeutic response. All these prescribed items could have been legally dispensed without contacting the prescriber. The use of clinical panels [40] to determine the theoretical value of pharmacist interventions has also been used to highlight the significance of interventions by hospital pharmacists [41]. If this approach is to be adopted and widely accepted as a method of placing theoretical 'values' on interventions then basic research needs to be carried out to determine its reliability, validity and the effect of combining different healthcare professionals. Preliminary indications are that hospital pharmacists, community pharmacists, General Practitioners and senior house officers rate the potential outcomes of 20 selected cases differently [42]. Thus clinical panels should be multi-disciplinary.

A multicentre North American study of 89 community pharmacies reported the interventions which occurred during the dispensing of 33 011 newly prescribed items [43]. There were 629 (1.9%) interventions and these were also assessed by an independent (but not multidisciplinary) panel. The panel decided that 176 (0.53%) of the interventions could have prevented harm to the patient. They also showed that the rate at which the community pharmacists identified prescribing problems was inversely related to the number of prescriptions dispensed per hour. This suggests that some may be exceeding a safe dispensing threshold. We have extended our pilot study of 9000 items in one community pharmacy [39] to 14 pharmacies who logged all their clinical pharmacy interventions with the prescriber over a 12 month period. In this multicentre study we have also identified an inverse correlation between interventions and dispensing volume (submission of results in progress).

Shulman *et al.* [36], during a prolonged survey of interventions from one community pharmacy, reported that 162 (0.13%) interventions were necessary out of the 64 406 items dispensed and that 89 (0.13%) had the potential to have prevented an adverse drug reaction. An Australian study [45] revealed that 29 community pharmacies over a period of 4 weeks, during which they dispensed 89 363 items, made 1273 (1.4%) similar clinical interventions. An intervention rate of 1.5% was also reported in New Zealand from a similar study of new prescriptions [46]. Other intervention studies in Canada, by Poston *et al.* [47], where community pharmacists are paid for not dispensing a prescribed item following an intervention, revealed a 2% intervention rate. 7% of these interventions resulted in the item not being dispensed which is equivalent to 0.14% (14 per 10 000 items dispensed). Focusing on the medication records of 300 cardiovascular patients, in Sydney, found that of the 5271 medications dispensed there were 1509 (38.6%) potential interventions [48]. In Scotland, of 5162 items monitored 354 interventions were highlighted [49] whilst in South Africa [50] it was found that prescriptions prescribed for the elderly required most interventions. Worldwide, therefore, the intervention rate is fairly consistent.

In general the intervention rate is less than one item for each 100 prescribed and of these less than half have the potential to cause a hospital admission or harm. This is much lower than the reports that have indicated that adverse effects are responsible for up to 11.4% of hospital admissions [1–4]. Nevertheless they highlight the need for a community pharmacy based pharmaceutical care service which could extend into disease management and thus ensure that prescribing is safe and effective at all times rather than only at the time of dispensing a prescription. It will also ensure that the chosen drugs are obtained at the best price.

#### *Clinical pharmacy outside the retail pharmacy environment*

In 1988 a working party report by the Royal Pharmaceutical Society of Great Britain [51] focused on the provision of a community pharmacy domiciliary visiting service. This report stated that 'any patient on medication who is unable to visit a pharmacy should be able to have access to a full pharmaceutical service which involves advice'. The type of advice that can be offered during a domiciliary visit by a Pharmacist has been reported [52] with 7 out of 31 patients visited advised to see their GP. Following training of 12 volunteer community pharmacists almost one third of the patients visited were experiencing adverse effects because of their medication [53]. Similar results have been reported in a study of 50 housebound patients [54]. Following a drug review of each patient's medication 88 therapeutic recommendations were made to their GPs and 85 were accepted. An independent multidisciplinary panel evaluated the data of these interventions and decided that five could have prevented an admission to hospital whilst for 22 other patients the likelihood of harm or side effects may have been prevented. They also decided that 31 other interventions may have been beneficial in that they were most likely to improve clinical control. The panel decided on the length of each predicted admission and using local Trust costs the saving to the primary healthcare budget was £6875 which is equivalent to £137.5 per visit. Each visit took an average of 2.5 hrs. From this study it was also reported that the 50 patients had £770 worth of medicines which were not required or out of date. This study highlights how effective clinical pharmacy can be even without patient registration (with one community pharmacy) and access to patients' medical records. These limitations are overcome by the clinical pharmacist's therapeutic and pharmaceutical expertise and the availability of time to spend with one patient. In another study [55] 39 patients were visited by 16 community pharmacists. The study identified 9 interventions to prevent adverse drug effects. Other problems were medicine administration and non-compliance with advice on pharmaceutical related issues given to 82% of the patients. 25 (64%) of the patients were referred to their GP. Other reports have indicated some value of a pharmaceutical domiciliary visiting service [56–72].

