

**A study of oral counselling and audit processes for
dispensed medications
in community pharmacy**



Thesis submitted in accordance with the requirements of
the University of London for the degree of Doctor of Philosophy by

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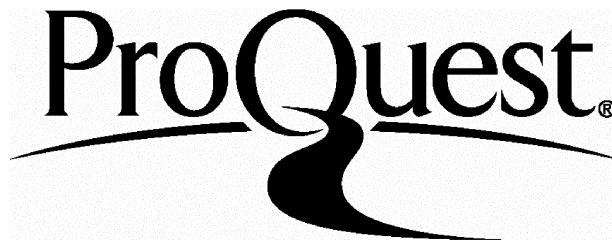
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Abstract

The concept of professional audit was introduced to the pharmacy profession by the Royal Pharmaceutical Society in 1992. Since then audit has been promoted as a tool for raising the standard of practice and improving the quality of patient care. The aim of this study was to develop and implement an audit cycle as a tool to explore a community pharmacy service whilst assessing the impact of audit on the service provision and examining its acceptability and feasibility in community settings.

The study was based on six stages of an audit cycle. The first stage comprised of semi-structured interviews with community pharmacists, in which provision of oral counselling for dispensed medications was prioritised. This was a service without an universally accepted definition, an issue which was addressed in stage two of the study using a Nominal Group technique. In stage three, the level and content of oral advice given for dispensed medications in community pharmacies were established. It was found that 33% of all the dispensed medications received oral advice in community pharmacies. Standards for the extent of advice for repeat medications as well as items dispensed for the first time were set in stage four which were implemented in the next stage. Feasibility and acceptability of the audit processes and tools devised during the study were examined in a group of self selected pharmacists in stage six of this study.

Analysing the findings indicated that the provision of oral advice for dispensed medications was influenced by multitude of variables including the ownership or employment status of pharmacist, number of years of post registration as well as medication status as a repeat or new. The only variable remaining significant in predicting community pharmacists counselling behaviour for different patient groups as well as various therapeutic groups was medication status as repeat or new. Implementation of the audit cycle resulted in pharmacists meeting the agreed standards for provision of counselling demonstrating that audit can be a flexible tool which can accommodate different levels of practice and still achieve an improvement of standards. Implementation of audit continually raises standards of pharmacists' counselling services helping them to meet the public expectations as well as preparing pharmacists to face the challenges involved in embarking on the new roles such as provision of medicine management and the repeat dispensing services as proposed by the Government.

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Chapter 1: Introduction

INTRODUCTION

1.1. An Historical Perspective of Pharmacy

The history of pharmacy, which in the past has been defined as the science of collection, preparation and compounding of medicinal products, can be traced to earliest human civilization and beyond (Grier, 1937). In prehistorical times man, unable to explain the incidence of diseases on a scientific basis, attributed them to devils and evil spirits. Magic reinforced by a custom of using plants and objects with friendly spirits was employed to overcome diseases and ills. Throughout history tribes and races have developed an extensive folklore of remedies partly based on superstitions and partly on facts. In Babylonia there was a distinct class of compounders of medicines called *Pasius* who prepared ointments and cosmetics and who were the equivalent of modern day pharmacists (Grier, 1937).

The variety of preparations used in Egyptian medicines requiring professional skills implies that a distinguished group of preparers of medicines were in existence at that time (Kremer and Urdang, 1976). Medical Egyptologists have concluded that there were associates or assistants to physicians who had specific responsibility for pharmaceutical works. However, in some instances both medical and pharmaceutical tasks were performed by physicians (Sigerist, 1995).

It has been claimed that in the early days of the Roman Empire, under the changed conditions of society life, pharmacy allied to medicine, became a practical art necessitated by an increasing number of drugs used and the need for presenting them in suitable forms (Grier 1937).

During the 8th century in the Arabic world, a growing recognition of government responsibilities for the health of people in connection with documented advances made in pharmaceutical knowledge and techniques, was accompanied with a definite division

of labour between medicine and pharmacy. This Arabic development is believed to have helped in establishing and shaping Western pharmacy as we know it.

In the 11th century in line with the Middle East, public pharmacies in urban centres began to appear in European countries, such as Italy and France (Kremer and Urdang, 1976).

1.2. An historical perspective of community pharmacy in Great Britain

The origins of pharmacy in Great Britain can be traced to the 12th century, when Peppers and Spicers sold goods, including drugs and spices, brought from the East and the Mediterranean (Kremers and Urdang , 1976). The Peppers acted as wholesalers merely selling articles in the raw or unprepared state. The spicers were retailers, of whom; some more knowledgeable and skilful members specialised increasingly in dispensing and compounding medicines. By the thirteenth century they were being called spicer or apothecary interchangeably (Kremers and Urdang , 1976). In 1428, the Peppers who had changed the name of their guild to the Grocers' Company received a charter. The Grocers' Company had authority over the apothecaries and physicians had powers of inspection of the apothecaries' premises and drugs.

Physicians utilised the apothecaries to make up the preparations that were ordered, and used their shops as consulting rooms. The physician regarded the apothecary as an agent to increase his patient numbers and whilst the physician received his fee, the apothecary was expected to charge for the ingredients plus a small fee for compounding the drugs (Trease, 1964). In 1617 the apothecaries obtained a charter from James I giving them an independent existence as a city guild, under the title of the Society of Apothecaries (Wootton, 1910). Only a few decades after the founding of the Society of Apothecaries of London the new group found itself in a fight on two fronts: against the physicians, to defend their assumed rights as minor medical practitioners and against chemists and druggists to safeguard their pharmaceutical duties (Kremer and Urdang, 1976).

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Although their fight against the physicians lasted almost a century, they were finally victorious in gaining recognition as medico pharmaceutical practitioners. The battle involved charges and counter charges against prescribing apothecaries and dispensing physicians (Trease, 1964). In 1703 the College of Physicians initiated a prosecution against an apothecary for prescribing medication. Although the first judgment was found in favour of the College of Physicians, in the appeal the House of Lords reversed the decision and announced that the apothecary, by service to the community over the years, had the right to practice medicine (Wootton, 1910).

Most apothecaries moved further towards the practice of medicine and the term apothecary became synonymous with that of general practitioner. With apothecaries becoming more involved in their new and accepted role the opportunity was provided for the chemists and druggists to claim an increasingly higher share of the pharmaceutical work. This trend was sustained into the first few years of 19th century when chemists and druggists practically monopolised the sale of drugs and medicines (Thompson, 1929).

In 1815 Parliament passed an Apothecaries Act (Kremer and Urdang, 1976) granting the Society of Apothecaries certain powers over professional standards and medical education throughout England and Wales. The Act specified that only qualified persons namely physicians, surgeons and apothecaries had the authority to diagnose diseases. To define the role of the chemists and druggists, a clause in the Act described their business as:

“Buying, preparing, compounding, dispensing and vending drugs and medicinal compounds by wholesale and retail” (Wootton, 1910).

The above definition effectively drew the boundary between the medical and pharmaceutical professions.

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To unite chemists and druggists and gain recognition as an independent profession the Pharmaceutical Society was founded by a group of chemists and druggists in 1841. The aim of the Society was to protect the general interest of members and to advance pharmacy by furnishing a uniform system of education to ensure the safest and the most efficient administration of medicines to the public (Holloway, 1991). The Pharmaceutical Society continued on a road diverging from that of apothecaries, moving slowly but continuously toward a professional status for practitioners of pharmacy. The Society's Charter (1843) empowered it to regulate the education and the admission of members.

1.3. Inception of the NHS and Changing of Community Pharmacists' Role

Prior to inception of the National Health Service (NHS) in 1948, the majority of the British population had to pay for their medical and pharmaceutical care. A free service was only available to the very poor living in inner urban areas whom had to seek medical care mostly from casualty departments in voluntary hospitals. The introduction of the National Health Insurance Act in 1911 instigated free care from general practitioners for low-paid working people earning under £160 per annum (Ham, 1992). However, workers' families were excluded from the scheme as was any hospital care. Other members of the population, including children and the elderly, had to pay for a consultation with the doctor or join one of the clubs run by the general practitioners. When a doctor prescribed a medication he would very often dispense it himself at an additional cost. This situation led many people to visit their general practitioners only as a last resort and consult their pharmacists in the first instance for treatment of minor ailments. Although patients had to pay for the medicine dispensed, the advice was free. Consequently the high street chemists served as a major provider of advice and primary health care selling many medicines (Reed, 1998).

The separation of prescribing and dispensing was achieved through the National Health Insurance Act in which dispensing was recognised as the sole right of pharmacists (Hunt *et al*, 1994). The introduction of the National Health Service superseded the National

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Health Insurance scheme to include all British citizens in accessing health services. The health care scene changed drastically and everyone became entitled to free health care at the point of delivery. The demand for medical services increased considerably and the main source of income for general practitioners became the capitation fee paid for each patient registered on their lists.

The pharmacist spent less time acting as the first point of contact and over the counter business decreased as the result of free prescriptions and the public's consequent unwillingness to self medicate. At the same time the number of prescriptions rose significantly and pharmacists, in response to an increasing demand, retreated into dispensaries consolidating their role as suppliers of medication (Jones, 1998). The dependence of turnover on NHS income started to increase, a trend that has continued steadily to date in the case of the independent proprietors. In 1948 less than 10% of pharmacies' turnover derived from the NHS dispensing contract whereas in 1999 this has risen to almost 70% of total turnover (Jones, 1998). This has been due to an increasing volume and cost of prescriptions and the gradual reduction of sales of traditional over the counter goods.

Over the same period a succession of scientific discoveries and developments has greatly increased the part played by medicines in therapy. Modern medicines are more effective and sophisticated in their usage. There has been a change in community pharmacists' roles so far as dispensing is concerned. The way in which the pharmaceutical industry prepares and pre-packages medicines have reduced the opportunities for pharmacists to exercise their full range of compounding skills. However, the change in the nature of products has increased the potential demand on the pharmacist's knowledge.

In 1986 the Nuffield Report recommended greater pharmacist involvement with members of the public and an extension to their advisory role (Nuffield, 1986). Whilst this role had been accepted by many, in 1992 a joint working party report on the future role of the community pharmaceutical services endorsed counselling patients on the effective use

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of their medication as part of the dispensing process (RPSGB, 1992). Two years later patient counselling was included in the Standard for Good Professional Practice published by the Royal Pharmaceutical Society (RPSGB, 1995).

In response to continually changing health services driven by growing patient expectations, new health care priorities, demographic changes and new technology, the Royal Pharmaceutical Society embarked on a public consultation on the future of the pharmacy profession (RPSGB, 1996a). Informed by the debate a new strategy, Pharmacy In A New Age (PIANA), was launched identifying five main areas of activities (RPSGB, 1996a). These areas highlighted by the Pharmacy In A New Age document were: the management of prescribed medicines, the management of long-term conditions, the management of common ailments, health promotion advice and provision of advice to other health care professionals. Patient counselling and advice giving were central to all five activities identified by the Royal Pharmaceutical Society as the areas where pharmacists would be able to make a major contribution to patients' health care (RPSGB, 1996a).

Also in response to an increasing public dissatisfaction with the National Health Service the Government conducted a public consultation on the future of the Service resulting in publication of the NHS Plan in 2000 (DOH, 2000a). This was soon followed by the Pharmacy in the Future- implementing the NHS Plan (DOH, 2000b) in which the Government set its vision of how pharmacy could play a full part in delivering the vision of the new NHS. One of the key areas identified by the Government in meeting the changing needs of patients was with specific references to the supply of medicines and provision of advice on medications. Three main objectives were set for pharmacists in the Pharmacy in the Future document to achieve this:

- to ensure that people receive their medicines or pharmaceutical advice easily and at a time and at a place of their choice if possible

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- to provide support for people to take their medications correctly to lessen their health problems and reduce wastage of medications
- to keep up to date with the latest professional knowledge to provide the public with the confidence that they are getting good advice.

Under the current legislation and pharmacists' contractual agreements with the NHS some of the proposed changes of community pharmacists' role would not be deliverable. To facilitate implementation of Pharmacy in the Future (DOH, 2000b) the Government has proposed a list of changes to be put in place including electronic transfer of prescriptions from GPs' surgeries to pharmacies, provision of repeat prescriptions in instalments and medicines management by community pharmacies, more flexible contractual arrangements and giving some pharmacists independent prescribers status.

The account of changes in community pharmacists' roles provided so far is from an inter-professional perspective. However, by means of contractual agreements pharmacy became the main supplier of medicines for the NHS and as such has been affected by organisational changes and reforms that have taken place in the NHS since its inception. In order to gain a better understanding of the driving forces behind the changes in pharmacy it is essential to review the major reforms of the NHS which could have influenced the course of events in the profession.

The following is an account of major reforms in the structure and organisation of the NHS with particular reference to events leading to the introduction of audit as a tool to assure the quality of care as delivered by health care professionals in the Health Services.

1.4. National Health Service reforms

The organisation and administrative structure of the NHS, at its inception, was mainly shaped by two elements: firstly the bargaining and negotiation which took place, in particular between the medical profession and the Government, and secondly the

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historical arrangement for health service delivery (Ham, 1992). It was therefore viewed as a representation of what was possible rather than what might have been desirable.

The widespread public support for a national health service that was mainly funded by general taxation and free at the point of delivery was not shared by the medical profession. The Royal Colleges and the British Medical Association representing the medical profession were deeply antagonistic to the possibility of State control of medical practice through a national health service and restrictions on private practice (Ham, 1992). In order to attract and persuade doctors to join the new NHS, Aneurin Bevan, the Minister for Health at the time, granted the medical profession with concessions which in essence secured clinical freedom, a major role in the administration of the services at all levels, retention of independent status (for general practitioners) and allowance of hospital consultants to practise privately.

The result was an implicit bargain between the State and the medical profession, that the former would set the overall level of funding for the NHS, while the latter were free to spend it largely as it wished. The concept of clinical freedom posed difficulties for the NHS administrators responsible for managing the budget. This point was acknowledged by the Department of Health and Social Security in evidence when reporting to the House of Commons' Expenditure Committee:

“The existence of clinical freedom undoubtedly reduces the ability of the central authorities to determine objectives and priorities and to control individual facets of expenditure”. (Expenditure Committee, 1971)

One of the assumptions that lay behind the NHS was that there was a backlog of ill health in the community which the introduction of a health service, free at the point of delivery would gradually reduce. It was therefore expected that expenditure would soon level off and even decline as people became healthier. However, demand for state funded health care greatly exceeded expectations and the costs of the NHS rose over and above the

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anticipated level in the immediate years after its inception (Ham, 1992). The cost of medical facilities rose in line with the growth of clinical knowledge and the introduction of new technology vastly extended the range of conditions the NHS could treat. Increased life expectancy has led to a larger number of older people with greater need for health care and social change has inflated expectations of the kind of service the NHS should be providing.

The evident failure of the NHS to meet all the demands placed upon it has meant that financial crisis has been a recurrent feature throughout its history which in turn has brought about reviews by successive governments regarding its financing method, the level of funding, efficiency of resources used and its organisational structure.

1.4.1. Debates on the method and level of financing

In order to establish what would be an adequate budget to satisfy the spending needs of the NHS, two major independent reviews were conducted: the Guillebaud Committee in 1953 and the Royal Commission on the NHS in 1979 (Guillebaud, 1956; Royal Commission on the National Health Service, 1978). They both concluded that it was not possible to determine a level of adequate funding for the NHS and that whatever the expenditure on health care, demand was likely to rise to meet and exceed it. The Royal Commission's view was that since extra spending improved the comfort and quality of life of patients, and pay conditions of staff, it was right the Nation should spend more on health care as it grew wealthier however, the Commission was unable to define how much more was required.

The method of financing the NHS had also been scrutinised and despite all the debates about the funding of the NHS the Governments and the public have remained convinced that taxation is the best way of resourcing the Service (Fowler, 1991; DOH, 1997).

1.4.2. Organisational reforms

The NHS structure remained almost unchanged for the first twenty five years, despite an increasing level of criticism. During the 1970s and 1980s the NHS changes mainly revolved around administrative structures with the implementation of the Griffiths Report recommendations (Griffiths, 1983) being the most notable.

In 1983 Sir Roy Griffiths was commissioned by the Government to report on management arrangements in the NHS. The main thrust of the critique offered in the Griffiths Report was that the NHS lacked a clearly defined general management function. It also recommended that doctors should be encouraged to play a more active role in management and that management budgets for doctors should be developed (Griffiths, 1983).

During the late 1980s the NHS was faced yet again with a financial crisis and in response the Prime Minister announced a fundamental review of the NHS which eventually led to the introduction of an internal market in health services as described in the White Paper: *Working for Patients* (DOH, 1989). The idea was that market forces would result in greater efficiency in the use of resources and services would become more responsive to patients and their needs.

The reforms instigated by this White Paper represented a transition from an integrated system of health service financing and delivery to a system of contracts (Ferlie and Fitzgerald, 1995). The idea of a health care system governed by an internal market and driven solely by price was not an acceptable model to the NHS users unless there was an assurance that the element of quality in delivery of the care was not overlooked.

To this end one of the main areas for the reforms as described by the White Paper: *Working for Patients* (DOH, 1989) was the strengthening of quality management and the introduction of audit arrangements. As a result medical audit was instigated as a routine part of clinical work for both general practice and hospitals and became a contractual

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obligation for hospital consultants. Although in primary care the Government created Medical Audit Advisory Groups (MAAGs) as an audit infrastructure, it left general practitioners to organise audit activities voluntarily.

Following the publication of the Government Working document on Medical Audit, Working Paper 6 (DOH,1990) funding was made available to the Standing Medical Advisory Committee to consider and report on how the quality of care could be improved by medical audit. The Working Paper 6, the Standing Medical Advisory Committee (DOH, 1990) and the subsequent circular elaborated an audit framework, which characterised audit as a confidential peer review process, owned and led by the medical profession. The allocated funds for audit were ring-fenced and distributed through regional and local committees composed solely of clinicians. This ring fencing coupled with the confidential nature of the process seemed to set audit apart from other related policies. Furthermore, within the medical profession audit was promoted as a structured analysis of medical work in a non-threatening manner and as an educational experience for doctors (Kerrison *et al*, 1993).

Initially, audit was targeted at the medical profession, but it quickly became apparent that the same principles could be applied to other health care professions. In 1991 the audit initiative was expanded to nursing and therapy professions. Two years later, the separate medical, nursing and therapy groups were integrated into a single audit initiative involving all health care professionals.

The Royal Colleges took on a particular role with respect to quality. They agreed to take responsibility for developing quality controls and accepted central Government funding to assist them in implementing systematic professional audit within their prospective professions (Tomlin, 1990; Pharmaceutical Journal, 1992A)

Successive Governments have attempted not only to improve the NHS performance by setting explicit performance targets but also to make it more transparent. The 1990s saw

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the introduction of national performance targets for a number of areas. However, these targets mainly addressed the Service rather than clinicians' performance. Introducing audit as a requirement for health care professionals was the first step to assure quality and improve clinical performance in the NHS.

Assurance of quality of Health Services has always been an integral to service delivery, a point that has been endorsed by the Governmental policies. The New NHS: Modern Dependable (DOH, 1998) states that:

“The new NHS will have quality at its heart. Without it there is unfairness. Every part of the NHS, and everyone who works in it, should take responsibility for working to improve quality.”

Any one of the approaches or systems used to assure quality such as Total Quality Management (Richards, 1994), Continuous Quality Improvement (Kitson, 1994), The King's Fund Quality Assurance Approach (King's Fund Centre, 1990) or Audit, include an assessment where performance is measured against a set of standards. REFS

One definition of audit is:

“An attempt to improve the quality of care by measuring the performance of those providing that care, by considering the performance in relation to desired standards, and by improving on this performance.” (Marinker, 1990)

Viewing the NHS at a macro level, prior to the launch of any National Service Frameworks (NSFs) (DOH, 1999) there were no clear national standards of care which health services were expected to meet. The New NHS: Modern and Dependable (DOH, 1997) marked a significant change by advocating a greater central role in setting standards and monitoring clinical performance at the national level.

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A First Class Service: Quality in the New NHS (DOH, 1998) announced the launch of the National Institute for Clinical Excellence (NICE) as the organisation responsible for the assessment of current and future treatments and procedures available in the NHS. The Paper also introduced the National Service Frameworks (NSFs) which outline how services can best be organised to care for patients with particular needs and the standards that services would have to meet. The current NSFs include: mental health, coronary heart disease, older people services and the National Cancer Plan.

Setting standards is only the first step in a continuous cycle of improving the delivery of health care and, like an audit cycle, it could only better the service if it is followed by monitoring the performance against standards set. The Government monitors implementation of standards through three mechanisms: a Commission for Health Improvement, a National Framework for Assessing Performance and an annual National Survey of Patient and User Experience (DOH, 1998).

The Performance Framework assesses the performance of each part of the NHS against the local objectives from the patients' perspective. The National Survey of Patient and User Experience (DOH, 1998) seeks views of the user about clinical quality of the service. If the report identifies areas where services consistently fail to satisfy the patients' requirements the Commission for Health Improvement can be called in for investigation. Clinical governance is the system by which delivery of standards at the local level is monitored. Clinical governance has been defined as :

“A framework through which the NHS is accountable for continuously improving quality of services and safeguarding high standards, by creating an environment in which excellence will flourish.” (NHS Executive, 1998)

The approach taken for assuring quality in the New NHS to some extent resembles an audit cycle. The process could be compared with an external audit process where the standards have been set up by an external agency, (i.e. external to the health care

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professionals concerned) and performance is compared with these standards and necessary changes are implemented through clinical governance at local level. The monitoring of the performance informed by the annual National Survey of Patient and User Experience, is carried out by an external agency in accordance with the National Framework for Assessing Performance. It is hoped that this critical and systematic approach to quality will improve the performance of health services. However, in the case of persistent poor performers an intervention from the Commission for Health Improvement ensures appropriate standards are met.

1.5. Audit

A feature of health care professionalism concerns accepting responsibilities and determination to serve. Striving for quality and constantly seeking improvement by being self-critical, self-adjusting and doing one's best is a fundamental characteristic of professionalism (Donabedian, 1966). It is a fundamental professional responsibility to provide a quality service. Quality assurance assists professionals in remaining self regulatory and autonomous and helps to assure them that they are doing the best for their clients.

Quality assurance is defined as embracing all activities and functions concerned with attainment of quality. In essence it includes any activity that contributes towards maintaining, improving and assessing the quality of services. Professional audit is a component of quality assurance for professional services and is carried out within the profession with the aim of continual improvement of performance. Success of professional audit depends on the motivation and commitment of the participants hence it should be voluntary and non-threatening.

The main factors contributing to initiation of professional audit are public accountability, professional credibility and Government pressure.

Public Accountability

There is an increasing acceptance of the patient as a consumer of, and partner in, health care. People feel that they have the right to know in order to make informed choices about treatments (Kitching, 1990). They are beginning to question professionals and demand a good service. Educational aspects of audit which lead to increased and appropriately targeted training, promote patients' confidence in health care professionals. It reassures patients that the advice they receive is based on the latest information and evidence.

Professional Credibility

The pharmacy profession must be seen along with other health care professions to be actively participating in all developments leading to improved quality of care. Audit is perceived as a component of quality assurance by other health care professionals and equips pharmacists to participate on equal terms in multi disciplinary audit.

Government Pressure

The Government introduced audit as a mechanism whereby health care professionals become more accountable and can justify their professional decisions. Audit is also seen as a possible way by which practice may be evaluated and questioned. The Government provided funding to the Royal Colleges to promote audit activities within the health care professions.

In 1992, the Council of the Royal Pharmaceutical Society agreed that the Society should promote professional audit within pharmacy practice (RPSGB, 1992a) and provided a definition for pharmaceutical professional audit as:

“Professional audit in pharmacy is the study of some part of the structure, process and outcome of pharmacy practice, carried out by individual pharmacists or groups of practitioners engaged in the activity concerned, to measure the level

of attainment of agreed objectives, the use of resources and the resulting outcome.” (RPSGB, 1992b)

This definition refers to the structure of a professional audit activity based on Donabedian’s concept for quality of health care, which has been adopted by health professionals including pharmacists as a framework for audit.

1.5.1. A Framework for assessing care

Audit requires a framework in which the description, measurement, comparison and evaluation of the quality of health care can be made. Avedis Donabedian has presented a framework for the assessment of health care interventions based on the separate consideration of the structure of services, processes in their delivery and the outcomes of care (Donabedian, 1966).

Structure → process → outcome

Structure - Structure can be defined as physical and personnel resources of an organisation. The advantage of assessing the structural characteristics of care is that they are tangible and can be measured with relative ease. Examples will include quantity and types of available resources, number of trained staff, stock levels and equipment employed by the pharmacy. Although the presence of desirable structural attributes does not of itself ensure that the individual pharmacist will provide good care, better care is more likely. For example computerised patient medication records in the pharmacy enables the pharmacist to check for drug interactions before sale of OTC medication. However its presence does not guarantee that it will be used every single time an OTC drug is purchased.

Donabedian does not view structure as a measure of quality of care, but he argues that the structural characteristics of the health care setting will influence the process of care and hence its quality. He also views appropriate structure as the most important means of protecting and promoting good quality care.

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Process - Process refers to the actions taken by all those involved in the aspect of care that is being audited. Examples include interventions made by the pharmacist, quality of patient medication records kept, the pharmacist's response to requests for information. The process of care reflects the pharmacist's attitude, knowledge and skills. Assessing quality of care by examining the process rather than its outcome is justified by the assumption that one is interested not in the power of medical and pharmaceutical technologies to achieve results, but in whether what is known as "good" standards of care has been applied (Donabedian, 1966). The measurement of process is the most common activity in medical audit (Marinker, 1990).

Many assessments of advice giving have focused on the processes of interactions, considering it as a proxy for the outcome. Both structural characteristics and the process of delivery are important in determining the outcome of care.

Outcome- Outcome refers to changes in a patient's current and future health status that can be attributed to antecedent health care (Donabedian, 1966). Outcome describes the effectiveness of care provided to the patient. Although the validity of outcome as a dimension of quality is seldom questioned, there are a number of considerations which limit the outcomes as measures of the quality of care. Good measurements of outcome are not easy to identify because it is difficult to distinguish between antecedent care and other factors that may influence the patient's condition. Because outcomes relating to pharmaceutical services are dependent on many factors which are not directly associated with pharmacy *per se* this approach has not often been used in studies evaluating the quality of pharmaceutical services. Outcomes usually do not provide insights into the nature and location of shortcomings or strengths in the situation being evaluated. The length of time that may have elapsed between care and its effects on the patient can also distort the suitability of outcome measures. Nevertheless outcomes, by and large, remain the ultimate validators of effectiveness and quality of medical care (Donabedian, 1966). However, when evaluating quality of care it should be borne in mind as to whether the outcome of care, is in fact, the relevant measure.

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Audit of structure assesses the quality of the environment in which care is provided. A process audit describes quality of work done and outcome audit highlights the benefits achieved for patients. Audit can be based on any or all aspects of health care. There have been several studies of the relationship between structure and process in hospital and community pharmacies indicating an association between components of structure and process in both settings (Jackson *et al*, 1975; Lazarus, 1970). If only structure and process are audited, it should be established that there is a causal link between these and outcome (Alexander, 1993). Better process does not always result in better outcome.

Audits that assess performance of health care professionals investigate a combination of process and outcome. The relationship between process and outcome is not unlike the relationship between means and ends. However, it is often difficult to ascertain where one ends and the other begins. It may be possible to define outcomes in ways other than ultimate patient outcomes. One may consider several sub-objectives of the health care process and measure these. Differentiating between process and outcome is somewhat of an abstraction, and many procedural end points and intermediate outcomes may be used as indicators of the quality of care (Jackson *et al*, 1975).

In developing and assessing health care, the Government is keen to ensure that services (structure and process) are responsive to the priorities and needs of patients. Structural components (such as privacy and accessibility) and processes of advice giving are known to be important issues to clients in determining whether or not the client's goals are achieved (Smith F J, 1992; Krska *et al*, 1995; Rogers *et al*, 1998). Therefore the processes of care themselves may be an important part of desired outcome as well as a proxy for outcome measurement (Eadon *et al*, 1996).

1.5.2. An audit cycle

The audit process is often described as a cycle of establishing objectives, setting standards, collecting and analysing information, evaluating performance, implementing changes and monitoring their effects. To achieve a progressive improvement through

audit, standards should be reviewed and updated frequently. This additional step will change the audit cycle to an audit spiral.

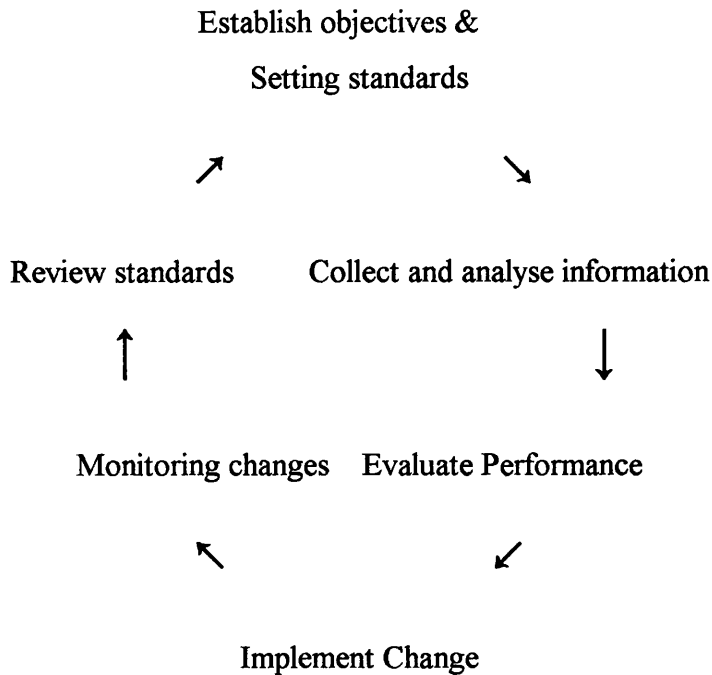


Figure 1.1 Essential steps of an audit cycle

Establishing objectives

After selecting a topic the next stage is to identify aims and objectives of the audit. By clearly expressing these, the desired outcomes of the audit become apparent.

Setting standards

Setting standards uses the process of reflecting on one’s own practice as well as looking outwards towards practices of others within the profession and considering the standards established elsewhere. As professionals it can be assumed that pharmacists have an idea of what constitutes "good practice" which guides them in conducting their professional activities. In its broadest sense "good practice" is largely implicit, subjective and open to individual interpretation. To achieve uniformity in delivery of “good practice”

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standards should be converted to explicit written statements, which are objective and describe the expected level of care to be achieved. Explicit standards can be communicated more clearly and are more easily applied.

One of the initial stages of the audit process is to define the criteria and standards. Criteria are general statements about the delivery of services and patient care (Centre for Medical Education, 1993), an example of which is the statement: “asthmatic patients should be counselled on their use of inhalers”. However, this statement is not sufficiently defined or quantifiable for an audit process. It would be very difficult to collect data and measure one’s performance against this criterion. A standard is quantitative, referring to the proportion of occasions on which a criterion should be fulfilled (Centre for Medical Education, 1993). For example, 90% of asthmatic patients receiving inhalers in the pharmacy should be counselled.

To set standards, useful guidelines can be derived from the literature. Standards may be determined by the profession, the contractor or the law; these may be perceived as an imposition by individuals embarking on an audit. Standards can also be based on personal experience of those involved in the audit creating a greater sense of ownership.

It is also essential to ensure that the standards set are achievable, realistic and practicable.

Collecting and analysing information

Data can be collected in many ways and obtained from different sources. Information on patient medication records, numbers of prescriptions in community pharmacy, prescription interventions or duration of stay in hospital are examples of data collected routinely. Retrospective data can be inexpensive and easy to acquire. If recorded data are not completed or specific information is required, then a prospective documentation should be carried out. The main methods used to collect data include: reviews of routinely collected information, documentation of specific activities and/or outcomes,

direct observation, interviews and questionnaires. A more detailed account of these methods is provided in chapter two.

Evaluating performance

Once data are collected, performance has to be evaluated by comparing the results with the standards set. If the standard is not met, the information collected should be used to ascertain the reason(s). It is not sufficient to establish that a problem exists, or even to describe it in detail. Once a problem has been identified the underlying causes need to be sought and understood otherwise the strategies for change may not address the fundamental problems. This process may seem self evident but it has not formed part of many audit studies (Crombie *et al*, 1992).

Implementing change

At this point the factors which may have prevented the standard being achieved have been identified. However, prior to implementing any changes there are some issues to be considered. All the relevant staff should be involved in the process and the need for change should be understood by them. Any required changes should be explained clearly to the people involved, along with any implications for other procedures or activities, and the need for documentation should be emphasised.

Monitoring change

A period of monitoring then follows to evaluate the changes that have been implemented. Improvement in the performance towards the set standard can indicate that the underlying cause of the shortcomings has been correctly identified and the audit process has been successful.

Reviewing standards

Standards should be revised and updated regularly so that an audit cycle can become an audit spiral (Alexander, 1993). Audit is an ongoing exercise achieving higher standards and better quality of care.

1.5.3. Types of Audit

Depending on who conducts the audit, there are three types: self-audit, peer audit and external audit. Audit can be undertaken by individuals looking at their own performance or by a group of peers or others who are external to the health care professionals concerned.

Self audit

A characteristic of professionals is that they should regularly review their professional activities. The individual practitioner may assess his or her performance against published standards or personal objectives. Self audit is fundamental to quality assurance and is undertaken by professionals such as community pharmacists who practise in isolation.

The advantages of self-audit include full commitment and understanding of the process by the individual undertaking the audit, increased job satisfaction and improved practice which is ultimately beneficial for patients. However, regular self audit can be difficult to sustain as often other activities may take priority, and its successful completion depends solely on the auditor's interest and motivation. It is also quite likely that threatening or awkward topics will be avoided.

Peer audit

Peer group audit is undertaken by fellow-professionals. This describes audit undertaken by equal partners, aware that they are also subject to scrutiny or audit of their own practice (College of Pharmacy Practice, 1993). Local peer groups are ideal for generating inter-practice criteria and standards. One of the advantages of peer audit is that having a similar background of knowledge and understanding helps to choose topics of common interest and to proceed with audit in the group. Also having an open and honest comparison of personal performances with those of peers reduces any prospect of self deception in relation to personal standards. As more people are involved a wider dissemination of good practice can be achieved.

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One of the disadvantages is that it may become collusive. An example familiar to most pharmacists is when the level of counselling can be adversely affected by the high volume of prescriptions to be dispensed for waiting patients. The fact that the majority of pharmacists may occasionally be guilty of such shortcomings, the reduction of counselling may not be examined as rigorously as it should and thereby *status quo* could become the accepted practice. Peer audit can be perceived as more threatening than self audit, specially if it involves peers from outside an established circle of colleagues.

External audit

This is undertaken by people outside the practice or profession with the result that auditors may have different approaches, views, and priorities from those whom they are auditing. It is mainly performed to satisfy funding bodies and the public interest that the standard of service conforms to that of contracts. This is also called contractual or extrinsic audit.

The fact that external audit is undertaken by assessors with different values can bring a greater objectivity to the assessment of performance. It is also a primary means by which any of the practice's standards and performance can be monitored against a national norm or regionally agreed standard. Other advantages include: offering the best opportunity of raising the basic standard and of identifying individual health professionals who fall below that minimum.

However, there are some perceived disadvantages to external audit. For example standards set by external auditors are usually based at minimum requirements rather than the more positive approach by internal auditors in which standards are likely to be set higher to lead to better practice. External audit can be seen as threatening in that unsatisfactory practice could lead to withdrawal of contracts or of professional recognition and thus it tends to provoke a defensive attitude from those whose performance is being assessed.

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All types of audit are valuable when used appropriately. Self audit is a foundation of any system of quality assurance that undergoes regular review. There is no external intervention and the standards against which audit can be carried out is set by the person himself. Self audit is a demonstration of personal commitment to the delivery of quality care.

Peer audit is local, inexpensive and can act as a source of new ideas. External audit is objective and provides consistency in approach and uniformity in standards. It seems clear that the more a profession does to set and monitor its own standards, the less there will be a perceived need for an external audit.

1.5.4. Audit in health care professions

The literature on audit reflects involvement of all the health care professions in unidisciplinary and multidisciplinary audit. Prior to the introduction of professional audit by the Government in 1991, its concept had been explored and established in medicine and nursing. However, to others, including dentistry and pharmacy, it was a novel notion.

Audit in medicine

In the United Kingdom studies in the 1950s and 1960s described the nature of general practice (Hadfield, 1953; Taylor, 1954), some concentrating on describing the structural characteristics of general practice such as the quality of the buildings, equipment, staffing and the organisation of general practice (Collings, 1950; Irvine and Jeffreys, 1971).

In the 1970s and 1980s, increasing numbers of individual British general practitioners performed and reported the results of audits that were mainly based on the process of care. The results described activities such as prescribing patterns, hospital referral patterns and the functioning of appointment systems (Barley and Mathers, 1980; Colmer and Gray, 1983; Hart, 1975).

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During the late 1980s many articles within the medical literature argued that audit could both improve patient care and benefit the organisation of medical work. Many studies demonstrated a relationship between audit and improved process of care (Fowkes *et al*, 1986; Ahmed *et al*, 1992), and a smaller number provided evidence that audit could influence the outcome of care (Anonymous, 1992; Hancock, 1990). Therefore it was not surprising that in 1989 when the Government announced a series of NHS reforms, introduction of audit was singled out and welcomed by the Royal Colleges of Physicians and Royal College of Surgeons as a means of showing their commitment to improving the quality of care (1989).

However, the introduction of medical audit received a mixed response from members of the medical profession. When audit was presented as an educational tool, designed to help doctors to identify areas of need for new knowledge or skills, it was seen by the medical profession in a positive light (Newton *et al*, 1992; Batstone, 1992). However, those doctors perceiving audit as a threat to their clinical freedom found it unacceptable. Audit was introduced at a time when the extent of the profession's self-management arrangements were being called into question and demands were made for doctors to be more accountable for the use of resources. A key mechanism for exercising managerial accountability in a modern organisation is measuring the extent to which departments, groups or individuals conform to predetermined standards (Day and Klien, 1983). As conformity to standards was also the central focus of audit, it was not surprising that audit was seen by some doctors as a tool for increasing accountability which could result in unacceptable threats to their clinical freedom (Irvine and Irvine 1991; Tomlin 1991).

The White Paper: Working for Patients (DOH, 1989) made audit a contractual obligation for hospital consultants, however, in primary care the Government chose instead to establish an infrastructure by creating Medical Audit Advisory Groups (MAAGs) and left the profession, in collaboration with management, to organise audit activities voluntarily. MAAGs were subcommittees of the Family Practitioner Committee (FPC) which changed their name to initially the Family Health Services Authorities (FHSA)

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subsequently becoming Health Authorities. By April 1992 it was expected that all general practitioners would participate in audit.

The principal responsibilities of MAAGs which have been retained to date include:

- the institution of regular and systematic medical audit in which all practitioners participate.
- implementing adequate procedures to maintain anonymity of the patients and GPs who participate in audits
- establishing appropriate mechanisms to ensure that problems identified through audit are addressed by the practitioners involved
- providing the Health Authorities (previously FPC and FHSAs) with regular reports on the general results of the audit programme.

Since their inception MAAGs have promoted a “bottom up” approach to audit which is practice based and problem oriented (Irvine and Irvine, 1991). Individual practices have access to the MAAG facilitator for advice, education and training and are free to select audit topics pertinent to their practices. In 1996 a report from the National Audit Office estimated that the number of medical audit projects undertaken in hospital and community health services in 1993-1994 as more than 20,000. In a questionnaire survey for the NHS Executive during the same period, 83% of consultants, 77% of junior doctors and 82% of general practitioners were reported to have participated in medical audit (nahat, 1996).

Audit in nursing

Within the nursing profession issues which have been subject to audit include: workforce problems, legislation, resource constraints and publicised examples of poor care and practice (Hunt, 1990). The agreed definition of audit for nursing services states:

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“Nursing Audit is part of cycle of quality assurance. It incorporates the systematic and critical analyses by nurses, midwives, and health visitors, in conjunction with other staff, of the planning, delivery and evaluation of nursing and midwifery care, in terms of their use of resources and the outcomes for patient/clients, and introduces appropriate change in response to that analysis” (Bradshaw, 1987).

Nursing differs from other disciplines as its emphasis is to try and find an audit instrument that would provide an indication of the level of overall quality in a ward, unit or hospital. The main three audit approaches taken in nursing include:

- generic - ie measuring overall quality in a unit, ward etc
- problem specific - ie measuring quality related to a clinical topic
- activity specific -ie measuring the quality of care provided by a particular person/s.

The generic approach is the most widespread and popular approach in nursing (Hunt, 1990).

Nursing differs from medicine in that there is considerable pressure to assess quality in terms of efficiency as well as effectiveness, because of the large size of its workforce and the implications in terms of changed costs of increases or decreases in the number of nurses employed. The most frequently used quality measurement tools are therefore linked with patient dependency, workload and nurse staffing systems (Kitson, 1989; Balogh, 1992; Harvey, 1991).

1.5.5. Audit in pharmacy

Pharmacists are one of the most accessible members of the health care team who are constantly interacting with the public. Dispensing medication, counselling on dispensed and pharmacy medicines, response to symptoms and health promotion are among many services provided by pharmacists. The extensive advisory role of community pharmacists is expected by the general public and willingly accepted by pharmacists (RPSGB, 1992b). To fulfil public expectations and maintain the professional status as a first contact for help and advice, it is important that all aspects of pharmacy are practised to the highest attainable levels by all practitioners. The Royal Pharmaceutical Society, as governing body of the profession, has taken a number of initiatives by appointing working parties to investigate the feasibility of introducing quality assurance measures in pharmacy practice (College of Pharmacy Practice, 1993; Alexander, 1993). Two of these initiatives have been on competence assessment and professional audit.

In October 1990 the Working Party responsible for considering the linking of assessment of competence to the continued right to practise as a pharmacist published its report. In this report competency assessment was described as a type of extrinsic evaluation carried out by the profession on behalf of the public (RPSGB, 1990). When the Working Party considered competency assessment as a method of quality assurance for pharmaceutical services, a number of problems were highlighted.

First it would only be possible if all the elements of competence and associated performance criteria for the core of pharmacy practice, with appropriate methods for their assessment, had been determined and agreed upon. This task was considered to be time-consuming, very costly and needing an expert team. Secondly, competency assessment was purely intended to find out whether or not a pharmacist could carry on an activity, and not how well he or she performed. Thirdly, a mandatory competency assessment carried the right of sanction and pharmacists could feel threatened by it. Concluding this report the Working Party recommended that:

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“ It would not be feasible to introduce mandatory competency assessment from a set date for the majority of the profession. This would pose insurmountable logistical and financial difficulties and meet much resistance from established practitioners” (RPSGB, 1990).

In November 1991 the Royal Pharmaceutical Society decided to establish another working party to consider professional audit within community and hospital pharmacy (RPSGB, 1992a). The report which was received by the Royal Pharmaceutical Society in April 1992 included a general overview of audit, its implementation in other health care professions, its impact on the future of health care and recommendations concerning pharmaceutical audit (RPSGB, 1992b). The arguments for and against the further development of professional audit in pharmacy were also covered in the report. Based on experiences of other health care professions the Working Party listed some of the benefits to be derived from this process as follows:

- to provide a means of identifying patients' needs and expectations and of ensuring that they were met
- to highlight deficiencies, allowing pharmacists to adopt the most appropriate approach to overcome problems
- to enable professionals to examine their practice activities which in itself could lead to improvements in efficiency
- to provide high standards of professional practice and pharmaceutical services, through the review of standards
- to allow setting of standards by the practitioners which would result in more realistic and achievable standards and create a sense of ownership

The two reports on competency assessment and professional audit were considered together at the Society's Council meeting in April 1992. The concept of audit as a tool

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to achieve quality assurance in a professional setting was more akin to the nature of health care professions. The fact that professional audit was conducted to improve the quality of patients' care by pharmacists themselves, fitted in well with two fundamental characteristics of health care professions: striving for quality and self-regulation. Therefore the Royal Pharmaceutical Society as the governing body of pharmacy profession, in line with other Royal Colleges, decided to promote professional audit.