The value of a pharmacy domiciliary service, to deliver pharmaceutical care, has also been shown when patients are visited soon after they are discharged from hospital. Cochrane *et al.* [73] found that in 45 out of 50 elderly patients visited there was a lack of continuity between the drugs prescribed on discharge from hospital and those prescribed one to two

weeks later. Providing a clinical pharmacy domiciliary visit to 53 patients within 7–10 days of discharge revealed that an intervention with the GP was necessary for 31 (58.5%) of the patients [74]. The medication of one patient was different from that of discharge and their GP had made intentional changes. For the remaining 30 patients the GP was unaware that the 'old' repeat prescription had been issued. All these were restored to that of discharge. These interventions were put to an independent clinical panel who decided that 7 (13.2% of the patients) were likely to have resulted in a hospital admission if left unaltered, 6 (11.3%) may have prevented toxicity/side effects and for 16 (30.2%) of the patients there was the likelihood that improved clinical control would have been obtained following the restoration of the discharge medication. This panel was provided with extensive information from the physician's notes. The admitting physician had indicated why they thought the patient had been admitted to hospital in the first instance.

Pharmaceutical care can also be provided in the primary healthcare sector during a visit to a residential or nursing home. During this visit a full medication review can be made with recommendation to stop drugs, start others, alter drugs or monitor therapeutic and biochemical parameters to ensure safety and efficacy and improve the patient's quality of life. Advice on the correct methods of administration for each medicine can also be provided. Recently an audit of 433 patients residing in registered nursing or residential homes [78] has highlighted the potential cost savings to the drug budget. A preliminary report of a major study (soon to be submitted for publication) has highlighted the drug review process by a pharmacist visiting residential and nursing homes. One hundred and seventy-seven changes were recommended to the medication of the 312 patients visited, drug costs were reduced by approximately 8% and 7.4% of the drugs prescribed were stopped [78]. Other studies on providing a similar pharmaceutical visiting service have shown that 12 interventions were made to 80 residents in residential homes [77] and 44 out of 60 patients in a nursing home [78]. Thus the provision of a domiciliary pharmaceutical care service to those in residential and nursing homes could have significant benefits in terms of healthcare and prescribing costs.

#### **Conclusion**

The studies described above have highlighted the potential of pharmaceutical care in the primary care sector. With appropriate funds disease management protocols could be implemented with the emphasis on controlling repeat prescriptions. A stock control policy together with pharmaceutical care services minimises costs in hospitals and thus a similar service, in the primary care sector, should provide benefits to patient outcomes and control drug costs. However for this type of approach to be effective a primary healthcare multidisciplinary team will be necessary.

In the future community pharmacy will take one of two models. In the first model the pharmacist would become more involved with retailing and their healthcare delivery would be related to selling non-prescription only medicines (or referral to the GP) following the presentation of

symptoms by a customer. Their involvement with the dispensing process may be restricted to accurate supply or this may be replaced by other methods. However the above literature reveals that GPs require more pharmaceutical help than they receive at present. In the second model community pharmacists would become part of an integrated, patient-centred system of healthcare and be proactive in all aspects from decision making (on which medicines to prescribe) through to administration by the patient. If community pharmacists are to become part of an active system of patient-centred pharmaceutical care then the services described in the above studies need to be developed now.

However community pharmacy may not develop in future to become an integral part of the healthcare system without changes to the remuneration. At present the current remuneration structure in England and Wales is that for the dispensing of more than 1600 items per month there is a monthly practice allowance of £1380 with a pro-rata payment of £755–£1380 for dispensing 1100 to 1600 items per month. In addition there is a flat rate dispensing fee of 94p per item. Furthermore if an intervention is made and the result is that the prescribed item is not dispensed then, in the UK, no remuneration is received.

The indications in the literature (above) highlight the need for a pharmaceutical care service to assist the GP. Instead of a remuneration structure based on volume dispensing, the Global Sums i.e. the amount the Government sets aside for the dispensing of prescriptions by the community pharmacist, should be divided in a different manner. A remuneration process by which community pharmacy receives more of a salaried structure could enable the development of pharmaceutical care in the community sector as described in this review. If new services are identified and there is real evidence for their value, eg pharmaceutical domiciliary visits, then these should be remunerated out of the budget from where the savings can be made. This is how it successfully occurs in hospital pharmacy. If hospital pharmacy had been remunerated by the same processes as their colleagues in the community then the development of clinical pharmacy, and more recently pharmaceutical care, during the past 25 years may not have occurred.

In the new NHS, as proposed by the current Government, the money to develop and implement pharmaceutical care may be available from the budget of the primary care groups. Some GPs are already contracting community pharmacists to provide prescribing advice to control drug costs. Other pharmacists have extended into more clinical pharmacy orientated services such as warafarin clinics. It is important to collect extensive outcome data from these to show their real value such that evidence based practice is available.

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