In order to implement any changes successfully, the need for the change should be established in first place. It is essential that people involved understand why the current practices are no longer satisfactory and gain an insight into the nature and extent of anticipated improvements brought about by the introduction of change. This was the approach that the Royal Pharmaceutical Society took in introducing audit to its members and in seeking the Department of Health funding for the following:

- to launch the concept by convening a meeting to promote audit
- to commence training of audit facilitators
- to appoint a member of staff to examine the current audit activity in pharmacy
- to develop an audit database
- to promote and evaluate audit aids.

Audit as a process and activity was a novel subject for the majority of pharmacists when it was introduced to pharmacy in 1992. There were a number of publications indicating pharmacists' involvement in medical audit in hospitals. The first pharmacy peer audit was conducted in a group of 14 hospitals in the West Midlands in 1990 a report of which appeared in the *Pharmaceutical Journal* in 1993 (Hynam, 1993; Fitzpatrick, 1994). However, at that time there was no publication to indicate any community pharmacists' involvement in audit activities.

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The plan of introduction of audit to pharmacists included a funded post at the Royal Pharmaceutical Society and the appointment of a number of audit facilitators in two National Health Service Regions to facilitate the implementation in community pharmacies. The posts were filled by practising pharmacists working 20 hours a week, promoting audit to pharmacies in their areas (Anonymous, 1994b).

In line with promoting professional audit in pharmacy a distance learning package entitled "Moving to Audit" was launched at the British Pharmaceutical Conference in 1993 (Centre for Medical Education, 1993). This package, comprising a resource book and two sets of six "challenges", provided examples of audit carried out in community and hospital settings. Each challenge was presented in the form of a pharmacist's diary note of the situation and was followed by a series of questions. Pharmacists were invited to answer the questions and return their answers to designated centres in England, Scotland and Wales. Pharmacists who responded to challenges received comments on their answers, an analysis of overall returns from other respondents and the view of experts in professional audit.

The issue that was not addressed or acknowledged by the Government or the Royal Pharmaceutical Society at that time was that the audit initiative had not been introduced in response to needs identified by pharmacists and driven by them. Hence, by and large, there was no recognition on the part of pharmacists that a change was needed (Armstrong, 1994). In addition the NHS pharmacy remuneration system was not, and still is not, conducive to the introduction of any quality improvement process may be time consuming and adversely effect the volume of prescriptions dispensed. It seemed that as far as involvement in audit activities was concerned, both hospital and community pharmacists' main concerns evolved around resources, especially lack of time (Cotter *et al*, 1993; Anderton, 1994).

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Based on the lack of explicit standards in many aspects of pharmacy practice, the Government funded a project at the University of Keele (Panton *et al*, 1994) resulting in publication of nine model standards for self-audit in community pharmacy in England (Anonymous, 1994). The Department of Health funded the project as it was felt that setting standards was an essential component of the audit cycle without which pharmacists would not have any benchmark against which to measure their practices (Anonymous, 1993).

Having explicit standards are even more crucial in community settings as the majority of pharmacists work in isolation and there is no peer review in place. These standards were developed with the recognition that whilst internal standards, as set by practitioners, provided a sense of ownership, they may be based on inadequate information. On the other hand external standards, particularly those from professional bodies, may have a high degree of rigour and may not be achievable by most practitioners (Crombie *et al*, 1993).

The nine models contained standards on the dispensing process, written and verbal information with dispensed medicines, purchasing and stock analysis, guidance for relief pharmacists, premises and equipment, health promotion, domiciliary services, residential and nursing homes and responding to symptoms (Panton *et al*, 1994). Pharmacists scored their performance against the proposed model and were encouraged to amend the model if it did not suit their particular practice.

Many of the standards were just statements of legal and ethical requirements (Keele University, 1994a). Pharmacists scoring their performance against these criteria could have been misled to believe that there were different degrees to which they could fulfil their obligations, underestimating the necessity of full compliance with these legal and professional requirements. Other standards were simply good basic pharmacy or

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business practices such as the following example from Purchasing and Stock Analysis Model which states: “Purchase your supply from a reputable source” (Keele University, 1994b). In some cases the standards were unrealistic such as “*All prescription items owed to patients should be dispensed within 24 hours*” (Keele University, 1994c)

The “model standards” tried to cover each area so extensively that a word of warning was felt warranted by the Pharmaceutical Journal editorial when it asked for audit not to be trivialised (Anonymous, 1994d). It went to state that unless the concept of audit was fully embraced to show pharmacists how it helped them to be more competent and how it could bring benefit to patients’ care, audit would be regarded as being pointless (Anonymous, 1994d).

However, it seemed that after publication of these model standards, there was a general shift by the Pharmaceutical Society from a descriptive approach to audit to providing broader views of audit implementation and demonstration of resulting benefits in patient care (Pruce, 1994). This was in conjunction with the publication of a series of audit articles in which practice based topics such as “antibiotic audit” and “auditing of owings” were selected and a pragmatic and stepwise guide on how to conduct the audit process was described. (Pruce, 1994; Kelly and Mason- Duff, 1994). The variety of approaches taken to promote audit in pharmacy by the Royal Pharmaceutical Society was believed to succeed in increasing pharmacists’ awareness of audit in the year following its launch as reported by the pharmacy press (Anonymous, 1994B).

In Scotland in 1989, the Clinical Resource and Audit Group, under the auspices of the Scottish Office Home and Health department, was established to promote and support audit in medical and other clinical areas. Before audit was formally embraced by the profession, in 1991 a local pharmaceutical committee was established in Grampian which set about promoting pharmaceutical audit in the region (Krska, 1994). The emphasis was

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placed on encouraging participation of community pharmacists in particular and a number of training courses were organised to enable them to embark on the audit (Bond *et al*, 1993). Since 1993 participation in audit has been a requirement for the professional allowance, which form part of the pharmacy contractor's income in Scotland (DOH, 1993).

Professional audit is a tool by which practitioners may objectively measure their own performance (RPSGB, 1992b). Community pharmacists are often relatively isolated in their pharmacies. They work long hours with little contact with their professional colleagues. Therefore they do not experience the type of interaction, which allows them to assess their own performance or opportunities to learn from others. Professional audit can remedy this problem by allowing pharmacists to measure their performance against external or national standards.

Current social attitudes demand increasingly high quality of health care in response to patients' needs. Audit is an invaluable tool in helping health care professionals to meet this expectation by identifying areas of their practice which requires improvement. It also highlights areas in which health care professionals' performance could benefit from further education and training.

It is believed that pharmacy as a profession will benefit from audit in many respects, with the main advantages being to formalise and quantify current practice, and to convert the implicit standards of pharmacy practice into explicit standards (Alexander, 1993). Audit provides the impetus to create changes in practice and to improve standards consequently reducing the level of organisational and professional errors. Therefore audit is a powerful tool for change and for raising standards in the pharmacy profession.

Clinical governance is the Government's new vehicle for continuously improving the quality of patient care and developing the ability of the NHS in England to maintain high standards. It shares many of the features of successful quality management schemes.

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Professional self-regulation, which will include pharmacy, locally and nationally are key features of the system which aims to bring together the professional and organisational elements of quality management. Among many components of clinical governance outlined in : The new NHS, Modern, Dependable (DOH,1997), commitment to audit and its implementation by health care professionals has been recognised as a quality improvement process which is currently in place.

Since the early 1970s the continual quest for quality and cost effectiveness has been a recurrent theme in the NHS; whether it was the concept of quality assurance in the 1980s or professional audit in the 1990s or clinical governance in 2000. For the last decade in the United Kingdom the audit process, a component of quality assurance, has been used extensively in all fields of health care to improve the quality of care. It is a tool tried and tested and appropriate for the future assessment and promotion of quality. It was also the approach selected for this study when assessing the level and extent of oral counselling on dispensed medications in community pharmacies.

1.6. Review of the literature on pharmacists' provision of counselling on dispensed medications

One of the objectives of this study was to identify an aspect of practice, judged by pharmacists as a priority, for the audit process. The intention was to select a less explored service where the level of provision was not governed by an explicit standard. In stage two of this study pharmacists identified provision of oral counselling on dispensed medications as a priority which was consequently selected as the topic for this project. The following is a review of the literature regarding this aspect of pharmacy practice.

1.6.1. Provision of counselling on prescribed medications by pharmacists

The Royal Pharmaceutical Society launched the Pharmacy in the New Age initiative (PIANA) in response to continually evolving health services, new health care priorities and increasing population needs and demand. PIANA provided an opportunity for practising pharmacists to debate the future of pharmacy services and promote innovation in the light of changes in the provision of healthcare and consumer expectations (RPSGB, 1996a).

The areas in which pharmacists could make a major contribution to health care were identified by the Royal Pharmaceutical Society as: the management of prescribed medicines, the management of long term conditions, the management of common ailments, health promotion advice and provision of advice to other health care professionals. In all five areas counselling and advice giving were fundamental (RPSGB, 1997).

Counselling and advice giving were also the main areas identified by the Government in its vision of pharmacists' roles and their contribution to the New NHS (DOH, 2000). The Government sees pharmacists as supporting people in taking their medications correctly, tailoring advice to the needs of patients and providing extra help for those who require it.

The term "patient counselling" has been used by pharmacists for many years. Although the use of the term in pharmacy is quite consistent with a dictionary definition of "*advice or guidance on conduct or behaviour*" (Collins English Dictionary, 1979), it differs from the definition used by the professional counsellors (Raynor, 1996). In a publication by the British Association of Counselling (1979), the terms counselling is defined as:

“Giving the client the opportunity to explore, discover and clarify ways of living more resourcefully and toward greater well-being”.

In recent years within the pharmacy profession there has been a recognition that effective counselling and advice giving is not solely imparting the information in a predominantly didactic manner. It is an interactive process that involves as much listening as speaking to the patient. The Royal Pharmaceutical Society is currently promoting the concept of concordance as a framework within which there is partnership between patients and professionals in decisions about health care and drug therapy (RPSGB, 1997).

The ethos of concordance is also in line with the concept of “pharmaceutical care” which is increasingly promoted as an important part of modern pharmacy practice. Pharmaceutical care has been defined as a practice in which the practitioner takes responsibility for a patient’s drug related needs and holds him or herself accountable for meeting those needs (Hepler and Strand, 1990). To deliver pharmaceutical care, pharmacists are expected to assume more responsibility for the results of the drug treatment and this can only be achieved through effective communication with the patient as well as working closely with other health care professionals.

It is well known that many patients have a poor understanding of the terminology used to describe medications and that they may, consequently have a poor understanding of the detail of their medication regimen (Sarrif *et al*, 1992; Cleary *et al*, 1995). Community pharmacists are often the last health professional to see patients before they start taking their prescribed medications. Thus, the pharmacist’s role may be crucial in providing adequate information to ensure patients’ full understanding of their medication regimen. The counselling and advice provided by the pharmacist should complement and reinforce information provided by other members of the health care team and present the patient with a further opportunity to ask questions (Krska *et al*, 1995).

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Provision of oral counselling on prescription only medication (POM) is a well established aspect of practice which is expected by the public in community pharmacy settings (Williamson *et al*, 1992; Vallis *et al*, 1997; Hargie *et al*, 1992). Work commissioned by the Department of Health found that verbal instruction about prescribed medicines was found useful by consumers as it introduced a “consumer care” element in which people found personal contact of the pharmacist reassuring (Aston University and MEL Research, 1991). A national United Kingdom survey explored patients’ satisfaction with medicines information and found that over 70% of respondents wanted more information than they were given (Gibbs *et al*, 1990). This point was also highlighted in a study by Krska *et al* (1995) in which 81% of patients expected to receive advice, but the level of counselling provision was only 33%.

A study investigating satisfaction of patients with pharmacists’ consultations found that patients who received longer consultations and were provided with more types of information during their consultation were more satisfied with the service (Schommer, 1995). In a similar study it was reported that the level of provision of drug information resulted in a higher level of consumer satisfaction leading to an increase in consumer patronage and loyalty to the community pharmacy (Whitehead *et al*, 1999).

A survey conducted on behalf of the Royal Pharmaceutical Society found that 94% of the population visits community pharmacies to obtain pharmaceutical services including obtaining medicines on prescription, purchasing medicines with or without concomitant advice and obtaining advice without a purchase (BMRB International Ltd, 1996). Tully and Temple reported a slightly less, but similar usage of pharmacy services by the UK population (89%). Their results indicated that 83% of those who used pharmacy services had a prescription dispensed in the previous year, 45.9% of whom received advice on usage of their medication (Tulley and Temple, 1999).

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The pharmacist' consultation is not only thought to have a significant effect on drug information recall and increase patient's adherence (Woroniecki *et al*, 1982), but also to improve the outcome of the treatment (Rehder *et al*, 1980; Blenkinsopp *et al*, 2000). A study of post-operative pain illustrated that patients who received counselling on their patient controlled analgesia had better pain management and less incidence of side effects than those who received no counselling (Berwick *et al*, 1994). Lack of proper and clear information on drugs to the patient may result in therapeutic failures, economic waste and detrimental effects to the patient (Alkhawajah and Eferakeya, 1992; Malahy, 1966).

Counselling patients about their prescription medicines is recognised as an integral part of the dispensing process (RPSGB,1994) and its provision by pharmacists is recommended by the Royal Pharmaceutical Society of Great Britain and is included in the Standard of Good Professional Practice (RPSGB,1995). However, research has shown that patients are not routinely counselled when collecting their prescriptions (Hayes and Livingstone, 1990; Livingstone *et al*, 1993; Krska *et al*, 1995)

1.6.2. Provision of advice on dispensed medication: written or oral?

A national survey conducted in 1986 revealed an unsatisfactory level of patients' knowledge about prescribed medicines with 55% not knowing how, when or with what they should take their medications (Busson and Dunn,1986). The majority of respondents in the survey wanted written information about their medicines.

Gibbs *et al* (1989, 1990) investigated the benefits of Patient Information Leaflets distributed by pharmacists and reported that as well as improving their recall, patients receiving the leaflets were more satisfied with the information they received. This finding was in line with earlier work where Sharpe and Mikeal (1974) found that patients receiving written information on their medications had a higher rate of compliance.

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Following the publication of European Community directive 92/27/EEC, provision of written information for patients about medicines is strongly recommended by the Government and since 1994 original packs of new products must include a patient information leaflet. According to a pharmaceutical industry prediction it was anticipated that the transition of product packing to original packs would have been completed by 1998 (Association of the British Pharmaceutical Industry, 1995). Although not all, the majority of medicines are currently supplied in original packs enclosed with patient information leaflets. Before long all patients should receive a patient information leaflet with every prescribed medicine.

Several studies have raised serious concerns about patients' misunderstanding of written information (Holt *et al*, 1992; MacFarlane and Tonks, 1992). Clinite and Kabat (1976) found that patient information leaflets improved concordance only when accompanied by oral counselling and that medication errors increased when written information was provided on its own. When McBean and Blackburn (1982) investigated patients' compliance and the recall of medication instructions a few weeks after receipt of dispensed items, they found that the most effective method of providing information for patients was a combination of oral and written information.

In a study by Williamson *et al* (1992) it was found that 56% of the respondents who wanted more information when collecting of their medications, preferred to receive a combination of both written and oral information. It is by means of oral counselling that pharmacists customise manufacturers' written information and label instructions to the information needs of patients. Oral counselling provides the opportunity for pharmacists to address patients' anxieties and concerns and can increase patients' motivation to take their medications appropriately (Redher *et al*, 1980).

1.6.2.1. Variation in frequency of provision of oral counselling for dispensed medications

Researchers investigating the extent of oral counselling in patients who had received prescription medications uncovered significant variations in the content and level of counselling provided by pharmacists. McMahon *et al* (1987) reported a 68% rate of counselling when interviewing 154 patients immediately after collection of their prescriptions. Carroll and Gagnon (1983) interviewing people in their own homes found the level to be 50%. A level of 28% was reported by Morris (1982). A study by Kirking (1982) based on self reports of pharmacists found that counselling was provided for 42% of patients. Livingstone *et al* (1996) in a patient questionnaire study reported 56% of patients receiving oral counselling.

Observational studies have generally found lower levels of counselling, Berardo *et al* (1989) reported 20% rate of pharmacists' counselling and Krska *et al* (1995) study found 33% of patients were counselled. Not only is there variation in the extent of provision of oral counselling, the content of consultations also greatly differ.

1.6.2.2. Content of oral counselling provided for dispensed medications

Several studies have reported that information provided by community pharmacists' is almost entirely limited to aspects of the dosage regimen, notably dosage quantity and the frequency of administration (McMahon *et al*, 1987; Berardo *et al*, 1989; Livingstone *et al*, 1996). Other information regarding contraindications, maximum dosage, storage conditions and side effects were not often raised.

In a study conducted by Krska *et al* (1995), of 50% of patients who expected to receive information on the possible side effects of the medications, only 2% were provided with this information.

Concern is sometimes expressed by pharmacists that providing oral information on side effects may result in an increased frequency with which they are reported and anxious patients may discontinue their treatment in fear of potential side effects of their medications (Mottram *et al*, 1989). However, the provision of information on side effects meets a particular need already identified by patients themselves (Gibbs, 1989; Myers and Calvert, 1973; Myers and Calvert, 1978). Myers and Calvert (1984) investigated whether counselling patients on the beneficial effects or advising them on side effects would have a greater impact and found that there was no difference in rates of adherence between two groups.

Livingstone *et al* (1996) reported that 86% of the patients receiving information on the side effects of their medication found it useful and were then able to identify the potential side effects of their medications from a list provided by the researcher. Other workers have found that forewarning patients about possible side effect does not increase the frequency with which they are reported (Gibbs, 1989; McBean and Blackburn, 1982).

One of the factors influencing frequency and content of oral counselling by pharmacists is patients' characteristics with age being the main predictor of likelihood that counselling will take place.

1.6.2.3. Provision of oral counselling and the patient's variables

A Study by Morrow and Hargie found that when pharmacists considered groups of patients requiring counselling, elderly people and mothers/babies were highlighted as priorities (Morrow and Hargie, 1992). Parents of young children are recognised as core customers of pharmacies (BMRB, 1996) and more likely to present prescriptions for dispensing than other groups. They have also been found to received a high rate of counselling (63.4%) which reflects pharmacists' claim to prioritise mothers/babies in providing medication advice (Tully and Temple, 1999).

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Pharmacists have also claimed that they are more likely to advise elderly people (Morrow and Hargie, 1992), or those who have three or more items on their prescriptions (McGovern and McElnay, 1995).

Worldwide there is an increase in the number of elderly people. The World Health Report 1998 states that by the year 2025, the proportion of people over 65 will have risen from 6.6% to 10 % of the total population (World Health Organisation, 1998). Old age is associated with pharmacokinetic and pharmacodynamic changes which make the patient more vulnerable to drug related problems. Because of changes in the absorption, distribution and elimination of drugs and target organ responsiveness (Meyer and Reidenberg, 1992), a drug's risk:benefit ratio may be altered. Thus, doses of drugs may need to be more carefully titrated to ensure adverse outcomes are avoided.

In the UK, it has been reported that approximately one in ten hospital admissions of elderly patients was a result of an adverse drug reaction (Royal College of Physicians, 1997). In Canada, 9.6% of elderly admissions to an acute medical unit were shown to involve adverse drug reactions (ADRs) and in the United States 16.8% of elderly admissions to a community teaching hospital were attributed to ADRs (Grymonpre *et al*, 1988; Col *et al*, 1990).

Thus, elderly people have been identified as one group with particular needs for information about their medicines and pharmacists, in acceptance of this fact, claim to prioritise elderly for counselling provision (Morrow and Hargie, 1992). However, Livingstone in a study (1996) reported that only 12.5% of the elderly received oral counselling by community pharmacists and Ortiz *et al* (1989) found the value to be 15%.

Other researchers have found that clients over 60-65 years, in particular, prefer only to receive advice when they request it (Mottram *et al*, 1989), and those elderly people who do not want further information about their prescribed medication consider that they have obtained all they require (Livingstone, 1996). In a study by Williamson *et al* (1992)

elderly people were found to be least likely to request advice on dispensed medication from pharmacists (46% compared with 83% the other age groups). Despite the possible reluctance among elderly people to accept the pharmacist in this role, Roberts (1986) has shown that attitudes can be changed. All elderly patients who actually received a domiciliary visit and medication counselling from a pharmacist found it beneficial (Roberts, 1986).

1.7. Consumers' Expectations

There is an increasing acceptance of the patient as a consumer of, and partner in, health care. People feel that they have a right to know in order to make informed choices about treatments (Kitching, 1990). Current users of the NHS are perceived to be more informed and better educated than their predecessors and expect to have access to new technologies as they become available. They also have a higher expectation of the environment in which care is provided and of standards of personal service. Herzlinger (1997) states that what today's consumers want is convenience and mastery. People have become accustomed to the level of services provided by the private sectors and have come to expect more than public health services often provide.

In response to these changes the recent Government Paper entitled Pharmacy in the Future- implementing the NHS Plan (DOH, 2000b) envisages the role of pharmacists as educators and facilitators, focusing on individual patients' clinical needs and in particular supporting them to obtain maximum benefits from their treatment whilst experiencing the least adverse effects.

It is now pharmacists' responsibility to critically assess the level of counselling services they provide in order to prepare themselves for meeting the public's and Government's expectations. This study addressed the level of provision of oral counselling for prescribed medicines in community pharmacies, and in the search for improved quality of the service explored the introduction of professional audit.

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METHODOLOGY

2.1. Aim and objectives

The aim of this study was to develop and implement an audit cycle in relation a community pharmacy service, assess its impact on the service provision and examine its acceptability and feasibility in community settings. Specific objectives for this study were:

- to identify an aspect of practice judged by pharmacists as a priority for the audit process. The intention was to select a less explored service where the level of service provision was not defined by an explicit standard,
- to define the identified service and its components,
- to establish the current level of practice through observation,
- to achieve a consensus on a set of standards among practitioners,
- to implement the agreed standard and evaluate the impact,
- to assess feasibility and acceptability of the audit approach in a practice setting.

The study methods

The study design was based on various stages of an audit cycle which include: selecting the topic, observing the practice in order to establish the baseline, setting the standards, comparing the practice with the standards, implementing the necessary changes and evaluating the impact of the changes introduced. The final stage, stage six, was to allow the researcher to examine feasibility and acceptability of the audit process used in this study in community pharmacy settings (**Figure 2.1**). In this chapter, an overview of the methodological aspects of the study is presented, prior to detailed accounts of the methods used in each stage. A pictorial presentation of various stages of the study is illustrated on page 60, Figure 2.1.

Stage One: The first objective was addressed by using semi-structured interviews with a randomly selected sample of sixteen community pharmacists. From this, “Oral counselling of dispensed medications” was selected as the topic of the audit, as this service was

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recognised as an integral part of medication supply by community pharmacists, but lacking explicit standards regarding its acceptable levels.

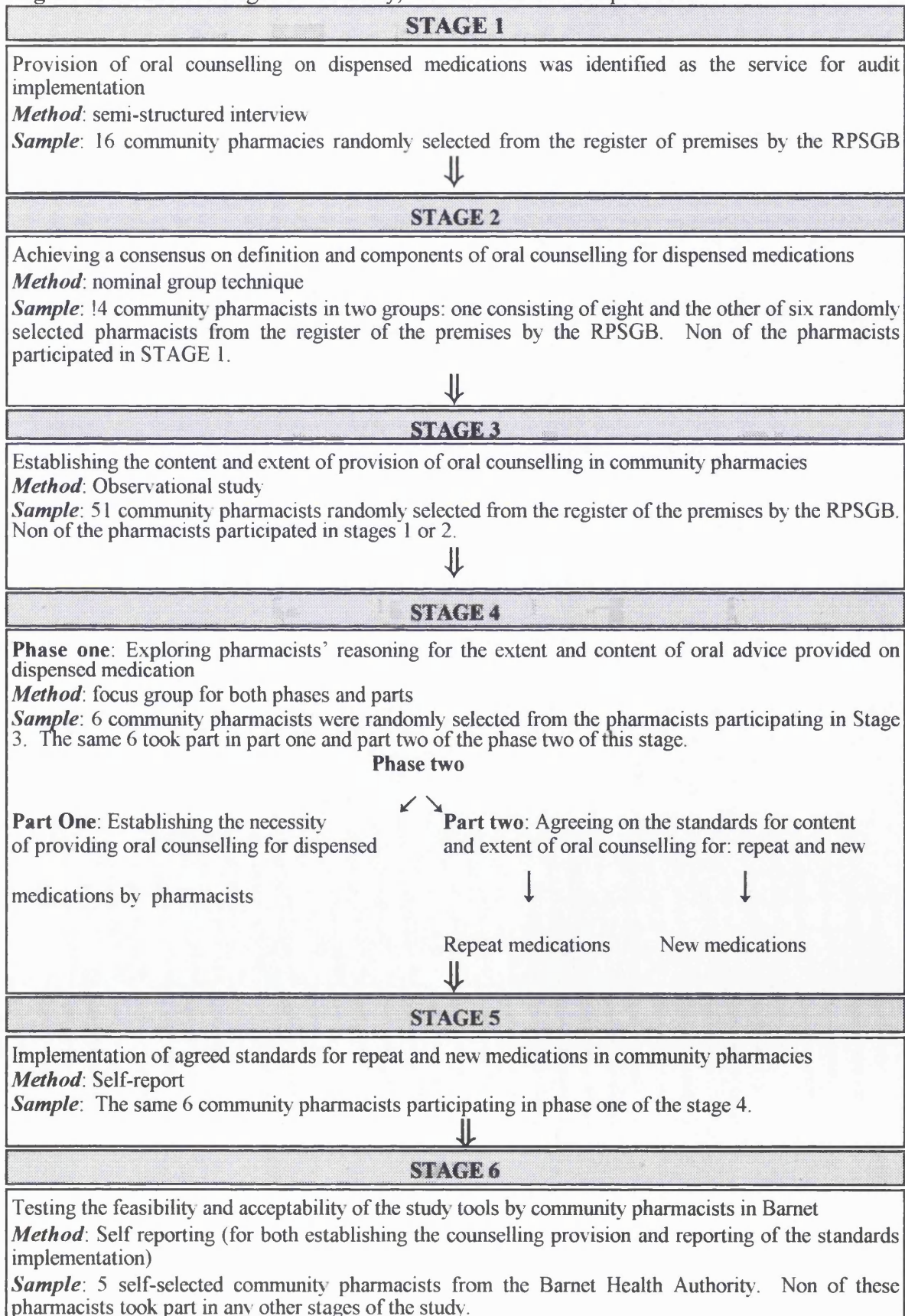
Stage Two: a literature search revealed that there was no definition of oral counselling and its components that was universally accepted in the pharmacy domain. Nominal group technique was applied in two groups of randomly selected community pharmacists in order to define oral counselling and identify its components.

Stage Three: based on the results of the Nominal Group meetings, non participant observational method was employed to collect data on structure and process aspects of patient counselling in fifty-one randomly selected community pharmacies in the Greater London area. A data collection form was developed and piloted. A validation procedure was devised and implemented to determine the extent to which the participants' behaviour was influenced by the observer's presence. This involved recruitment of an experienced member of staff in twenty-five pharmacies who discreetly collected data on the counselling behaviour of pharmacists.

Stage Four: a focus group technique with a group of community pharmacists was employed to achieve a set of acceptable and workable standards regarding oral advice with prescription medicines. To ensure that the group set the standards within the context of current practice whilst considering findings of other studies in the field, a literature search was conducted and findings were presented to the group.

Stage Five: pharmacists incorporated the standards into their practice and self reported the new level of oral counselling using a data collection form devised for this purpose. When the data collected before and after the standards implementation was compared, it became evident that pharmacists introduced some changes in the provision of oral counselling for dispensed medications as the result of audit process. Finally, pharmacists were interviewed by telephone in order to evaluate the feasibility and acceptability of data collection procedures and the tools.

Figure 2. 1 Different stages of the study, the methods and samples used.



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Stage Six: A group of community pharmacists from Barnet Health Authority were recruited to examine the feasibility, reliability and acceptability of the audit process developed during this study and to assess whether it could be used as a tool by community pharmacies to improve the provision of oral counselling on dispensed medications. The data collection tool which was devised during the study, was also tested for its ability to capture the content of oral counselling of dispensed medications.

2.2. Limitations of the study

The intensive procedures of qualitative research necessitate small samples. Despite employing random sampling in the first five stages of study, the small sampling fraction, and the possibility of sampling bias, limit the generalizability of the findings to wider populations of community pharmacists. This is, therefore, an exploratory study to provide insights into community pharmacists' advisory role and to examine the impact of the audit implementation on the provision of this service with dispensed medications. The study also attempted to determine any associations between pharmacists' provision of oral counselling and characteristics of the patient on the medicines dispensed, the results of which would generate hypotheses for future research.

The probable sources of sampling bias common to all stages of this study including the sampling frame and the process of following up non respondents are discussed next.

2.2.1. Sampling frame

The community pharmacists were selected from the register of premises maintained by the Royal Pharmaceutical Society of Great Britain (RPSGB) which provided a complete list of all registered pharmacies by postal district. However, the method had a number of limitations resulting in sampling bias. The Royal Pharmaceutical Society Register of Premises (1991) lists pharmacies and not pharmacists. Thus, it does not take into account the fact that more than one pharmacist may be working in a premises. This results in selection bias towards the single handed pharmacists as pharmacists engaged in pharmacies with more than one pharmacist had a smaller chance of being selected in the study sample.

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The Royal Pharmaceutical Society Register of Premises is updated annually and changes occurring during the year are not reflected on the list. Currently in the UK there is no comprehensive list of registered community pharmacists that can be used as a sampling frame for studies. Such a register could be particularly useful in studies where attitudes and opinions of individual pharmacists are sought.

The sample frame only covered pharmacies in the Greater London area. Although there is a reasonable representation of different types of pharmacy in London and the issues raised with participants were on the national agenda, care should be taken when generalising any of the study findings to all community pharmacists.

2.2.2 Non Respondents

The information obtained on non respondent pharmacists indicated that the participant and non participant groups were similar in many respects. Apart from a few instances when pharmacists volunteered their reason for non participation as a lack of interest, it was not possible to gather information about their attitudes towards audit or the current level of provision of oral counselling services. Therefore, it was not possible to establish whether attitudes about audit and/or provision of counselling affected their decision to take part. This could have introduced a response bias in the study.

2.3. Stage One: To identify an aspect of practice as a priority for audit process

At the time of this study, professional audit was a novel concept in community pharmacy. In order to plan the study, the level of understanding and knowledge of audit was investigated and a preliminary exploration of how this concept was perceived by pharmacists was undertaken.

Prior to consultation with a randomly selected group of community pharmacists, opportunistic face to face interviews were conducted with a few community pharmacists. Three Local Branch Meetings of the Royal Pharmaceutical Society held at different locations in Greater London areas were attended by the researcher based on the assumption that the participant pharmacists were self selecting and may be more likely to be

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knowledgeable of new concepts and policies within the profession. Therefore if the findings indicated that there was little or no understanding of professional audit amongst these groups, then it would have been reasonable to expect similar if not lower level of knowledge among a wider population of community pharmacists.

These “conversation like” interviews took place with six pharmacists during these meetings. The researcher introduced herself as a community pharmacist with an interest in practice research. Otherwise the purpose of these interviews were not disclosed to interviewees with the justification that the data were treated anonymously. A record of these “conversations” was made immediately after the meetings.

Pharmacists expressed both pessimistic and optimistic views regarding the future of the profession. When they were asked about professional audit there was an uncertainty about what the term implied and a general unfamiliarity of the concept although one pharmacist stated that:

“ Yes audit is the new phrase nowadays. But is it new? We pharmacists are always reviewing what we do. Every time I advise a patient on their medication and they look puzzled I review my counselling points, how can I make it clearer? How can I improve it?”

These preliminary interviews indicated that professional audit was largely an unknown concept for practising community pharmacists. Since the objective of stage one was to ask a randomly selected group of pharmacists to prioritise a pharmaceutical service for audit then it was essential they understood what audit meant. To examine pharmacists’ level of knowledge as well as ensuring that they all had a basic understanding of audit and its processes, a method had to be selected that allowed flexibility of approach. It had to be a method that not only was able to capture pharmacists’ overall views on audit but also gave an opportunity to explore their ideas in a greater detail over series of specific topics including the potential problems and benefits of an audit process.

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These requirements eliminated self completion questionnaires as this method denied the researcher the opportunity of clarifying any ambiguous responses or further exploration of interviewees' thoughts and responses. A qualitative interview on the other hand possessed the required flexibility and was selected for this stage of study. As this study was an early exploration of audit in community pharmacy settings, a semi structured interview schedule would have required presumptions regarding the relevant questions and the range of responses. On the other hand semi-structured interview containing open questions allowed the researcher to set up a framework of questions to gather pharmacists' view and opinions whilst also providing the opportunity of clarifying any ambiguous statement and exploring the participants' responses further.

A face to face semi structured interview was conducted to identify a specific pharmaceutical service deemed a priority for implementation of audit procedures by community pharmacists.

2.3.1 Sample Selection

To choose the interviewees the Royal Pharmaceutical Society Register of Premises (1991) was used. Employing stratified sampling six premises from each geographical direction were chosen. The community pharmacists who were unable or refused to participate in the interview were replaced by another pharmacist, randomly selected from the list.

Basic information was gathered from the non responders during the initial or follow up telephone calls in an attempt to identify any major differences between this group and the participants. The study limitations associated with the sampling frame used and the procedure adopted for follow up of non respondents have been discussed above.

2.3.2 Development of the interview guide

The interview guide consisted of open-ended questions based on audit as a concept and a process. The interview guide was then piloted in a convenience sample of six community pharmacists which resulted in minor modifications.

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The interview's preamble provided information about the interviewer, the aim of the study, the selection of interviewees and an overview of the content of the interview schedule. It also reiterated confidentiality and anonymous analysis of the obtained data. The preamble was followed by nine questions (See Appendix 1.2) to explore the following areas:

- pharmacists' knowledge and experience of professional audit
- implications of audit implementation by pharmacy profession and individual pharmacist
- implications of audit implementation for staff, clients and other health care professionals
- pharmacists' knowledge of the Royal Pharmaceutical Society's audit initiative
- potential problems and benefits of audit
- pharmaceutical services that could improve by implementation of the audit process
- views on introduction of audit as mandatory part for the payment of a professional allowance

2.3.3 Method

Initially a letter was sent to randomly selected pharmacists inviting them to participate in the study (see Appendix 1.1). This was followed by a telephone call to arrange an interview and provide further information if required.

An interview is a conversation between interviewer and the respondent with the purpose of eliciting certain information from the respondent. It is recognised that the outcome may be influenced by the interaction of interviewer and respondent. To minimize this effect the interviewer avoided stating her own ideas, asked probing questions in an impartial way and appeared to have a permissive attitude so that the respondent felt free to express any view, and generally conducted the interview in a way that was least likely to influence the respondent's answers. Any answer to questions proposed to the researcher by pharmacists was referred to the end of interview to eliminate the possibility of biasing their replies.

All interviews were carried out in pharmacies during a "quiet" time as identified by the pharmacists. To reduce the distraction they were requested to interrupt the interview as and when necessary in order to pursue their professional tasks.

After seeking participants' agreement, all interviews were tape recorded except in two cases in which pharmacists requested that the interviews were manually transcribed.

2.3.4 Reliability and validity

The following are accounts of the measures taken to ensure reliability (where appropriate) and validity of the data collection.

Reliability

The reliability of a survey instrument relates to the extent to which findings are repeatable, reproducible or internally consistent. In qualitative studies, unlike quantitative research reproducibility of findings is not often an essential issue as the data are intended to be context specific (Smith, 1998). In exploring pharmacists' attitudes to professional audit, in this stage of study the difference of opinions among individuals were explored in the context of their views, experience and characteristics such as employment status as well as their practice settings. The aim was to understand the underlying reasons for variation of pharmacists' responses rather than finding consistent views and perceptions of professional audit.

As the researcher (ZA) was the only person involved in the data collection, problems of variation between investigators did not arise.

Validity

The validity of data refers to the extent to which it is an accurate reflection of the phenomena that are the subject of the research. At the time of this research, audit was a novel subject in the pharmacy profession and there were only a few published works on the attitudes of community pharmacists on the subject. In addition, pharmacists' attitudes to barriers and facilitators of the audit process found in this study were compared with similar studies conducted in medical and nursing professions.

2.3.5 Analysis of data

The data were transcribed verbatim from the tape recording. The qualitative data were then

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annotated with descriptive labels and a holistic approach was taken to data categorization (Jones, 1985). In an holistic approach the aim is to identify basic themes or issues in the data by absorbing them as a whole rather than analyzing them line by line (Glaser and Strauss, 1967). Broad categories and their interconnections were then distilled from a general overview of the data before a more detailed analysis resulted in the emergence of subcategories. Some of these results were then reported quantitatively as frequencies or as a proportion of all responses.

Analysis of the results indicated that oral counselling for dispensed medication was identified as a priority by pharmacists. Based on an audit model, having identified a topic the process should have moved on to the next stage to set standards. However, at the time of the study there were only a few small scale studies conducted in this area in the UK, the results of which were not sufficiently informative for the process of setting standards or establishing the level of practice. Therefore it became apparent that establishing current level of oral counselling for dispensed medication in community pharmacies was an essential step without which the study would not have been able to achieve its objectives successfully.

Having a clear definition of oral counselling and its components was a pre-requisite for conducting an objective and meaningful assessment of the service level. A search of professional guidelines and literature was pursued to seek this definition. The Standards for Good Professional Practice (RPSGB, 1995) defines counselling as “ *The discussion of medicines and treatment and the giving of advice in a professional context.*”, it also advised pharmacists that: “*Verbal communication should be used to reinforce and supplement written information, including reference to the medicine label*”. However, these statements were too vague and non specific regarding the key pieces of information on which counselling should be focused. The literature on the other hand revealed that there was no consensus on the definition of counselling, the context and components of which varied in different studies.

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Therefore it was decided to obtain a consensus on the definition and components of oral counselling in order to enable the researcher to determine relevant measures for this service and to devise a data collection tool capable of gathering quantifiable information to allow comparison of practice amongst pharmacists.

2.4. Stage Two: to achieve a consensus on the definition of oral counselling and its components

The number of definitions cited for counselling in community pharmacy settings is probably matched by the number of publications on the subject (Berardo *et al*, 1989; Hargie and Morrow, 1990; Wiederholt *et al*, 1992) . “Provision of oral advice on medications and/or any related health issues” was the definition of oral counselling on dispensed medication adopted throughout this study. Although the definition is descriptive of the general concept of oral counselling, it deliberately lacked specification on its components. As one of the objectives of the study was to establish the current level of counselling in community pharmacies, it became apparent that the constituents of counselling have to be identified in order to enable any meaningful measurement to be made.

With the study being focused on audit and its emphasis on ownership of concepts and standards, a consensus method deemed appropriate.

2.4.1 Method

The focus of consensus methods lies where unanimity of opinion does not exist owing to lack of scientific evidence or where there is contradictory evidence on the issue (Jones and Hunter, 1995). The methods attempt to measure the extent of existing agreement and to develop consensus by resolving disagreement.

A literature review of the methods applied for developing consensus revealed the following approaches: the Delphi technique, nominal group technique and consensus development conference (Van de Ven and Delbecq, 1972; Cantrill *et al*, 1996). The last method was disregarded as the resources required for its implementation were beyond the disposal of this

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research. The other two methods were compared on their theoretical merits, their applicability and from practical standpoints.

Delphi and nominal group technique (NGT) are similar in many aspects (Delbecq and Van de Ven, 1975). They both rely on the independent generation of ideas by participants. In NGT participants write their ideas on a sheet of paper in silence although in presence of the group members who are seated around a table. In Delphi technique, isolated and typically anonymous respondents independently write their ideas or express their opinions in a questionnaire.

Pooling of individual judgements is the second stage in both processes. In NGT the ideas of the members are presented to the group and listed on a flip chart. In Delphi technique participants mail their completed questionnaire to the monitoring team where the ideas and opinions are collated and fed back to them.

The next stage is an idea-evaluation stage. In NGT the participants discuss, debate, elaborate and clarify each idea listed on the flip chart. In Delphi technique each respondent independently reads, evaluates and interprets the ideas on the feedback report sent by monitoring team. In both techniques finally mathematical voting procedures are utilized to achieve a consensus by aggregating individual ideas and opinions (Gallagher *et al*, 1993).

In a qualitative comparison of these two methods many common strengths become apparent (Delbecq *et al*, 1975). Through having a structured approach to achieving the study objective, the normative pressure for conformity is minimized or eliminated. The structured procedures deny or limit vocal and expressive members from polarising or dominating the discussion, maximising equality of participation. The group members are focused on the task at hand, generating specific ideas.

In choosing an appropriate consensus method the practical issues including length of time and the amount of administrative cost and effort required should also be considered. In a comparative study conducted by Van de Ven (1974) it was illustrated that the Delphi

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process required almost twice as much administrative time and cost as did the NGT when involving a comparable number of participants. In terms of calendar time, to collect the same information the Delphi technique required significantly longer time than NGT.

Reasons for selecting NGT included:

- In terms of having a feeling of accomplishment by the participants when a consensus achieved at the end of the meeting, NGT is demonstrated to be superior to Delphi (Van de Ven, 1974)
- In NGT, the participants have the opportunity of discussing, elaborating and clarifying the issues and points raised
- NGT group members confront disagreement openly and more frequently and depersonalize the problem
- In comparing NGT and Delphi, the former requires less administrative cost and effort and data collection is less time consuming
- The physical proximity of participants in this study would not prohibit them from attending meeting.

2.4.2 Sample selection

How well a sample represents a population depends on the sampling frame, the sample size, and the specific design of selection procedures (Floyd and Fowler, 1988)

The Royal Pharmaceutical Society of Great Britain (RPSGB, 1991) register of pharmacy premises in London areas was used as the sampling frame. The sample was chosen using the table of random numbers. The sample size was restricted by the choice of method. The recommended sample size ranges from 5 to 12 participants with eight being indicated as an optimal number (Van de Ven and Delbeq, 1972; Jones, 1995). To test the reliability of the findings two consecutive meetings were arranged and eight pharmacists were invited to attend each meeting. Despite confirmation of their attendance the day before, two of the pharmacists did not turn up on the day for the second nominal group meeting reducing the group size to six.

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To increase the probability of recruiting sufficient numbers of pharmacists during the first call the number of pharmacists approached was three times the number needed to attend. A stratified random sampling was used to recruit two independent groups of pharmacists to attend the meetings, to ensure even geographical representation. From community pharmacies in London, two pharmacies were randomly selected from north, south, west and east postal codes for each nominal group.

2.4.3 Recruitment of community pharmacists

A map and a letter of invitation were sent to the selected pharmacies. The letter introduced the researcher, explained the purpose of the study and emphasized the importance of community pharmacists participation in achieving an acceptable and workable standard for practice (Appendix 2.1). The letter also assured pharmacists of confidentiality and anonymity of the study and explained that pharmacists would receive a phone call from the researcher in few days time. A nominal fee was offered to cover the participants' travelling expenses.

The purpose of the telephone calls was to encourage pharmacists to attend the meeting and answer any queries they might have in relation to the study. In a few cases where the letter had not been received or had been misplaced a duplicate of the letter was forwarded. The pharmacists were contacted one week prior to the meeting in the early hours of the afternoon when pharmacies are generally quieter. During telephone calls the contents of the letter were discussed in more detail and pharmacists given an opportunity to ask questions. A further phone call was made on the day of the meeting to remind attendees.

2.4.4 Conducting the Nominal Group meetings

Among the preparatory tasks of nominal group meetings the tasks that can influence the outcome the most are constructing the statement question and the opening statement.

Constructing the question

Constructing the question on which participants generate their ideas is the most crucial aspect of data collection (Van de Ven and Delbecq, 1972). Many studies have demonstrated

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that a slight change in wording of the question may result in a substantial change in the character of the generated data (Speak, 1967; Gallagher *et al*, 1993).

Delbecq and Van de Ven (1975) stated that:

"NGT is like a microscope. Properly focused by means of a good question, NGT can provide a great deal of conceptual detail about the matter concerning you. Improperly focused by a poor or misleading question, it tells you a great deal about something in which you are not interested."

The aim of NGT was to achieve a consensus on the concept of counselling as perceived by community pharmacists through defining its components. To elicit a comprehensive list of counselling issues, four questions were constructed and piloted on a convenience sample of five pharmacists. The following question was selected on the criteria of clarity, ease of understanding, (as stated by the pharmacists), and as it elicited an extensive response:

"What are the issues that counselling on dispensed medications should cover?"

Two further questions were also chosen as supplements to be included in the task statement to broaden pharmacists' responses about provision of oral counselling on dispensed medications:

"For what aspects should we have a standard?"

"On what characteristics and activities should the audit be based?"

(structure and process)

The opening statement

When individuals come together to engage in group tasks, perceptions of why the group was formed will affect performance (Delbecq and Van de Ven, 1975). The opening statement provided the participants with a general background to the project and the results of the stage one face- to- face interview with pharmacists. The importance of the group task was

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emphasized by highlighting the necessity of obtaining a consensus on a definition of counselling prior to any meaningful measurement. All the group members were urged to contribute in order to improve the outcome of the meeting. It was explained that the resultant list of issues was to devise a data collection instrument to establish the baseline for oral counselling by community pharmacists as a part of the audit process. The ultimate goal of the study was expressed as setting standards for oral counselling on dispensed medications that are acceptable and workable in community pharmacy settings.

The meeting

The meeting was conducted according to the nominal group technique.

1. Introduction

The Nominal Group Meeting (NGM) commenced by a welcoming statement. This was followed by background information about the role of community pharmacists', concepts of professional audit and Donabedian's approaches to assessing quality of care. The researcher (ZA) then described how the oral counselling on dispensed medicines was chosen as the service to be audited.

At the end of the introductory statement sequential stages of the nominal group meeting were briefly described for the participants. Delbecq *et al* (1975) summarise the NGT process as follows:

1. The introductory statement.
2. Silent generation of ideas in writing.
3. Listing of ideas on the flip chart.
4. Serial discussion of ideas listed on the flip chart.
5. Break.
6. Selection of the important issues and ranking each priority issues on a given scale/preliminary vote
7. Discussion of the preliminary vote
8. Final vote

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Then the question constructed for the meeting in combination with the two supplementary questions were presented to participants.

2. Silent generation of ideas in writing

The participants were supplied with paper and pen and were given 10 minutes to write their answer to the proposed question independently.

3. Listing of ideas on the flip chart

After participants listed their thoughts independently in writing, they were requested to share their ideas in turn and one at the time with the group. The organiser listed all the issues on a flip chart. The participants were eager to discuss the individual items at this stage; however they were discouraged from doing so until all ideas were collected. All the group members actively contributed to the list of issues and they were encouraged to add new ideas to their lists even at this stage of the meeting. No issues were amalgamated or altered without the consent of the participant concerned.

4. Serial discussion of ideas on flips chart

Discussion followed in which the issues were clarified or elaborated rather than being debated or disputed.

5. Break

The group then had 10 minutes break.

6. Selection of the most important issues and ranking each priority issue on a given scale.

Pack of nine cards was distributed to each participant and they were asked to select the nine most important issues from the list. Each issue was written on a single card with its corresponding number placed in top left-hand corner. The participants were then requested to rank the issues on a scale of nine to one, with nine representing the most important item. It has been shown that individuals are able to rank about seven (± 2) items with some reliability of judgment (Jones and Hunter, 1995). The ranking numbers were placed at the bottom right-hand corner and were underlined three times to distinguish them from the

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number of the issue. After participants finished ranking, their cards were collected, the vote was tallied and the results were recorded on the flip chart.

7. Discussion

The purpose of this discussion was also to examine any inconsistent voting patterns and providing an opportunity to re-discuss issues which were perceived to have received too many or too few votes. Prior to starting the discussion the researcher explained that the aim was clarification and not pressure toward an artificial consensus and cautioned group members to think carefully about any changes they made in their voting. The discussion was kept brief as not to distort participants' judgement by focusing too much attention on the items discussed against the total array of items.

8. Final Vote

Another set of cards was distributed to each group member and the same ranking procedure as outlined above was followed. To record the results the researcher read out each issue number asking each participant to call out the rank they had allocated for that particular item. Using a different colour marker, the ranks were recorded next to each issue on the original list on the flip chart. Then the cards were collected to ensure the correctness of the recording. At the end the meeting, the group was invited to comment on any of the issues. However in both meetings the participants expressed their satisfaction with the results reporting that there was no need for further clarification. The organisers thanked the group members for their participation and the meeting was concluded.

2.4.5 Analysis of the results

Nominal Group Technique generates data that can be analysed either quantitatively or qualitatively. As the originated ideas are ranked by the group, results can be presented quantitatively and may be analysed mathematically (Gallagher *et al*, 1993). However, the data generated by nominal group technique does not automatically become useful in developing data collection tools. The intermediate task is to perform a content analysis of the generated issues which enables themes to be constructed out of individual items (Van de Ven and Delbecq, 1972). This allows the results to be analysed qualitatively by grouping

similar themes and creating categories.

I. *Creating categories*

Grouping data involves developing a set of criteria in terms of which to distinguish observations as similar or related. Categories must be grounded conceptually and empirically. That means they must relate to an appropriate analytical context, and be rooted in relevant empirical material (Day, 1993). Considering that one of the objective of stage two of this study was to identify components of oral counselling on dispensed medications, the empirical aspect of content analysis of individual items was to create a category containing counselling components. This was to inform the next stage of the study by defining areas for data collection.

After analysing the items two main categories emerged: the first one comprised issues addressing the ethos of oral counselling and factors influencing its quality in general terms such as establishing a two way communication with patients. This category was labelled the Concept and was subdivided into: Criteria, Effective communication and Patient education.

The second category, Components, included all the generated issues covering specific points or information relating to the counselling process itself. It was then divided into the following twelve subgroups: dosage, side effects, contra-indication, interaction, food & drink, demonstration of appliances, expiry date, brand and generic name and changes in instruction of repeat items.

A data collection tool was then devised incorporating all the issues in the Component category which was used to compile data on the level of oral counselling on dispensed medications in community pharmacy settings in stage three.

II. *Quantitative analysis*

To compare and combine the ideas generated by the two groups the final ranking of each issue needed to be standardized. In both groups pharmacists ranked the items in descending order of importance with nine representing the most important issue. As there were eight

participants in the first meeting and six in the second one, the maximum score which could have been allocated to an item was 72 in the first meeting and 54 in the second one. Therefore to standardize the findings, final score for each item in the first meeting was multiplied by 54/72. The resulting weighted scores illustrated the relative importance given to each issue by participants allowing a direct comparison between different items and categories.

2.4.6 Reliability and validity

The reliability of a survey instrument relates to the extent by which findings are repeatable and reproducible. The validity on the other hand refers to the extent to which the result is an accurate reflection of the phenomena that are the subject of the research. Reliability of this stage was assessed by measuring the level of agreement in decisions reached by two similarly constituted but independent groups of community pharmacists. To test the validity, the list of generated items which were identified as counselling components and their allocated ranking were compared with the findings of other studies, were found to be comparable.

2.4 Stage three: to establish the current level of practice through observation

To estimate the extent of patient counselling various methods have been employed amongst which self-completion questionnaires, diaries and direct observation are the most commonly used. Methods have been compared and researchers have found that self-completion questionnaires by pharmacists tend to overestimate the counselling frequency (Ortiz *et al*, 1989; Laurier and Poston, 1992). Diaries kept by pharmacists tend to underestimate the patient counselling activities due to pharmacists' lack of time to complete them (Ortiz *et al*, 1989). Comparing methods used in the assessment of patient counselling in Australian community pharmacies, Ortiz *et al* (1989) found that data collected by diaries under-reported, whereas self-completion questionnaires over-reported, counselling events. He concluded that direct observation was the most reliable survey method especially with respect to the accuracy and consistency of recording counselling events. Krska *et al* (1995) also found that pharmacists overestimated their frequency of oral counselling on dispensed medications by almost twice the level observed.

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When the research question concerns what actually happens in health care settings, rather than participants' perceptions and views, a more objective method of data collection such as direct observation is appropriate (Fitzpatrick and Boulton, 1994). This method involves data collection by participant or non-participant observers. Participant observation (sometimes covert) is where the observer either participates in the daily life of the organisation over an extended period of time to gain insight into the establishment (Goffman, 1961) or the observer poses under the guise of a service user to get first hand experience and information (Hayes and Livingstone, 1990). Covert observation has become less common as a research method, partly because of questions about the ethics of covert procedures. As data collection for this stage of the study was expected to take place in fifty pharmacies over a three hour period in each, non-participant observation was deemed most appropriate.

In non-participant observation the researcher remains as an accepted outsider, watching and recording the interactions as an independent researcher. This method was clearly the method of choice, allowing detailed information to be compiled on oral counselling of dispensed medications causing minimal disturbance to the pharmacist's normal work pattern.

The main advantage of direct observation as a method of data collection is in allowing the observer to "see for themselves" thus avoiding the biases inherent in participants' reports, such as selective perception, poor recall and the desire to present themselves well. It may also uncover behaviors or routines of which participants themselves are unaware.

The issue of reactivity of the subject, or extent by which the behaviour observed is altered by the presence of an observer has been extensively studied (Haynes 1978; Haynes and Horn, 1982). This altered behaviour or so called Hawthorne effect (Roethlisberger and Dickson, 1939) could pose as a potentially serious methodological problem in observational research. Therefore with all observational studies it is important to establish the extent to which observed behavior is influenced by the observer's presence. For this reason it is paramount that data obtained by observation is validated. Validation was addressed in this study; an account will be presented in section 2.5.4.

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Non-participant observation method entails close observation and recording of actions and behaviors of observed and in doing so it relies heavily on the researcher to act as the research instrument to document all the events (Mays and Pope, 1995). It is important that observations are systematically recorded and analysed. To achieve this a data collection form based on the list of counselling components, as defined by pharmacists in the Nominal Group meetings, was devised.

Determination of sample size

In determining the sample size for a study, whilst time and cost constraints should be borne in mind, the size of the sample should be large enough to be able to detect any existing differences. To achieve the objectives of the study a sample size of fifty community pharmacists was deemed appropriate and feasible. To increase generalisability of the findings the sample was randomly selected.

2.5.1 Sample Selection

Fifty community pharmacies were selected randomly from the Royal Pharmaceutical Society Register of Premises (1991) in the London Postal Districts. The sample was stratified according to the postal codes to ensure representations from all locations. A letter was sent to each pharmacy explaining the purpose of the study and inviting them to participate (Appendix 2.1). The pharmacists were contacted by telephone within two days of receiving the letter to discuss any queries and to arrange an appointment. Sixty-one pharmacists were approached in order to achieve a sample of fifty. During the course of observations one of the pharmacists who was originally contacted and had not replied, contacted the researcher with the request to be included in the study. His request was accepted and consequently the sample size became fifty-one. Hence the overall rate of response was 82%.

2.5.2 Data collection

The data were collected on two separate forms. The first one included data on the structural aspects of services including personal information about pharmacists and characteristics of the pharmacies e.g. availability of PMRs, number and composition of staff (Appendix 3.1).

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The second form focused on the process aspects of advice giving which was recorded during all pharmacist-patient interactions at the point of prescription collection. The data comprised of two sections, prescription information (patient's age, NHS or private prescription, paid or exempt, details of medication and formulation etc.) and details of the counselling content e.g. the dose, maximum daily dose, purpose, dose in relation to food and activities, storage, ADRs, changes in regimen, counter interaction and demonstration where applicable. These data collection forms were then piloted in five pharmacies and assessed for feasibility, comprehensiveness and acceptability. They were used to collect data on pharmacist-patient interactions in each pharmacy for a three hour period.

To investigate the extent of counselling offered for chronic and acute medications an attempt was made to ascertain whether or not each dispensed item was a repeat prescription. This data are based on the content of the pharmacist-patient interactions. If the subject of whether the prescription was repeated or was for the first time was raised during the interaction, then this information was recorded, otherwise it was marked as missing.

In order to reflect the variation of workload in a community pharmacy, the visiting times were arranged at different times of the day and different days of the week. The collected data to some extent also reflected the seasonal variation as it took almost six months to complete the visits. Each pharmacy was visited once and data were collected over a three hour period.

2.5.3 Minimizing the effect of the observer's presence in the pharmacy

As with all observational studies an important question was the extent to which the observed behaviour was influenced by the observer's presence. If an observational procedure is highly reactive, the results may not reflect what happens in normal practice, and validity is threatened. Observation procedures which alter the natural environment, intrusive observers, and the amount of observer-subject interaction are all factors conducive to reactivity (Haynes, 1978). Therefore the researcher tried to be as inconspicuous and unobtrusive as possible whilst collecting data. Ortiz *et al* (1989) reported an increase in the rate of oral advice on dispensed medication when an observer was present in the dispensary.

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To avoid affecting the rate of counselling and minimising observer- subject interaction the researcher ensured that she was not based in the dispensary area in any of the pharmacies. However, to gather the relevant information reliably the observer had to be situated where she could see and hear the interactions which meant that she was usually located behind the medical counter, next to the cash register and away from the dispensary entrance to avoid hindering staff movements. This close proximity to the medical counter enabled her to record the interactions during the prescription handling as well as provision of prescription information.

Other steps were also taken by the researcher to minimize the Hawthorne effect including spending an average of thirty minutes to establish rapport with the pharmacist and the staff prior to data collection. This time was allocated to the task of familiarization with members of staff and layout of the shop as well as providing time for participants to become accustomed to having the researcher around. The second tactic was to emphasize that data would be collected on a variety of topics including structure and process variables, over which they could not have any influence. This was to discourage them from altering their routine practice in any way. And lastly the importance of obtaining a true picture was explained to the participants requested them to perform their jobs and duties as usual.

2.5.4 Reliability and Validity

Reliability

In this stage of the study there were two research instruments: the data collection form and the investigator. The data collection form was tested in five community pharmacies first. It was then retested by a colleague researcher in the same pharmacies. The data collection form was found to produce a reliable record of the relevant information.

Studies in which several observers record activities, differences in the way they interpret and report events can lead to bias (Baker, 1980). In this study there was only one observer who conducted all the observational studies.

Validity

The validity of data refers to the extent to which it is an accurate reflection of the phenomena that are the subject of the research. Despite many researchers using observation methods to study pharmacists' advice-giving activities, very few attempted to validate their results and assess the degree of the Hawthorne effect on their findings. Validation has usually been undertaken by triangulation, ie. using different data collection methods. The term triangulation is used where the degree of convergence between sources of information obtained by different methods on a particular topic is compared (Fitzpatrick and Boulton, 1994). However, other data collection methods used in studying pharmacists' advice-giving including: log books, diary cards and questionnaires have the disadvantage of being dependent on the pharmacist's willingness or ability to report the data and are subjective.

Covert observation could not be used to validate the results as data had to be collected over two to three hours and had to be quite detailed. In addition in the past when covert research was conducted to assess pharmacists' performance in advising patients (Goodburn *et al*, 1991) it attracted criticism from pharmacists as an unacceptable approach (Anonymous, 1991).

Hence a validation procedure was devised in which individual pharmacists' permission was sought before data were collected covertly. This involved recruiting an experienced member of staff in the pharmacy who would covertly collect structured information on the counselling behaviour of the pharmacist (Appendix 3.4).

The issue of further participation in validation stage was discussed with 25 participant pharmacists who had appropriate numbers of staff and layout of premises. All of those approached agreed to take part. An experienced member of staff working on the medical counter was recruited during the observational study and the validation procedure discussed with them. He/she was provided with data collection forms and written instruction on their completion. The validation form comprised three columns: number of prescription forms, who handed the prescription out and whether there was any counselling offered to the

patient. For the purpose of validation counselling was defined as :

“an attempt to provide any information related to the medication dispensed.”

This definition corresponded to the definition of pharmacist-patient interactions which was recorded as a variable in the main study. It should be noted that as the intention was for pharmacy staff to collect the data covertly and in the least intrusive manner they were requested to log the number of prescription forms and not the number of medication items on the forms. The information was gathered over a two hour period at a time selected by the member of staff without the knowledge of the pharmacist. The completed forms were then posted to the researcher in self addressed stamped envelopes for analysis.

2.5.5 Analysis of the collected data

The analysis of quantitative data, was conducted using the Statistical Package for Social Sciences (SPSS for Windows, 7th Version). This included the generation of frequency data and summary statistics. Statistical comparisons were undertaken using non-parametric procedures. These included the chi-squared test to compare counts between nominal variables. Mann-Whitney U test for comparison of ordinal data between two independent groups, Kruskal-Wallis tests when more than two groups were being compared. In all cases a $p < 0.05$ was accepted as conferring statistical significance.

2.6 Stage four: setting standards for oral counselling of dispensed medications

The setting of specific, realistic standards of care that are acceptable to those involved is a major challenge for audit. Standards are formal statements of level of service provision within the resources limitation (Irvin and Irvin, 1991) and their primary purpose is to highlight the deficiencies by clarifying the expected level of service. Although setting standards is considered as a single step in audit, it fulfills three important objectives: fostering discussion, highlighting problems and motivating changes. Setting standards helps to focus attention on a specific area of service and promotes debate among professionals leading them to review their practices and encourage them to search the literature in pursuit of a gold standard. In audit, comparing the current practice with the standard, highlights the

deficiencies that may remain unnoticed otherwise.

It should be remembered that simply recognising a deficiency does not necessarily identify the underlying causes and problems. The reasons for which the current practice fails to meet the standards should be identified if the deficiency is to be addressed and remedied. This was demonstrated by contrasting two audits conducted on the incidence of avoidable clinical errors in the Accidents and Emergency Department of two hospitals (Sharples *et al*, 1990; Dearden and Rutherford, 1985). The two audits were identical in all stages but one. In the first audit where practice was compared with the standards the deficiencies were identified and described in detail and a proposal was made to set up a new guideline to tackle the problems. In the second audit after deficiencies were identified, Dearden and Rutherford (1985) initiated an investigation to discover the cause which was found to be a result of inexperience of junior house officers in dealing with severe emergency cases. They then devised an algorithm for dealing with these cases indicating when junior staff should call upon a senior doctor. After six months the result of a re-audit showed no significant reduction of clinical errors in the first hospital whereas the second one had a 50% reduction in the incidence of clinical errors.

A number of surveys on oral counselling of dispensed medications have demonstrated that patients' expectations regarding the type of information sought was not met by pharmacists' counselling and the overall level of advice was much lower than expected by the consumers (Krska *et al*, 1995; Morrow and Hargie, 1992; Gibbs *et al*, 1990). However, when pharmacists were asked to comment about their advisory role for dispensed medications, they believed that quantity and quality of the service as it was, met public expectations. (Morrow and Hargie, 1992; McGovern and McElnay, 1995) Meanwhile observational studies of pharmacists counselling behaviour have reported a much lower level of activity in comparison to what pharmacists believed they provided (Berardo, 1986; Hayes and Livingstone, 1990; Krska *et al*, 1995), indicating a gap between pharmacists' perceptions of their practice and actual behaviour in providing counselling services.

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In health care, the key to implementing an effective change lies in establishing the cause of deficiencies which can often point to possible solutions resulting in a successful resolution of the existing problem. With this point in mind this study incorporated an exploratory phase in addition to the conventional audit process in order to investigate pharmacists' views, reasons and opinions on the identified gap between their perception of their counselling behaviour and the observed level of provision of this service for dispensed medications.

The choice of method for this stage was the focus group technique. This would enable the researcher to explore pharmacists' perspectives on the provision of oral counselling on dispensed medications in the context of their experience, views, priorities and concerns.

Focus groups, with an ideal size of four to eight participants, are a form of group interview that capitalizes on group interactions in order to generate data. It is useful in exploring participants' knowledge and experiences and can be used to examine what people think and their reasons for doing so (Kitzinger, 1995). Focus groups are a qualitative technique and the idea behind them is that interactions between group members can provide insights into their thought processes, allowing them to examine and clarify their views in ways that would be less easy in one to one interviews (Bissell and Hibbert, 1997).

Focus group techniques use interactions occurring during a discussion including agreement, disagreement, confrontation, support and sharing an experience to produce findings. As people's knowledge and attitudes are not entirely encapsulated in a reasoned response to direct questions having access to different forms of communication can provide a better insights into participants thoughts (Kitzinger, 1994). However, often the rich and varied nature of data is not evident in published reports of these meetings as observed by Kitzinger (1994) and Smith (1999).

When the objective is to examine how knowledge and ideas are constructed and operated within a given cultural context, as was the case at stage four of this study, the focus group is a particularly useful technique to apply (Aston University and MEL 1991; Kitzinger, 1995).

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This stage of the study was conducted in two phases. The objective of the first phase was to identify the influencing factors on pharmacists' counselling behaviour. This was achieved through a focus group discussion of a randomly selected community pharmacists after they were presented with the findings of, stage three (the observational study on the current level of oral counselling with dispensed medications). Phase two comprised of two parts. In part one a group discussion was conducted on the necessity of provision of oral counselling on dispensed medications. The reason for doing so was two fold. Firstly pharmacists were not legally obliged to provide this service and secondly the literature indicated that there was a significant correlation between pharmacists' beliefs and their counselling activities (Blom *et al*, 1993). Therefore it was deemed essential to establish, at the outset, whether all participants agreed that counselling on dispensed medications was an integral part of their roles and it had positive outcomes. Otherwise if the result had indicated that pharmacists did not meet the agreed standards for provision of oral counselling, it could have been either the design of the study or equally pharmacists' lack of commitment to counsel their patients in the first place.

In part two, pharmacists embarked on setting standards for the service. In the absence of an external standard the group embarked on setting an internal standard for oral counselling on dispensed medications. The main advantage of internal standards was the sense of ownership and the added motivation for the group to implement the product of their own work. One option was to adopt an empirical standards which was an average of the current level of practice. This approach was deemed inappropriate as an empirical standard would only represent the statistical averages which might or might not reflect good care (Crombie *et al*, 1993).

To ensure that the internal standard possessed a high degree of rigour it had to be based on evidence. The necessary evidence for setting standards were obtained from several sources, including: a literature review, current social and professional values and existing data on current practice.

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Throughout this study counselling practice on dispensed medications was examined from two perspectives: the extent of service provision and the content of counselling per item dispensed. The number of counselled items was recorded and the extent of counselling was reported as the percentage of the total items dispensed. The content was noted according to the nature and numbers of issues covered by pharmacists for each item.

To set standards for the extent of oral counselling pharmacists took “the advice given for one dispensed item” as a unit, within which they agreed on a minimum number of issues needing to be counselled. To address the content of advice, pharmacists ranked the counselling issues in order to focus their minds on priorities of counselling components without setting any specific standards. This approach provided pharmacists with the flexibility to exercise their professional discretion in choosing the appropriate issues for oral counselling of each dispensed medication, allowing them to individualise their services according to patients’ requirements.

Sample selection

Nine community pharmacists were randomly selected from the list of participants of observational study and invited to attend a whole day meeting. The initial invitation letter described the aims of this meeting as discussing the findings of the observational study, debating the level of standards to be set and examining the proposed scoring system for achieving workable and acceptable standards (Appendix 4.1). Pharmacists were also requested to take part in a pilot study following the meeting, assessing the feasibility of implementation of the standards set. The meeting took place on a Sunday and the pharmacists were paid £80 for participation.

Six pharmacists accepted the invitation and a second letter was sent to them highlighting the objectives of the meeting (Appendix 4.2). Enclosed was an anonymised summary of data obtained from the observational study, stage 3, for attendees’ attention and they were asked to familiarise themselves with the data prior to the meeting.

2.6.1 Choice of method for conducting the meetings

The researcher employed focus group technique to facilitate two meetings attended by the same group of community pharmacists. There were six pharmacists participating in the meetings which took place in the morning and afternoon of the same day. The objective for the first meeting was to identify factors influencing level and content of pharmacists' oral counselling on dispensed medications. After a lunch break the second meeting was convened in which the necessity of providing oral advice on dispensed medications in community pharmacies was established first, followed by pharmacists' agreement on the standards for service provision. In both meetings the group discussion was tape recorded and later transcribed.

2.6.2 Factors influencing the extent and content of counselling on dispensed medications

The objective for this phase of study was to investigate pharmacists' thoughts and reasoning in prioritising patients for whom they provided medication counselling. It also examined factors influencing pharmacists' counselling behaviour including patients' age, type of prescriptions, type of medications etc.

In addition, as participants were expected to implement some changes in their practice during the next stage of the audit cycle, it was essential to explore their perception of difficulties and problems that needed addressing if the service provision was to improve. It was thought that the results of this exploration could inform the discussion on findings of the observational study.

The introduction was deliberately kept short and included the definition of audit, community pharmacists' roles in improving patients' compliance, background information about the study and usage of observational methods to establish the baseline for this audit. Finally, it was pointed out that majority of existing community pharmacy standards concerned structural aspects and emphasised the need to establish explicit standards for process aspects of pharmaceutical services.

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After thanking the participants for taking part in the observational study, they were presented with a questionnaire containing nine multiple choice questions based on the findings of the study. This included the rate of counselling in community pharmacies, the provision of oral counselling in relation to patients' age, the most and least counselled therapeutic areas and the most and least counselled issues (Appendix 4.3).

The purpose of the questionnaire was two fold, firstly to stimulate an in-depth discussion among the participants leading to a debate around some of the controversial issues and secondly to provide a structure for group discussion to ensure that all the points were covered.

When participants had completed their questionnaires, the researcher provided the answer to each question in turn, asking participants to compare it with their response and to comment on the results expressing their views and opinions. This led to a group discussion on each question topic. The researcher explained that the aim was for the participants to talk with each other and not to the researcher. The researcher took a back seat at first, allowing for a type of "structured eavesdropping". Later on in the discussion, however, the researcher adopted a more interventional style urging debate to continue beyond the stage it might have stopped otherwise, by encouraging the group to discuss the inconsistencies both between participants and within their own thinking. Disagreements within the group were used to encourage participants to elucidate their point of view and to clarify the reasons behind their counselling practice. After discussion on the questionnaire was exhausted the participants had a lunch break.

2.6.3 Setting a set of standards for counselling of dispensed medications

In 1994 the Royal Pharmaceutical Society included patient counselling in its Standards of Good Professional Practice (RPSGB, 1995). Currently in the UK, counselling patients on their medications is a recommendation and not a legal requirement for pharmacists. This is unlike the United States and Australia where pharmacists are required by law to provide this service.

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Studies conducted in the UK have indicated that patients do not routinely receive counselling when collecting their prescriptions (Krska *et al*, 1995; Hayes and Livingstone 1990; Livingstone *et al*, 1996). This is despite the fact that counselling has been shown to improve patients' recollection of drug information (Williamson *et al*, 1992) and that the service is expected by patients (Morrow *et al*, 1993). Results of the observational study, stage 3, also reflected the findings of other UK researchers about a low level of counselling provision and variations in its content.

Phase One: establishing the necessity of provision of oral counselling for dispensed medication

It was deemed essential to ensure that participants agreed that there was a need for providing oral counselling on dispensed medications in community pharmacies. Prior to setting standards for the service delivery by pharmacists. This was achieved through a focus group discussion where the following question was used as a prompt:

“Is there a safe and simple medicine for which counselling would not be required?”

Each group member was requested to name a medication which they considered not to require counselling in most instances. Meanwhile other pharmacists were asked to suggest potential side effects or contra indications that the product could present. The researcher ensured that all group members participated at this stage. Finally pharmacists were provided with opportunity to comment on the result and suggest ways by which they could improve their counselling level in the areas identified by the observational study including provision of information on the adverse drug reactions and advising elderly patients.

Phase two: setting standards for the extent and content of counselling

The evidence required for the standards setting process was provided by the researcher who carried out a literature search on the provision of services, patients' expectations, the current social and professional values with specific reference to the least counselled areas as highlighted by the questionnaire in phase one. In order to inform the pharmacists'

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decision making process the relevant issues were presented to the group for discussion in relation to appropriate standards.

To ensure that the standards were set at an achievable and realistic level the extent of current provision for oral counselling on dispensed medications was also considered. Then pharmacists deliberated on the standard for the content of oral advice before agreeing on standards for the extent of oral counselling to be provided for each dispensed item.

I. The content of counselling

First, the content of advice was addressed by requesting pharmacists to rank the twelve counselling components as derived through the nominal group meetings (stage 2) with number one representing the most important component. The objective was to see whether the knowledge of consumers' needs and expectations, as presented by the researcher, affected pharmacists' prioritisation of counselling issues. And if so, to what degree pharmacists' would reflect on their own prioritisation and change their counselling behaviour to address consumers' needs.

II. The Extent of counselling

Data published by Blom *et al* (1993) and Mason and Svarstad (1984), in agreement with findings of this study, suggested that the level of oral counselling received for a medication prescribed for the first time was significantly higher than a repeat item which had been previously dispensed for the patient. Therefore pharmacists were asked to set two standards for the extent of counselling, one for repeat and one for newly dispensed medications. Two identical forms were distributed to group members containing a list of counselling issues derived from the Nominal Group meetings (Appendix 4.4). Each participant was then asked to determine the required minimum number of counselling issues for an acceptable and workable standards for repeat and newly dispensed medications.

The forms were then collected and minimum numbers were recorded on a flip chart. An average was obtained for repeat and new medication categories.

2.6.4 Analysis of the focus group data

To analyse results of this stage two approaches were taken. Firstly to gain some understanding of factors influencing pharmacists' oral counselling behaviour with dispensed medications, the content of the discussion was analysed, this was followed by an analysis of group interactions to capture the dynamic of the group and its effects on the generated data.

I. Content analysis of the group discussion

The data was transcribed verbatim from the tape recording. The qualitative data was then annotated with descriptive labels and themes were assigned to the appropriate portions of the transcripts. Further analysis was carried out to develop the subcategorisation of the data, the results of which are reported in the next chapter.

II. Analysis of the group interactions

To capture context of the focus group discussion and the ways in which data was evolved, an account of interactions among group members is reported in the results chapter. The most widely used research tool to examine interactions is the Interaction Analysis System (Marks *et al*, 2000). This is an observational instrument which allows the researcher to identify, categorise and quantify features of interactions. The most frequently cited Interaction Analysis System is Bale's framework where audio or video recorded interactions are analysed by categorising each statement into one of a large number of mutually exclusive and exhaustive content categories. The four categories of Bale's Interaction Process Analysis (1950) were used to analyse the patterns of interactions in the focus group. The group interactions were broken into segments. Each segment was coded using the following categories: Positive and Negative contributions and Questions and Answers. An interaction was categorised as a Positive contribution when the participant agreed, demonstrated understanding, shared their own experience to illustrate the point and/or passively accepted. Negative Contributions were when a participant demonstrated disapproval, disagreement or confrontation. The Questions category entailed asking for information, opinions and suggestions. Any provision of information, opinions and suggestions were categorised as Answers.

III. *Quantitative analysis*

Prioritisation of the counselling issues by pharmacists resulted in a range of responses which needed to be standardised. The scoring system used for this purpose ensured that the total score used by all participants was the same. It also provided a weighting for each item demonstrating the degree of importance attached to each one by the participant as illustrated in example 1. To finalise the overall prioritisation of issues, their scores were used to provide a numerical value for each item reflecting the collective importance given to it by the group. This enabled the process to produce a final ranking of counselling issues which represented pharmacists' collective priorities.

Issues which were given the same scores by a participant were ranked in sequence first and an average rank was calculated for them. This average was then applied to those equally important issues as their valid ranks as illustrated by the following example:

Example	Score	Ranking	Valid ranking
Dosage	1	1	2.5
Interval	1	2	2.5
Maximum dosage	1	3	2.5
Timing & Food	1	4	2.5
Total	10 : 4 = 2.5		

This meant that the next issue scored two by the participant in effect was in the fifth rank due to having four equally important issues listed before it.

2. 6.5 Reliability and validity

One of the objectives of this stage was to examine various reasoning and beliefs held by pharmacists in explaining the variations observed in their provision of oral counselling on dispensed medications. Therefore the consistency of data was not an objective; on the contrary it was variation of pharmacies' opinions that were sought.

As for the validity, the findings of each section (including pharmacists' beliefs on provision of counselling, its extent and content) were compared with the published works in the appropriate field. In almost all cases the study findings were found to be closely comparable with other workers' reports. In a few circumstances when they were not, the reasons behind the discrepancies are fully explored and reported.

Limitations of this stage of study

Through observations, at stage three of this study, data was collected on the oral counselling activities of pharmacists for dispensed medications which was used as the baseline measurement for setting standards in stage four. After an agreement was reached on the standard, it was then implemented by pharmacists whom self reported on their new level of oral counselling provision. Reviewing the literature on different methods of data collection on counselling activities of pharmacists, the major differences between the results obtained from direct observations, self-completion questionnaires and diaries kept by pharmacists, related to the frequency and duration of each counselling. Ortiz *et al* (1989) reported that self-reports in questionnaires overestimated these values whilst diaries slightly underestimated frequencies although they overestimated duration when compared with direct observation (Krska *et al*, 1995; Laurier and Poston, 1992; Meade, 1992; Kirking, 1982). One of the main reasons for the low estimates based on the diaries was found to be the failure of pharmacists to record all the counselling activities especially if the data was collected over a period.

This issue was addressed in this study by designing easy to complete data collection forms and having a short (three hours) data collection time. However, data obtained by self-reported diaries could have underestimated any increase in the level of counselling as the result of the standards implementation. It should be acknowledged that usage of different data collection methods was one of the study's limitations as it could distort the magnitude of any changes achieved in pharmacists' counselling activities. To overcome this bias when the audit was conducted at stage six all the data was collected using self-reporting diaries and the standard was set using the baseline level established by participants themselves.

2.7 Stage Five: implementation of the standard and evaluation of the impact on provision of oral counselling in community pharmacies

Having agreed on the standards for provision of oral counselling, these five pharmacists were then asked to implement the agreed standards and collect information on their advisory behaviour. This was to investigate whether engaging in a peer audit can positively affect oral counselling by community pharmacists. This also provided an opportunity to try the audit model and all the data collection tools and to test how helpful they could be in reviewing a pharmaceutical service in community settings.

To proceed with the audit cycle, participants were requested to implement the agreed standards and to self report on their level of oral counselling on dispensed medications using the data collection tool devised specifically for this purpose (Appendix 5.1).

Written instructions on how to complete the form and a glossary of the terms used were provided (Appendix 5.2). Pharmacists were asked to collect data for three hours a day on five days. The choice of sessions had to represent pharmacies' busy and quiet times. The context and layout of data collection form were based on the form used for the observational study and was piloted by five community pharmacists who only participated in stage three of the study.

The group agreed to complete the data collection within four weeks and return the forms, in stamped self-addressed envelopes, to the researcher for analysis. During this period the researcher contacted all participants to ensure that the data collection was completed in time. All the forms were returned by the end of the fourth week. The data was analysed and participants were sent a copy of the findings.

2.7.1 Analysis of the data

The quantitative information from the implementation of the agreed standards was coded and analysed using the Statistical Package for Social Sciences (SPSS for Windows, 6th Version). The statistical analysis, used non-parametric procedures, including: chi-squared tests to compare counts between nominal variables, Mann-Whitney U test for comparison

of ordinal data between two independent groups, Kruskal- Wallis test when there were more than two groups being compared. Attention was drawn to significant differences at the $p < 0.05$ level.

In this stage of study the level of oral counselling for dispensed medications had been established and a consensus on a minimum standard for this service was agreed. Using an audit model the standard was successfully implemented resulting in a higher provision of the service in participant pharmacies.

2.8. Stage six: Feasibility of the peer audit to review provision of oral counselling on dispensed medications in community pharmacies in Barnet

To further examine applicability, acceptability and validity of the model used in this study it was decided to test the same approach in a group of community pharmacists in one of London's health authorities rather than a randomly selected group across London. Two pharmaceutical advisors from the Thames region were contacted and one agreed to collaborate and fund community pharmacists' participation in the audit as part of the health authority's professional development programme (Appendix 6.1). A letter was drafted by the researcher and circulated by the health authority inviting pharmacists to participate in an audit of oral counselling of dispensed medications (Appendix 6.2). To express an interest pharmacists could either contact the researcher or attend a local branch meeting where the researcher was presenting the study. The presentation entailed background information on the study and an explanation on pharmacists involvement and the process of data collection.

2.8.1 Method

Five community pharmacists participated in this stage of the study. Two pharmacists were recruited during the local branch meeting and three contacted the researcher after one reminder had been sent out. Pharmacists were asked to collect information on their oral counselling of dispensed medications for five sessions of three hours duration using the same form as the one used in stage five of the study. The forms were then returned

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to the researcher for analysis. The pharmacists were invited to attend a meeting in order to set standards for the delivery of the service. Using the same questionnaire as in stage four, and presentation of findings of observational stage three, participants engaged in a debate on the level of current practice identifying factors influencing the extent and content of oral counselling on dispensed medications. After a short break they were then presented with data on their own counselling activities and were asked to rank and decide on a minimum number of counselling issues they felt appropriate and practical as a standard. The average numbers of items suggested by participants, four for newly dispensed and three for repeat medications, were accepted as the standard for the audit by the group.

The pharmacists were then requested to check their counselling against the agreed standards and to implement any necessary changes within the following two weeks. To measure the extent of implementation pharmacists were provided with data collection forms to collect a second set of counselling data for five sessions and return them to the researcher in stamped self addressed envelopes. The data obtained after standards' implementation was then compared with the baseline information sent by the participants at the beginning of the audit cycle.

Regarding the extent of advice given, comparison was performed by calculating the number of counselled items as a percentage of total number of dispensed medications. For the content of advice the frequency of advice on each issue was calculated as a percentage of total counselled items. The results were presented pictorially and each participant pharmacist was provided with feedback on their counselling practices before and after the audit cycle, highlighting the changes achieved as the result. This stage completed the audit process and demonstrated the effect of a locally agreed standard on the provision of oral counselling on dispensed medications.

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However, audit is a continual process and meeting the agreed standards is a point where the completion of one cycle leads to start of the next one. As each cycle of audit concludes, the agreed standards are reviewed with the view of improving the service. This incremental and incessant raising of standards ultimately evolves an audit cycle into a spiral of improvement.

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RESULTS

3.1. Introduction

The study was conducted in six stages. Different cohorts of community pharmacists were recruited for almost each stage of the study and the number of participants varied based on methods used. The sample selections, response rates, analysis of the data quantitatively and qualitatively, where appropriate, are reported separately for each stage of the study. Results of validity and reliability tests, where performed, as well as characteristics of non-respondents are described in this chapter.

Results of six stages of the study

The results are presented according to the stage in which they were generated, however, some of the terms used to describe the sample characteristics or measure pharmacists' counselling activities were common to all six stages of the study. The followings are definitions of these terms as used in the study.

In the analysis of community pharmacists' characteristics, an independent pharmacy was defined as the single pharmacy owned by a proprietor. A small chain pharmacy was defined as a pharmacy that was a branch of a group of pharmacies, ranging in size from two to ten pharmacies inclusive and a multiple pharmacy was defined as a pharmacy that was a branch of a group of pharmacies with more than ten branches.

Throughout the study the data obtained on counselling activities of community pharmacists has been reported under three terms: the level of advice, the **extent** and **content** of counselling. The **level** of counselling was defined as the number of dispensed medications that received oral advice as a percentage of the total medications dispensed. In stage two the components of counselling were defined and agreed on by the participant pharmacists. Using each component or issue as an unit of advice the **extent** of counselling was defined as the number of issues raised during counselling of a dispensed medication. The **content** of advice reflected on the nature of the counselling issues, such as information on the dosage, timing, storage, and frequency by which they were covered during provision of advice for each medication dispensed.

3.2 Stage one: to identify an aspect of practice as a priority for audit process

To conduct the semi-structured interviews twenty-four community pharmacists were contacted and sixteen agreed to participate. The overall rate of response was 67%. The interviews were conducted in participants' pharmacies and they took between fifteen to forty five minutes. Eight non participants stated the following reasons for not taking part: lack of time (5), lack of interest in the topic (1), being locums and not having permission to participate in the study (2). Basic information was gathered from all eight pharmacists showing that non participants were similar to the participant pharmacists in terms of the following characteristics: pharmacists' gender, position, number of years since being first registered and whether self-employed or employed by an independent or a multiple pharmacy.

Characteristics of community pharmacies and the pharmacies

Table. 1.1. represents the characteristics of the community pharmacists being interviewed and the pharmacies were they worked. There were eleven male and five female community pharmacists in the sample. With regard to position, eight were proprietor, five managers and three were locum pharmacists. Representation from different type of pharmacies were as follows: three multiple, twelve independent that in turn included seven small chain of independent and eight single proprietor pharmacies. Although there was a wide spectrum of years in registration, the majority had eleven to twenty years of experience as pharmacists.

Defining professional audit

Pharmacists were asked to define professional audit and share their understanding on the subject with the researcher. Participants whose response included the two elements of assessment and improvement of practice were considered to have a basic knowledge of

Table 1.1 Characteristics of community pharmacists and pharmacies in stage 1

CP No*	Sex	No years of being registered	Type of pharmacy	position
1	Male	30+	Single.Indep	Locum
2	Female	6-10	Small.Indep	Proprietor
3	Male	11-20	Single.Indep	Manager
4	Male	11-20	Single.Indep	Proprietor
5	Male	11-20	Small.Indep	Proprietor
6	Male	21-30	Single.Indep	Proprietor
7	Male	11-20	Single.Indep	Proprietor
8	Male	6-10	Multiple	Manager
9	Male	11-20	Small.Indep	Proprietor
10	Female	11-20	Small.Indep	Proprietor
11	Female	1-5	Multiple	Locum
12	Male	30+	Small.Indep	Proprietor
13	Male	21-30	Single.Indep	Manager
14	Male	11-20	Multiple	Manager
15	Female	1-5	Small.Indep	Locum
16	Female	1-5	Small.Indep	Manager

KEY:

CP Community pharmacist

Sing. Indep The proprietor pharmacist owned one single pharmacy

Small.Indep Independently owned pharmacies with less than ten branches in a chain

Multiple More than ten pharmacies in the chain owned by a national company

*(Quotations from pharmacists' interviews in stage 1 are numbered according to their CP No, when reported in the results chapter)

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audit. Six (38%) of participants definition was correct, four (25%) mentioned the assessment element only and two improvements of practice. Three (19%) stated that they did not know much about professional audit and one pharmacist (6%) had only heard of audit in a financial context. Overall 75% of pharmacists had some understanding of professional audit.

All but two interviewees' definition and understanding revolved around self audit and their individual practices and standard. The former two were knowledgeable about different stages of an audit cycle and identified its different types as self, peer and external audit and named the first two types of audit as the most accepted processes. Despite a degree of uncertainty expressed by pharmacists when defining professional audit, a few common themes emerged from the interviews which are reported below. The quotes are numbered with the Identity number (CP No) of each interviewed pharmacist. For a list of CP numbers and their corresponding characteristics please refer to **Table 1.1**.

I. Audit is assessing practices critically.

This can be illustrated by the following quotes from the interviews:

“It is basically a question of assessment of our activities, critically checking them.” (1)

“It (Audit) means to sit back and reflect. It gives you a chance to evaluate yourself and your professional activities.” (13)

II. Audit raises the quality and improves practice.

Audit was generally considered in a positive light, a way to improve quality and efficiency of pharmacy services as demonstrated in the following statements:

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“ We look at our shop, our performance and our behaviour with the general public to see how it can be improved. Then we try to change them for better, it is an ongoing process.” (3)

“I am in favour of auditing because you can judge, check and correct your mistakes and improve. It (audit) helps you to do your job more effectively ” (10)

III. Setting standards or measuring practice against standards as a part of the audit process

This theme was identified by eight pharmacists:

“It is a way of creating standards that you measure yourself against to improve your professional activities” (11)

“It is about setting standards, standards of quality control in your own practice.” (5)

Experience of audit

Overall 44% of participants reported that they had experience of audit, 12% stated that as professional people they were continually auditing their professional activities and the remaining 44% did not have any experience of the process. Subsequently responses were categorised as positive, some experience and negative accordingly. There were seven negative responses where in two cases the reason stated was lack of training:

“No, I have not had any training in audit.” (15)

“No, there will be an all day session in the High Street scheme (Barnet) next month, I may try after that.” (2)

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Two pharmacists whose replies were categorised under “some experience” believed audit to be an inherent part of their practice and although they did not document the process it was actively implemented in their daily practices:

“Most people do it without realising it, I had an incident of wrong delivery of a CD (Controlled Drug), it took me a long time to sort it out as a result now I personally sign for CD deliveries and there has not been any more problems.” (8)

“Audit is looking at what we do and how we can improve that and it has been going on all the time without writing or trying to discuss it but it is always there.” (4)

Among seven pharmacists who had experience of audit four specified their experience as self audit and four provided examples of the topics covered including audit of stock level, waiting time for dispensing of prescriptions, number of telephone calls received by the pharmacist and counselling and advice provided for OTC products by the pharmacist.

“Moving to audit” the Royal Pharmaceutical Society’s initiative

Participants were asked to comment on the “Moving to audit” package launched by the RPSGB that had been circulated to all community pharmacists. Out of sixteen, eight pharmacists had not received the package and five had not had time to read it. The overall opinion of three pharmacists who had read the booklet was positive, however, they felt that its content was too simplistic.

“It improves every time I read it although I found some part of it too simplistic.” (11)

“It is a bit simplistic, some of it we do anyway. Because the idea (audit) itself is so good, it certainly helpful to go through the package.” (6)

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Another comment was about the presentation of the package. The package design was such that participants were expected to send their answers to the assessment questions at the end of each chapter on a series of cards to the centre for feedback. However, one of pharmacists commented that it would be more practical and less time consuming if the card system was replaced by a booklet containing all the questions and answers for use in conjunction with the package.

Implications of audit implementation on the profession, pharmacists, their staff and patients

Participants were asked for their opinion on implications of audit implementation on pharmacy as a profession, on an individual basis and on pharmacy staff. They were also invited to comment about the possible effects of professional audit on patients' care. Pharmacists' responses were analysed and the main themes are reported below.

I. Implications on the profession

Ten pharmacists were very positive about the effect of audit on the profession as a whole and listed improvement of pharmacy standards (3), professional image (3) and quality of service (3) as well as changing of pharmacists role in accordance with public expectations (1) among the benefits of audit. Five of these respondents however, thought that the success of audit would also depend on factors such as level of uptake by community pharmacists, choice of audit topics, having an agreed standards by the Pharmaceutical Society and voluntary participation (2) as exemplified below:

“Audit success depends on the level of response and its uptake by pharmacists.”

(11)

“Yes but to some extent it depends on what you choose to audit, topics that focus on appropriate prescribing and minimising wastage of medicines could be successful.” (4)

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“I think for it to affect the profession as a whole there would have to be some sort of standard published by The Society.” (1)

“ It should not be imposed otherwise it would not be beneficial for the profession.” (3)

Three participants did not think that audit would have any effect on the pharmacy profession and three expressed concerns over its introduction into pharmacy:

“Audit’s main concern is quality whereas in community pharmacy the financial aspects matter too. The antacid product with higher profit margin will be the one I recommend, therefore nothing will be gained by auditing what product should be sold and how.”(7)

“If people are happy the way they run their business even if it is not efficient they might want to continue in their own individual ways. If the idea is standardisation in any way it will not.” (12)

“My colleagues do not think much of the idea(audit) and they feel it tends to be a waste of time and effort...I am inclined to agree with them.” (15)

II. Effects on pharmacists’ own practice

When pharmacists were asked to comment on the effect of audit implementation on their own practice, six pharmacists said that under the current conditions they would not be able to participate in audit activities due to lack of time (3), no financial incentive (2) and lack of training (1). Some of their statements are as follows:

“ Lack of time will not permit me to take part in audit, I do not think it will have any effect anyway.” (2)

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“To meet the standards set during audit pharmacists need to spend more time on professional aspects and to cope with other duties a second pharmacist is needed. Who will pay for it? It is just not viable financially.” (9)

“I have not had any training, it would have been more effective if there was some structured training about it.” (8)

Ten pharmacists believed that an improvement in the standard of their practice would be achieved as a result of audit implementation however, two had some reservations about audit uptake on a large scale as the current pharmacy remuneration system did not recognise or reward pharmacists for professional activities. On the other hand two participants thought that their improved performance would attract more patients and would be beneficial for the business as well as providing them with more job satisfaction (3).

Participants identified two main factors which could contribute to success of audit in improving performance. There were firstly that pharmacists involvement in examining their activities and highlighting any problem or deficiency would result in more effective remedial actions to be put in place (6) and secondly that audit as an ongoing process would encourage pharmacists to keep their knowledge up to date (3).

“ Audit makes you more efficient. It helps you to identify the area where you have gone wrong and the process keeps you up to date.” (4)

III. *Effects on pharmacies' staff*

Six interviewees were uncertain about impact of audit on staff, three of whom stated that they only worked as locums and did not have sufficient insight to predict the effect. Overall nine participants believed that audit could be beneficial for staff too. However, five stated that the level of staff involvement and the success of the audit process would be based on the owner/manager's enthusiasm and motivation and the level of delegation of duties to his/her staff.

“It (audit) will have a positive effect. If the pharmacist is motivated he will bring it down to the shop level and get all staff involved.” (13)

Four pharmacists were quite positive and stated that some degree of audit could benefit everyone whereas the others expressed reservations including extra resources required for training. However, three pharmacists felt that staff had a right to refuse to participate in audit activities. These pharmacists pointed out that if staff felt unable or unprepared to meet these new training requirements they would leave, resulting in crisis in employees' recruitment and retention.

“ They (staff) should critically look at their conduct as how they treat the customers and it probably means more training for staff too.” (3)

“Staff need to accept it (audit) as well. If it improves things fine otherwise they have a right to criticise or even abandon it.” (7)

One pharmacist strongly disagreed with the introduction of audit at the staff level stating that it would be too demanding and he would lose his staff.

IV. Effects on patients

Eleven interviewees said that audit implementation would have a positive effect on patient care because it would improve the standard of service delivery (6) lead to a more professional and patient focused environment (3) put patients at ease in communicating effectively with the pharmacist (2). Two pharmacists were uncertain about the effects of audit on patients however, they emphasised that clients' views should be sought before any change was introduced as illustrated in the following quote:

“One should ask the customers first. If as the result of audit the pharmacy becomes more efficient and slick but more impersonal the customers might not like it” (12)

Three pharmacists thought that audit implementation would have a negative effect on patients' care as it would be too demanding on their time leaving insufficient time to deal with patients' request promptly. One of the pharmacists felt that even engaging a second pharmacist could not resolve the problem as his regular customers would not be happy to deal with a different pharmacist.

“If there are two pharmacists, there will be a difference of opinion and my regular customers would not like that because they may get different advice from the second pharmacist causing confusion.” (9)

Table 1.2 Pharmacists' views on implications of audit implementation for pharmacy profession, pharmacists, their staff and patients (N=16)

Implication of audit implementation for	Positive effects (%)	Negative effects (%)	Don't know (%)
Profession	9 (56)	3 (19)	4(25)
Pharmacists	10 (63)	1(6)	5 (31)
Staff	10 (63)	1(6)	5 (31)
Patients	12 (75)	2 (13)	2 (13)

Inclusion of audit as a criterion for the payment of the professional allowance

Pharmacists were asked to comment on speculation that participation in audit might be included on the list of criteria for the professional allowance payment. Five pharmacists were unhappy about mandatory audit:

“I think everyone will put it (audit) down as another thorn in the side of already overburden pharmacists.” (1)

“If it is left to us to do it (audit) it is fine but if the Government comes and stands over me as an external auditor I will be very unhappy about it.” (4)

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Despite welcoming the idea, eleven participants had some reservations about the ways and means of monitoring and payments of audit implementation in community pharmacies.

“How are they (the Government) going to check unless they send questionnaires etc. What are the criteria for payments? All these should be clarified before anything is put in place.” (9)

The general view was that the uptake would improve if financial incentives were offered. It was also felt that including audit is a positive move towards shifting the payment from unit per item dispensed to service elements.

Potential problems and benefits

I. Potential problems

Participants were asked what potential problems they foresaw in implementing audit in community pharmacy. Twenty-three responses were given by sixteen interviewees with a range of one or two responses per pharmacist. The anticipated problems were classified under seven categories:

- ***Time***: Lack of time was the highest cited problems (seven participants)
- **Remuneration**: concern was expressed that unless there is a financial incentive, it would be very unlikely that pharmacists could sustain audit activities (cited by three)
- ***Enthusiasm***: maintaining an adequate level of enthusiasm throughout an audit process was considered a potential problem by two pharmacists
- ***Resistance to change***: Some resistance specially initially was expected from practitioners unwilling to change their attitudes or practices.
- ***Record keeping*** and monitoring were envisaged as potential problems by three pharmacists.
- ***Standards*** : in some areas of practice existing standards are not very far reaching. However, agreeing on a universal standard might not necessarily be appropriate due to variation between practice settings and patient populations.

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- *External audit* is not favoured. Four participants expressed their concerns on possible implications of any unfavourable findings on the future remuneration of community pharmacies, uncertainty regarding future sanctions for pharmacists failing to achieve the audit standards and confidentiality of the collected data.

II. *Potential benefits*

When participants were asked about the potential benefits of audit, two were uncertain and two thought that there would be no benefits gained. The remaining responses were categorized as follows, the first item was the most commonly cited benefits (Seven pharmacists):

- Raising the standards of services and improving patient care and raising pharmacists' professional status
- Updating practice, identifying underlying problems and addressing them
- As a result a better remuneration could be negotiated
- In long term, audit would save time
- Improve efficiency and job satisfaction
- Prevent external bodies' involvement in standard setting and maintaining our professional autonomy

Setting standards

The following are responses to the question of "Who do you think should set standards for pharmaceutical services provided in community pharmacy settings?" The majority of interviewees (eleven=69%) stated that the most appropriate group to do this was pharmacists practicing in the community, with five participants' defining the group further to say that it should be a locally formed community pharmacists' group. Three of these respondents declared that standards should be sensitive to the community pharmacy environment and clientele which could not be achieved if it was set by academia (1) or the Royal Pharmaceutical Society (2), as illustrated by the following quotes:

"If the standard is set by practicing pharmacists with hands on experience it

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would be more appropriate, not someone whose being lecturing 10-15 years and is cut off from community pharmacy.” (8)

“The best way to set up standards is by peer audit that can inspire group members to achieve a higher level of standards than the one set by the Pharmaceutical Society anyhow. Some of these people in the Society or NPA have never worked in a community pharmacy.” (4)

Five pharmacists (31%) believed that standards should be set by representatives of the profession with two mentioning the Royal Pharmaceutical Society as the best representative to perform the task.

“ It should be the Pharmaceutical Society and not an external body or authority with no knowledge of the profession.” (8)

Prioritising pharmaceutical services for audit implementation

Participants were asked to prioritise different aspects of pharmaceutical services for implementation of audit. Thirty-two responses were given by sixteen participants with a range of one to five responses per pharmacist. The median number of responses was two.

Patient counselling on dispensed medications was given the highest priority followed by dispensing, pharmacist and GP interaction and counselling patients for over the counter medicines. All participants who highlighted dispensing as a priority also identified counselling and provision of advice on dispensed medications as an important area for audit as illustrated by the following examples:

“The most important one is dispensing, also the advice we give but that is part of the dispensing process.” (12)

”The main priority is dispensing, proper labelling, counselling the patient about their medications and give them information about it.” (3)

Table 1.3 Areas of priority for audit implementation as identified by the pharmacists in stage 1.

Areas of priority for audit	No of responses
Patient counselling on dispensed medications	10
Dispensing	7
Pharmacist and GP interaction	6
Patient counselling on over the counter medications	4
Diagnostic test	2
Financial aspects	1
layout of the shop to improve our professional image	1
delivery of prescription	1
Return of unwanted medicines to pharmacy	1

In four cases pharmacists prioritised counselling as a stand alone service and attached great importance to it:

“I think the emphasis should shift from the traditional role of dispensing to giving information to the patient and advising.” (8)

“Counselling patients is my priority. This is what we have always done but is not formally recognised.” (9)

Three pharmacists stated that although they had clear priority areas for audit implementation, they were baffled as how to execute their audit. Lack of an existing standard and complexity of setting an agreed and adaptable standards for all were two areas of concern.

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“ I don't know how these aspects (counselling and over the counter prescribing) can be audited as they are so changeable.” (14)

“I can not understand how they will be able to set standards for all these (counselling, pharmacist and GP interactions) aspects. I find the concept of setting standards for these services difficult to grasp” (1)

Further comments

At the end of the interview each participant was given the opportunity to add any comments they may have. Eight took the opportunity and expressed additional views or elaborated on some of the points they had made earlier. Once more lack of time (3) and financial incentives (2) under the current pharmacy remuneration system were highlighted as obstacles in improving professional standards. Also the difficulty of keeping a balance between business and professional interests in community pharmacy was pointed out by one of the participants who felt that sometimes professional improvement may take a back seat if they were not financially attractive.

Six pharmacists once more endorsed implementation of audit as a positive step in community pharmacy and added that guidelines were necessary to unify the approach as well as help those pharmacists who on their own did not or could not set standards for different aspects of pharmacy practice.

The data gathered in these interviews indicated that when pharmacists were asked to identify a professional aspect of practice requiring audit, the highest priority was given to counselling on dispensed medications, followed by dispensing. However, interviewees who highlighted dispensing as the main priority also identified counselling as an integral part of the dispensing process. Therefore it was concluded that conducting an audit for counselling on dispensed medications would also address some aspects of dispensing process.

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A literature search was conducted to evaluate the level of information available on these aspects. The bulk of published data on patient counselling activities in community pharmacies originated in the United States and only limited data was available for community pharmacists in the United Kingdom. The other important issue that emerged from the literature search was that there was no standard definition for patient counselling or its components in community pharmacy settings. It was decided that the first step was to achieve a consensus on the definition of patient counselling before any data could be collected on this activity.

3.3 Stage two: to achieve a consensus on definition of oral counselling and its components

First, the rate of participation is reported and then the results of the two nominal group meetings including the items generated by the participants.

Response rate

For the first Nominal Group Meeting one pharmacist could not be contacted as the letter sent to the shop was returned by the post office and there was no reply on the telephone number listed for the premises. Out of 23 pharmacists, eight people were on annual leave. Fifteen pharmacists were contacted by the telephone and eight accepted to attend the meeting. For the second nominal group meeting there was only one pharmacist who, despite many attempts, could not be contacted. From the remaining twenty-two pharmacists, eight accepted the invitation but only six attended the meeting (**Table 2.1**).

Table 2.1 Rate of response for pharmacists participated in the NGMs.

Nominal Group Meeting	No of letters sent to pharmacists	No contacted by the telephone	No who attended the NGM	% positive response after phone contact
1	23	15	8	53%
2	23	22	6	27%

Reasons stated by pharmacists for non participation in Nominal Group Meetings

Overall thirty seven pharmacists were contacted by the telephone, of whom, twenty-three did not participate in the meeting. The dates of meetings were found to be inconvenient for three people and four more had other professional commitments on those dates. Both meetings were held in the evening, this presented difficulties for four pharmacists. Five pharmacists declared a lack of time and three lack of interest as their reasons for not taking part in the meetings. Two pharmacists replied that they were approaching retirement within the following few months.

3.3.1 Item generated during two Nominal Group meetings

The participants of the first meeting generated thirty items by end of the first round. Following clarification and discussion these were combined and the final number of items was twenty-two. Thus twenty-two were included in the ranking process. The second nominal group meeting produced thirty-five items. Despite requests by participants to combine issues with common themes, the group could not reach an agreement on items to be eliminated. The quantity of generated items presented a problem in both groups when pharmacists were requested to select nine items from all the listed issues. In the first group twenty out of twenty-two items were included in ranking whereas in the second meeting twenty-two items out of thirty five were prioritised. (see **Table 2.2**).

As described in chapter two (section 2.4.5), items generated in both Nominal Group meetings were combined and through content analysis the common themes were identified. Initially two main categories emerged: the first one contained issues addressing the ethos of oral counselling and factors influencing its quality in general terms such as establishing two ways communication with patients. This category was labeled as the "Concept". The second category contained more specific and detailed issues on the content of counselling such as technical information including drug interactions, inhaler technique or contra indications.

Table 2.2 Ranking of all the generated issues (combined results from both Nominal Group Meetings)

Issues	Rank	Subcategories
Tell the patient how to take/use medications	1	Criteria
Dosage	2	Components
Side effects	3	Components
Drug/drug interaction	4	Components
Interaction food/drink	5	Components
Demonstration of appliance	6	Components
Contra-interaction	7	Components
Storage	8	Components
Making sure patient realises need to take medications	9	Criteria
Two way communication to show patient understand	10	Effective communication
Identify patient so to give correct instruction	11	Criteria
All dispensed medications should have counselling as part of dispensing procedure	12	Criteria
Not to share medication	13	Patient education
Keep medicine out of reach of children	14	Patients education
Create an atmosphere so patients feels able to ask questions	15	Effective communication
Change in repeat medication	16	Components
Medication name	17.5	Components
Indication	17.5	Components
Check GP's instruction to avoid patients' confusion	18	Effective communication
If medication did not work refer to doctor	19	Patients education
Counsel on how to avoid recurrent health problem	20	Patient education
Other members of staff giving medications should be suitably qualified	21	Criteria
Listen to patient carefully with regard to their medication	22	Effective communication
What to do with unwanted medicines	23	Patients education
Clarification of information in different languages	24	Effective communication

The Concept category

The Concept category contained general issues regarding the necessity of provision of oral counselling and educating patients on dispensed medications emphasizing the establishment of an effective communication between pharmacists and patients. Further analysis identified three common themes in this category, namely Criteria, Effective Communication and Patient Education. **Tables 2.3, 2.4 and 2.5** represent the items assigned to each subcategories and their adjusted scores and their original ranks as allocated by participants of each meeting.

III. Criteria

These items addressed the fundamental requirements for the provision of oral counselling for dispensed medications, for example the necessity of staff having appropriate training if they were to counsel patients as presented in the **Table 2.3**

Table 2.3 Counselling issues categorized under “Criteria” subcategory (1= most important issue).

“Criteria” Subcategory	Total adjusted score	Item Generated in NGM*	Rank**
Tell the patient how to take medications	141.1	1&2	1
Make sure the patient realises the need to take his/her medication	23.3	1	9
Identify the patient so to give correct instruction	18	1	11
All dispensed medications should have counselling as part of dispensing procedure	13.5	1	12
Other members of staff giving medications should be suitably qualified	4.5	1	21

*Item was generated in first (1) or second (2) or both (1&2) Nominal Group Meeting/s

**Rank for each issue after all the generated issues from both Nominal Group Meetings were standardised and ranked.

I. Effective Communication

The items assigned to this subcategory described or stated elements of good communication techniques in order to provide oral counselling of dispensed medication successfully as represented in **Table 2.4**.

Table 2.4 Counselling issues categorized under “Effective Communication” subcategory (1= most important issue)

“Effective communication” subcategory	Total adjusted score	Item generated in NGM*	Rank**
Two way communication to show that the patient understands	19.5	1	10
Create an atmosphere so patients feel able to ask questions	9.3	2	15
Check the GP’s instructions to avoid patients’ confusion	6	2	18
Listen to the patient carefully with regard to their medication	4	2	22
Clarify information in different languages for patients who do not speak English	0.8	1	24

*Item was generated in first (1) or second (2) or both (1&2) Nominal Group Meeting/s

**Rank for each issue after all the generated issues from both Nominal Group Meetings were standardised and ranked.

II. Patient Education

This subcategory contains all the items relating to either providing education or health promotion for patients with regard to dispensed medications as listed in **Table 2.5**.

Table 2.5 Counselling issues categorized under the “Patient Education” subcategory (1= most important issue).

“Patient education” subcategory	Total adjusted score	Item Generated in NGM*	Rank**
Not to share medication	13.1	1&2	13
Keep medicine out of reach of children	10.7	2	14
If medication did not work refer to doctor	5.7	1&2	19
Counsel on how to avoid recurrent health problem	5.3	1	20

*Item was generated in first (1) or second (2) or both (1&2) Nominal Group Meeting/s

**Rank for each issue after all the generated issues from both Nominal Group Meetings were standardised and ranked.

The overall ranking for the concept category

The overall ranking and importance given to different elements of counselling is listed in **Table 2.6**.

Table 2.6 Ranking of subcategories in the “Concept” category.

Category	Subcategory	Total adjusted scores	Rank*
Concept	Criteria	200.4	1
	Effective Communication	39.6	2
	Patients’ Education	34.8	3

*Rank for each issue after all the generated issues from both Nominal Group Meetings were standardised and ranked.

The Component category

This category included all the issues generated which related to specific points or information in the consultation of dispensed medication itself. This category was then divided into twelve subgroups: dosage, side effects, contra-indication, interaction, food & drink, demonstration of appliances, expiry date, brand and generic name and changes in instruction of repeat items. The following are the examples of items assigned to some of the subcategories:

I. *Side Effects*

“Important side effects that patients must be aware of” (8, Group I)

“Warning about drowsiness” (5, Group II)

II. *Dosage*

“Check dosage especially for children” (3, Group II)

“Telling the maximum dose, especially if there is no direction.” (1, Group I)

III. *Interactions*

“Trying to establish if the patient is taking other medication.” (4, Group I)

“Avoidance of other medication specially paracetamol when appropriate” (6, Group II)

Comparison of two categories

The total sum of adjusted scores (weights) were calculated for the two Nominal Group meetings. These were compared to provide an indication of importance pharmacists attached to each aspect of oral counselling on dispensed medications.

Table 2.7. Ranking of counselling categories emerged from the NGMs.

Category	Adjusted score	Rank
Components	397.4	1
Concept	274.8	2

The Overall Ranking of the Component category

The priority given by participants to different components of counselling is represented in **Table 2.8**.

Table 2.8 Ranking of the components of oral counselling

Category	Subcategories	Adjusted score	Rank (1=most important)
Components	Dosage	97.4	1
	Side Effects	72.4	2
	Drug/drug Interaction	59.7	3
	Interaction Food/drink	45.6	4
	Demonstration of Appliance	45.3	5
	Contra-indication	34.3	6
	Storage	29.3	7
	Change in Repeat Medication	6.8	8
	Medication Name	6.7	9.5
	Indication	6.7	9.5

The list of components was used to devise a data collection tool to record information on counselling behaviour of community pharmacists in the observational study which comprised stage 3. This provided baseline data on advice giving with prescribed medications in community pharmacy. This would enable a comparison of the rankings pharmacists gave to different components in the Nominal Group meetings with pharmacists' actual practice.

3.3.2 Reliability: comparing findings of two groups

During the first meeting participants listed ten components from the overall list and in the second meeting all the eleven components were covered. In the concept category the first group covered three subcategories out of total of four and the second group raised all four subcategories during the meeting. The results of the two independent Nominal Group meetings compared very favourably with each other as well as the overall list.

3.4 Stage three: to establish the current level of counselling practice through observation

To investigate and establish the level of oral counselling on dispensed medications in community pharmacy settings data was collected on both structure and process aspects of this service. The findings are reported here. The first section “sample characteristics” describes the structural aspects including characteristics of the pharmacies, pharmacists and their staff. This is followed by an account of oral counselling processes and the associated variables. Further analysis of the data examines associations between the level of oral counselling and various attributes measured in the study in section 3.4.3. The last section, 3.4.5, reports on how multiple regression was used to explore interconnection and association of predictive variables in constructing five models to predict provision of oral counselling on dispensed medications in community pharmacy.

3.4.1 Sample characteristics

Sixty-one randomly selected community pharmacists were contacted and fifty-one were recruited for the study (response rate was 83.6%). This section begins by describing the pharmacies', their staff and pharmacists. It then presents information on patient-pharmacist/staff interactions, prescriptions characteristics and medications dispensed during stage 3 of the study.

Pharmacies' characteristics

The sample of fifty one community pharmacies included independent, small and large multiples which were all based in the Greater London area (Table 3.1). Pharmacies were categorized into three groups, single independent proprietor (where the proprietor pharmacist owned one pharmacy), small independents (independently owned pharmacies with less than five branches) and large multiples (where there were more than five pharmacies in the chain which included those owned by a national company). Twenty (39%) pharmacies had only one member of staff in addition to the pharmacist, fourteen (27%) had two, ten (20%) had three and seven (14%) employed more than three staff members. As far as staff composition and skill mix was concerned thirty six (71%) pharmacies had only counter staff whilst in seven (14%) a pre-registration student was employed and in five (10%) a dispensing technician. There were only three (6%) pharmacies with both a dispensing technician and a pre-registration student. Only one (2%) pharmacy did not have computerized patient medication records. A purposely built counselling area with seats for patients and leaflets and other educational materials on display existed in five (10%) pharmacies. In thirty three pharmacies (63%) there was an area out of earshot of staff and other customers referred to as a quiet area, where patient could have been counselled in private. The remaining thirteen (27%) pharmacies were either too small or their layouts were such that it was not possible for pharmacist-patient conversations not to be heard by others in the pharmacy.

Pharmacists' characteristics

The fifty-one participants comprised of ten (18%) female and forty-one (82%) male pharmacists. Thirty-four (67%) pharmacists both owned and managed their pharmacies, ten (19%) were employee managers and seven (14%) were engaged as locums. Pharmacists were categorized into four age groups. There were five (10%) pharmacists in 20-30 years age category, twenty-one (41%) in both 31-40 and 41-50 years categories and four (8%) aged 51 years or over. Data on the number of years they had been registered indicated that the sample was normally distributed with fifteen (29%) pharmacists being registered for 0-10 years, twenty-nine (57%) for 11-20 years and seven (14%) for over twenty years (Table 3.1).

Table 3.1 Characteristics of pharmacists and pharmacies involved in the observational study (stage 3).

Characteristics	(n=51)	
	No of prescription items dispensed	(%)
Gender		
Male	41	(82)
Female	10	(18)
Age		
20-30	5	(10)
31-40	21	(41)
41-50	21	(41)
>50	4	(8)
Years being registered		
0-10	15	(29)
11-20	29	(57)
>20	7	(14)
Employment status		
Proprietor	34	(67)
Manager	10	(19)
Locum	7	(14)
Number of Staff		
One	20	(39)
Two	14	(27)
Three	10	(20)
More than three	7	(14)
Staff composition		
Counter assistants	36	(71)
C. Assistant* + Pre-reg**	3	(6)
C. Assistant +D.Technician***	7	(14)
C. A*+ D.Technician +Pre-reg	5	(10)
PMR		
Yes	50	(98)
No	1	(2)
Counselling area		
Purpose built	5	(10)
Quiet area	33	(63)
None	13	(27)

*Counter assistant/s

** Pre-registration trainee

***Dispensing Technician/s

Pharmacist- patient interaction and counselling

The total number of observed dispensed items were 1496, of which 458 (31%) were accompanied by oral counselling. However, the rate of interaction observed between pharmacists/pharmacy staff and patients was much higher than oral counselling provision (833 items i.e. 58%). The nature of these interactions varied from providing oral counselling to inquiring about patients' general well-being or even purely social conversations. Pharmacists handed out 1057 (71%) of dispensed items, followed by counter assistants 294 (20%), dispensing technician 74 (5%) and pre-registration students 55 (3.7%) (Table 3.1).

Prescription Characteristics

The total of 1496 observed items consisted of 1426 (95%) medications prescribed on NHS prescription forms and 70 (5%) as private prescriptions (Table 3.2). The majority, 1236 (83%), of items supplied on NHS forms were exempt from prescription charges, 252 (17%) were paid for. Overall, 633 (44%) of items were either the only one or one of two medications prescribed on a prescription form. As many as 149 (10%) of items were prescribed as prescription forms containing three to five items. Ten (1%) prescription forms included seven to nine medication items (Table 3.6). Where possible, the status of prescriptions as new or repeat was established. This information was obtained in 514 (34%) cases. Of these 383 (26%) were repeat medications and 131 (9%) were prescribed for the first time.

Patients' characteristics

Table 3.2. shows that 166 (11%) dispensed items were for children aged up to 16 years old, 633 (43%) were for adult (16-60) years and 665 (45%) were for those over 60 years.

Frequencies of dispensed medications according to formulation

Items were also categorized according to formulation. Oral solid dosage forms comprised 920(62%) of items and oral liquid 175(12%). There were the most frequently dispensed. Formulations of the remaining dispensed items in a descending order of frequency were ointment/cream and other topical preparations(9%); inhalers and sublingual, 110(7%); eye and ear and nasal preparations, 74(5%); reagents and appliances, 44(2.9%); dressing and patches; 19(1.3%) and suppositories and pessaries, 12 (0.8%) as illustrated in Table 3.4 and Figure 3.3.

Table 3.2 Characteristics of prescription items dispensed during the observational study (stage 3).

Characteristics	n =1,496	
	No of prescription items dispensed	(%)
Type of prescription items dispensed		
NHS	1426	(95.3)
Private	70	(4.7)
NHS prescription items and charges		
Exempt from payment	1236	(82.6)
Paid for prescription charges	252	(16.9)
Missing	8	(0.5)
Prescription items were		
Repeat medications	384	(25.7)
New medications	132	(8.8)
Unknown	980	(65.5)
Patient's age		
Child	166	(11.1)
Adults (16-60 years)	633	(42.5)
Elderly (over 60)	665	(44.5)
Missing	42	(1.9)
Prescription items handed out by:		
Pharmacist	1057	(70.7)
Dispensing Technician	74	(4.9)
Pre- reg student	55	(3.7)
Counter assistant	294	(19.7)
Missing	16	(1.0)
Oral counselling was provided:		
Yes	458	(30.6)
No (missing data = 5)	1033	(69.1)
Pharmacist- patient interaction		
Yes	833	(55.7)
No	663	(44.3)

Table 3.3 Variations of oral counselling by number of items per prescription form

No of items per prescription form	Items dispensed		Items counselled	
	No	(%)	No	(%)*
One	459	(55.8)	196	(42.5)
Two	408	(24.8)	148	(36.3)
Three	303	(12.3)	66	(21.8)
Four	128	(3.9)	28	(21.9)
Five	80	(1.9)	20	(25.0)
Six	47	(0.9)	0	(0)
Seven	7	(0.1)	0	(0)
Nine	18	(0.2)	0	(0)
Total	1496	(100)	458	---

* Dispensed items receiving counselling as a percentage of total items dispensed per each group

Table 3.4 Variations of oral counselling by pharmaceutical formulation of the dispensed items in stage 3

Formulations	Items dispensed		Items counselled in each category	
	No	(%)	No	(%)*
Eye/Ear/Nose prep.	74	(4.9)	34	(45.9)
Oral liquid	175	(11.7)	65	(37.6)
Oral solid	920	(61.5)	295	(32.1)
Suppository & Pessary	12	(0.8)	3	(25.0)
Topical preparations	139	(9.3)	33	(23.9)
Dressing & Patches	19	(1.3)	4	(20.6)
Reagents & appliances	44	(2.9)	8	(18.2)
Inhaler/Sublingual	110	(7.4)	15	(13.6)
Total	1496	(100%)	458	--

* Dispensed items receiving oral counselling as percentage of total items dispensed in each pharmaceutical formulation group

Figure 3.1 Prescription items observed in stage 3 by number of items per prescription form

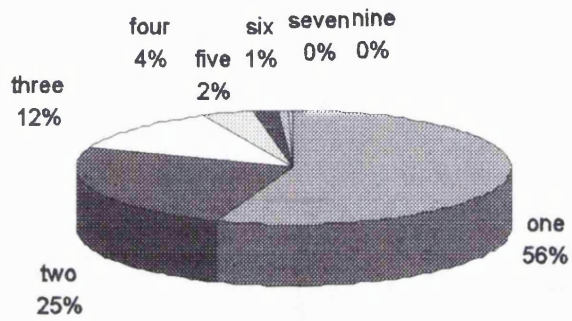


Figure 3.2 Variation of oral counselling in stage 3 for prescription items by number of items per prescription form

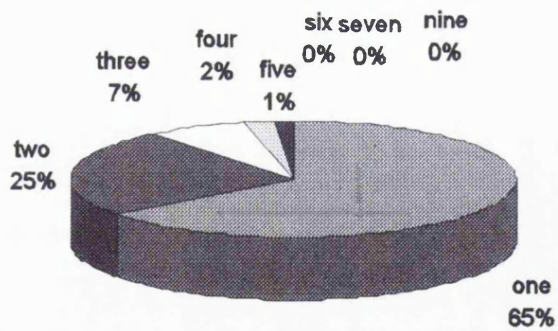


Figure 3.3 Prescription items observed in stage 3 by pharmaceutical formulations

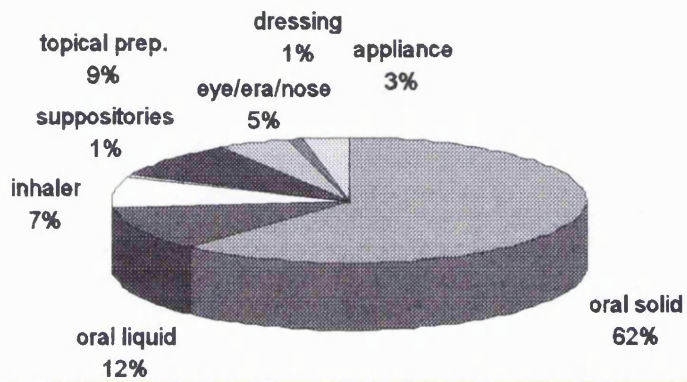
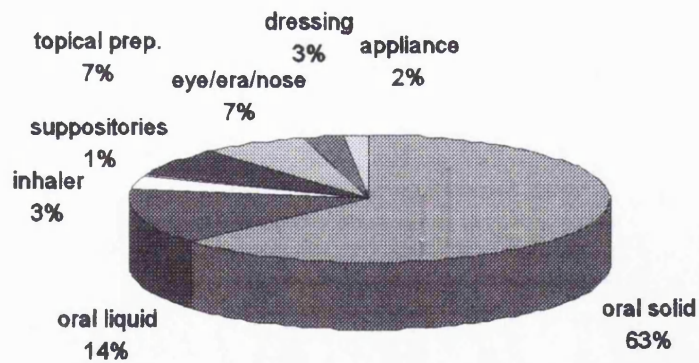


Figure 3.4 Prescription Items counselled in stage 3 by pharmaceutical formulations



Therapeutic categories of dispensed medications

When dispensed items were categorised according to therapeutic group as in the British National Formulary, the most frequently dispensed items were (in descending order): medications for Central Nervous System, 249 (17%); Cardiovascular, 224 (16%); Infection, 193 (13%) and Respiratory, 177 (12%). Other therapeutic groups consisted of too few items to be categorized separately hence they were all placed in “others” group (Table 3.5 and Figure 3.5).

3.4.2 Bivariant analysis of provision of oral counselling on dispensed medications

A series of bivariant analyses were carried out to investigate the association of oral counselling provision and characteristics of pharmacies, pharmacists, patients, prescriptions, therapeutic categories and pharmaceutical formulation of dispensed items.

Variations by pharmacies' characteristics

Prescription items dispensed in single independent proprietor pharmacies (where the proprietor pharmacist owned one pharmacy), ($X^2=18.92$, $p\leq 0.001$, $n=1496$) and fewer staff received significantly more oral counselling (Kruskal-Wallis 1-way Anova, $X^2=22.16$, $p\leq 0.001$, $n=1496$). The second highest rate of oral advice was provided in pharmacies employing pre-registration students, followed by pharmacies with dispensing technicians. It was noted that pharmacies employing both a pre-registration student and a dispensing technician gave the lowest level of oral advice to patients, however, this could be due to having a smaller number of these pharmacies in the sample. (Table 3.7).

Having a purpose built counselling area did not significantly increase the level of oral counselling ($p=0.104$, $n=1496$). Computerised patient medication records in pharmacies significantly increased provision of oral advice given for dispensed medication, however, it should be borne in mind that there was only one pharmacy without computerised patient medication record in this sample (Table 3.7).

Table 3.5 Variations of oral counselling by therapeutic classifications (according to the British National Formulary) of the dispensed items in stage 3

Therapeutic categories	Items dispensed		Items counselled in each therapeutic group	
	no	(%)	no	(%)*
Infection	193	(13.3)	136	(70.5)
Eye/Ear/ Nose/ oropharynx	88	(5.9)	40	(45.5)
Others	43	(3.0)	19	(44.2)
Musculoskeletal	114	(7.9)	42	(36.8)
Obstetric/ Gynecology	44	(3.0)	12	(27.3)
Respiratory	177	(12.2)	45	(25.4)
Central Nervous System	249	(17.2)	62	(24.9)
Gastro-intestinal	113	(7.8)	27	(23.9)
Skin	125	(8.6)	26	(20.8)
Endocrine System	77	(5.3)	15	(19.5)
Cardiovascular	224	(15.5)	20	(8.9)
Total	1496	100	458	---

* Dispensed items receiving oral counselling as a percentage of total items dispensed in each therapeutic group

Table 3.6 Variations of oral counselling for dispensed items in stage 3 by patients' age groups

Patients' age	Prescription items dispensed		Prescription items counselled	
	No	(%)	No	(%)*
Child (<16)	166		78	(47.0)
Adults (16-60)	634	(11.3)	232	(36.3)
Elderly	662	(43.4)	145	(21.8)
Data not available	34	(45.3)	-	-
Total	1496	100%	458	-----

*Dispensed items receiving oral counselling as a percentage of total items dispensed for each patients' age group

Figure 3.5 Prescription Items observed In stage 3 by the BNF therapeutic categories

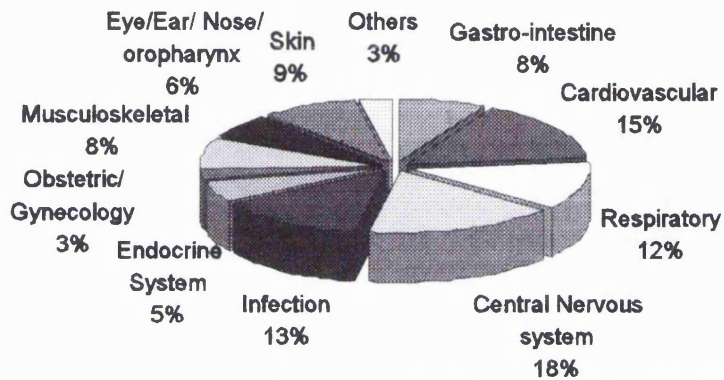
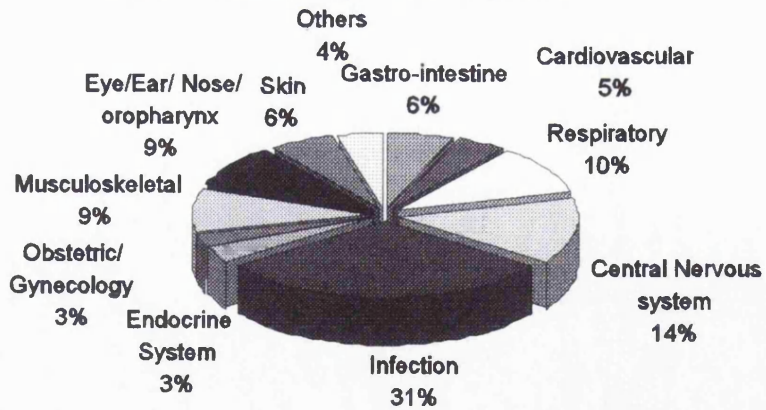


Figure 3.6 Prescription Items counselled In stage 3 by the BNF therapeutic categories



Variation by pharmacists' characteristics

Female pharmacists counselled almost half of the dispensed medications they gave out which was significantly more than male pharmacists, who gave oral advice on less than third of the items dispensed (Kruskal-Wallis, $p \leq 0.001$, $n=1496$). Pharmacists' age and number of years that they were registered was not found to be associated (Wilcoxon, $Z=117.57$, 2 tailed $p \leq 0.001$) for the pharmacists participated in this study. Therefore throughout the analysis these two characteristics were treated as independent variables. Pharmacists' age was found not to have a significant effect on provision of oral counselling. The employment status and number of years that pharmacists were registered had both significant associations with counselling level (Kruskal-Wallis, $n=1469$, $p=0.023$ and $p=0.021$ respectively). Results indicated that owner/manager pharmacists, followed by employee managers, were more likely to provide oral counselling than locum pharmacists. The highest oral counselling was provided by pharmacists who had been registered for more than thirty years. Pharmacists registered for 10-20 and 20-30 years gave a similar level of oral advice whereas those who had been less than 10 years provided the least oral counselling on dispensed medications (Table 3.7).

Variations by prescription characteristics

There was a significant difference between the level of oral advice that accompanied dispensed items on private prescriptions and those on NHS prescriptions (Table 3.8). Half of dispensed items on private prescriptions received oral counselling in comparison to one third of items on National Health Service forms (Mann-Whitney U-test, $z=-2.785$, $p=0.005$, $n=1469$). Similarly a higher proportion of NHS items that were paid for received oral advice in comparison to those NHS items that were exempt from payments (Mann-Whitney U-test, $z=-7.237$, $p \leq 0.001$, $n=1469$). Where the status of prescribed items as new or repeat was established, it was found that 70% of new items received oral advice in comparison to 20% of repeat items, a difference which was statistically significant (Mann-Whitney U-test, $z=-10.603$, $p \leq 0.001$, $n=1469$).

Table 3.7 Variations of oral counselling for dispensed items by pharmacists' and pharmacies' characteristics in stage 3.

Characteristics	Items for which counselling was provided (n=1496)		p value
	No of items	(%)	
Gender			
Male	344	(27.9)	0.000
Female	114	(44.5)	
Age			
20-30	54	(31.6)	0.882
31-40	199	(31.7)	
41-50	166	(29.2)	
>51	39	(31.5)	
Years being registered			
0-10	124	(25.6)	0.021
11-20	268	(32.9)	
21- 30	49	(30.6)	
>31	17	(53.1)	
Employment status			
Proprietor	321	(33.5)	0.023
Manager	81	(28.1)	
Locum	56	(22.8)	
Number of Staff			
One	209	(39.5)	0.000
Two	99	(22.6)	
Three	92	(27.4)	
More than Three	58	(31.0)	
Staff composition			
Counter assistants	355	(34.7)	0.000
D. Technician	37	(20.0)	
C. Assistant + Pre-reg	53	(27.2)	
C. A+ D. Tech+Pre-reg	13	(14.1)	
PMR			
Yes	440	(30.2)	0.07
No	18	(51.4)	
Counselling area			
Purposely Built	54	(38.3)	0.104
Quiet area	273	(28.6)	
None	131	(33.2)	

There was an inverse correlation between the number of items dispensed for a patient and the oral counselling they received: the higher the number of items the lower the counselling given ($X^2=100.660$, $p\leq 0.001$, $n=1469$), (Table 3.3). Two measures were used as proxy of dispensing workload, one was the total number of items dispensed in three hour period of observation and the second was the number of items dispensed in each hour as counted during the observation study (stage 3) and referred to as “pharmacy busyness”. The latter measure was more reflective of the fluctuation of pharmacists’ dispensing workload. It was found that neither the total items dispensed nor the busyness of pharmacies had any association with the level of oral counselling (number of medications advised as a percentage of total items dispensed) by pharmacists.

The counselling rate differed significantly depending on who handed out the prescription (Kruskal-Wallis, $X^2=67.315$, $p\leq 0.001$, $n=1496$). Pharmacist counselled patients the most (38%) followed by preregistration students (29%) , dispensing technicians (19%) and counter staff (8%).(Table 3.7)

Variations by patients’ age

Results indicated that the likelihood of receiving oral counselling for a child’s medication was twice as that for medications for a person aged 60 or over, and that adults (16-60 years) were 50% more likely than elderly to receive counselling. This variation was statistically significant (Kruskal-Wallis, $X^2=35.083$, $p\leq 0.001$, $n=1496$). (Table 3.6)

Variations by therapeutic groups

There was a significant association between the level of oral counselling and the therapeutic group of the dispensed medications (Kruskal-Wallis; $X^2=150.035$; $p\leq 0.001$; $n=1496$). Items for infections received the highest oral counselling (70.5%) followed by preparations for eye,ear and nose (46%) and musculoskeletal (37%) whilst cardiovascular medications had the lowest oral advice at only 9%. (Table 3.5 and Figure 3.6)

Variations by pharmaceutical form

Provision of oral counselling was significantly associated with the formulation (Kruskal-

Wallis; $X^2=22.028$; $p \leq 0.001$; $n=1496$). Almost half (46%) of the preparations for eye, ear and nose were accompanied by oral advice followed by oral liquids (38%) and oral solids (32%) preparations. Counselling was least likely to be provided for medications formulated as inhalers and sublingual items. (**Table 3.4** and **Figure 3.4**)

Frequency of oral counselling components

The list of components covered and frequency with which they were raised during oral counselling is shown in **Table 3.9**. Dosage (80%), purpose (42%) and time of dosage in relation to food (21%) were the most frequently raised issues in the oral counselling. Among the least advised were adverse drug reactions (6%).

Variations of oral counselling components by prescription status

Variations in the actual issues raised during oral counselling for new and repeat medications is tabulated in **Table 3.9**. The overall counselling rate for new medications (75%) was almost four times higher than that for repeat medicines (20%). A similar trend was observed for specific counselling components. The frequency of all components for new items were almost four times higher than repeat medications with the exception of “time of dosage in relation to food” which was advised with the same frequency for new and repeat items.

Table 3.8 Variations of oral counselling on dispensed items by prescriptions' and patients' characteristics

Characteristics	Items for which counselling was provided (n=1496)		
	No of items	(%)	p value
Oral counselling was provided:			
Yes	458	(30.6)	
No (missing= 5)	1033	(69.1)	
Pharmacist- patient interacted			
Yes	833	(55.7)	
No	663	(44.3)	
Prescription characteristics			
NHS	426	(30.0)	0.05
Private	32	(45.7)	
Exempt	331	(26.9)	
Paid	126	(50.0)	<0.001
Repeat	76	(19.8)	
New	98	(74.8)	<0.001
Unknown	284	(29.0)	
No of items on prescription	(Refer to table 3.6)		<0.02
Patients' age	(Refer to table 3.7)		<0.001
Prescription handed out by:			
Pharmacist	(38.3)	404	
Dispensing technician	(18.9)	14	<0.001
Pre-registration student	(29.1)	16	
Counter assistant	(7.8)	23	
Type of dispensed items by:			
Therapeutic group	(Refer to Table 3.8)		<0.001
Pharmaceutical formulation	(Refer to Table 3.9)		<0.001

Variations of oral counselling components by therapeutic group

Table 3.10. illustrates variation in the issues raised for different therapeutic groups. Across all therapeutic groups dosage was the most commonly raised issue. Medications for infections had the highest numbers of components advised. Warnings regarding contra-indication of the medication were the most commonly raised in gastro-intestinal group (19%) followed by musculoskeletal(10%) medicines. Adverse drug reactions were most frequently raised for medications in obstetric and gynecology (17%), central nervous system (15%) and respiratory (13%) groups. Demonstration of use of medications were mainly provided for central nervous system (21%), respiratory (16%), obstetric and gynecological(17%) and skin (12%) items. The rate of oral advice on the maximum dosage of medications to be taken was the highest for items in central nervous system (16%) group. Time of taking dosages of the medication in relation to food was advised most commonly for musculoskeletal (69%) items followed by anti-infective (32%), gastro-intestine (22%) medications. The rate of interaction between pharmacists and patients, as the counselling rate, differed according to therapeutic groups. However, there was less fluctuation in interaction levels than there was in counselling rate.

3.4.3 Further Analysis of provision of oral counselling for dispensed medications

To construct a model including significant variables influencing provision of oral counselling on dispensed medications a discriminant analysis was first performed in order to identify variables to be entered into the model. After a list of variables was drawn, a multiple regression model was attempted in order to quantify the level of contribution of each variable in predicting the level of counselling. The model only explained 18.5% of the cases. Data analysis illustrated that antibiotic items and medications for children received the highest level of oral counselling. Therefore it was decided to construct three separate multiple regression models for age groups (children, adults (16-60 years) and elderly) and compare the results in search of more explanation for variation of oral counselling provision. A similar approach was taken for antibiotic medications and the result was compared with the general findings of stage 3 of the study.

Table 3.9 Issues covered during oral counselling of dispensed items in stage 3.

Counselling components	Number of times covered					
	Total items (%)		New items (%)		Repeat items (%)	
Dosage	365	(79.7)	78	(59.5)	51	(13.3)
Purpose	190	(41.5)	46	(35.1)	24	(6.3)
Time of dosage in relation to food	98	(21.4)	7	(5.3)	20	(5.2)
Hours between doses	39	(8.5)	9	(6.9)	5	(1.3)
Storage	25	(5.5)	8	(6.1)	1	(0.3)
ADRs	25	(5.5)	6	(4.6)	1	(0.3)
Maximum Dose	25	(5.5)	7	(5.3)	5	(1.3)
Contra-indication and interaction with OTC medicines	24	(5.2)	6	(4.6)	5	(1.3)
Changes of dosage or/and strength	20	(4.4)	-	-	15	(3.9)
Demonstration	19	(3.9)	5	(3.8)	3	(0.8)
Food/Drink to avoid	14	(2.8)	5	(3.8)	0	(0)
Total items	1496	(100)	131	(100)	383	(100)
Total counselled items	458	(30.6)	98	(74.8)	76	(19.8)

Table 3.10. Counselling issues that were covered for dispensed items in stage 3 according to their therapeutic group.

	GI no (%)	Cardio-vascular no (%)	Resp. no (%)	CNS no (%)	Infection no (%)	Endocrine no (%)	Obs/Gyn no (%)	Musclsket no (%)	Eye/ear/ nose no (%)	Skin no (%)	Others no (%)
no in each therapeutic group	113	224	177	249	193	77	44	114	88	125	43
Total counselled	27(24)	20(9)	45(25)	62(25)	136(71)	15(20)	12(27)	42(37)	40(46)	26(21)	19(44)
Total Interacted	52(46)	123(55)	92(52)	127(51)	136(71)	43(56)	23(53)	56(49)	45(51)	64(51)	19(44)
Dose	23(85)	13(65)	32(71)	51(82)	121(89)	14(93)	11(92)	37(88)	34(85)	24(92)	4(21)
ADRs	0(0)	0(0)	6(13)	9(15)	4(3)	0(0)	2(17)	2(5)	1(3)	1(4)	0(0)
Avoiding food/drink	0(0)	0(0)	1(2)	2(3)	10(7)	0(0)	0(0)	0(0)	0(0)	0(0)	0(0)
Change	3(11)	1(5)	4(9)	2(3)	0(0)	1(7)	0(0)	1(2)	1(3)	0(0)	0(0)
Contraindication	5(19)	1(5)	2(4)	4(7)	5(4)	1(7)	1(8)	4(10)	1(3)	0(0)	0(0)
Demonstration	27(0)	1(5)	7(16)	13(21)	1(0.1)	0(0)	2(17)	1(2)	3(8)	3(12)	0(0)
Dosage before or after food	6(22)	1(5)	1(2)	7(11)	44(32)	2(13)	2(17)	29(69)	1(4)	1(4)	0(0)
Interval of doses	0(0)	2(10)	3(7)	2(3)	24(18)	0(0)	2(17)	1(2)	0(0)	0(0)	1(5)
Maximum dosage	2(7)	0(0)	4(9)	10(16)	5(4)	0(0)	0(0)	1(2)	1(4)	1(4)	0(0)
Storage	0(0)	2(10)	0(0)	0(0)	11(8)	0(0)	1(8)	0(0)	1(4)	1(4)	4(21)

3.4.4 Discriminant analysis of oral counselling

To explore variables which determined the provision of oral counselling on dispensed medications, a discriminant analysis was performed. This technique is used where the variables are mainly quantitative and the criterion variable is dichotomous, e.g. Yes and No. The use of discriminant analysis carries some restrictive assumptions, e.g. data are multivariate normal and variance-covariance matrices are homogenous. Normality of distribution was checked by plotting the data. A correlation matrix was generated for all variable combinations which was subsequently inspected for correlation coefficients greater than 0.55 to minimize multicollinearity, a condition where the variables are very highly (though imperfectly) correlated. The data was also searched for outlier which were removed from the data set.

A stepwise discriminant analysis was used in which statistical criteria determined the order of variables entry and Wilks' Lambda (Λ) a commonly used statistic for this type of analysis weighed up the addition or removal of variables from the analysis. Wilk's Lambda evaluates the hypothesis that two or more groups come from populations with the same means for a set of variables and its value ranges between 0 and 1 with one indicating that groups are all the same. The significance of change in Wilks' Lambda (Λ) when a variable is entered or removed is obtained and forms a "F test". At each step of analysis after adding a variable, the variable with the largest F value was included and the one with the lowest F value was removed. This process was repeated until there were no further variables above or below the threshold values of 2.71 and 3.84. The variables remaining in the analysis were used in discriminant function which provides the best means of predicting the outcome of the dependent (provision of oral counselling on dispensed medications) variable. The discriminant function had 0.80 for Wilks' Lambda and accounted for 100% of the variance (chi square=175.58; p=0.000; n=1496). **Table 3.11** represents the structure matrix which is a table of pooled within groups correlations between the nine selected discriminating variables and the function.

Table 3.11 Discriminant analysis of variables for the prediction of provision of oral counselling on dispensed items.

No.	Variables	Function
1	Professional status of person handing out dispensed items	-0 .630
2	Pharmacy staff composition	-0 .377
3	Patient's age	-0.347
4	Exempted from prescription charges or paid	0.345
5	No of items on the prescription form	-0.329
6	Number of total items dispensed	-0 .257
7	Number of pharmacy staff	-0.256
8	Pharmacist' gender	0.249
9	Pharmacist's employment status	-0.154
10	Repeat or new items	0.149
11	Availability of counselling area	-0.099
12	Pharmaceutical form of items	-0.084
13	NHS or private prescription	0.081
14	Therapeutic category of dispensed items	-0.065
15	Pharmacist' age	-0.061

The value of discriminant function reflects the magnitude by which each variable predicts the provision of oral counselling on dispensed medications. Negative values represent an inverse correlation between variables and the outcome. The outcome of the discriminant analysis indicated that the highest level of oral counselling for dispensed medications is provided for dispensed items that are given out by a pharmacist who is an owner manager or employee manager in a smaller pharmacy or has both dispensing technician and a preregistration student. It is more likely that oral advice is provided if items are given out by a female pharmacist and the medication is for a child, prescribed for the first time, paid for or is privately prescribed with fewer items on prescription form and if the pharmacy is less busy dispensing fewer items. Availability of counselling area increases the likelihood of receiving oral advice on dispensed medication especially if it is a special formulation such as eye drops or it belongs to anti-infective therapeutic group.

To assess the success rate of the discriminant function developed in this analysis to predict provision of oral counselling for dispensed medications in community pharmacies a summary table was constructed. **Table 3.12** indicates that the overall success rate is 67.34%. and that 72.9% of medication which receive oral counselling can be successfully identified using the combination of variables derived from the analysis, the rate of success for prediction of medications that would not receive oral counselling is slightly less at 64.9%.

Table 3.12 Summary of prediction of provision of oral counselling on dispensed medication using discriminant analysis

Counselling provided		Predicted numbers		Total
		No	Yes	
Number	No	670	363	1033
	Yes	124	334	458
%	No	64.9%	35.1%	100%
	Yes	27.1%	72.9%	100%

3.4.5 Multiple regression analysis of provision of oral counselling on dispensed medications

Multiple regression analysis was performed in order to establish predictive values of each independent variables on provision of oral counselling on dispensed medication. The variables listed below were all entered into the model, the majority of which were significantly associated with provision of oral counselling at the $p < 0.05$ level.

A combination of the following variables were tested in the model:

- Pharmacist's gender
- Pharmacist's age
- Pharmacist's employment status

- Number of years of being registered as pharmacist
- Availability of purpose built counselling area, quiet area or neither
- Availability of computerized Patient Medication Record
- Pharmacy staff number and composition
- Total number of items dispensed
- Number of items handed out by different member of staff
- Total number of items handed out by pharmacist
- Number of items on a prescription form
- Patient's age
- Types of prescription: private or National Health Service
- Exempt from prescription charges
- Repeat or new medication
- Therapeutic group of item dispensed
- Formulation of items dispensed

I. Model one: provision of oral counselling for dispensed medications

A combination of eight variables were accepted in model one (Table 3.13). In descending order of association and degree by which each variable could predict provision of oral counselling on dispensed medication they were: professional status of the person who handed prescription items out (8.8%), patient's age (2.8%), composition of staff (2.3%), number of items on the prescription form (1.6%), whether the item was paid for or not (1.2%), was repeat or new (0.9%), employment status (0.5%) and age of pharmacist (0.4%). Although the F statistic which represents how well the model fits the data and provides evidence of a linear relationship was significant ($F=23.62$; $p<0.001$), based on r^2 value the model only explained 18.5% of variation of oral counselling provided for dispensed medication. The model shows that all independent variables except two ("repeat or new" and "paid or exempt") were inversely related to the dependent variable. The multiple regression equation of provision of oral counselling is as follows:

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[Provision of counselling = -0.119x (who handed the prescription out) + -0.124x (patient's age) + -0.054x (composition of staff) + -0.057x (no of items on the prescription) + 0.136x (paid or exempt status) + 0.062x (repeat/new item) + -0.049x (pharmacist's employment status) + -0.049x (pharmacist's age) + 6.830 (model constant*)]

**(6.830 is the value of the model's constant)*

Dispensed items which received higher rate of oral counselling were:

- handed out by pharmacist
- items dispensed for children, followed by medications for adults (16-60 years) with older patients (over 60) receiving the least oral counselling on their dispensed medications
- dispensed in smaller pharmacy
- had less number of items on the prescription form
- paid for
- for new medication
- handed out by owner/ manager pharmacist followed by pharmacy manager and then locum pharmacist
- handed out by younger pharmacist

Model one suggests that overall medications dispensed in a small independent pharmacy and handed out by younger owner/manager pharmacist receive higher level of oral counselling. There is an increase in level of oral advice if the item is a new medication dispensed for a child or alternatively is a new medication which is paid for and was for an adult (16-60).

Table 3.13 Model 1: a regression model for provision of oral counselling on dispensed medications

Predictive variables	B*	Adj. R ² #	t value**	p value
Who handed the prescription out	-0.119	0.088	-8.791	0.000
Patients' age	-0.124	0.028	-5.131	0.000
Composition of staff	-0.054	0.023	-4.726	0.000
Number of items on the prescription form	-0.057	0.016	-4.015	0.000
Paid or Exempt from prescription charges	0.136	0.012	3.458	0.000
Repeat/new item	0.062	0.009	3.214	0.000
Pharmacist' employment status	-0.049	0.005	-2.410	0.000
Pharmacist' age	-0.449	0.004	-2.188	0.000
Model's constant	6.830			
Model's R²	0.193			
Model's adjusted R²	0.185			
n	1496			
No of items handed out by pharmacists (%)	1057(71%)			

Key: **B**: regression coefficient

Model's R²: a positively biased estimate of the proportion of the variance of the dependent variable accounted for by regression

Model's Adj. R²: corrects R² bias and therefore has a lower value

n: Total number of dispensed items

t value: t-test for testing the regression coefficient for significance

p value: the p-value for t (0.00 means t is significant beyond the 0.01 level for the variable concerned)

Further multiple regression models of provision of oral counselling for specific groups of patients and medications

To explore the predictive variables influencing outcome of oral counselling on dispensed medications for patients in different age groups, three separate models were constructed for children, adults (16-60 years) and elderly patients using multiple regression. The fifth model was constructed based on the level of oral counselling provided for anti-infective medications in stage three. A stepwise approach was used in all three models.

II. Model two: provision of oral counselling for dispensed medications for children

From 1496 dispensed items observed in stage 3, 166 (11.3%) were for children out of which 78 (47%) received oral counselling. Model two was constructed to identify predictive variables for oral advice on children's dispensed medications. This model shows that a higher level of oral counselling is offered for children's medications:

- When there is a female pharmacist handing dispensed items out
- When the medication is new and prescribed for the first time

The pharmacist's gender explained 14.9% of the variation and status of prescriptions as repeat or new explained a further 7.8%. This model can explain 22.7% of variations in provision of oral counselling for dispensed medications for children (**Table 3. 14**).

Table 3.14 Model 2: provision of oral counselling on dispensed medications for children

Children	variables	B	Adj. R²	t value	p value
Predictive Variables	Pharmacist's gender	156532	0.149	3.407	0.001
	Repeat/new item	-75831	0.078	-2.369	0.022
Model's constant		229334			
Model's R²		0.260			
Model's adjusted R²		0.227			
n		78			
No. of items handed out by pharmacists(%)		63 (81%)			

III. Model three: provision of oral counselling for dispensed medications for adults (16-60 years) patients

During stage 3, 634(43.4%) observed dispensed items were for adults (16-60 years). Number of items for which oral advice was provided were 232 (36.3%). A multiple regression model was constructed to explore the degree to which each variable contributed in predicting provision of oral advice for dispensed medication for this patients' age group. Model three indicates that a higher level of oral counselling is offered for these patients' dispensed medications when:

- Consultation or quiet area is available
- Owner/manager or employed manager pharmacist hands the medication out
- Pharmacy is less busy
- The medication is prescribed on a private prescription
- Pharmacists are registered for longer than 5 years
- When the medication is new and prescribed for the first time

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The percentage by which each variable explained the variations of oral counselling of dispensed medications for adults (16-60 years) are availability of consultation/quiet area 13%; employment status of pharmacist, 5%; total number of items dispensed, 5.9%; prescription form being NHS or private, 3.5%; pharmacist's years of being registered, 2.2%; and finally whether medication was new or repeat, 2.3%. Overall the model explained 30.3% of variation.

Table 3.15 Model 3: provision of oral counselling on medications dispensed for adults (16-60).

Adults (16-60 years)	variables	B	Adj. R ²	t value	p value
Predictive Variables	Counselling area	-66912.683	0.130	-3.933	0.000
	Employment status of the pharmacist	80898.313	0.050	5.380	0.000
	Total items dispensed	-2057.639	0.059	-3.078	0.003
	NHS/ Private prescription	81656.000	0.035	2.238	0.027
	Years of being registered	45829.924	0.022	2.428	0.016
	Repeat/new item	-31028.35	0.023	-2.181	0.031
Model's Constant value		193937.860			
Model's R²		0.329			
Model' adjusted R²		0.303			
n		232			
No of items handed out by pharmacists(%)		204(88%)			

IV. Model four: provision of oral counselling for dispensed medications for elderly patients

There were 662 (45.3%) medication items for elderly patients in the observed sample in stage 3. Oral advice was provided for 145 (21.8%) of these items. To determine the predictive value of significant variables for provision of oral counselling on dispensed medications model four was constructed. This model demonstrates that a higher level of oral counselling of dispensed medications is offered for elderly patients when:

- Consultation or quiet area is available
- Owner/manager or employed manager pharmacist hands the medication out
- Pharmacists are registered for longer than 5 years
- A medication prescribed on private prescription
- When the medication is prescribed for the first time

Overall this model explained 55.2% of variation in provision of oral counselling for elderly patients when receiving dispensed medications. The following are percentages by which each variable explained the variation: availability of consultation/quiet area; 16%, employment status of the pharmacist; 13.2%, how long pharmacist has been registered; 18.5%, prescription form being NHS or private; 15.1%, and finally whether medication was new or repeat; 3.6%. (Table 3.16)

V. Model five: provision of oral counselling for medications prescribed for infections

During stage 3 a total of 1491 medication items were observed out of which 456 (30.7%) received counselling. 193 of the items observed were antibiotics and 136 (70.5%) of these medications were counselled for. The bivariant analysis illustrated that there were few variables which significant effected the provision of oral counselling ($p < 0.05$). To explore predictive variables for provision of oral counselling medications prescribed and dispensed for infections model five was constructed using multiple regression analysis.

Table 3. 16. Model 4: provision of oral counselling for medications dispensed for elderly patients

Elderly	variables	B	Adj. R²	t value	p value
Predictive Variables	Counselling area	-64337	0.160	-3.566	0.001
	Employment status of the pharmacist	127738	0.132	6.632	0.000
	Years being registered	113163	0.185	5.932	0.000
	NHS/ Private prescription	145194	0.151	2.824	0.006
	Repeat/new item	-31520	0.036	-2.284	0.025
Model's constant value		-189766			
Model's R²		0.581			
Model's adjusted R²		0.552			
n		143			
No. of items handed out by pharmacists(%)		134(92%)			

Model five indicates that the higher level of oral counselling for medications used for infections were provided when:

- Items are handed out first by owner/manager pharmacist followed by employee pharmacist with the least oral advice given by locum pharmacist
- Pharmacy is quieter and had less items to dispensed
- Prescription is paid for
- The older the patient the more oral advice on antibiotics are given

This model explained 30% of variations in provision of oral advice for items used for infection the degree by which each variable can predict the outcome is as follows: pharmacist's employment status; 11.3%, total items dispensed; 9.0%, whether prescription is paid for or exempt from prescription charges; 5.1%, patient's age; 4.6%.

Table 3. 17 Model 5: provision of oral counselling for medications used in infections.

Anti-infective medications	variables	B	Adj. R²	t value	p value
Predictive Variables	Pharmacist's employment status	63008	0.113	3.828	0.00
	Total items	-2922	0.203	-3.606	0.00
	Exempt/paid for NHS prescription charges	72831	0.254	2.856	0.01
	Patients' age	48035	0.300	2.783	0.01
Model's constant value		5558			
Model's R²		0.326			
Model's adjusted R²		0.300			
n		193			
No. of items handed out by pharmacists(%)		136 (71%)			

3.4.6 Validation of observation method

It should be noted again that pharmacy staff collected the data covertly and in the least intrusive manner which meant that they could only log the number of prescription forms handed out by pharmacists and not the number of prescription items on the forms. Consequently, the findings of the validation study were compared with the corresponding number of prescription forms handed out by pharmacists in observational study in stage 3. Some prescription forms contained more than one prescription item therefore the total number of prescription forms reported here may seem lower than the results reported elsewhere in stage 3.

During the validation study a total of 520 prescription forms was observed by pharmacy staff in twenty five pharmacies. The results were compared to the data obtained from 852 prescription forms observed in Stage 3 of this study (**Table 3.18**). The number of prescription forms handed out by pharmacists in the main study found to be 578 (67.8%) and in the validation study was 292 (56.2%). Although a higher promotion of prescriptions were handed out by the pharmacists in the main study this difference was not to be found significant (chi square=20,83,d.f=210, p=0.290). Despite not being statistically significant, it was interesting to see that the rate of counselling in the validation study was higher than the main study (33.3% verses 30.9%), (chi square=193.06, d.f=168, p=0.090). Differences in the results of the main and validation studies were not found to be statistically different and were in close agreement.

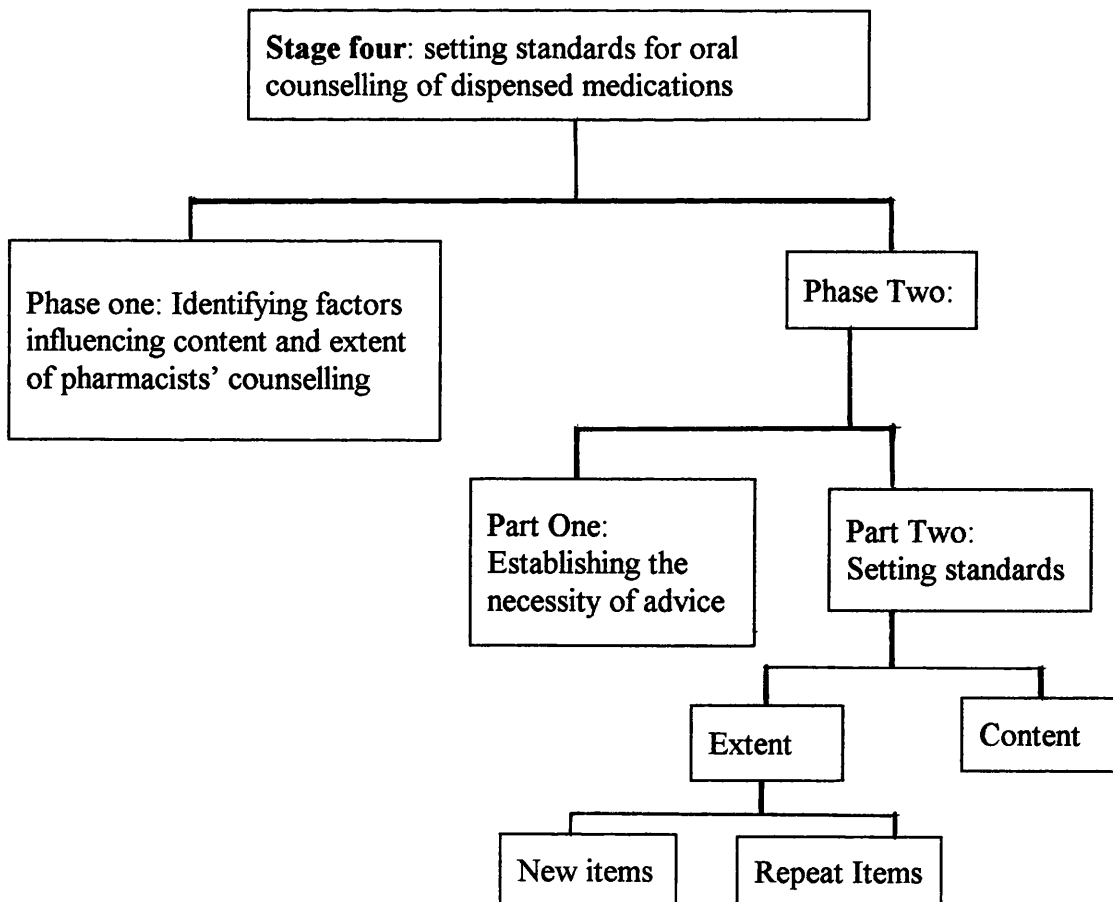
Table 3.18 Comparing provision of oral counselling obtained from the validation method with the observational data in stage 3

Prescription forms	Validation results		Results of stage 3		p value
	Prescription forms No .	(%)	Prescription forms No.	(%)	
Handed out by pharmacist	292	(56.2)	578	(67.8)	chi square=220,83, d.f=210, p=0.290
Counselled by pharmacist	173	(33.3)	263	(30.9)	chi square=193.06, d.f=168p=0.090
Total dispensed	520	(100)	852	(100)	

3.5 Stage four: Setting standards for oral counselling on dispensed medications

This stage consisted of two meetings or phases which took place in the morning and afternoon of the same day. Focus Group technique was employed to facilitate both meetings attending by the same group of six community pharmacists. The morning meeting or the first phase was exploratory with the objective of identifying factors influencing the extent and content of counselling on dispensed medications. To stimulate the discussion pharmacists were presented with a questionnaire containing nine multiple choice questions based on findings of the stage 3 including the rate of patient counselling in community pharmacies, provision of oral counselling in relation to patients' age, the most and least counselled therapeutic areas and the most and least counselled issues. (Appendix 4.3). The questionnaire also provided a structure for discussion..

Figure 3.7. Flow chart of Stage four of the study



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The focus group discussion of the same group of six community pharmacists in the afternoon meeting or the second phase included two parts. The first part addressed the issue of necessity of oral advice for dispensed medications. This resulted in an in depth discussion around pharmacists' counselling role, providing valuable insights into their perceptions and behaviours. The data generated from this discussion was combined with the data obtained from pharmacists' debate in the first phase.

To analyse these data two approaches were taken. Firstly to gain some understanding of factors influencing pharmacists' oral counselling behaviour with dispensed medications, the content of discussion was analysed in order to identify common themes and create categories, a report of which is presented in the first section. Secondly as the data was generated using a focus group discussion rather than one to one interviews, there was an element of participants' interactions which also needed to be taken into account. In order to capture dynamic of the group and its effects on the generated data, group interactions were analysed and the findings are reported in the first section.

In the second part of phase two, pharmacists set standards for the extent of oral counselling for repeat and new items before moving on to setting standards for the content of oral advice. Acknowledging the range of variables influencing the content of counselling, such as patients' attributes and medications' characteristics, pharmacists discussed and prioritised types of issues to be advised, without setting specific standards for this aspect of the service.

3.5.1 Factors influencing the extent and content of counselling services

Content analysis of the findings indicated that although pharmacists considered some of the issues proposed by the questionnaire important, they identified additional patients' traits and medication attributes which influenced their advisory behaviour. Therefore, when the content of the discussion was analysed new common themes emerged which subsequently resulted in new categories being created. The results are reported under these new categories. Pharmacists' discussions on the necessity and value of provision of oral counselling on dispensed medication is reported first, followed by the results of

the debate on factors influencing the extent and content of advice under the new categories as described above.

Should pharmacists provide oral advice on dispensed medications?

The discussion was prompted by an open question on safety of medications in general terms asking each participant to name a simple and safe medication that in the majority of cases did not require any oral advice. Participants named a few products including aqueous cream, antacids and simple linctus. However, other group members suggested a list of issues and information that patients could be counselled on in relation to these. The following is the example for aqueous cream:

“Aqueous cream, they want to know how to use it, the pharmacist may also be able to give patients advice on their skin condition and the frequent usage of aqueous cream to prevent excessive dryness of skin”. (4)

Each participant was then asked individually and they believed that no medication was simple or safe enough to warrant lack of provision of counselling by pharmacists. All the participants stated that they believed in counselling patients and were committed to it. However, their views of its delivery and patients' choice differed. Four pharmacists believed that the pharmacists' role was to empower patients through providing them with required information to make an informed choice on taking their medications e.g. :

“It will help patients to comply if the information is given on the medications and the side effects. They understand it better”. (4)

“I agree that oral counselling is necessary and important for patients to understand their medications and build up their confidence.” (6)

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This group advocated a customised counselling in which the pharmacist was guided by the patient as to the type and extent of advice needed, as exemplified by the following statements:

“The pharmacist should make himself available to patients and also to encourage the patient to ask questions important to them.” (1)

“ Counselling should start from the time you have a prescription in your hand before you dispense it. You should provide the information patients require to help them understand their medications.” (6)

The other two participants believed that it was pharmacists' role to judge the level of information the patient should receive. The followings are some of their comments:

“ You should be very careful especially with the elderly not to tell them too much about the side effects and contraindications. By telling them about ADRs they will not take their medications.” (2)

“ You have to assume that the patient does not know and just give them the necessary information and not waste patients' or your own time.” (5)

There was also a recognition by pharmacists that the provision of oral counselling on dispensed medications promoted their professional profile and was beneficial for their business.

“My patients complain that GPs don't have time. They say that they don't want to go to the doctor, as they think I help them more than the doctor and that makes me feel good and I want to do more and more for them.” (3)

“ They want to know about their medications, sometimes they say that they took their prescription to a multiple and the pharmacist did not advise them on their medications. They appreciate the information and it is good for the business too.” (5)

Factors influencing the extent of oral counselling on dispensed medications

Two categories of variables were identified as the main influencing factors on the extent of oral advice provided by pharmacists for dispensed medications. These were patients' characteristics and pharmacists' perception of patients' medication knowledge. In the course of the discussion some barriers to provision of oral counselling were also identified by pharmacists.

I. Patient characteristics

Three characteristics of patients identified by pharmacists as determinants of advice were: age, disease/ condition and desire and motivation to seek and receive advice.

(a) Patients' Age

The findings of the observation study in stage 3 illustrated that the counselling rate of dispensed medications was the highest for children, followed by adults (16-60 years) and older people. This was found to be an expected and acceptable practice by the participants:

“Children I tend to take more care of, making sure the mother understands the dosage and directions.” (4)

“If we think about patients at risk, we prioritise children as high risk” (2)

“This is my own practice experience, I counsel children more and next comes the elderly.” (5)

Although not all participants agreed that children's medications should receive the highest oral counselling, using the patient's age as an indicator of their need for advice seemed acceptable to pharmacists.

"Middle aged need more counselling. It's the menopause etc. and they should be counselled. Children and elderly are the standard, I counsel the middle aged more, (women with menopause, men with heart disease)." (3)

(b) Patient's Disease/ Condition

The type of disease or condition from which a patient suffered from was also highlighted as a predictor of oral advice received on the dispensed medication as demonstrated by the following statements:

"It is not the medication you are dispensing it is also the person who has come for the medication and what they are suffering from that may be a counselling point".(6)

"Mentally ill patients living in the community are vulnerable. They do not always know why they are taking all the medications for. We have to emphasise the direction and ensure that they take their medications." (5)

(c) Patients' Desire and Motivation to Seek Information and Request Advice From Pharmacists

Pharmacists stated that the level of counselling they provided also depended on the patient's desire to have more information and their motivation in seeking it and receiving the advice when offered by the pharmacist. Willingness to receive information from pharmacists was perceived to be partly age related. Pharmacists perceived older people to be reluctant or disinterested in receiving oral counselling on dispensed medications whereas in the case of younger adults (16-60 years) group counselling was mainly patient initiated as they tend to ask about their medications:

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“Elderly patients just like to take the medications and go home. Middle aged, they tend to ask. They know what the medication is about. I do not counsel them as much as I do children.” (4)

“There are some that just want their medications they get upset if I ask them some specific questions. They are some who you can talk to, they ask questions. And there are some that you can not and that is all we can do.” (2).

“If they are obviously in a hurry, the one who comes in and can't wait...I don't take my time over it. Also if they are nervous and do not want to know too much then I do not provide a lot of information. It's a matter of psychology I think, over the years you sort of learn, experience tells you who to counsel more.” (5)

II. Pharmacists' perception of patients' medication knowledge

Analysis of the focus group discussion revealed that pharmacists' perceptions of patients' knowledge on dispensed medications was one of the main factors influencing the extent and content of the counselling they provided.

(a) Medication Status As New Or Repeat Item

When pharmacists were asked to comment on the low level of counselling for some therapeutic and patient groups, the majority view was that these medications were prescribed and used on a repeat basis for chronic conditions and that they required less counselling than the newly prescribed ones. This point is illustrated in the following comments by the participants:

“I presume when you show the patient how to use an inhaler or peak flow metre once, you do not show them again and again” (1).

“Elderly patients have been taking their medications for 5-6 years, they already know about them and they do not want to hear the same thing again” (4)

On the other hand pharmacists believed that any dispensed medications prescribed for the first time or for an acute condition had to be counselled on, as exemplified by the following statements:

“Antibiotics are prescribed for acute conditions therefore we tell them (patients) about the dosage and other directions.” (2)

“That is what I do basically I ask them if this is the first time they are having the medications? Then I talk about the medication etc.” (3)

(b) Therapeutic Grouping of the Medication

Depending on the therapeutic grouping of a medication, pharmacists may alter the extent of oral counselling they offer to a patient. In this study the rate of oral counselling was the highest for anti-infective medications and the lowest for the cardiovascular items. The following are the reasons participants stated for this observation:

“It is quite important for the infection to clear up quickly and that they(patients) take their medications regularly. If the infection stays it makes the patient worse.” (4)

“Cardiovascular medications tend to be repeats when you counsel them the first time you do not need to counsel them again.” (2)

(c) Medication Forms and Special Requirements

The counselling rate for eye preparations was the second highest in the observational study and when pharmacists were asked to comment, unfamiliarity of patients with pharmaceutical form of eye preparations and the special requirements for these products such as storage and shelf life were among reasons quoted by pharmacists. The followings are two examples of participants' views:

“In my case it is whether the patient knows how to use the eye preparations properly in the first place, specially drops.” (6)

” I have not any facility to print the labels in a larger print therefore information like discard after 28 days of opening may not be noticed unless emphasised orally”.(3)

(d) Availability Over the Counter

The study findings indicated that products such as antacids and H₂ antagonists in gastrointestinal group or emollients and creams in skin section were among the lowest counselled items. Pharmacists justification was that since these products were available over the counter patients were familiar with them. This is illustrated in the following examples:

“I think with the GIs they usually have bought them over the counter and that is when you counsel them. That is why when a prescription for Tagamet etc comes in I assume they know it already.” (3)

“Doctors tend not to include the direction on the prescription as the majority of these products are repeats or patients can purchase them over the counter.” (2)

Factors influencing the content of oral counselling on dispensed medications

The findings on the content of oral counselling that were provided during stage 3 of the study were presented to the group and they were invited to comment.

I. *Dosage*

The observational study, stage 3, indicated that one in every four prescriptions handed out in community pharmacies received counselling on the dosage. This observation was received with disappointment by pharmacists:

“One in every four items received oral advice on their dosage instructions? This is very low. We should think about quantity as well as quality of our advice.” (5)

The lack of instructions by the doctor and missing dosage on prescriptions were among factors listed by participants that adversely influenced the level of counselling on the dosage.

II. Indication

The pharmacists unanimously agreed that not having access to patients' diagnosis greatly hindered and in some cases prevented pharmacists providing counselling on the indication. The consequence was that the pharmacist had to question the patient in order to find out or speculate on the diagnosis.

“Sometimes a patient goes to the doctor and is given a prescription and then they come to you (pharmacist) and ask what is it for. And it is only when you ask them why they saw the doctor, that you may be able to answer their question. That is why I think you better wait for the patient to ask you about the indication rather than the pharmacist telling them.” (1)

The situation was worse for medications that had different indications, which could cause confusion for patients and pharmacists alike. The following are examples provided by the participants:

“There was a prescription for Zolidex for a lady and it is prescribed usually for prostate. The father came in to pick the prescription up and I asked him to send the daughter in. When she came in she confirmed that she had it previously.”(2)

“Beta blockers that are usually used for high blood pressure or heart problems and in a few patients the usage is for anxiety. If you start explaining to the patient about Beta blockers and that they are for your heart and so forth, the patient will say:” Oh, but there is nothing wrong with my heart, or they may get worried”. (6)

III. *Adverse Drug Reactions (ADRs)*

During the discussion participants commented that too much information should not be given to patients. The researcher asked them to identify counselling issues that they had in mind. ADRs was named as an aspect of counselling for which half of the participants were reluctant to initiate provision of information. They felt that knowing a list of potential side effects could even prevent patients taking their medications for fear of unwanted effects. The following comment was made by a participant:

“Knowing the potential side effect can lead to the patient to not taking the tablet or even worse they take them but not so often. They may take it every other day or every third day to lessen the side effects “. (6)

The participants were asked to consider the value of educating and informing patients about side effects of medications in the context of knowledge verses ignorance. All participants agreed that at least one or two of more probable side effects could be discussed with the patients. However, two pharmacists had reservations about volunteering this information as illustrated by this question which was proposed by one of the participants:

“Do you volunteer to tell them (patients) about the side effects ? Or as the result of them reading the leaflet and asking you, you then respond?”(6)

It was agreed by all participants that patients should be informed of side effects as ultimately they would decide whether to comply with a medication or treatment. Pharmacists agreed that their role was to facilitate patients' decision making processes by putting the information into context as stated in the following comments:

“There are also some who want me to tell all the side effects from the BNF. I read them out to them but also emphasise that they will not get all these. Sometimes they just want to know.” (3)

“It will help patients to comply if the information is given on the medication and the side effects. They understand it better.” (4)

“ Pharmacists can not hide the truth about side effects, they may find it elsewhere. You have to tell the patient and it is their decision at the end of the day.” (2)

Despite the fact that all participants agreed that patients should be informed of the possible ADRs, half of the group declared that they did not volunteer this information and only would respond if asked by patients.

Patient Information Leaflet

At this point pharmacists were asked to comment on the new requirement that would eventually lead to all Patient Medications Packs having a Patient Information Leaflet enclosed. The general opinion was that pharmaceutical manufacturers should consult pharmacists in order to strike a balance in providing sufficient information without causing undue concerns to patients.

“The manufacturers should ask pharmacists’ opinions and shorten the information to a right amount. Not to give out too much information as to put off the patient from taking the medication.” (6)

“They (manufacturers) can say these are the common side effects, if you suspect there are others discuss with your pharmacist.” (1)

Pharmacists stated that despite the provision of Patient Information Leaflets in medication packs, pharmacists should still provide oral advice in order to customise the information to patients’ needs.

3.5.2 Focus group interactions: implications for data

The group interactions were analysed and grouped under the Positive and Negative Contributions and the Questions and Answers categories and are reported here.

Positive contributions

Analysis of the group interactions in the first phase illustrates that where pharmacists discussed the findings of observational study, i.e. stage 3, over eighty percent of contributions were positive. Group members reflected on the comments and views of others, illustrated their points by examples of their own practice and experiences and proposed possible explanation for some of the findings of observational study. The following extracts refers to when the participants were asked to comment on the high level of counselling for dispensed medications used to treat infections.

“Antibiotic is acute treatment we tell them about the dosage and other direction. Also those extra labels on the computer remind you to tell the patient about it.”(2)

“You counsel them to make sure they finish the course, you will be surprise how many patients do not”. (5)

“It is quite important for the infection to clear up quickly and for the medication to be taken regularly. We can do it by counselling patients”(4).

“I think it is the acute nature of infections that makes us to counsel more. We want to make sure they take it correctly and of course the patient asks can I take alcohol with this?” (1)

“The antibiotics usually prescribed for middle aged(16-60 years) who do not take medications and you look at them as people who probably do not realise the

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importance of taking the medications regularly. You want to tell them that they should take it for 5 to 7 days and that is the end of it and hopefully they will then take the full course.” (6)

Questions and answers

As the participants were involved in earlier stage of the study (stage 3) and were also sent an agenda and a copy of study findings prior to the meeting there were no questions asked of the researcher. However, as part of the discussion there were occasions where group members exchanged questions and answers in order to clarify a point or elaborate on an issue. The following extract is an account of the discussion pursued by pharmacists on provision of oral advice on adverse drug reactions of dispensed medications.

“Tell them the side effects, or one or two of them but emphasise that they may not get it. I tell all my patients” (3)

“You can not hide it from them, They may find the information elsewhere.” (2)

“Is there something you volunteer for? Or as the result of them(patients) reading the leaflet?” (6)

“The common ones I volunteer like the dry cough and ACE inhibitors then they will not come back to me and say. I tell them and they appreciate it as well.” (3)

“How far do you go? For example do you tell them to take it night time etc?” (6)

“Doctors usually tell them to take it night time, I emphasised on that. There are also some who want me to tell all the side effects from the BNF. I read them out to them but also emphasise that they will not get all these. Sometimes they just want to know.”(3)

Negative contributions

Apart from two instances there was no direct disagreement between pharmacists, negative contributions were made when pharmacists were asked to explain the reasons behind the low counselling provision observed for older people and on adverse drug reactions.

I. *Provision of counselling for old people*

One pharmacist (6) tried to soften his criticism of his colleague by generalising his comment to all pharmacists including himself:

“If we think about patients at risk, we prioritise children at risk and then Adults (16-60) years old.” (2)

“Middle aged (Adults 16-60 years old) are the ones that they are more likely to be educated and understand their medications and you as the pharmacist counsel them more than the elderly who are more at risk. We think elderly do not understand therefore we will not tell them. They are actually the ones needing the help. This is what it is about treating Edna as a person because Edna will end up in hospital. One in ten end up in hospital because you as the pharmacist fail to point out that two out of ten of medications she is taking interacts.” (6)

II. *Provision of counselling for adverse drug reaction (ADRs)*

In this case a sarcastic approach by another pharmacist (2) regarding advising patients on the ADRs of medications was challenged by pharmacist(6) which lead to a third group member highlighting the underlying problem. The following is an account of pharmacists' interactions which identified the lack of standards for the service as a reason for variation in pharmacists' perception and behaviour when advising patients on dispensed items.

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“ By telling them ADRs they will have a preconception about their medications and they will not take it.” (2)

“That is what we are assuming the data is telling us that we tell them about the ADRs and they comply much better. The data says we should tell them all the ADRs.” (4)

“No, the data does not say that. It says we should tell them the main ones and that will help them comply better. They will have the knowledge and if they suffer from ADRs they can judge for themselves what they can cope with. They should be told but there should also be an agreement with the GPs about the information you give the patient on the ADRs.” (6)

“When there is no standard it will be up to you as to what to tell the patient.” (3)

3.5.3 Barriers to provision of oral counselling for dispensed medications

The barriers identified by pharmacists to provision of oral counselling included: lack of time and funding, inadequate counselling skills, unavailability of a counselling area and the attitude of GPs.

Pharmacists stated that the lack of time and remuneration were barriers for them in providing oral advice as they have to balance the needs of other patients and clients in the time available. Unless there were more pharmacists on the premises they thought providing oral counselling for all medications even at the minimal level would not be feasible.

“I routinely counsel for dispensed medications. But there are times you can not. Partly because when you are counselling there are other people waiting for you and there is the question what is the reasonable time for people waiting.”(1)

“We need more funding from the Government to employ a second pharmacist if we are to achieve 100% rate of counselling.” (5)

I. Inadequate counselling skills

During the course of discussion there were two occasions when some pharmacists admitted that they did not counsel patients after ascertaining that patients knew about their medications. However, their questioning techniques were scrutinized by other group members in an attempt to demonstrate that provision of advice should be based on a sound technique for gathering information from the patient:

“You ask the patients have they been shown how to use their inhaler and the answer is yer, ask them to demonstrate and up to 40% do not have the right technique, the way the question is asked is important.” (1)

“ If you ask them a closed question the answer is yes or no. The point is if you ask the right question and in the right manner the answer may be different.” (6)

II. Unavailability of counselling area

There was an acknowledgement that there should be a minimum level of privacy for patients and pharmacists to feel at ease to initiate the counselling specially if it involved personal situations:

“The counselling level for obstetric products are quite low because there is no quiet area where you can counsel the patient in private, it can be embarrassing for the patient and pharmacist”. (6)

III. GPs' attitude

Pharmacists were unclear of other health care professionals' understanding and expectations of their advisory role and services. They stated that an agreement or clarification was needed between GPs and pharmacists about the level of information each would provide on medications for patients. These points are illustrated in the following statements:

“ There is also problems with the GPs as to how much information you can give the patients. ” (2)

“We have to have more cooperation from GPs. There should also be an agreement with the GPs as some of them are not happy with you giving a list of side effects to the patient” (5)

Proposed solutions

Group members proposed a number of ways in which counselling of older patients on dispensed medications could improve. These included: domiciliary visits, counselling and educating home helps, establishing a rapport with this group of patients, being guided by them regarding the extent of counselling needed and avoiding imposing unwanted advice. It was also strongly emphasised that there should be a close liaison between community pharmacists and GPs in order to agree and harmonise the level of information provided for patients.

3.5.4 Setting standards for oral counselling of dispensed medications

One of the issues raised by pharmacists during the debate on the necessity of providing oral advice was that although in principle all dispensed medications required oral counselling, the standard should be set realistically and be achievable within available resources.

Standards for the content of oral advice

As explained in the Methodology (2.6.4) using the scoring system the individual participant's prioritisation of issues was validated. Then an overall ranking was obtained as illustrated in Table 4.1. In the overall result, dosage with the lowest score was judged to be the most important counselling issue followed by side effects, demonstration, indication, contraindication, drug/ drug interactions, drug/ food interactions and lastly the storage.

Table 4.1. Standards for the content of oral advice provided by pharmacists for dispensed medications

Components	Total Score*	Rank (1= most important)
Dosage	177.5	1
Side effects	54.5	2
Demonstration	41.5	3
Indication	37	4
Contra indication	26	5
Drug/ drug interaction	23	6
Drug/food interaction	20	8
Storage	17	9

***Total Score:** represents the weighting given to each issue by pharmacists

Standards for the extent of oral advice

The group agreed that as a minimum number, four issues for a new and three for a repeat item was an achievable and acceptable standard for oral counselling for dispensed medications.

Table 4.2 Standards for the extent of oral advice given by pharmacists for new and repeat dispensed medications.

Participant	No. of issues to be raised in counselling	
	New Medications	Repeat Medications
participant 1	5	4
participant 2	5	3
participant 3	4	0
participant 4	5	3
participant 5	3	4
participant 6	5	2
Total	27	16
Minimum No. of issues	4.5	2.7
Agreed numbers of issues	4	3

3.6 Stage five: Implementation of the agreed standards and evaluation of the impact on the extent and content of oral counselling for dispensed medications

To proceed with the audit cycle, participants were requested to implement the agreed standards and to self report on their level of oral counselling on dispensed medications for three hours a day for five days. The choice of sessions had to represent busy and quiet times. Data was collected on a specially designed form based on the tool used in Stage 3. The recorded data by pharmacists was compared with the baseline information obtained in the observational study in stage 3. The results are reported under two main headings, Standard Implementation and Evaluation of Impact on pharmacists' counselling.

3.6.1 Implementation of the standard

After implementation of the agreed standards, the six pharmacists who participated in stage four, collected data on provision of oral counselling on new and repeat dispensed items. The number of items which received oral counselling was then presented as a percentage of total items dispensed. In order to examine the impact of implementing the standards, data was analysed further by grouping the oral advice provided for dispensed items according to the number of issues raised. In section 3.6.2 pharmacists' counselling activities are compared before and after implementation of the standards in order to evaluate the impact of the audit.

The extent of oral advice on dispensed medications

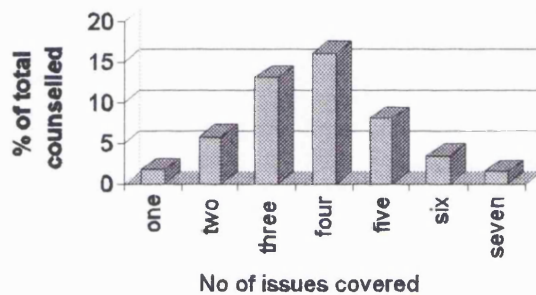
Pharmacists agreed on four issues as the minimum number for counselling of new items and three for repeats. Data obtained after standards implementation are reported below:

New medications

As illustrated in **Figures 3.8** when pharmacists counselled patients on their new medications, the mean coverage of items receiving oral advice on four issues was 16% (range 7%- 28%, s.d.14.9), on three issues was 13% (range 2%-20%, s.d.12.7), on five issues was 8% (5%-17%, s.d. 8.9). The maximum number of issues covered with one

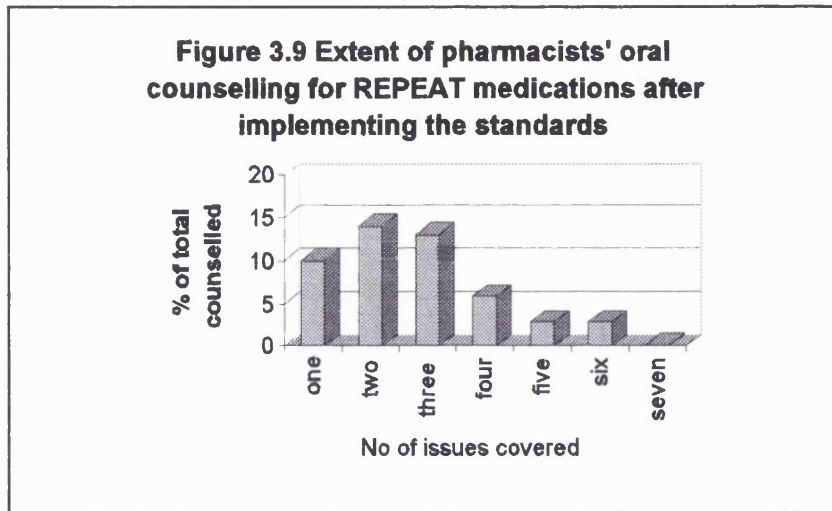
dispensed item was seven (range 0-3%, s.d.2.1) and there were cases in which pharmacists did not provide any oral counselling (range 0-3%, s.d. 2.1).

Figure 3.8 Extent of pharmacists' oral counselling for NEW medications after implementing the standards



Repeat medications

Pharmacists reported that overall they covered a lower number of issues for repeat items than new ones. **Figure 3.9** shows that majority of items were counselled orally on two issues with a mean counselling rate of 14% (range 8%-26%, s.d.12.7), this followed by oral counsellings which contained three issues with a mean rate of 13% (range 2%-25%, s.d. 16.3), coverage of one issue with mean rate of 10% (range 4%-25%, s.d.14.8). Oral advice containing four or more issues were less frequent and occurred less than 6% (1%-11%, s.d.7.1). **Figure 3.9** illustrates pharmacists' individual counselling provision for repeat medications after standards implementation. Four pharmacists covered two or more issues the majority of the items. One pharmacist (4) advised patients on one issue



The content of oral advice on dispensed medications

Pharmacists did not set any standards for the type of counselling issues that needed to be covered for each dispensed item. However, they indicated the priorities of counselling issues that should be covered during the provision of oral advice. After pharmacists implemented the standards, the collected data was analysed in order to examine whether the process of prioritisation had influenced the types of counselling issues offered by pharmacists (**Figure 3.11**).

3.6.2 Evaluating the impact of standards implementation on the extent and content of oral counselling on dispensed medications

The impact of standards implementation was assessed with respect to the extent and content of pharmacists' oral counselling, comparing data on their advisory activities before and after the audit.

The level of provision of oral counselling

The majority of the pharmacists failed to comply with the study requirement to record the total number of items dispensed for the duration of data collection period. This meant that the level of counselling as percentage of total items dispensed could not be established and compared to the level of counselling before standards implementation.

However, the average number of items for which counselling was provided for this group of pharmacists remained the same before and after implementation of standards at the rate of 28 items per hour.

The extent of oral counselling

During the observational study prescription status as new or repeat could be established in only 30% of cases. This meant that the total number of items in each groups were too small to be reliably compared to the data obtained from stage 3. Therefore, to evaluate the impact of audit on pharmacists' provision of oral counselling, it was decided to treat the sample as a whole and not to segregate counselling results of repeat and new items. **Figure 3.10** illustrates the findings. Before the audit pharmacists' covered two counselling issues for 45% of the items, one issue for 40% and three issues for 13% of counselled items.

After implementation of the standards a shift was observed where pharmacists covered more issues per counselling provided (**Figure 3.10**). Three issues were covered for 25% of items, two and four issues were counselled with equal frequency of 21% of items. One issue was advised for 13% of medications and five issues for 10% of dispensed items..

The impact of standards implementation on the content of oral counselling

To standardise the results, the frequency of oral advice for each counselling issue was calculated as a percentage of the total number of dispensed items counselled by pharmacists. These values were then used to compare the frequency with which pharmacists raised each issue in their oral advice of an item before and after implementing the standards (**Figure 3.11**). The only issue which was less frequently counselled after rather than before the audit was the dosage instruction (90% versus 69%). The rest of counselling issues were covered more frequently after the audit, with some receiving twice as much advice (**Figure 3.11**).

Figure 3.10 Extent of pharmacists' oral counselling on dispensed medications before and after the audit

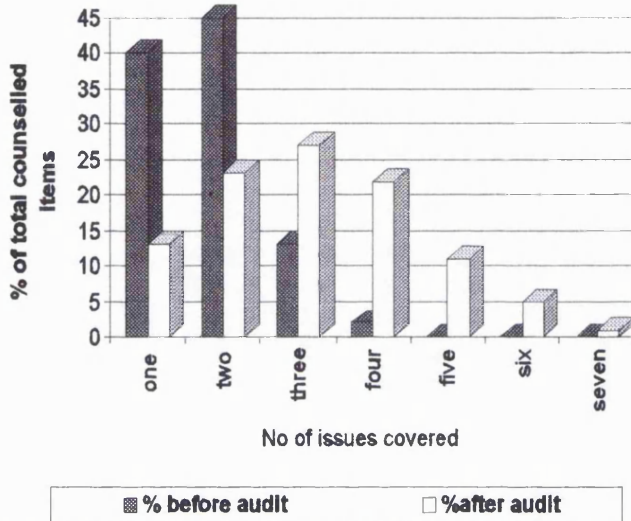
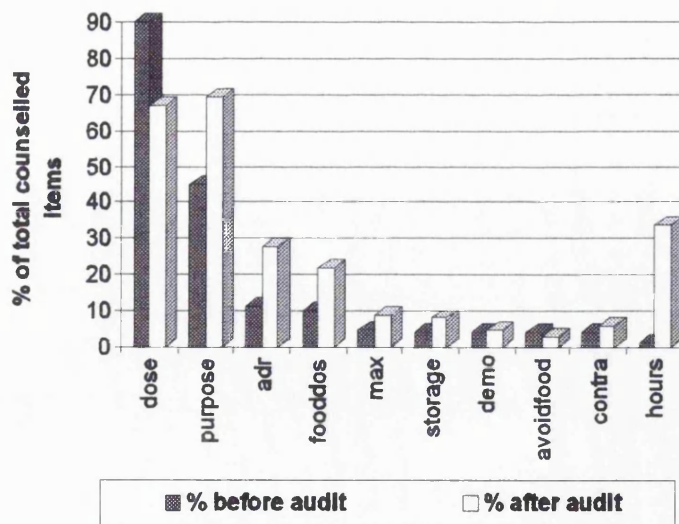


Figure 3.11 Content of pharmacists' oral counselling on dispensed medications before and after the audit



3.6.3 Evaluating feasibility and acceptability of procedure and the tool used for data collection

After the final forms were sent in by participants the researcher conducted a telephone interview with each in order to evaluate the procedure and the data collection form used. The overall response was very positive and pharmacists including single independent proprietor found the process acceptable and quite feasible to be carried out in community pharmacy settings.

As far as the time and duration of data collection was concerned pharmacists commented that more frequent data collection with a shorter duration (e.g. half to one hour) would be more manageable in busy pharmacies and it would be practical and acceptable to conduct the audit cycle every three to four months. With regard to the form all participants found it simple to use and the accompanied instructions were found to be clear and easy to follow. However, two of the pharmacists commented that if the data collection tool was printed on a smaller form, A5 instead of A4, it would have been easier to keep at the counter and complete whilst counselling was carried out.

3.7. Stage six: Feasibility of the peer audit to review provision of oral counselling on dispensed medications in community pharmacies in Barnet

A letter inviting pharmacists to participate in the audit was sent out by Barnet Health Authority which led to recruitment of a self selected group of five community pharmacists. Participant pharmacists were then sent data collection forms enclosed with full instructions on their completion and a request to collect data for five sessions, each three hours long. This data was sent to the researcher for analysis and was then used as the baseline measurement. A meeting was convened and pharmacists, after discussing the results, agreed on the standards for oral counselling of dispensed items. They were then given two weeks to implement the standards and collect data on their advisory service for five sessions, each three hours long. This information was also forwarded to the researcher where after analysing and comparing them with the baseline measurement, gave participants feedback on the outcome of the audit and its effects on their provision of oral counselling for dispensing medications.

Data generated from the audit conducted in Barnet is reported in two sections: section (3.7.1) considers factors influencing the extent and content of pharmacists' oral counselling and section (3.7.2) evaluates implementation of the standards on the extent and content of oral advice with prescribed medications provided by community pharmacists in Barnet.

3.7.1 Factors influencing the extent and content of pharmacists oral counselling on dispensed medication reported by Barnet community pharmacists

The content of the focus group discussion was analysed in order to identify the factors influencing pharmacists oral counselling on dispensed medications as identified by Barnet pharmacists. As the emerged themes were almost identical to the ones highlighted at stage 4, it seemed appropriate to use the same categories for this stage too. These results are reported under two headings: factors influencing the extent and the content of oral counselling on dispensed medications.

Factors influencing the extent of oral counselling on dispensed medications

The subcategories under this heading were identical to those of the main study and included patients' characteristics and pharmacists' perceptions of patients' knowledge of medications.

I. Patients' characteristics

The only characteristic of patients Barnet pharmacists believed to influence their oral counselling was their desire and motivation to seek and receive advice.

a. Patient's Desire and Motivation to Seek and Receive Advice From Pharmacists

Pharmacists stated that the level of counselling they provided depended on the patients' willingness to receive the advice which they assessed by the patients' attitude and body language as exemplified in the following statement:

"You can see by their (the patients) body language, their attitudes. If they take their time then they are obviously interested in what you have got to say then you give them more of your time." (3)

Unlike pharmacists at stage 4, Barnet pharmacists did not perceive elderly patients to be less receptive to information than others. Instead they thought that older patients required different types of counselling. These pharmacists had a distinct approach to counselling of this group of patients. They would initiate a general talk during the course of which pharmacists were asking them about their general well being, a discussion which may unearth patients problems. This approach was illustrated by the following quotes from group members:

“If I know a patient has been on a medication for a long time, I am not going to tell him about the dosage, I just ask him: How are you getting along? How do you find it? You should realise that this is a different kind of counselling.” (4)

“When they (elderly patients) are on six different medications, it is worth asking them: Do you want me to go through them, are you okay with them?” (1)

II. Pharmacists' perception of patients' medication knowledge

Analysis of the focus group discussion found that pharmacists' perceptions of patients' knowledge on dispensed medications was one of the main factors influencing the extent and content of counselling they provided. Pharmacists used the following characteristics as indicators of patients' knowledge: medication status as a new or repeat item and therapeutic group of the item dispensed.

b. Medication Status As New Or Repeat Item

When pharmacists were asked to comment on the low level of counselling for items dispensed in some therapeutic groups, the majority view was that some medications were prescribed and used on a repeat basis for chronic conditions and these required less counselling than the newly prescribed medications. This point is illustrated in the following comments by the participants:

“If it is an hypertensive medication prescribed for the first time then you advise the patient, but if they had them for long you tend not to counsel them”. (3)

c. Therapeutic Grouping of the Medication

Depending on the therapeutic class of a medication pharmacists may alter the extent or content of oral counselling they offer to a patient. Antibiotics and painkillers were perceived simple to advise by Barnet pharmacists since a set of standardised information such as dosage and timing of the dosage was applicable to the majority of patients. On the contrary advising on medications such as anti-depressants required more sensitivity in order to provide the appropriate types of information for each patient.

Factors influencing the content of oral counselling on dispensed medications

The group was presented with data on the contents of counselling as found in stage 3. This illustrated that there was a wide range of coverage with the dosage instructions as the most and ADRs as one of the least advised counselling issues. However, unlike the pharmacists in stage 4, this group only discussed the provision of advice on adverse drug reactions.

I. *Adverse Drug Reactions (ADR s)*

The group members were unanimous on advising patients on the major potential adverse effects. Participants believed that counselling patients on the most probable adverse effects could reduce the patient’s anxiety when reading the list of potential ADRs as listed in the patient information leaflets. However, pharmacists felt that advice on ADRs should be sensitive to patients’ needs. The following strategy was thought to prevent alarming anxious and confused patients.

“I think it is a good idea to give them some of the side effects, like frequent ones. I don’t think it is advisable to go too deep into other side effects.” (3)

Patient Information Leaflets

Pharmacists in Barnet endorsed enclosure of patient information leaflets in medication packs. They thought it would promote patients access to information and believed that patients were keen to receive them too. Two of the pharmacists used patient information leaflets as a basis of their oral advice:

“You use patient information leaflets with your oral counselling. That is how I do it, it has all the items we should tell the patients about and in the case of oral syringes or appliances the illustrations are very helpful to go through with the patient.” (2)

Barriers

The only common barrier identified by Barnet pharmacists and the main study group was the layout of pharmacies. Where the dispensary area was closed and separated from the rest of pharmacy, the opportunity to interact with patients would be adversely affected leading to a reduction of the pharmacist’s counselling:

“If you have contact with the patient and being able to see them when you are dispensing, it is easier to come out and give the medication and talk to the patient” (4)

Business did not affect the level of counselling provided by Barnet pharmacists, instead it influenced the amount of information provided with each item:

“If you are too busy, you just pick out the important bits and tell them about it. Somehow you always fit the advice in when you give the medication out.” (3)

“If it is a busy period the information is less than when you have more time to have a long chat with the patient, but you advise them all the same.” (1)

Availability and visibility of pharmacists were also perceived to be crucial, as the group believed that oral counselling of dispensed medication was the role of pharmacists and had to be provided by the pharmacist to be effective.

3.7.2 Evaluation of standards implementation on the level, extent and content of oral advice on dispensed medications by community pharmacists in Barnet.

On completion of the second set of data collection by Barnet pharmacists, provision of oral counselling on dispensed medication before and after standards implementation was compared and its effect on the level, extent and content of oral advice were assessed. As explained previously, the level of counselling was defined as the number of counselled items as a percentage of total dispensed items. The extent of counselling was defined as the number of counselling issues raised per each dispensed item as a percentage of all counselled items and lastly the content referred to: the number of times each counselling issue was advised as a percentage of total counselled items.

The level of counselling

To take into account variations of workloads the following process was adopted. First a collective set of data was obtained by adding the results of five sessions of data collection for each participant. Then the number of counselled items was calculated as a percentage of the total number of items dispensed in the two categories of new and repeat medications.

Pharmacists in Barnet counselled 48% of new medications dispensed before the audit a figure which was increased to 58% after they embarked on the audit process. In the case of repeat items 49% of dispensed medications received oral counselling before the audit which slightly decreased to 43% after the standards implementation.

Table 6.1 Provision of pharmacists' oral counselling before and after implementing the standards in Barnet.

	NEW		REPEAT	
	Before Audit	After Audit	Before Audit	After Audit
Total items dispensed	281	301	281	301
Total items counselled	135	172	149	129
% of counselled items/total dispensed	48%	58%	49%	43%

The extent of oral counselling

The number of issues covered by pharmacists for each item was plotted for data obtained before and after the audit implementation for each individual pharmacist. **Figures 3.12** represents this data for new medications and **3.13** for repeat items.

The baseline measurement for new and repeat items indicated that despite variations among pharmacists in Barnet there were some similarities in the number of items they covered. For new medications 28% of items were advised on three issues and 20% of medications received advice on two and four issues. As for repeat items 30% of medications were counselled for three issues and 28% of dispensed medications received advice on two counselling issues.

Pharmacists in Barnet, as the pharmacists in stage 4, believed that fewer counselling issues for repeat items compared with new items was as an acceptable and achievable standard to aim for. The figures illustrate changes of pharmacists' oral counselling of new and repeat medications after implementation of agreed standards in Barnet. **Figure 3.12** illustrates that the level of oral counselling did not change greatly, it seems that

pharmacists were more focused on the number of issues on which they counselled ensuring that more issues were covered for each counselled item. After the audit frequency of advice containing one, two and four issues was all the same at 20%.

Figure 3.13 indicates that for repeat medications, standards implementation encouraged pharmacists to cover more counselling issues per item dispensed. Before the audit, repeat items received advice on two issues in 28% of cases and on three issues in 30% of times. However, after the audit pharmacists counselled 35% of dispensed items covering three issues per advice given.

The content of pharmacists' oral advice

Analysis of the contents of pharmacists' oral counselling on dispensed medications in Barnet is presented in **Figure 3.14**. Although the frequency by which different issues were raised increased after the standards implementation the pattern remained the same. The likelihood of an issue being raised by the pharmacists before and after the audit implementation was stable. Pharmacists were most likely to counsel their patients on the dosage followed by purpose (indication), interval between dosage (hours), taking the medication with/out food and the maximum dosage. The issues to be raised on were storage, adverse drug reaction, demonstration of an appliance and types of foods/drink to avoid.

Figure 3.12. Extent of oral counselling for NEW medications before and after the audit in Barnet

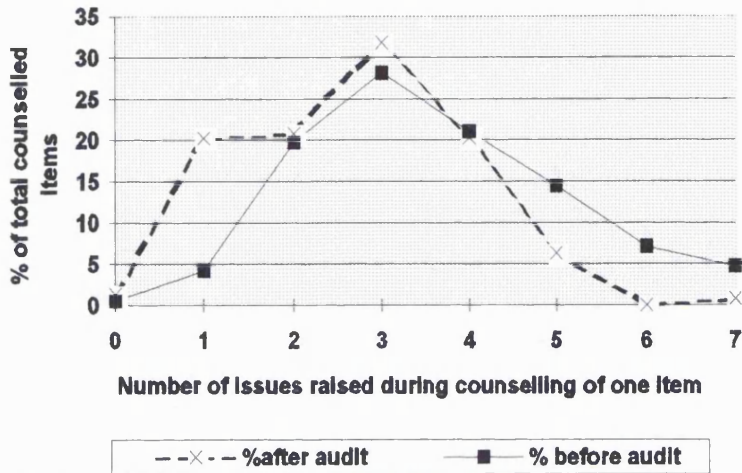
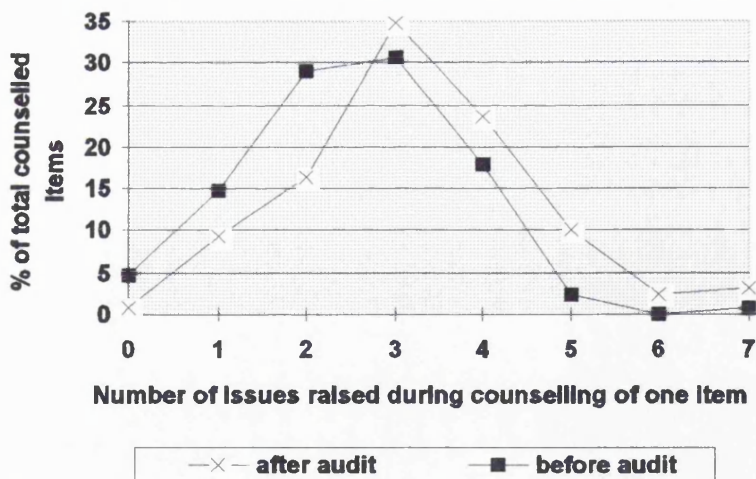
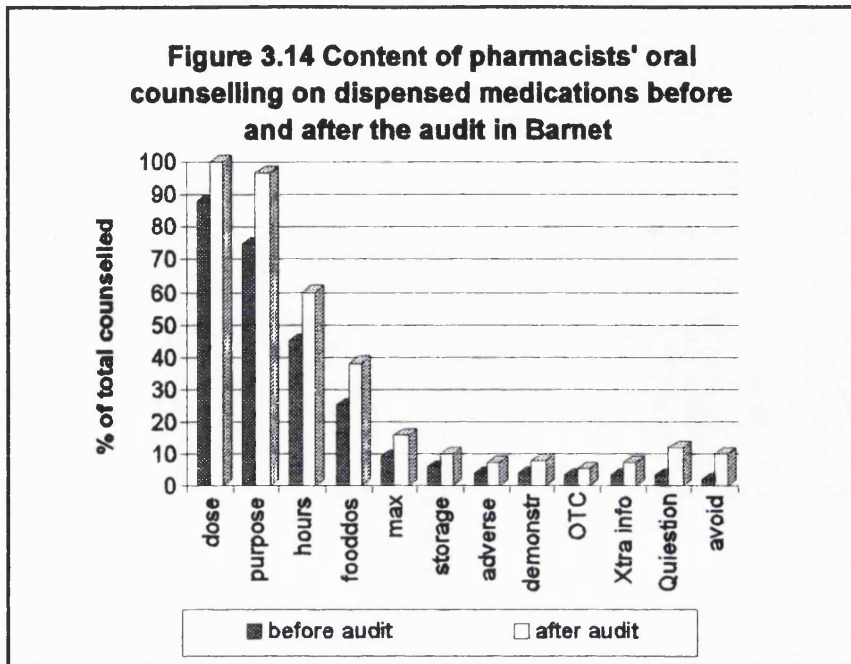


Figure 3.13 Extent of oral counselling for REPEAT medications before and after the audit in Barnet





Chapter 4: Discussion and Conclusion

DISCUSSION

4.1 Pharmacists' knowledge and attitude towards professional audit

The sample consisted of five female (31%) and eleven male (69%) pharmacists, a proportion that closely resembles the latest manpower report for male representation and an under representation of female pharmacists (The Royal Pharmaceutical Society, 1996b). Despite the sample being randomly selected with a response rate of 67%, the small sample size necessitates caution in generalising the findings to all community pharmacists.

The results of this stage were very close to those of the study carried out by Krska (1994) on "attitudes to audit among Grampian's community pharmacists". The percentage of pharmacists who did not have any knowledge of professional audit was found to be 25% in this study and 28% in Krska's. This study found that many pharmacists in this sample (in line with those involved in Grampian) had a grasp of audit that was expressed as: "a critical observation of one's own practice resulting in the introduction of changes to improve standards and quality of services". Some of the participants said that identifying the problem and taking action to improve their practice, whether in professional or business aspects, was an integral part of their practice. However, they acknowledged that they did not have a structured approach and these activities were not documented.

Despite 44% of pharmacists claiming to have experience of audit only 25% provided examples in which different stages of an audit cycle could be identified. It was not surprising to see that participants' experiences were limited to self-audit, as community pharmacists generally practice in isolation which denies them the opportunity of peer audit. All pharmacists with previous experience had a positive attitude to audit and expressed willingness to take part in further audit activities. This finding is similar to the situation in early days of audit in general medical practice, in which experience of audit resulted in a higher level of agreement with a positive statement about audit than was found in GPs with no audit experience (Waters *et al*, 1983). Similarly Krska (1994)

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showed that previous experience of audit involvement had a statistically significant influence on pharmacists' attitudes and increased the likelihood of further participation.

Most participants (56%) were very positive about audit implementation in pharmacy and believed that it would promote pharmacists' professional status, improve standards and assist pharmacists in providing a better and more responsive service for patients. However, there were a number of issues that had to be addressed before successful audit could be guaranteed. These included an appropriate choice of topics for which standards would be defined, keeping participation voluntary and encouraging pharmacists to take up audit. Only 13% of respondents believed that audit would infringe their professional autonomy and was a time consuming process with no proven effects.

In examining the effect of audit on their own practice, although 63% of participants declared that audit would improve their standards of practice, they were quick to point out a host of problems preventing them from participation which included lack of time, appropriate training and financial incentives. The main obstacle identified by the interviewees was the current remuneration system for pharmacy in England which is based on the volume of prescriptions dispensed without taking into consideration the quality of pharmaceutical services provided. This point was clearly illustrated in the survey of Grampian's pharmacists in which they were asked to identify factors influencing their attitude to audit (Krska, 1994). Seventy four percent of pharmacists in Grampian claimed that the need (in Scotland) to undertake audit to obtain the professional allowance had an influence on their views, with 33% reporting that it created a positive attitude to audit. Training events have been also shown to help pharmacists to develop positive attitude to and become involved in audit (Kelly and Mason-Duff, 1993).

However, some pharmacists in this study believed that audit on its own right could be financially beneficial as the improved services could provide a better environment which attract more clients to the pharmacy. Two reasons why audit may improve professional practice were identified by participants: firstly, pharmacists' involvement in examining

Chapter 4. Discussion

their activities to highlight potential problems and deficiencies would enable more effective remedial actions and secondly, audit as an ongoing process would encourage pharmacists to keep their knowledge up to date. Overall, participants were more positive about the implementation of audit when considering the effects on an individual than on the profession as a whole. This could be a result of community pharmacists' professional isolation and their general lack of experience in peer activities.

When implication of audit for other pharmacy staff were considered, the majority of participants expressed positive views. However, reservations were expressed about the introduction of audit at that level. Implementation of audit for pharmacy staff requires input from the pharmacist and his or her motivation to engage the staff as well as training them. This could be demanding process requiring commitment. The majority of participants felt that they could not meet the extra resources that would be required for training staff. There was also concern about the acceptance of audit by staff and the extra workload it may create.

They believed that implementation of audit would improve the standard of services leading to a more professional and patient focused environment which would be conducive to better communication between pharmacist and patient. Seventy percent of participants thought that all these improvements would bring about positive effects on patients' care. This result was in line with findings of the study among Grampian's pharmacists (Krska, 1994) in which 63% of pharmacists agreed that audit could help patients in long terms. A minority of pharmacists were concerned that the audit process would be too time consuming not leaving them sufficient time to pursue other professional activities such as patient counselling.

Inclusion of audit as a criterion for the professional allowance payment was generally welcomed. It was thought that the payment would act as an incentive encouraging higher rates of participation. The idea of remuneration based on professional activities and

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services rather than unit item dispensed was considered a move in the right direction. Some pharmacists (31%) were apprehensive at the prospect of mandatory audit and the risk of sanction which could follow if standards were not met.

In addition to the remuneration structure, the participants' identified resistance to change and failing to maintain sufficient level of enthusiasm as potential barriers.

The majority of pharmacists believed that benefits would arise through the audit process, such as: raising of professional status, updating of practice, improved patient care and job satisfaction. Long-term potential gains included maintaining professional autonomy through self regulation and monitoring of service quality. It was also suggested that a better remuneration system could be negotiated based on the quality measures taken by the profession.

Participants were asked to identify an aspect of pharmaceutical services that they would prioritise for audit. In descending order of importance, patient counselling on dispensed medications, dispensing, pharmacist-GP interactions and patient counselling on over the counter medicines were identified. However, some participants were concerned about the practical aspects of audit implementation and were particularly perplexed as how a consensus could be achieved on appropriate standards.

A literature search revealed that there was no standard definition for extent and content of patient counselling in community pharmacy or the components of this activity. Many of the published studies on pharmacists' counselling on dispensed medications were from the United States or Scandinavian countries rather than the United Kingdom. A consensus on the definition of patient counselling was required before the study could proceed.

4.2 A consensus on definition of oral counselling and its components

When groups of pharmacists were convened to discuss and generate ideas Nominal Group technique provided them with freedom to express their ideas whilst eliminating the potential

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confirmative pressure which could be brought about by other group members. This pressure may be experienced through other interactive methods (Van de Ven, 1972 and 1974). It provided a pleasant social interaction between the group members and gave them a sense of satisfaction when meetings were concluded with a list of ideas which were regarded as the group achievement.

Donabedian (1966) distinguished the three aspects of health care as structure, process and outcome. This concept was introduced to pharmacists during the opening of the Nominal Group meetings to encourage participants to think laterally by considering all the aspects of services when listing issues to be covered during counselling and aspects for which standards should be set. However, in neither of the meetings did participants raise any issue concerning the structural or outcome aspects. Almost all the generated issues were based on the process of counselling (56 out of 57 items). Based on the fact that a more confidential environment is required for individuals to openly and freely disclose personal problems (Hargie *et al*, 1987), lack of privacy and unavailability of consultation areas has been an ongoing criticism of pharmacists' advisory services (Vallis *et al*, 1997; Anonymous, 1991). It was rather surprising that none of the participants raised privacy as an issue, as in other studies pharmacists have been reported to perceive a lack of a counselling area on their premises as a barrier to effective communication (Anderson, 1998a). One factor which could have contributed to the absence of structural issues in these discussions was the status of pharmacists as proprietor or employee. For proprietors the financial loss of dedicating an area of shopfloor to consultation area has to be weighed against the potential income generated by it and unless there is a clear indication that it would be commercially beneficial the addition of a consultation area may not be favoured. The employee pharmacist has no authority to alter the structure of the shop.

As far as outcome was concerned only one of the items was loosely associated with the outcome of treatments (this was "*Tell the patient what to do if the medication does not work*"). Determining and measuring outcomes that are specifically associated with provision of pharmaceutical services is particularly problematic. Many factors other than medical and pharmaceutical care may influence outcome. As patient outcomes for prescription activities

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are generally influenced by a wide range of individuals, their assessment may be more appropriate in the field of multi-disciplinary clinical audit. It may be possible to define outcomes in ways other than ultimate clinical outcomes. One may consider several sub-objectives of the health care process as outcome measures. In essence differentiating between process and outcome is somewhat of an abstraction, and many procedural end points and intermediate outcomes may be used as indicators of the quality of care (Donabedian, 1966; Jackson *et al*, 1975).

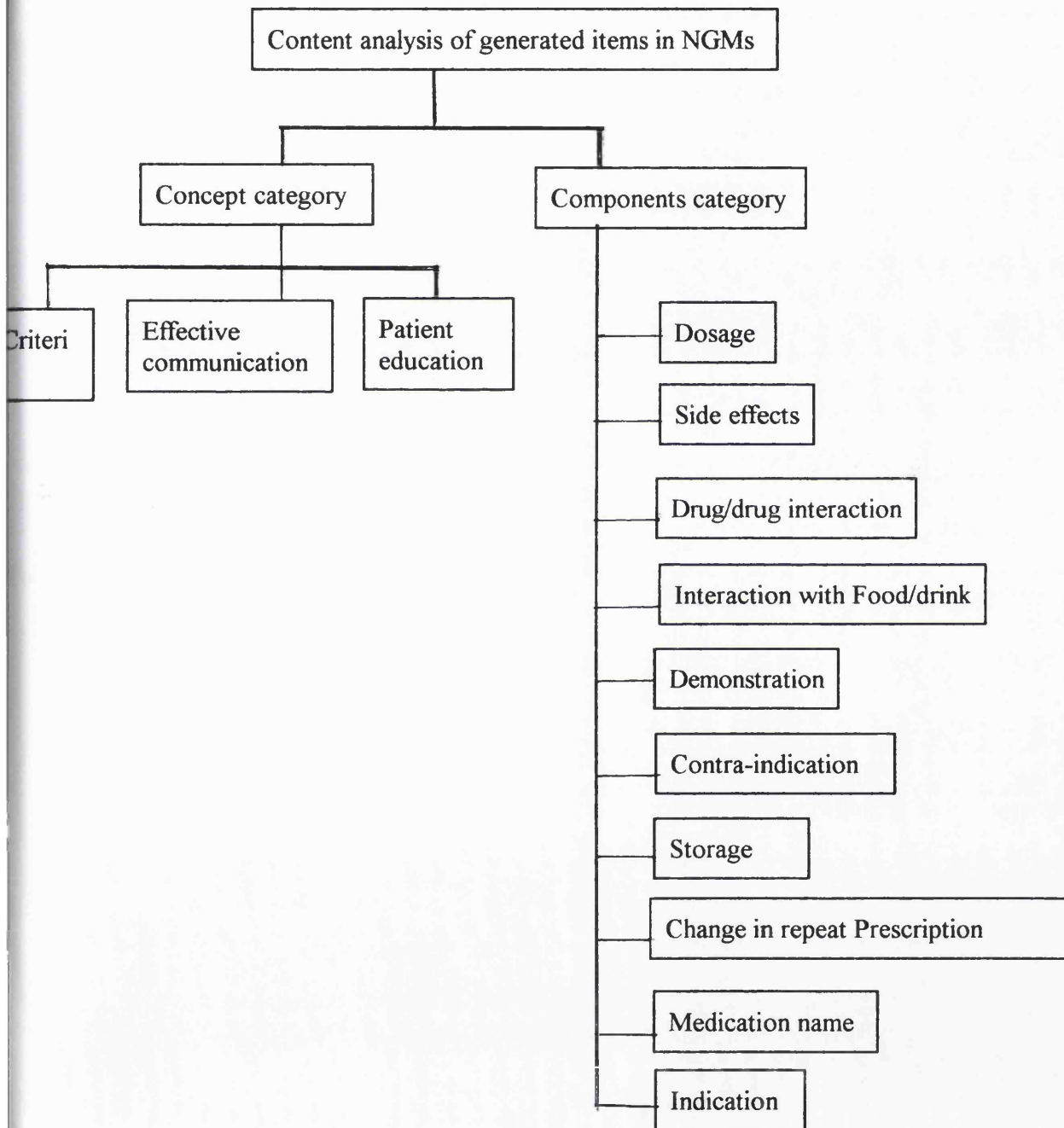
One of the limitations of NGT is that despite providing a prioritised list of ideas, the ranking does not necessarily represent the weighting given to each item. However the total score may be used as a proxy of importance attached to issues by participants. Bearing in mind that NGT is a qualitative approach, even total scores should only be taken as an indication and not as an absolute value of importance of issues. Therefore care should be taken in interpreting the results by acknowledging that the numeric value of scores are not directly correlated to the magnitude of importance attached to each issue i.e. an issue with score of four should not be perceived as twice as important as an issue with a score of two.

Analysis of items generated in the Nominal Group Meetings

In analysing the data two approaches were taken. First a mathematical approach (Gallagher, 1993) in which total scores of items generated in both meetings were standardised enabling the researcher to obtain an overview of priority given to various elements of counselling by pharmacists.

The second approach was qualitative and entailed content analysis of generated items. This resulted in the emergence of two categories based on specificity and technicality of data with regard to counselling of dispensed medications (**Figure 4.1**). The Concept category consisted of items that were mainly based on principals of the standards of good professional practice such as, counselling processes, interpersonal skills or ethical and professional requirements. In contrast the Components category consisted of issues focusing on drug information and technical components of advice with dispensed medications.

Figure 4.1 The categorisation of data derived from the nominal group meetings (using content analysis)



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4.2.1 Concept category

The Concept category was subdivided into three further subcategories each containing five items.

Criteria subcategory

The Criteria subcategory comprised of general statements about the delivery of services and of patient care. It was interesting to see that in both meetings pharmacists ranked the item: *“To ensure that patients understand how to take their medications”* as the most important issue. This indicated that pharmacists strongly believed that providing advice to ensure patients’ understanding of dispensed medications and their administration was part of their professional role. However, one of the items suggested that all medications should receive counselling. Only minority of pharmacists agreed with this which resulted in a low score for this item. This could be a reflection of the fact that there are many variables influencing the level of counselling and although pharmacists were committed to providing this service, there was no agreement on an acceptable level of provision. This also highlights the importance of setting realistic and achievable standards in order to maximise implementation of a criterion that despite being readily accepted by the profession, was not thought to be achievable in all cases by individual pharmacists.

Effective communication subcategory

The next subcategory contained items relating to effective communication between pharmacists and patients. Items listed in this subcategory showed that pharmacists were aware of personal skill components required for effective communication during counselling patients. Bearing in mind that patient satisfaction has been linked to the ability and willingness of health care practitioners to communicate with them and address their emotional concerns (Dickson *et al*, 1989), it was encouraging to see that pharmacists also acknowledged the importance of psychological as well as the technical aspects of counselling. Pharmacists’ recognition of effective communication as an element of a good quality counselling service is in line with other health professionals’ ethos where effective communication is seen as a requirement for competent performance (Dickson *et al*, 1989).

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In conceptualising counselling Egan (1982) proposed a strategy consisting of four well-defined stages: attending, exploring, understanding and action. Items in the Communication subcategory can be identified with in the first two stages of Egan's strategy. The first stage involves attending to the patient by demonstrating an active listening style, warmth and empathy as presented by the following items: "*listen to patients with regard to medications*", "*making patient feels at ease*" and "*clarification of information in different languages*".

The second stage involves exploring the patient's perspective and providing them with the opportunity to express their concerns. A central skill at this stage is questioning, especially exploring open questions which encourage patients to share their needs and voice their anxieties (Hargie and Morrow, 1990). Although pharmacists' questioning technique was not investigated in this study, other studies have indicated that 98% of all questions asked by pharmacists are closed, more than two thirds of which are of the yes or no variety (Hargie *et al*, 1993). Only 2% addressed psychological dimensions of practice with the vast majority being concerned with purely clinical matters. Smith (1992) found that 79% of pharmacists' questions were closed and that 62% of consultations included no open questions. However, in this study in agreement with others (Krska *et al*, 1995) pharmacists were aware that they should provide an atmosphere conducive for patients to express their needs as exemplified by the item: "*creating an atmosphere so the patient feels able to ask questions*". This is indeed a facet of pharmacists' counselling provision which is expected by patients as reported by other researchers (Livingstone *et al*, 1996; Hargie *et al*, 1993). Despite pharmacists' awareness and public expectations of having an opportunity of asking questions only one third of the patients are generally given this chance (Krska *et al*, 1995; Livingstone *et al*, 1996).

The third stage of counselling is for the counsellor to understand how the patient feels and to communicate his or her empathy and understanding with the patient. In the final stage the counsellor encourages the patient on a course of action after providing information on the potential negative and positive outcomes and helping the patient to make a decision. According to the results of this study there was no item to indicate pharmacists' knowledge

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of the need to demonstrate their understanding of patients' problems nor the fact that they perceived patients as equal and active participants in making a decision over their medications and/or treatment.

This point was further manifested when issues in the communication subcategory were analysed indicating a somewhat paternalistic and authoritarian stance of pharmacists. Statements such as "*making sure the patient realises the need to take medication*" bore the signs of pharmacists' lack of recognition of patient's role and the fact that ultimately it was the patient who decided whether to accept the recommended course of action, including the treatment.

These observations suggest that pharmacists' perception of their role fits a model of compliance, a term used to describe the extent to which patients follow the instructions of health professionals. Trostle (1998) argues that compliance defines patients' behaviour in terms of professional expectations alone implying an excessively authoritarian attitude of the health care professionals towards patients which does not reflect recent changes within health care systems (Feste and Anderson, 1995). Adherence, collaboration and concordance are alternative models, increasingly moving towards the concept of patient empowerment which seeks to enhance patients' self understanding and the potential for self care (Marks *et al*, 2000).

Patient empowerment can aim to involve the patient more in health care through attention to patient needs. However, not all patients wish to be actively involved in their personal health care, as Lupton's study (1997) indicated that many patients, especially older people, prefer to maintain a more passive role. Indeed research has shown a decline in patients' expressed wish to be involved in decision making as their age and severity of illness increases (Sensky and Catalan, 1992). Respecting patients' wishes and being sensitive to their information needs regardless of their level of involvement in decision making results in patient empowerment.

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Communication between pharmacists and other health care professionals was thought to affect pharmacist's counselling provision, the level and content of which could be influenced adversely by a pharmacist's fear of encroaching on another health care professional's domain.

Patient's education subcategory

The third subcategory consisted of items with educational and informative messages which promoted health or prevented risks. Returning unwanted medications to the pharmacy and keeping medicines out of reach of children were messages intended to reduce risk and possible harm. Pharmacists' counselling could be educational by informing patients at what point they should refer to their doctors if the medication did not resolve the problem. It could also promote health by advising patients on how to prevent recurrent health problems. Health promotion advice can be very effective as prescription customers may then perceive pharmacists as health promoters whose advice they can seek on general health issues (Anderson, 1998b).

The importance of subcategories were compared from pharmacists' perspective by using weighted scores they allocated to each issue during the Nominal Group meetings. The Criteria subcategory was judged to be the most important, when compared to the Effective Communication and Patient Education subcategories which were given almost the same weighted scores by pharmacists. This implies that although pharmacists unanimously agreed on the importance of providing counselling to improve patients' understanding of their dispensed medications, they did not consider effective communication which included being responsive to psychological needs of the patient as one of the important elements of counselling and did not give it a high score. This corresponds to a research by Maguire *et al* (1989) which showed that despite patients valuing acknowledgement and help with their psychological needs, health care professionals are generally ill equipped and reluctant to deal with these needs.

4.2.2 Component category

Items which described technical information about counselling of dispensed medication were included in the Components category. Pharmacists identified the most important component of counselling for dispensed medication as the dosage instructions, followed by the side effects, drug/drug interactions, interactions with food and drink, contra indications, storage, name and indication of products. These findings corresponds with data on patient counselling gathered in self-reports (Krska *et al*, 1995). Raisch (1993) also found that pharmacists reported most frequently providing information on drug name, dosage, side effects, drug interaction and indication of medications. In a study by Krska *et al* (1995) pharmacists thought that the types of advice that should be offered were in descending order of dosage instructions, side effects, storage, food/drinks to avoid and indication. This clearly indicates that pharmacists consider provision of information on side effects of the medication as a priority when counselling the patients. However, many observational studies have shown that this does not reflect practice. This point has also been highlighted by members of public as an issue on which their information needs are not currently met by the level of advice pharmacists provide (Morrow *et al*, 1993).

According to the total scores of the two main categories, the Components with 397 and the Concept at 275, pharmacists attached more importance to delivering detailed and technical information about medications than the processes of counselling. This was also observed when after tabulating and ranking all the twenty-four items, the first nine highest ranks belonged to technical items denoted as the Components with the first communication item appearing at the tenth rank. Pharmacists' emphasis on technical knowledge and advice does not reflect consumer needs priorities. A meta analysis of forty-one studies illustrated that patients' satisfaction was associated with better communication and social conversation as well as more information and the technical competence of health care professionals (Hall *et al*, 1988).

The initial rapport between patient and pharmacist, listening to patients sharing their concerns and demonstrating empathy and understanding of the patients' needs should be considered as prerequisite for an effective oral counselling by pharmacists. Patients who

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feel at ease in asking questions are more likely to guide the pharmacist to provide information and advice on the issues most pertinent to them, empowering them to take responsibility for their own health.

4.3 Establishing the level of oral counselling on the dispensed medications

The randomly selected sample of fifty-one pharmacists in the observational study consisted of ten female (18%) and forty-one male (82%) pharmacists. The most recent manpower survey of pharmacists (Royal Pharmaceutical Society, 1996b) reported that the percentage of women on the register of the Royal Pharmaceutical Society was almost 47%. However, as many as 37% of female pharmacists work part-time with half of them less than 13 weeks a year which could explain the small percentage of female pharmacists in the sample. As far as employment status is concerned 67% of pharmacists were owner/managers, a figure comparable to the Royal Pharmaceutical Society survey (1996) where the percentage of pharmacies owned by pharmacists with less than five branches in the chain was 67%. The proportion of locum pharmacists in the sample was 14% and in the manpower report was 20% whereas employee managers were under-represented (19% in this study, 30% in the manpower report).

Considering that the study sample was a close representation of the sampling frame coupled with 82% rate of response and inclusion of the validation procedure, it is likely that the results represent the current counselling practice in urban community pharmacies in Greater London and possibly to some extent beyond.

The findings of the validation procedure indicated that although the observer's presence might have encouraged pharmacists to hand out prescriptions more frequently to patients, the increase was not statistically significant. Similarly the rate of counselling was not markedly different and even showed a slight increase in validation procedure when compared with the results of stage three observations. As the data was collected covertly, staff did not know the medications on prescriptions and could not judge whether the advice was related to the dispensed items or not. This could have resulted in an unintentional overestimation of the number of oral counselling when they logged any pharmacist-patient

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discussion with medical or pharmaceutical content as provision of advice. Therefore cases which were recorded as pharmacist-patient interactions in stage three, could have been logged as oral counselling in the validation procedure resulting in an overestimate of pharmacists' consultations. Therefore it can be concluded that there was no strong evidence to indicate that pharmacists increased their rate of counselling when observed, a finding that was also reported by another UK study (Savage, 1995).

4.3.1 The extent of oral counselling on dispensed medications

The results of the observational study indicated that 30.6% of the dispensed medications received oral counselling. This closely compares with the results obtained by Berado *et al* (1989) at 24% and Krska *et al*(1995) at 33%, both of whom used observation methods and Livingstone *et al*(1993) at 25% who employed a covert method.

However, in the present study the overall frequency of pharmacist or staff interactions with patients was 55.7% which included any discussion around health issues that may or may not have been related to any of the medications dispensed at that time. The overall frequency of interactions compares well with the findings of Carroll and Cagon (1983) and McMahon *et al* (1987), in which the patients were asked about the level of advice they received for their medications from pharmacists. In a study conducted by Krska *et al*(1995) it was shown that patients reported receiving a significantly higher level of counselling in comparison to the level they were observed to receive. This may be due to differing interpretations of the phrase "counselling" by the patients and the researchers. It has been demonstrated that patients do not assess the medical or pharmaceutical consultations simply on their technical contents; other issues such as the practitioner's interpersonal competence, their communication skills and social conversation are also highly valued by patients (Hall *et al*, 1988). Therefore as far as patients are concerned it may well be that having a discussion with the pharmacist around any health issues (and not only receiving technical information about the dispensed medicines) constitutes receiving counselling.

This study found that 74% of prescriptions were handed out by pharmacists, a figure also reported by Krska *et al* (1995). Regarding prescribed medications, there is a clear demand

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from the public for easier access to, and direct contact with, pharmacists. This probably reflects the public's perception of pharmacists as medication experts and their beliefs that they would receive more or better advice talking to pharmacists than another staff. In a survey conducted by Hargie *et al* (1993) more than two thirds of the respondents stated that they would like pharmacists to hand them their prescriptions, spend more time counselling and provide an opportunity for them to ask questions. These are aspects of oral counselling that pharmacists should incorporate into their practice if they are to meet patients' needs and improve their satisfaction; especially since it has been found that patients' satisfaction is linked to their perception of ability and willingness of health care practitioners to deal with their emotional concerns (Dickson *et al*, 1989) as well as the practitioner's expertise and competency (Worley and Schommer, 1999).

4.3.2 The content of advice provided for dispensed items

In previous studies, as also found here, the majority of oral counselling consisted of repeating the label instructions (Schommer *et al*, 1995; Savage, 1995; Raisch, 1993; Morris *et al*, 1987). In this study the most frequent oral counselling for dispensed medications was instruction on the dosage, the purpose of the medication and the timing of the dosage with regard to food. Other information such as the time intervals of the doses, adverse effects, maximum dosage and storage conditions were not often advised. Despite the low frequency of oral advice for the latter group of issues, some variations in their counselling coverage for different therapeutic groups were observed. Medications in obstetric and gynaecology, central nervous system and anti-infective therapeutic groups were advised about their potential interactions and side effects the most.

Examining the oral advice given for different therapeutic groups, it was found that the content remained almost the same regardless of the clinical nature of medications dispensed, an observation best illustrated in the case of counselling provided for anti-infective medications. Despite pharmacists prioritising this particular group and frequently providing advice for them, they only repeated the label instructions with scarcely any extra information given to patients. This shows that more frequent provision of oral counselling does not necessarily affect the content of advice offered.

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The high incidence of oral contraceptives and antibiotics interactions for prescriptions dispensed in community pharmacists (Roger and Rees, 1995) could be the main contributor of the obstetric and gynaecology group receiving the highest level of ADRs advice. As for antibiotics, the well-documented high frequency of gastro-intestinal ADRs could be the reason for pharmacists providing more counselling for this therapeutic group. Many of the most frequently dispensed medications in the central nervous system group including analgesics and anti-depressants could cause drowsiness, a warning that should also appear on the label and probably the main contributor to the high rate of oral advice given for this therapeutic category.

As expected, therapeutic groups containing medications with complex or unusual formulations including respiratory, obstetric and gynaecology and skin had a higher rate of items being demonstrated to patients. The exception was medications for central nervous system medications which mainly prescribed as oral dosage forms by GPs, these had the highest rate of demonstration. The explanation was that the data collection period coincided with the launch of sumatriptan as the first anti-migraine product formulated in a self administered pre-filled injection dose, producing an initial surge of prescriptions for this new product and the subsequent demonstration of the product by pharmacists to first time users of pre-filled syringes. As far as oral counselling on the time of taking medication in relation to food was concerned musculoskeletal group received the most oral advice which was expected considering their high rate of gastro-intestinal ADRs caused by the non-steroidal anti-inflammatory medicines in this group.

Kraska *et al* (1995) found that pharmacists who did not consider counselling as part of their role counselled at lower rate. A study on the prescription monitoring role of community pharmacists (Greene, 1995) illustrated that the perception of pharmacists of the likelihood of a clinically significant error (incident) occurring with prescribed medications, such as adverse drug reactions, affected the number of incidents they detected. Pharmacists who considered the number to be small or insignificant, reported a lower volume of incidents than those who perceived the number to be considerable.

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By implication these findings may indicate a close association between pharmacists' perceptions and their behaviour, an association which may also be applicable to pharmacists' counselling behaviour and the content of advice they provide. Possibly pharmacists are not aware of the magnitude of iatrogenesis and incidences of health problems which are caused by taking medications, including the ones which can actually be attributed to complying with the recommended drug therapy. If so, it could be that this perception of low volume or "insignificant" number of incidents contributes to their lack or low level of counselling on issues such as adverse drug reactions and side effects. Although in this study, in the stages four and five, an attempt was made to increase pharmacists' awareness of different counselling issues and examined the impact on their counselling behaviour, this was confined to a small group and only concerned with some issues. There is a need for specially designed studies at a larger scale to explore the effect of pharmacists' beliefs and perceptions on their counselling behaviour.

Some pharmacists believe that patients will experience side effects if they are told about them which may result in non adherence to their medication regime. However, McBean and Blackburn (1982) found that providing patients with detailed information on the side effects did not result in more reports of their occurrence and Mayers and Calvert (1978; 1984) showed that providing patients with written and oral information including side effects of the medication actually improved their adherence.

Williamson *et al* (1992) and Krska *et al* (1995) found that side effects were the main concern for patients about which they wanted more information. Patients should be informed about common predictable side effects so that they can make rational decision as to whether any reaction they encounter is expected and should be tolerated or whether it should be viewed as a warning sign that requires medical advice. The estimated proportion of hospital admissions due to adverse drug reactions is estimated to be between 6 to 22% (Nelson and Talbet, 1996). While a proportion of these may be due to non compliance, others can be attributed to problems when complying with the recommended drug therapy.

4.4 Oral counselling and pharmacists' characteristics

There were variations among pharmacists in this study in the rate of oral counselling. When the association of pharmacists' characteristics and their advisory role was investigated pharmacist' gender, employment status and number of years of being registered was found to be associated with their counselling behaviour. This study indicated that women pharmacists tended to counsel more patient than men, a point that was also highlighted in Lauriel and Poston's study (1992). The gender difference in counselling behaviour of pharmacists concurs with findings in the medical profession. It is well established that there are gender differences in both quantity and quality of medical consultations, with female physicians spending more time with patients and being more attentative to their needs, especially psychological needs (West, 1990; Maheux *et al*, 1990). These findings resonate with the general literature of gender differences in communication (Tannen,1991) and suggest that it is highly likely that gender specific socialisation carries over into professional conduct of pharmacists and doctors.

Employment status was also found to influence counselling behaviour of pharmacists with owner/managers giving more advice about medications than employee managers and locums. There is evidence to show that the level of provision of drug information has the potential to increase consumer patronage and loyalty to a community pharmacy as well as consumers' satisfaction with pharmacy services (Whitehead *et al*,1999). Under the current NHS pharmacy remuneration system, pharmacists' payment is based on the number of prescription dispensed plus a small fee for additional professional services which is also known as the professional allowance. In 1994 the criteria for payment of the professional allowance based on a flat rate payment was reviewed and replaced with a tier system including three bands: contractors dispensing less than 1100, between 1100 and 1600 or more than 1600 prescriptions per month (Prescription Pricing Authority, 2000). Small contractors dispensing less than 1100 prescriptions per month receive the minimum rate of professional allowance which increases with the volume of dispensed prescriptions to a maximum for 1600 or more prescriptions dispensed, after which the payment will reach a plateau and remain constant.

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Considering that up to 70% of pharmacies' income (with the exception of multiple pharmacies) is generated from their NHS dispensing contract (Jones, 1998), it is essential for small independent contractors to retain their monthly dispensing above 1100 and preferably above 1600 prescriptions per month in order to remain financially viable. Therefore it is not surprising that by providing a higher level of oral counselling owner/managers and specially the single proprietor pharmacists attempt to maintain and increase their number of loyal prescriptions consumers.

Although, the overall trend in the data appeared to be that the longer the pharmacist had been registered the more counselling was given, there was a slight reduction in provision of this service by pharmacists who had been registered for 21-30 years in comparison to those registered for more than 31 years. A trend that was mirrored with pharmacists age, although it did not reach statistical significance.

4.5 Oral counselling and pharmacy characteristics

When association of pharmacy characteristics and provision of advice was investigated, the number of staff, staff composition and the professional status of the person handing the medication out were found to influence the level of counselling given for dispensed medications. Surprisingly neither availability of computerised Patient Medication Records (PMRs) nor presence of a consultation area had a significant influence on the level of advice offered to patients. The fact that these characteristics are available does not necessarily mean that they are actively used. In the future studies it may be more appropriate to collect data on the use of counselling areas and PMRs during advice giving rather than their availability.

The level of oral counselling received by patients varied significantly according to the professional status of the person handing the prescription out. The level of oral counselling offered by pharmacists was significantly higher than that of any other member of staff. This has also been reported by other researchers (Hayes and Livingstone, 1990; Livingstone *et al*, 1993). It was expected that the counselling level would be higher in the case of pre-registration students bearing in mind that the data collection took part in the later part of

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their training, however this was not found to be the case. Although the issue of undergraduate training is outside the scope of this study, it seems that more emphasis should be placed on the provision of information and oral counselling of patients during the pharmacy course. Their poor performance can equally be attributed to their training and the attitude of their tutors in encouraging them to actively participate in patients' counselling.

As far as staff numbers are concerned, it seems that with the exception of single proprietor pharmacists who provided the highest level of advice and mostly employed only one counter assistant, the counselling rate increased with the number of staff. As explained earlier on, under the current NHS remuneration system, small independent pharmacy contractors are highly dependent on the income generated by NHS dispensing contract. An additional explanation for the high level of advice in this group could be that in a pharmacy setting where there was only one additional staff member, pharmacists had less opportunity to delegate handing out of prescription items hence medications were given out by pharmacists who were more likely to provide advice for dispensed items leading to a higher overall rate of counselling. The same explanation may apply to other features of staff composition. Pharmacies only employing counter staff tended to be smaller with more prescription items being given out by pharmacists. In larger settings this task could have been delegated to dispensing technicians or pre-registration students as well as counter staff, all of whom gave less advice on the items dispensed resulting in an overall reduction of the service.

4.6 Oral counselling and prescription characteristics

A higher rate of oral advice was given when dispensed medications were paid for, whether they were dispensed on a private prescription or on National Health Service forms for which prescription charges were payable. A finding that was also reported by Carroll and Gagnon (1983). Financially, dispensing private prescriptions is more rewarding for pharmacists. The profit margin is usually up to 50% of the drug cost and the payment is immediate unlike

NHS payments which are made at the end of each month. These may act as an incentive for pharmacists to provide advice in order to maximise patients' satisfaction.

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The difference in provision of oral counselling was more significant in the NHS category when exempt and paid prescriptions were compared. The paid prescriptions received almost twice as much counselling as exempt ones. However, this variable was highly confounded. Thus, this finding could be explained by the fact that the paid prescriptions were more likely to be presented by the adults (16-60 years), who were more likely to suffer from an acute condition and receive a new medication to be taken for the first time. Therefore not only their unfamiliarity with the medication could lead them to ask for more information, pharmacists are also more likely to prioritise these cases for the same reasons and provide more advice.

The findings of this study indicated that there was no correlation between dispensing workload and the level of oral counselling provided on dispensed medications. Despite using two measures: the "total number of items dispensed" and the "number of items dispensed per hour" as proxies for dispensing workloads it appeared that the number of items dispensed in a pharmacy did not effect the quantity of oral advice received for dispensed medications. This supports the findings of other observational studies with prescription medications (Savage, 1995; Livingstone, 1996; Berardo *et al*, 1989).

It was observed that the greater dispensed items per patient the less oral advice was offered. It is likely that patients on multiple therapy were also taking long term treatment and it has been demonstrated that pharmacists give a lower priority to counselling with repeat and long term therapy (Wiederholt *et al*, 1992; Hayes and Livingstone, 1990). However, Stewart and Martin (1979) found that patients' knowledge about medication directions varied depending on the number of prescription items they were on, patients taking four or more items being less able to communicate the prescription directions correctly. Thus, there may be an argument for pharmacists to offer oral advice to patients taking multiple medications.

This study demonstrated that patients who had repeat prescriptions were 70% less likely to receive oral advice when compared to those who were prescribed a medication for the first time. Oral counselling was provided for one repeat medication out of every five dispensed, it may well be that a repeat item does not require reinforcement of dosage instructions.

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However, in these cases pharmacists should resume a drug monitoring role and by detecting the potential adverse effects of medications, ensure that the patient benefits maximally from the drug therapy. Consequently it is not unreasonable to expect that the content of the oral advice for new and repeat medications should vary, covering different issues. Examining the content of oral advice given for repeat and new medications in the study it became apparent that for both groups pharmacists mainly repeated the instructions already printed on the labels. Oral counselling for repeat items should include questions about patients' general wellbeing, management of their disease and their experience of any problems with their medications. The findings suggest that the current content of oral advice provided by pharmacists is not sensitive to the varying needs and requirements of different patient groups. Further studies should be conducted to establish ways by which pharmacists could assess patients' information needs and address them appropriately.

The therapeutic category of the medication is also a determinant of the counselling received. The counselling issues were more often discussed in the case of acute therapies than chronic ones. In this study the anti- infective agents received the most counselling at 63% and cardio- vascular preparations the least (6.2%). Anti- infective agents are mostly prescribed for acute conditions on a short term basis whereas cardiovascular and endocrine system preparations are for chronic illness and usually on a repeat basis. Krska *et al* (1995) found that pharmacists gave a low priority to providing oral advice for long term and regular medications. As already discussed this may be due to pharmacists' perception of patients' familiarity with the medication and already having an adequate level of knowledge. However, compliance is a greater problem in chronic than acute therapy (Melchewbaum and Turk, 1987). Patients on chronic therapy require reassurance and reminders to remain compliant. There is also a call for the pharmacist to monitor the therapy to ensure it is still appropriate.

A significant association was found between pharmaceutical formulation and the level of oral advice provided. Items dispensed for eyes, ears and nose were most likely to be counselled. These medications are generally formulated as drops and ointments and are likely to have special storage requirements. Many patients may not have used them

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previously. Therefore pharmacists may be more willing to give oral advice to these patients and similarly patients may be more receptive to it. The second highest counselled formulation was oral liquid preparations a favoured form of drug delivery for children in community settings. This, in conjunction with pharmacists tendency to give more oral advice for children's medication can explain the high rate of counselling for this formulation. The surprising finding was that the least counselled formulation was inhalers. Although it may be assumed that a high proportion of inhalers are repeat medications and (as for other repeats, less likely to receive pharmacists advice), this also suggests that pharmacists were not actively addressing potential problems in relation to use of these products.

4.7 Oral counselling and the patient's characteristics

The likelihood of providing oral counselling for a child's medication was found to be twice that of the medication for a person aged 60 or over, and adults (16-60 years) were 50% more likely than elderly people to receive counselling. These observations have also been reported by other researchers (Wiederholt *et al*, 1992; Tully and Temple, 1999). The proportion of new medications prescribed for an acute condition in children is the highest among all age groups (BMRB, 1996). Therefore parents' or patients' unfamiliarity with medications is probably an important factor in encouraging pharmacists' to give oral advice. This conclusion is similar to that of Schommer and Wiederholt (1994) in a study of pharmacists' perceptions of patients' needs for counselling, in which it was found that patient familiarity with medicines was the commonest determinant of the amount and type of advice provided by pharmacists.

However, pharmacist-patient consultation is an interactive and reciprocal communication and both participants should have a positive and receptive attitude if it is to proceed smoothly and successfully (Worley and Schommer, 1999). It has been reported that the pharmacists' rate of oral counselling for patients who request it was close to 100%, whilst only 25% of those who did not ask or were non-receptive were orally counselled on their dispensed medications by pharmacists (Ascione *et al*, 1985). The fact that pharmacists gave more advice for children's medications than other age groups may indicate that parents or

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carers of children were also positive towards pharmacists and receptive to oral counselling. This was indeed the case in a survey conducted by Williamson *et al* (1992) where it was found that as many as 89% of mothers had asked pharmacists for advice on prescription medications.

Elderly people on the other hand were least likely to ask pharmacists for advice on their medications. They have been reported to prefer doctors as the source of information about their prescribed items (Morris *et al*, 1987), their perception of pharmacists' role being the dispenser and supplier of medications (Williamson *et al*, 1992). It has also been suggested that patients' age correlates negatively with their need for information (Schommer *et al*, 1995). These characteristics could reduce elderly patients' receptiveness to pharmacists' advice-giving which consequently may discourage pharmacists from providing oral counselling for them. Furthermore, pharmacists have reported difficulties in communication with elderly patients including deteriorating vision and hearing (Smith *et al*, 1995).

There is also a high level of repeat prescribing for elderly patients. It may be a common assumption that if the patient had the medication on other occasions there is no need for information. However, previous usage of the medication does not necessarily eliminate the need for more information. It may just be that different or perhaps more in-depth information should be provided to these patients.

Elderly people are known to experience many medication-related problems. They are more susceptible to adverse drug reactions and contraindications due to likelihood of a lower hepatic and renal functions and polypharmacy (D'Arcy, 1984; Williamson, 1978). Perhaps a different approach to oral counselling of these groups of patients should be adopted. The focus of the advice offered should address the problems involved in chronic therapies. This study demonstrates that pharmacists mostly concentrate on provision of drug administration information which may be less appropriate in cases of long term therapy. Information on issues like ADRs, interactions etc. may be more relevant to give patients the opportunity to

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ask questions. This study also suggests that community pharmacists may benefit from educational programmes that reinforce the need for counselling patients who are receiving medications long term.

To identify variables predictive of the provision of oral counselling on dispensed medications a discriminant analysis was performed. Fifteen variables were identified as important factors which in a combination could predict whether the oral counselling would have been provided for 65% of dispensed items. These variables related to pharmacists, pharmacies, patients and prescriptions characteristics as well as the total number of items dispensed. Using multiple regression, a model was constructed where the predictive value of each variable was quantified. In this analysis all the variables associated with pharmacies' dispensing workload (including the total items dispensed, number of items dispensed per hour and total number of patients handing prescription forms in for dispensing) were eliminated. It indicated that a higher level of counselling would be offered if dispensed medications: were handed out by pharmacists rather than a member of their staff; were for children; were dispensed in smaller pharmacy; had a smaller number of items on the prescription form; were paid for; were new rather than repeat medications and if the pharmacist was an owner/ manager and younger. The model only explained 18.5% of the observed variation in oral counselling provided for dispensed medications. Widerholt *et al*(1992) also reported that his model containing similar variables, as in this study, only explained 15% of the variation.

This highlights the fact that pharmacists' oral counselling is influenced by a wide variety of variables. It may be neither practical nor useful to attempt to construct a single model to predict it. It was in pursue of this conclusion that the researcher constructed separate models for provision of oral advice by community pharmacists for different patients' age groups as well as for anti- infective medications as the highest advised therapeutic group.

In the models constructed for different patients' age groups a different range of variables remained in the models and the predictive values of all three models improved considerably. In the case of children's medications the model's predictive value was to 23%, for adults

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(16-60 years) 30% but most remarkably the predictive value for elderly patients' model was increased to 55%. There are no previous studies with which these findings can be compared.

The only variable common to all three models was the status of the medication as repeat or new. This meant that repeat medications would attract less advice regardless of the patient's age. The only other significant variable regarding counselling for children's medication was the pharmacist's gender, with female pharmacists providing a higher level of advice. As discussed earlier gender difference in counselling behaviour for health care professionals is well established (West, 1990).

The two models for provision of oral counselling for adults (16-60 years) and elderly patients were similar in the variables they contained. In both age groups the characteristic with the highest influence on pharmacists' counselling behaviour was the presence of a dedicated counselling area in the pharmacy. Pharmacists who share patients' views on the importance of having privacy for counselling, may also be more inclined to advise. Owner/manager pharmacists were more likely to counsel adult patients when compared with employee managers and locum pharmacists. This fact that independent pharmacists are highly dependent on the income generated from their NHS dispensing contracts may be a contributory factor. A good counselling service for dispensed items may be a strategy to retain and attract prescription clients.

In bivariate analysis it was found that medications dispensed on the private prescriptions attracted higher rates of oral counselling by community pharmacists. There may be a number of reasons for it. The fact that patients pay for their prescription items may create an expectation that they should receive advice, pharmacists may feel obliged to provide information and also dispensing private prescriptions is more lucrative than NHS prescriptions, hence pharmacists may deliberately counsel these patients to encourage loyalty to the pharmacy.

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The length of time the practitioner had been registered as a pharmacist (which can be taken as a proxy for her or his experience) also influenced pharmacists' counselling behaviour. In the model for elderly patients, pharmacists' experience was the highest determinant factor in their provision of oral advice. As elderly people are known to be reluctant to ask or receive advice on their medications from pharmacists (Williamson, 1992; Livingstone, 1996) it could be that the pharmacist requires a degree of experience and interpersonal communication skills to be able to overcome this and build up a rapport with this group of patients.

A model was constructed for provision of oral counselling on anti-infective medications. The combination of predictive variables in this model explained 30% of the counselling variation. As in other models, pharmacists' employment status was one of the predictive factors for the level of advice provided however, it had a greater predictive value in this model. Owner/manager pharmacists tend to give more oral advice on anti-infective agents than employee pharmacists and locum pharmacists. High dispensing workloads measured as total number of items dispensed, could also reduce the number of consultations for anti-infective medications dispensed. This is contrary to the other models, in which no association was found between advice giving of pharmacists and business of the pharmacy. The status of NHS prescriptions as paid or exempt was a significant factor in this model, as was the patient's age. However, in this model (and contrary to others) the level of advice increased with the patient's age implying that older patients receive more oral counselling on anti-infective medications. This therapeutic category is almost always prescribed for an acute condition hence as far as pharmacists are concerned none of the patients are familiar with this medication and as another studies have indicated unfamiliarity of patients with the medication dispensed is one of the strongest determinant factors for pharmacists in providing the oral advice (Schommer and Wiederholt, 1994; Krska *et al*, 1995).

Models regarding the provision of oral counselling on dispensed medications for specific groups of patients or medications in community pharmacy settings have not previously been developed in the UK. Further studies could explore, construct and test models for other

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users of community pharmacy services; and establish their value in communication and counselling training of under and post graduate pharmacists in the future.

Provision of medicine management and the repeat dispensing services are two new roles for pharmacists proposed by the Government in the Pharmacy in the Future- Implementing the NHS Plan (DoH, 2000). It is envisaged they will be in place by 2004. Successful implementation of these services requires pharmacists' to be competent in the monitoring of appropriateness of the prescribed medications, able to detect potential adverse drug reactions and to provide pertinent information for patients.

Thus pharmacists, and pharmacy as a profession, have limited time to audit their abilities and practices required for the delivery of the newly proposed services, with the view to addressing the shortcomings and implementing any remedial actions by 2004.

Currently, the evidence suggests that despite the general public's acceptance of the community pharmacist's advisory role, there is variation between different age groups, with elderly people more reluctant to request or receive advice from community pharmacists on their prescribed medications. Seventy five percent of prescriptions in Britain are repeats (Bliss, 1981), a figure which rises with the age of the patient (Tulloch, 1981; BMRB, 1996). Therefore it is reasonable to assume that elderly patients may constitute the majority of clients for pharmacists' proposed new services. Studies have shown that approximately half of the elderly people taking two or more prescribed medications were taking at least one potentially interacting combination (Duggan and Bates, 2000; Naylor and Oxley, 1997; Smith *et al*, 1995). Despite having identified elderly people as a group with particular needs in relation to their medication, there are currently obstacles to the development of this service in community pharmacy settings. These include: pharmacists' lack of ability or desire to communicate with patients; a low priority given by pharmacists to monitoring and detecting of unwanted effects of medication; and pharmacists' assumptions that patients' familiarity is directly and highly related to their knowledge of the drug. From the patient's perspective barriers include: the reluctance of some people to receive advice from pharmacists and an unwillingness to ask pharmacists questions about their medication.

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The findings of this study in line, with previous UK based studies, have demonstrated that the current advisory role of pharmacists for prescribed medications lacks a number of essential elements. The standards governing this professional service are ambiguous, not quantifiable and open to individual interpretation. The responsibility of promoting awareness of potential shortcomings in delivering pharmacists' new and extended role rests with the professional bodies and the duty of meeting an adequate competency level remains with individual pharmacists.

The fourth stage of this study examined pharmacists' views and justification for the extent of their counselling behaviour prior to assessing the effects of standard setting and implementation in practice. Although other studies had previously explored community pharmacists' attitude to the provision of oral counselling, this study also attempted to establish pharmacists' reasons for their behaviour by presenting them with data of their advisory services. All pharmacists in the group accepted their role as providers of oral advice for dispensed medications. They believed that it was an integral part of their professional role and it was a service that they were committed to provide. However, there were differences in their approach to its delivery.

Whilst some pharmacists would share the information with the patients to enable them to make an informed decision about adhering to their medication's regime, others may make a judgement on the patient's information needs and provide advice accordingly. This latter approach by these pharmacists may be a reasonable course of action if it is preceded by an assessment of the patient's information needs. Pharmacists by using their own perception of patients' needs could deny vital information from patients which could facilitate their adherence or lead to adverse effects not being recognised.

When the extent of oral advice, as observed in stage three of the study, in association with therapeutic group, formulation, whether medication was a repeat or new and age of the patient was shared with pharmacists, it emerged that the main underlying theme for explaining pharmacists' counselling behaviour was their perception of patients' knowledge on the medication dispensed. An example was when pharmacists were asked to comment

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on the higher level of counselling for children in comparison to adults (16-60 years) and elderly patients, the response was that a higher proportion of medications dispensed for children and adults (16-60 years) were for acute conditions with the likelihood that the patient may be unfamiliar with their medications. Therefore, pharmacists perceived these groups to be more in need of oral advice than elderly people who were commonly on repeat medications. Pharmacists' perceptions of patient's medication knowledge was found to be a predictor of their counselling behaviour. The same applied to other factors, in that variables which may increase patients' familiarity with their medicines adversely affected the rate of pharmacists' counselling. Products used for skin and gastro intestinal conditions, available over the counter received no or minimal advice.

Regarding the counselling issues covered, pharmacists were most inclined to repeat the instructions printed on the label with little other information about the medications. The main reason for some items not being advised on dosage instruction was missing direction on the prescription. In the UK, the labeling of dispensed medicines is controlled under the Medicine Act 1968 which states that a dispensed medicinal product must be labelled with directions for use. However, with the exception of Controlled Drugs, there is no legal requirement for a prescriber to specify dosage instruction. This can present difficulty for pharmacists especially if the medication is not a repeat or the prescription does not belong to a patient whose medication record is kept in the pharmacy. However, Rogers and Rees (1997) found that up to 32% of pharmacists consult the patient, prescriber or use their own knowledge to ensure that dosage instruction was given to patients.

The rate of counselling for medications' indication found to be among the least advised issues. However, pharmacists were not surprised by the findings as they knew that their lack of access to patient medical record and their diagnosis was the main contributor to the low rate of advice offered on indication of medications. The situation was specially problematical for medications with multiple indications such as benzodiazepines which may be prescribed as sedatives, anxiolytics or muscle relaxants.

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Provision of advice on the potential ADRs led to an in-depth debate among the group, with half of pharmacists advising patients on the main ADRs and half not prepared to volunteer this information. The latter group of pharmacists believed that patients would experience side effects if they were told about them and this could result in non-adherence to their medication regime. However, McBean and Blackburn(1982) found that providing patients with detailed information on the side effects did not result in more reports of its occurrence and Myers and Calvert (1973; 1978) showed that providing patients with written and oral information including side effects of the medication actually improved patients' concordance.

Williamson *et al*(1992) found that medications' side effects were the main concern for patients, a subject that they were expecting to receive information about. An expectation that was not often met by pharmacists' provision of oral advice (Krska *et al*, 1995). Patients should be informed about common predictable side effects so that they can make rational decisions as to whether any reaction they encounter is expected and should be tolerated or is a warning sign that requires medical advice. The estimated proportion of people admitted to hospitals due to adverse drug interactions ranges from 6 to 22% (Nelson and Talbot, 1996). While a proportion of these may be due to the noncompliance, others can be attributed to actually complying with the recommended drug therapy.

Other studies, like the current one, have reported that when counselling is provided on dispensed medications, pharmacists are mostly inclined to repeat the instruction printed on the label with no or a minimal amount of extra information. The provision of oral advice is part of pharmacists' professional obligations and not a legal requirement. The only specific requirement currently is the reinforcement of medication directions as stated in the Standards of Good Professional Practice:

“A pharmacist must seek to ensure that the patient or his agent understands sufficient information and advice to enable safe and effective use of the medicine. This must include seeking to ensure that the directions on the labels of dispensed products are understood.” (RPSGB, 1995)

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Beyond this there are no explicit standards regarding pharmacists' advice with prescription medicines. Any standards set for this service have to be versatile in order to accommodate the variations encountered by pharmacists in daily practice and according to the differing needs of patients. They must also be feasible in a practice settings. It seems that a more specific and explicit requirement consisting of patients' information needs assessment and details of counselling issues to be covered by pharmacists could be a good starting point. This calls for the Royal Pharmaceutical Society to review the Standards of Good Professional Practice in order to address deficiencies of pharmacists' advisory role as identified by this study.

4.8 Barriers to provision of oral counselling for dispensed medications

Pharmacists identified lack of finance and time, inadequate counselling skills and area as well as potential conflict with other health care professionals as barriers to provision of oral counselling on dispensed medications. The issue of finance, as discussed earlier, referred to lack of recognition and remuneration of the current NHS pharmacy payment system, where there is no reimbursement in lieu of time spent on advising patients about medications.

Lack of time was cited by the pharmacists as one of the hindrances to their advisory role, as also reported by Krska *et al* (1995) and Morrow and Hargie (1992) however, in this study like others (Berado *et al*, 1989; Savage, 1995) no correlation was found between workload as measured by the number of prescription dispensed per hour and provision of counselling using observational method. However, when pharmacists self-reported their advisory activities it was found that a high dispensing workload limited patients' counselling (Kirking, 1982; Laurier and Poston, 1992). This highlights the fact that pharmacists who are not committed to provision of counselling perceive lack of time as a barrier and are less likely to manage their time to accommodate their advisory activities than pharmacists who accept giving advice as an integral part of their role.

Unavailability of a dedicated area for counselling which may compromise patients' privacy, was cited by pharmacists as one of the barriers to provide advice. This was also one of

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patients' concerns as found by Hargie *et al* (1992). The influence of availability of a counselling area on the knowledge level of patients counselled was demonstrated by McBean and Blackburn (1982). They showed that after the pharmacist advice, the highest knowledge score was obtained by patients who were counselled in a private consultation area as they were more willing to discuss their medications including their concerns and anxiety about taking the medicine.

Other barrier to provide oral advice was pharmacists' fear of impinging on other health care professional's domain. However, Begley *et al*(1994) found that 88% of GPs and 86% of nurses supported pharmacists' counselling on medicine use and storage. Pharmacists would like to have an agreement with other health care professionals on the type and extent of information each advise the patient on which not only avoids giving conflicting messages to patients it also facilitate a team approach to the patient's care.

4.9 Implementing the standard and its impact on pharmacists' counselling activities

Identifying quantifiable components of oral advice enabled pharmacists to define standards for delivery of the service. Having two sets of standards for repeat and new items was a reflection on the reality of practice and ensured that the standards were realistic and achievable and not too ambitious or prohibitive for community pharmacists to attempt.

Comparison of the two sets of data prior to, and after implementation indicated a change in counselling pattern. This included a shift towards covering more counselling issues per item and also the numbers of newly dispensed items for which counselling was provided increased by 10% in comparison to baseline measurement. This could be due to pharmacists conscious attempt to improve and increase their counselling activities as a direct result of the audit.

With regard to the individual pharmacist's performance, participants did not significantly increase the number of items they counselled. However, it appears that for the items that advice was provided more units of information or issues were covered. This pattern was observed for new as well as repeat medications. It could be that defining counselling

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context as separate segments and quantifying the process as unit of information or issues, assisted pharmacists in being more precise and rigorous about the range and extent of counselling information they provide for their patients.

In some instances it was observed that the frequency of counselling decreased after implementing the standard. It could be that if pharmacists felt that they were achieving an acceptable level of practice, additional effort need not to be made. This indicates that setting standards may not necessarily result in an increase in pharmacists' workload. Nevertheless, it could harmonise the level of service delivery, inform patients on the level of service provision, reduce unrealistic expectations by consumers whilst providing a sense of professional satisfaction for pharmacists when they observe the standards.

Direct observation was the method used in stage 3 to establish the level of oral counselling in community pharmacies in this study, a decision which was made after an extensive review of the literature and balancing the strengths and weaknesses of different methods used in studies of health care professionals' counselling behaviour. This method, despite its apparent superiority, had to be abandoned in favour of self-reported data by pharmacists in stage four. This was a compromise which had to be made in keeping with the ethos of peer audit. Following implementation of the standards agreed by the group, having an observer to collect the data on counselling behaviour would have been too intrusive and would have jeopardized the participants' sense of ownership. However, this issue was addressed at the last stage of the study by using self-reporting method to collect data on pharmacists' provision of oral advice on dispensed medication before and after the audit implementation in Barnet.

To ensure the feasibility of data collection, it was limited to three hours a day for five days and was facilitated further by designing a special data collection tool which was easy and quick to complete.

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4.10 Feasibility of the peer audit in community pharmacies

The baseline counselling reported by Barnet pharmacists was higher than data obtained through the observational study. This variation may be attributable to the particular group of pharmacists from Barnet who participated in the audit. They were a self selected group and committed to the provision of counselling as an integral part of their daily routine and thus would not be representative of other pharmacists.

Both groups, the randomly selected pharmacists and the self selected Barnet pharmacists, agreed that counselling with dispensed medications was part of their professional role. They agreed that implementing an audit cycle involving standard setting could

improve their services. However, some differences between them were reflected in the discussion, for example varying perspectives regarding their roles in identifying patients' needs.

The randomly selected pharmacists perceived older people as less willing to receive advice, whilst Barnet pharmacists identified elderly patients as more susceptible to problems with medications and with whom a different counselling technique should be adopted.

One of the main influencing factor identified as a predictor of pharmacists' advisory behaviour was their perception of patients knowledge. It seems that a major part of decision making by pharmacists regarding the needs of patients is undertaken without any consultation with patients. Probably this is an issue we have to investigate further, ensuring that pharmacists (perhaps through education) are enabled to liaise with patients, identify their needs and promote concordance.

4.11 Conclusion

This study demonstrated that currently around 30% of prescribed medications receive oral advice when dispensed in community pharmacies. Despite variation in counselling activities, pharmacists believed that provision of oral advice was an integral part of their role. During the course of this study as many as fifteen predictive variables of the provision

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of oral counselling on dispensed medications were identified. However, the most significant determinant factor was found to be pharmacists' perception of patient's prior medication knowledge, an assumption made by pharmacists without any consultation with patients. Currently in England there is no agreed systematic approach for community pharmacists to assess patients' information needs on their dispensed medication. Medicine taking has been increasingly viewed by patients and professionals alike as a partnership; adopting the same approach, pharmacists' assessment of patients' information needs should be an interactive process with patients directly involved.

Counselling and advice-giving underpin the main areas identified by the Government in its vision of pharmacists' role and their contribution to the new NHS. *Pharmacy in the Future- implementing the NHS Plan (DOH, 2000)* sees the role of pharmacists as an educator and facilitator, advising and supporting patients in using their medicines. Audit as a quality assurance tool can improve quality and quantity of pharmacists' counselling services at an individual and group levels and by implementing the same set of standards the service level can be harmonised assuring quality and benefiting patients. This enables pharmacists to continually evolve their counselling services and remain responsive to changes in expectations and wishes of patients, outlooks of fellow health care professionals and government new policies and priorities for health.

References

REFERENCES

Ahmed S, Hicks N R, Stanwell-Smith R. Policy and practice: an audit of neonatal BCG immunisation in Avon. *Journal of Public Health Medicine* 1992; **14**:389-392.

Alexander A. Professional audit in pharmacy: Any pharmacist can carry out audit.. *The Pharmaceutical Journal* 1993;**251**:429-430.

Alkhawajah A M, Eferakeya A E. The role of pharmacists in patients education on medication. *Public Health* 1992; **106**:231-237.

Anderson C. Health promotion by community pharmacists: perceptions, realities and constraints. *Journal of Social and Administrative Pharmacy* 1999; **15**, No. 1:10-21.

Anderson C. Health promotion by community pharmacists: customers views. *International Journal of Pharmacy Practice* 1998; **6**:2-12.

Anderson C W, Alexander A M. Response to dysmenorrhoeas: an assessment of knowledge and skills. *Pharmaceutical Journal* 1992; **249**:R2.

Anderton S. From a community pharmacist. *Moving to Audit Newsletter* 1994; **1**:3.

Anonymous. *Collins English Dictionary*. London: Collins, 1979.

Anonymous. Covert research. *Pharmaceutical Journal* 1991;**247**:145.

Anonymous. North of England study of standards and Performance in General Practice. Medical audit. II. Effect on health of patients with common conditions.. *British Medical Journal* 1992;**304**:1484-1488.

References

Anonymous. Minister launches audit distance learning programme. *The Pharmaceutical Journal* 1993; **251**:405-407.

Anonymous. DOH funds audit posts in two regions. *Chemist and Druggist* 1994a ;608.

Anonymous. Model audit standards unveiled for England. *Chemist & Druggist* 1994b; 608.

Anonymous. Keele University is developing pharmacy practice standards. *Pharmaceutical Journal* 1994c; **252**:146.

Anonymous. Audit needs a point. *Pharmaceutical Journal* 1994d; **252**:141.

Armstrong P S. Seeing it for what it is. *Pharmaceutical Journal, Letters* 1994; **252**:109.

Ascione F J, Kirking D M, Duzey O M, Wenzloff N J. A survey of patient education activities of community pharmacists. *Patient education and counselling* 1985; **7**:359-366.

Association of the British Pharmaceutical Industry. *CASE: The case of patient packs*. London: 1995.

Aston University and MEL Research. *Consumer expectations of pharmaceutical services. A research report for Department of Health*. Birmingham: 1991.

Baker K N. Data collection techniques: observation. *American Journal of Hospital Pharmacy* 1980; **37**:1235-1243.

Bale R.F. *Interaction process analysis: a method for study of small groups size*. Reading, 1950.

References

- Balogh R. Audits of nursing care in Britain: a review and a critique of approaches to validating them.. *International Journal of Nursing Studies* 1992;**29**, No 2:119-133.
- Barley S L, Mathers N. An audit of post-gastrectomy patients. *Journal of Royal College of General Practice* 1980;**30**:365-370.
- Batstone G F. *Audit in Action: Educational aspects of medical audit*. London: BMJ, 1992; 171-177.
- Begley S, Livinstone C, Williamson V, Hodges N. Attitude of pharmacists, medical practitioners and nurses towards the development of domiciliary and other community pharmacy services. *International Journal of Pharmacy Practice* 1994;**2**:223-228.
- Berardo D H, Kimberline C L, Barnett C W. Observational research on patient education activities of community pharmacists. *Journal of Social and Administrative Pharmacy* 1989; **6**, No. 1:21-30.
- Berardo D H. Observations on the behaviour of pharmacists – implications for better patient counselling. *Patient Counselling In Community Pharmacy* 1986; **4**, nr 3:3-10.
- Berwick S J, Lanningan N A, Ratcliff A. Effect of patient education in post-operative patients using patient controlled analgesia. *The International Journal of Pharmacy Practice* 1994; **3**:53-55.
- Bissell P, Hibbert D. Spotlight on focus groups. *Practice Research Bulletin Manchester University* 1997; **5**:1-4.
- Bliss M R. Prescribing for the elderly. *British Medical Journal* 1981;**283**:203-206.

References

- Blenkinsopp A, Phelan M, Bourne J, Dakill N. Extended adherence support by community pharmacists for patients with hypertension: a randomised controlled trial. *International Journal of Pharmacy Practice* 2000; **8**:165-175.
- Blom A T, Kam A L, Bakker A, Claesson C. A comparative study between Swedish and Dutch pharmacists. *Journal of Social and Administrative Pharmacy* 1993; **10**, No 2: 53-62.
- BMRB International Ltd report. *Community Pharmacy: the choice is yours*. London: Royal Pharmaceutical Society of Great Britain, 1996.
- Bond C M, Williams A, Taylor R J, Grimshaw J, Maitland J, Macleod N. An introduction to audit in Grampian: a basic course for pharmacists. *The Pharmaceutical Journal* 1993;**250**:645-647.
- Bradshaw S. Nursing quality measurement: quality assurance methods for peer review. In: Pearson S A, *Pharmef's nursing audit*. Chichester: Wiley, 1987;45-52.
- Brend J M, Blackburn L. An evaluation of four methods of pharmacist-conducted patient education. *Canadian Pharmaceutical Journal* 1982; **May 1982**:167-172.
- British Association of Counselling. *Counselling: a definition of terms in use with expansion and rationale*. Rugby: 1979.
- Busson M, Dunn P M. Patients' knowledge about prescribed medicines. *Pharmaceutical Journal* 1986; **237**:624-626.
- Cantrill J A, Sibbald B, Buetow S. The Delphi and nominal group techniques in health services research. *International Journal of Pharmacy Practice* 1996;**4**:67-74.

References

Carroll N V, Cagon J P. The relationship between patient variables and frequency of pharmacists counselling. *Drug Intell Clinical Pharm* 1983; 17:648-652.

Centre for Medical Education. *Moving to audit: An education package for pharmacists*. Dundee: University of Dundee, 1993.

Cleary D J, Matzke G R, Alexander A C, Joy M S. Medication knowledge and compliance among patients receiving long term dialysis. *American Journal of Health Systems in Pharmacy* 1995; 52:1895-1900.

Clinite C, Kabat H F. Improving patient compliance. *Journal of American Pharmacy Association* 1976; NS16:74-76.

Col N F, Kronholm P. The role of non-compliance and adverse drug reactions in hospitalisations of the elderly. *Archives of International Medicine* 1990;150:841-845.

College of Pharmacy Practice. *A pharmacist's guide: introducing audit*. Coventry: The College of Pharmacy Practice, 1993.

Collings J S. General Practice in England today. *Lancet* 1950;1:555-585.

Colmer L J, Gray DJ. An audit of the care of asthma in general practice. *The Practitioner* 1983;227:271-279.

Cotter S M, Barber N. Hospital pharmacists' perception in audit in the United Kingdom. *Quality in Health Care* 1993; 2:228-231.

References

Crombie I K D, Davies H T O, Abraham S C S, Florey C V. Standards. In: *The Audit Handbook. Improving health care through clinical audit*. John Wiley & Sons Ltd: Chichester, West Sussex, England., 1993;85-99.

D'Arcy P F. Drugs and the elderly: an aging problem. *Pharmaceutical Journal* 1984; **18**:784-786.

Day I. Creating categories. In: *Qualitative data analysis: A user friendly guide for social scientists*. Routledge: London, 1993; 94-113.

Dearden C H, Rutherford W H. The resuscitation of the severely injured in the accident and emergency department – a medical audit. *Injury* 1985; **16**:249-252.

Delbecq A L, Van de Ven A H, Guftason D H. *Group techniques for programme planning: a guid to Nominal Group and Delphi processes*. Glenview: Scott Foresman, 1975.

Dickson D A, Hargie O D, Morrow C. *Communication skills training for health professionals: An instructor's handbook*. London: Chapman and Hall, 1989.

DOH. *Working for Patients*. London: The Stationary Office, 1989a.

DOH. *Medical audit, Working for Patients, Working paper No 6*. London: 1989b.

DOH. *NHS Circular PCA (P)*, 1993.

DOH. *The new NHS: modern, dependable*. London: Stationary Office, 1997.

DOH. *A first Class Service: Quality in the new NHS*. Wetherby: Department of Health, 1998.

References

- DOH. *The NHS Plan: A plan for investment, a plan for reform*. Norwich: The Stationary Office Limited, 2000a.
- DOH. *Pharmacy in the Future- Implementing the NHS Plan: A programme for pharmacy in the National Health Service*. London: Department of Health, 2000b.
- Donabedian A. Evaluating the quality of medical care. *Millbank Memorial Fund Quarterly* 1966; **44**:166-204.
- Duggan C, Bates I. Development and evaluation of a survey tool to explore patients' perceptions of their prescribed drugs and their need for drug information. *International Journal of Pharmacy Practice* 2000; **8**:42-52.
- Eadon H J, Batty R, Beech E F. Implementation of a patient-oriented pharmacy service. *International Journal of Pharmacy Practice* 1996; **4**:214-220.
- Egan G. *The skilled helper*. Brooks-Cole: Monterey, California, 1982; 39-49.
- Expenditure Committee: Employment and Social Services Subcommittee.. *Minutes of Evidence*. London: HSMO, 1971; **HC**: 323ii.
- Ferlie E A, Fitzgerald L. *The new public management*. Oxford: Oxford University Press, 1995.
- Feste C, Anderson R M. Empowerment: from philosophy to practice. *Patient Educational and Counselling* 1995; **26**:139-144.
- Fitzpatrick R, Boulton M. Qualitative methods for assessing health care. *Quality in Health Care* 1994; **3**:107-113.

References

- Fitzpatrick R W, Hynam B M, Phillips W M. Audit in hospital pharmacy: three years of experience. *The Pharmaceutical Journal* 1994;**253**:31-33.
- Fowkes F G R, Evans K, T Davies E R, Green G, Hartly G, Hugh A E, *et al.* Multicentre trial of four strategies to reduce the use of a radiological test. *Lancet* 1986; **i**:367-370.
- Fowler N. *Ministers decide*. Chapmans, 1991; 184.
- Gallagher M, Hares T, Spencer J, Bradshaw C, Webb I. The nominal group technique: a research tool for general practice? *Family Practice* 1993; **10**, No. 1:76-81.
- Berardo S, Waters W E, George C F. The benefits of prescription information leaflets (1). *British Journal of Clinical Pharmacology* 1989; **27**:723-739.
- Gibbs S, Waters W E, George C F. Communication information to patients about medicines: a national survey. *Journal of Royal Society of Medicine* 1990; **83**:292-297.
- Glaser B G, Strauss A L. *The discovery of grounded theory*. Aldine: New York, 1967.
- Goffman E. *Asylums*. Harmondsworth: Penguin, 1961.
- Goodburne E, Mattosinhos S, Mongi P, Waterston T. Management of childhood diarrhoea by pharmacists and parents: is Britain lagging behind the Third World. *British Medical Journal* 1991; **302**:440-443.
- Greene R. Survey of prescription anomalies in community pharmacies: (1) prescription monitoring. *The Pharmaceutical Journal* 1995;**254**:476-481.
- Grier J. *An history of pharmacy*. London: The Pharmaceutical press, 1937.

References

Griffiths Report. *NHS Management inquiry*. Department of Health and Social Security, 1983.

Grymonpre R E, Mitenko P A, Sitar D S, Aoki F Y. Drug- associated hospital admission in older medical patients. *Journal of American Geriatrics Society* 1988;**36**:1092-1098.

Guillebaud C W (Chair). *Report of the Committee of Enquiry into the cost of the National Health Service*. London: HMSO, 1956.

Hadfield S J. A field survey of general practice. *British Medical Journal* 1953;**2**:683-706.

Hall J A, Roter D L, Katz N R. Meta analysis of correlates of provider behaviour in medical encounters. *Medical Care* 1988; **26**:1-19.

Ham C. *Health policy in Britain, the politics and organisation of the National Health Service*. London: The MacMillan Press Ltd, 1992.

Ham C. *Management and competition in the new NHS*. Oxford: Ratcliffe Medical Press, 1997.

Hancock J. Audit of major colorectal and biliary surgery to reduce rates of wound infection. *British Medical Journal* 1990;**301**:911-912.

Hargie O D, Saunders CY, Dickson DA. *Social skills in interpersonal communication*. London; Routledge, 1987.

Hargie O D, Morrow C. Counselling and healthcare: a perspective from pharmacy. *International Pharmacy Journal* 1990; **4**, No. 6:255-259.

References

Hargie OD, Morrow C, Woodman C. Consumer perceptions of and attitudes to community pharmacy services. *The Pharmaceutical Journal* 1992; **249**:688-691.

Hart J T H. The management of high blood pressure in general practice. *Journal of Royal College of General Practice* 1975;**25**:160-192.

Harvey G. An evaluation of approaches to assessing the quality of nursing care using (predetermined) quality assurance tools. *Journal of Advanced Nursing* 1991;**16**, No 3:277-286.

Hayes A, Livingstone C. Advice on prescribed medicines in community pharmacies. *Pharmaceutical Journal* 1990; **245**:R36.

Haynes S N, Horn W F. Reactivity in behavioural observation: a methodological and conceptual critique. *Behavioural assessment* 1982; **4**:369-385.

Haynes S N. *Principles of behavioural assessment*. New York: Gardener Press, 1978.

Hepler C D, Strand L M. Opportunities and responsibilities in pharmaceutical care. *American Journal of Hospital Pharmacy* 1990;**47**:533-543.

Hertzlinger R E. *Market-driven health care: who wins, who loses in the transformation of America's largest service industry*. New York: Addison-Wesley Publishing Co Inc, 1997.

Holloway S W F. *The Royal Pharmaceutical Society of Great Britain: A political and social history*. London: The Pharmaceutical Press, 1991.

Holt G A, Dorcheus L, Hall E. Patients interpretation of prescription label instructions. *American Pharmacy* 1992; **NS32**:242-246.

References

Hunt J. Quality assurance and nursing. In: Glasser B, ed. *QAP. Information Sheet*. King's Fund Centre, 1990.

Hunt J A J, Jones I F. David Lloyd George- His influence on pharmacy in Britain. *Pharmaceutical Journal* 1994;253:912-915.

Hynam B. Pharmaceutical audit in practice. *Pharmaceutical Journal* 1993; 250: 844-845.

Irvine D, Irvine S. *Making sense of audit*. Ratcliffe Medical Press: Oxford, 1991.

Irvine D H, Jeffreys M. BMA Planning Unit survey of general practice. *British Medical Journal* 1971;4:535-543.

Jackson R A, Smith M C, Mikeal R L. The quality of pharmaceutical services: structure, process and state board requirements. *Drugs in Health Care* 1975; 2:39-48.

Jones I F. Community pharmacy and the National Health Service. *Supplement to Pharmaceutical Journal 50 Years of National Health Service* 1998; July 4:24-27.

Jones S. The analysis of in-depth interviews. In: Walker R, ed. *Applied qualitative research*. London: Gower, 1985.

Jones J, Hunter D. Qualitative research: consensus methods for medical and health services research. *British Medical Journal* 1995;311:376-380.

Keel University (Department of Pharmacy Policy and Practice). *A set of Model standards for self audit in community pharmacy in England* 1994a.

References

Keele University (Department of Pharmacy Policy and Practice). *Model standards for self audit in community pharmacy in England. Purchasing and stock control.* 1994b.

Keele University (Department of Pharmacy Policy and Practice). *Model standards for self audit in community pharmacy in England. The dispensing process.* 1994c.

Kelly CA and Mason-Duff J. Two years on the audit train in Scotland. *Pharmaceutical Journal* 1993;251 (Suppl):HS42-HS43.

Kelly C A, Mason-Duff J. Auditing owings. *Chemist and Druggist (Practice Supplement)*. 1994; **3 September**: iv.

Kerrison S, Packwood T, Buxton M. *Medical audit: taking stock. Respondents' view of the factors inhibiting audit.* London: King's Fund Centre, 1993.

King's Fund Centre. *King's Fund Centre Quality Improvement Programme. Organisational audit(Accreditation UK). Standards for an acute hospital.* London: King's Fund Centre, 1990.

Kirking D M. Pharmacists' perceptions of their patient counselling activities. *Contemp Pharm Pract* 1982; **5**:230-238.

Kitching J B. Patient information leaflets – the state of the art. *Journal of Royal Society of Medicine*;1990; **83**:298-300.

Kitson A. *A framework for quality. A patient centred approach to quality assurance in health care.* Harrow: Scutari, 1989.

References

Kitzinger J. The methodology of focus groups: the importance of interaction between research participants. *Sociology of Health and Illness* 1994; **16**:103-121.

Kitzinger J. Introducing focus groups. *British Medical Journal* 1995; **311**:299-302.

Kremers E, Urdang G. *History of pharmacy: a guide and a survey*. Lippincott Company: 1976.

Krska J. Attitudes to audit among community pharmacists in Grampian. *Pharmaceutical Journal* 1994; **253**:97-99.

Krska J K, Kennedy E J, Milne S A, Mckessack K J. Frequency of counselling on prescription medicines in community pharmacy. *International Journal of Pharmacy Practice* 1995; **3**:178-185.

Laurier C, Poston J W. Perceived level of patient counselling among Canadian pharmacists. *Journal of Social Administrative Pharmacy* 1992; **9**:104-113.

Lazarus H. *Quantification of quality of pharmaceutical care in Mississippi hospitals under one hundred beds*. University of Mississippi, 1970.

Livingstone C R, Hayes A, Ladenheim D. Verbal advice about prescription medicines in community pharmacy. *International Journal of Pharmacy Practice* 1993; **251**:R6.

Livingstone C R. Verbal interactions between elderly people and community pharmacists about prescription medicines. *International Journal of Pharmacy Practice* 1996; **4**:12-18.

References

Livingstone C R, Pugh A L, Winn S, Williamson V K. Developing community pharmacy services wanted by local people: information and advice about prescription medicines. *The International Journal of Pharmacy* 1996; **4**:94-102.

Lupton D. Consumerism, reflexivity and the medical encounter. *Social Science and Medicine* 1997; **45**:373-381.

MacMahon T, Clarke C M, Baillie G R. Who provides patients with drug information: *British Medical Journal* 1987; **294**:355-356.

Maguire P F, Fletcher C. Consultation skills of young doctors-benefits of undergraduate feedback training. In: Stewart M R, ed. *Communicating with medical patients*. London: Sage, 1989;124-137.

Mahueux B D, Bland F. Female medical practitioners: more preventative and more patient oriented? *Medical Care* 1990; **28**:87-92.

Malahy B. The effect of instruction and labeling on the number of medication errors made by patients at home. *American Journal of Pharmacy* 1966; **23**:283-292.

Marinker M. *Medical Audit and General Practice*. The MSD Foundation: BMJ, 1990.

Marks D F, Murray M, Evans B, Willig C. *Health psychology: theory, research and practice*. Sage Publications: London, 2000.

Mason H L, Svarstad B. Medication counselling behaviour and attitudes of rural community pharmacists. *Drug Intell Clinical Pharmacy* 1984; **18**:409-414.

References

- Mays N, Pope C. Observational methods in health care settings. *British Medical Journal* 1995; **311**:182-184.
- McBean B J, Blackburn J L. An evaluation of four methods of pharmacist-conducted patient education. *Canadian Pharmaceutical Journal* 1982; **May**: 167-172.
- McFarlane L L, Tonkes R S. Seniors and their medicines. *Canadian Pharmaceutical Journal* 1992; **125**:167-172.
- McGovern D, McElnay J C. Counselling elderly patients on their prescribed medication: the value of professional audit. *Pharmaceutical Journal* 1995; **255**:R9.
- McMahon T, Clark C M, Baillie G R. Who provides patients with drug information? *British Medical Journal* 1987; **294**: 355-356.
- Meade V. AphA survey looks at patients counselling. *Am Phar* 1992; 307-309.
- Melchewbaum D, Turk D C. Factors affecting adherence. In *Counselling content*. New York: Plenum Press, 1987; 41-68.
- Meyer B R, Reidenberg M M. Clinical pharmacology and ageing. In: Evans J G, Williams, editors. *Oxford textbook of geriatric medicine*. Oxford: Oxford University Press, 1992.
- Morris L A. Survey of patients' receipt of prescription drug information. *Med Care* 1982; **20**:596-605.
- Morris L A, Grossman R, Barkdoll G. A segmentational analysis of prescription drug information seeking. *Medical Care* 1987; **25**:953.

References

- Morrow C, Hargie O D, Improving interpersonal communication in pharmacy practice. *Pharmaceutical Journal* 1985; **235**:23-25.
- Morrow C, Hargie O D. A new focus for CST: pharmacy practice as a helping relationship. *Pharmaceutical Journal* 1989; **243**:E16-E18.
- Morrow C, Hargie O D. Patient counselling: an investigation of core situations and difficulties in pharmacy practice. *International Journal of Pharmacy Practice* 1992; **1**:202-205.
- Morrow C, Hargie O D. Consumer perception of and attitudes to the advice- giving role of community pharmacists. *Pharmaceutical Journal* 1993;**251**:25-27.
- Mottram D R, Ford J L, Markey B, Mitchelson K. Public perception of community pharmacy. *Pharmaceutical Journal* 1989; **243**:R14-17.
- Myers E D, Calvert F J. The effect of forewarning on the occurrence of side effects and discontinuance of medication in patients on amitriptyline. *British Journal of Psychiatry* 1973; **122**:461-464.
- Myers E D, Calvert F J. Knowledge of side effects and perseverance with medication. *British Journal of Psychiatry* 1978; **132**:526-527.
- nahat (National Association of Health Authorities and Trusts). Clinical Audit in England (National Audit Office report). *nahat Briefing* 1996;**94**.
- Naylor D M, Oxley D V. Assessing the need for a domiciliary pharmaceutical service for elderly patients using coding system to record and quantify data. *Pharmaceutical Journal* 1997; **258**:479-484.

References

Nelson K M, Talbert R L. Drug-related hospital admissions. *Pharmacotherapy* 1996;16:701-707.

Newton J, Hutchinson A, Steen N, Russell I, Haines E. Educational potential of medical audit: observations from a study of small groups setting standards. *Quality in Healthcare* 1992; 1:256-259.

NHS Executive, North Thames. *Clinical Governance: Moving from rhetoric to reality..* London: The NHS Executive, 1998.

Nuffield. *Pharmacy: The report of committee of inquiry appointed by Nuffield Foundation..* 1986.

Ortiz M, Walker W L, Thomas R. Comparisons between methods of assessing patient counselling in Australian community pharmacies. *Journal of Social and Administrative Pharmacy* 1989; 6, No. 1: 39-48.

Panton R, Blackshaw C A, Bourne J G, Clapinski W G, Day J I, Flint R G. The development of model standards of professional community pharmacy practice for use in self audit. *The Pharmaceutical Journal* 1994; 542-545.

Petrie A S. *Medical Statistics at a Glance.* Blackwell Science Ltd: London, 2000;

Prescription Pricing Authority on behalf of the Department of Health. *Drug Tariff.* London: The Stationary Office, 2000.

Pruce D. First, consider the evidence. *Pharmaceutical Journal* 1994a;252:142.

Pruce D. Antibiotic audit. *Chemist and Druggist (Practice Supplement)* 1994b;3:v.

References

- Raisch D W. Patient counselling in community pharmacy and its relationship with prescription payment methods and practice settings. *The Annals of Pharmacotherapy* 1993; **27**:1173-1179.
- Raynor D K. Time to redefine “counselling”? *Int J Pharm Pract* 1996; **4**:185-186.
- Reed C. Before the NHS – the run-up to 1948. *Supplement to the Pharmaceutical Journal* 1998; **July 4**:16-17.
- Rehder T L, McCoy L K, Blackwell B, Whitehead W, Robinson A. Improving medication compliance by counselling and prescription container. *American Journal of Hospital Pharmacy* 1980; **1980**; **37**:379-385.
- Richards K F. Developments in total quality management in the United States: the intermountain Health Care perspective. *Quality in Health Care* 1994;**3**:S20-S24.
- Roberts K. Attitudinal survey in community practice. *British Journal of Pharmacy Practice* 1986:387-395.
- Roethlisberger F J, Dickson, W J. *Management and the worker*. Cambridge: MA: Harvard university press, 1939.
- Rogers PJ, Rees J E. A standardised pharmacist intervention factor (SPIF) for identifying drug products most likely to require professional intervention in community pharmacy. *Journal of Social and Administrative Pharmacy* 1995;**12.No 2**:80-85.
- Rogers A, Noyce P, Hassell K. Advice provided in British community pharmacies: what people want and what they get. *Journal of Health Services Research and Policy* 1998; **3**:219-225.

References

Royal College of Physicians. *Medical audit – a first report: what, why and how?* London: RCP, 1989.

Royal College of Physicians. *Report of the Royal College of Physicians. Medication for older people.* London: 1997.

Royal College of Surgeons. *Guidelines to clinical audit in surgical practice.* London: RCS, 1989.

Royal Commission on the National Health Service. *Report (Cmnd 7615).* HMSO: 1978.

RPSGB. The feasibility of assessing competence to practise pharmacy. *The Pharmaceutical Journal* 1990;496-499.

RPSGB. Council agrees to promote preprofessional. *Pharmaceutical Journal* 1992a:505-509.

RPSGB on behalf of the Department of Health and the pharmacy profession. *Pharmaceutical Care: the future for community pharmacy. Report of the joint working party on the future role of community pharmaceutical services.* London: 1992b.

RPSGB. *Medicine, ethics and practice. A guide for pharmacists.* London: 1994.

RPSGB. Standards of Good Professional Practice. Number 15. *Medicine, Ethics and Practice* 1995; 15.

RPSGB. *Pharmacy in new age: developing a strategy for the future. A discussion paper.* London: RPSGB, 1996a.

References

RPSGB. Survey of Pharmacists 1993 and 1994. *Pharmaceutical Journal* 1996b; **256**:784-786.

RPSGB. *Pharmacy in new age. Building the future; a strategy for a 21st century pharmaceutical service*. London: RPSGB, 1997.

Sariff A, Aziz NA, Hassan Y. A study of patients' self interpretation of prescription instructions. *Journal of Clinical Pharmacology and Therapeutics* 1992; **17**:125-128.

Savage I T. Time for customer contact in pharmacies with or without a dispensing technician. *The International Journal of Pharmacy practice* 1995;**3**:193-199.

Savage I T. Observing pharmacists at work: quantifying the Hawthorne effect. *Journal of Social and Administrative Pharmacy* 1996;**13**, No.1:8-19.

Schommer J C, Wiederholt J B. Pharmacists' perceptions of patients' needs for counselling. *American Journal of Hospital Pharmacy* 1994;**51**:478-485.

Schommer J C. Higher levels of consultation services increase patient satisfaction. *American Pharmacy* 1995; **NS35**, No. 8:33-39.

Schommer J C, Sullivan D L, Haugtvedt C L. Patients' role orientation for pharmacist consultation. *Journal of Social and Administrative Pharmacy* 1995; **12**, No. 1:33-38.

Secretary of State for Social Services and others. *Promoting Better Health*. HMSO, 1987.

Secretary of State for Health and others. *Working for patients*. HMSO, 1989.

References

- Sensky T, Catalan J. Asking patients about treatment. *British Medical Journal* 1992; **305**:1109-1110.
- Sharpe T R, Mikeal R L. Patients compliance with antibiotic regiments. *American Journal of Hospital Pharmacy* 1974; **31**:479-484.
- Sharples P M S. Avoidable factors contributing to death of children with head injury. *British Medical Journal* 1990; **300**:87-91.
- Sigerist H. *A History of Medicine: Volume 1: Primitive and Arabic Medicines.*. New York: 1955.
- Smith F J. Community pharmacists and health promotion: a study of consultation between pharmacists and clients. *Health Promotion International* 1992; **7**:249-255.
- Smith F J, Farquhar M, Bowling A P. Drugs prescribed for people aged 85 and over living in their own homes in an area of inner London. *International Journal of Pharmacy Practice* 1995; **3**:145-150.
- Smith F J. Health services research methods in pharmacy: Qualitative interviews. *International Journal of Pharmacy Practice* 1998; **6**:97-108.
- Smith F J. Analysis of data from focus groups: Group interaction – the added dimension. *The International Journal of Pharmacy Practice* 1999; **7**:192-196.
- Stewart J E, Martin J L. Correlates of patients' perceived and real knowledge of prescription directions. *Contemporary Pharmacy Practice* 1979; **2**, No. **3**:144-148.

References

- Speak M. Communication failure in questioning: errors, misrepresentation and personal frames of reference. *Occupational psychology* 1967;41:169-179.
- Tannen D. *You just don't understand. Women and men in conversation.* London: Virago, 1991.
- Taylor S. *Good general practice.* London: Oxford University Press for Nuffield Provincial Hospital Trust, 1954.
- The Royal Commission on the National Health Service *The working of the National Health Service: a study for the Royal Commission on the National Health Service by a team from the Department of Government, Brunel University - Research Paper 1.* London: HMSO, 1978.
- Thompson C J. *The mystery and art of apothecary.* London: 1929;86-100.
- Tomlin Z. Hurdles on the path to medical audit. *Health Service Journal* 1990; 1104.
- Tomlin Z. Grasping the nettle. *Health Services Journal* 1991; **27 June**:31-32.
- Trease G E. *Pharmacy in History.* Balliere, Tindall and Cox: London, 1964.
- Trostle J A. Medical compliance as an ideology *Social Sciences and Medicine* 1998; **27**:1299-1308.
- Tulloch A J. Repeat prescribing for the elderly. *British Medical Journal* 1981; **282**:1672-1675.

References

- Tully M P, Temple B. The demographics of pharmacy's clientele – a descriptive study of the British general public. *International Journal of Pharmacy Practice* 1999; 7:172-181.
- Vallis J, Wyke M A S, Cunningham-Burley S. Users' view and expectations of community pharmacists in a Scottish commuter town. *The Pharmaceutical Journal* 1997; 258:457-460.
- Van de Ven A H, Delbecq A L. The nominal group as a research instrument for exploratory health studies. *American Journal of Pharmacy and Health* 1972; 337-342.
- Van de Ven A H. *Group decision making and effectiveness: an experimental study*. Kent State University: OH: Kent State University Press, 1974.
- Van den Hombergh P, Grol R, Ram P. Structure and Process: the relationship between practice management and actual clinical performance in general practice. *Fam Pract* 1998; 15:354-362.
- Waters W H R K. Attitude to audit. *Journal of Royal College of General Practice* 1983;33:263-264.
- West C. Not just doctor's orders: directive-response sequences in patients' visits to women and men physicians. *Discovery and Society* 1990; 1:85-113.
- Whitehead P, Atkin P, Krass I, Benrimoj S I. Patient drug information and consumer choice of pharmacy. *International Journal of Pharmacy Practice* 1999; 7:71-79.
- Wiederholt J B, Clarridge B R, Svarstad B. Verbal consultation regarding prescription drugs: findings from a statewise study. *Medical Care* 1992; 30, No. 2:159-173.
- Williamson J. Prescribing problems in the elderly. *Practitioner* 1978; 220:749-755.

References

Williamson V K, Winn S, Livingston C R, Pugh A L. Public views on an extended role for community pharmacy. *International Journal of Pharmacy Practice* 1992; 1:223-229.

Woffindin L C M. Additional information that patients wish to be given about their medicines. *Pharmaceutical Journal* 1994; 253:R7.

World Health Organisation. *World Health Report 1998. Life in the 21st century- A vision for all*. Geneva: WHO, 1998.

Worley M M, Schommer J C. Pharmacist-patient relationships: factors influencing quality and commitment. *Journal of Social and Administrative Pharmacy* 1999; 16, No. 3/4:157-166.

Woroniecki C L, Mckerchner P L, Flagler D G, Berchou R, Cook J A. Effect of pharmacist counselling on drug information recall. *American Journal of Hospital Pharmacy* 1982; 39:1907-1909.

Wootton A C. *Chronical of pharmacy*. London: Macmillan and Co Ltd, 1910.

Appendices

Appendicies

Appendix 1.1: Letter to community pharmacists inviting them for an interview on professional audit

**THE SCHOOL OF PHARMACY
UNIVERSITY OF LONDON**

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29-39 BRUNSWICK SQUARE
LONDON WC1N 1AX

Telephone (switchboard) 071 753 5800
Zoe Aslanpour 071 753 5927
Facsimile 071 753 5920

Date

Name of Pharmacy
Pharmacy Address

Dear Pharmacist

My name is Zoe Aslanpour and I am a research pharmacist, studying for a PhD at the School of Pharmacy, University of London. As part of my project I would like to explore pharmacists' perspective on introduction of professional audit and the aim of my research is to investigate effects of audit implementation in one of the pharmaceutical services identified as a priority by community pharmacists.

Audit has increasingly become an important part of professional activities in health care. In the last few years it has been mandatory for many health care professionals including the community pharmacists in Scotland and it is likely to become so for the rest of us. It is important for community pharmacists to be involved in the development of the audit procedure to ensure that the standards are acceptable and workable in the community pharmacy setting.

To ensure that community pharmacists thoughts and ideas are reflected in future developments and implementation of audit, a group of twenty four pharmacists, including yourself, have been randomly selected from the Royal Pharmaceutical Society Register of Pharmacies in London. I would require 20 minutes of your time and will come to your pharmacy at a time convenient for you. Any information obtained through the interview will be anonymised and treated confidentially.

I very much hope that you agree with me on the importance of your participation and allow me to come and interview you. I will telephone you within the next two weeks to discuss and arrange the time and date of our meeting.

Meanwhile if there is any aspects of the study you would like to know more about, I will be very happy to hear from you.

Yours faithfully

Zoe Aslanpour

Appendix 1.2: Community pharmacists interview schedule on the professional audit

Community Pharmacists Interview Schedule

Preamble: My name is Zoe Aslanpour and I am a research pharmacist, studying for a PhD at the School of Pharmacy, University of London. As part of my project I would like to find out about pharmacists' thoughts and ideas on the introduction of professional audit in pharmacy. To do so I am interviewing a random sample of twenty four pharmacists in London.

This interview will take about 20 minutes and to help me concentrate better on your comments and thoughts I would be grateful if you allow me to use a tape recorder to ensure that I capture our discussion fully. This information will be anonymised and treated in confidence. If duty calls, please feel free to stop the interview which we can resume as soon as you are ready again.

i. Assessing pharmacists' knowledge of audit

What does audit mean to you?

Prompts: What does it try to achieve?
 What do you think it involves?
 Have you had any experience of it?

If there is no knowledge, or not clear about it then share the two definitions with them:

"Audit is about taking note of what we do, learning from it and changing it if necessary. Professional audit is the improvement in the quality of care through standard setting, peer review, implementation of change and reevaluation." (Moving to Audit Resource book, 1993)

"Professional audit in pharmacy is the study of some part of the structure, process and outcome of pharmacy practice, carried out by individual pharmacists or groups of practitioners engaged in the activity concerned, to measure the level of attainment of agreed objectives, the use of resources and the resulting outcome." (RPSGB 1992)

ii. Effects of audit on the profession and patients

How do you think audit in pharmacy will effect the

A. Pharmacy as a profession

B. Patients

Ensure both positive and negative aspects are covered.

iii. Effects of audit at the practice level

How do you think audit will effect your practice in the pharmacy?

What would be the effects on your own practice

Effect of audit on your patients or clients

Effects of audit on the staff

Ensure both positive and negative aspects are covered.

Appendix 1.2: (continued....)

iv. Advantages and disadvantages of audit

What potential problems do you foresee in implementing audit in pharmacy?

What benefits do you think will come out of it?

v. Prioritising aspects of practice for audit implementation

What aspects of pharmacy should have priority in your mind for auditing?

**vi. The launch of the Royal Pharmaceutical Society educational package
"Moving to audit"**

The Pharmaceutical Society has produced an educational pack for pharmacists called "Moving to audit" which has been sent to all registered pharmacists in England.

Have you received your pack?

What are your thoughts about it?

vii. Audit as a requirement for professional allowance payment

There has been talks around addition of audit as one of the requirement of professional allowance payment by the Government in the future,

What do you think about it?

Do you agree or disagree with this proposal?

viii. Pharmacists' thoughts on the current professional standards

What do you think about the level of current standards set by the Royal Pharmaceutical Society?

If there are standards to be set for pharmaceutical services provided,

Who do you think should set them?

Information on pharmacists' background (Demographics)

Sex M/F

How long have you been registered as a pharmacists?

Position held: Owner, Owner/Manager, employee manager, employee pharmacist, locum

Classification of pharmacy eg: independent, small chain, multiple?

If small chain what is the total number of branches in the chain?

That completed all the question I wanted to ask you.

Opportunity for comments

Have you any other comments you would like to add?

Is there anything you would like to ask?

Thank you very much for sharing your thoughts with me and many thanks for your time.

Appendix 2.1: Letter to community pharmacists inviting them for the Nominal group meeting

**THE SCHOOL OF PHARMACY
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LONDON WC1N 1AX

Telephone (switchboard) 071 753 5800
Zoe Aslanpour 071 753 5927
Facsimile 071 753 5920

Date

Dear colleague,

I am a community pharmacist based at the Centre for Pharmacy Practice in the School of Pharmacy, University of London, undertaking a project on "Audit in Community Pharmacy". The aim of audit is to improve the quality of care through setting standards, assessment of current practice against the standards, implementation of changes if necessary and re-evaluation of practice.

Audit is already mandatory for some health care professionals and it is likely to become so for pharmacists. It is important for community pharmacists to be involved in the development of the audit procedure to ensure that the standards are acceptable and workable in the community pharmacy setting. However there will be variation amongst pharmacists as to what constitutes appropriate standards for different aspects of pharmacy. Therefore to achieve a consensus pharmacist participation is essential.

The aim of this project is to derive a set of standards for aspects of pharmacy practice that are relevant and workable. The technique we propose to use is called Nominal Group Technique, this is a structured discussion which leads to a consensus of standards. I am approaching a random sample of community pharmacists and inviting them to participate in the development of the standards. Once a consensus is achieved these standards can then be tested in community pharmacies.

I know that community pharmacists are busy and work long hours, however it is important that community pharmacists with different backgrounds are involved in the development of audit procedures.

We have scheduled a meeting for 8.00pm on Wednesday 28th of September 1994 at the School of Pharmacy, 29-39 Brunswick Square, London, WC1N 1AX. The closest underground station is the Russell Square on the Piccadilly line, there is also a map enclosed. I hope you will be able to participate. We are able to make a nominal payment of £25 to cover your expenses for attending the meeting.

In a few days time I will telephone to see if you are able to attend and to provide any further information you may need. I thank you for your co-operation and look forward to hearing from you.

Yours faithfully
Zoe Aslanpour

Appendix 3.1: Letter inviting community pharmacists to participate in the observational study

**THE SCHOOL OF PHARMACY
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Telephone (switchboard) 07175300
Zoe Aslanpour 071 753 5927
Facsimile 071 753 5920

Dear Pharmacist

Audit has increasingly become an important part of professional activities in health care. In the last few years it has been mandatory for many health care professionals including the community pharmacists in Scotland and it is likely to become so for the rest of us.

Setting standards against which current practice is assessed, is the initial stage of the audit process. It is important that the standards set are appropriate and workable in a wide range of pharmacies and not imposed by an external body. I am a community pharmacist, working on a project to investigate suitable standards that take into account the practicalities of pharmacy practice and the views of community pharmacists. I have already had many discussions with community pharmacists, and counselling on dispensed medication emerged as a priority. Currently no explicit standard exists for this and there is little data available from either the pharmacist or client perspective.

The next stage of the project is the observation in a wide range of community pharmacies to ensure that a relevant and workable standards are adopted. *It is essential that a representative sample of pharmacists are involved and your pharmacy was randomly selected from Register of Premises published by the RPSGB.*

The study is designed to take a minimum of your time. Your participation involves allowing an observer to be present in your pharmacy to collect data on pharmacist-patient interaction. This will be arranged with you to ensure that it is as unobtrusive as possible. **All the data will be anonymous and confidential.**

I hope you will agree to take part. I will telephone you in few days time to provide any further information required and arrange the time to come and see you. I would like to thank you in anticipation and look forward to speaking to you soon.

Yours faithfully

Zoe Aslanpour

Appendix 3.2: Data collection form for pharmacy and pharmacists' characteristics used at stage 3.

Data Collection form for structural data

Pharmacist Gender	Male1
	Female2
	Missing3
Pharmacist's age	(20-30)1
	(31-40)2
	(41-50)3
	(51-60)4
	Over 60.....5
	Missing9
Pharmacist' position	Owner/Manager) ...1
	Manager.....2
	Locum.3
	Missing4
Years on register	(0-5)1
	(6-10)2
	(11-20)3
	(21-30)4
	Over 30.....5
	Missing9
Total number of staff	1.....1
	2.....2
	3.....3
	Over 3.....4
	Missing.....9
Staff composition	Counter assistant1
	Pre-reg.....2
	Dispensing technician..3
	Missing.....9
Availability of computerised PMR	Yes.....1
	No2
	Missing9
Availability of Counselling area	Purposely built.....1
	Quite area.....2
	No.....3
	Missing9

Appendix 3.3: Data collection form for process of provision of oral counselling on dispensed medications

Pharmacy.....	Date.....	Day of the week.....	Time
Type of R	NHS.....1 Private.....2 Missing3	Purpose Yes.....1 No.....2 Missing....9	A B C D E
NHS R	Exempt.....1 Paid.....2 Missing..... 9	Time of dosage in relation to food Yes.....1 No.....2 Missing.....3	A B C D E
R Handed Out by	Pharmacist.....1 Pharmacy technician 2 Pre-reg.....3 Staff.....4 Missing9	Storage Yes.....1 No.....2 Missing.....9	A B C D E
Patient's age	Child.....1 Adults(16-60 years)..2 Elderly.....3 Missing4	ADRs Yes.....1 No.....2 Missing.....9	A B C D E
<i>Counselling issues covered</i>		Foods/drinks To avoid Yes.....1 No.....2 Missing.....9	A B C D E
No of items on R		Changes in regime Yes.....1 No.....2 Missing.....9	A B C D E
Medication/s	A..... B C D	Contra-indications & interactions Yes.....1 No.....2 Missing.....9	A B C D E
Dosage emphasised	A B C D E	Demonstration Yes.....1 No.....2 Missing.....9	A B C D E
Yes.....1 No.....2 Missing9			
Hours between Doses	A B C D E		
Yes.....1 No.....2 Missing.....9			
Maximum Dosage	A B C D E		
Yes.....1 No.....2 Missing....9			

Appendix 3.4: Data collection form and accompanying instructions for the validation process

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Telephone (switchboard) 071 753 5800
Zoe Aslanpour 071 753 5860
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Dear Assistant

Thank you for taking part in this project. The current work is about advice received by patients when collecting their medications from pharmacies. Your pharmacist has already participated in the first stage and has kindly accepted to complete the second phase of this project. He/She will provide you with some forms. We would like you to collect some information over a period of two hours on who hands the prescriptions out and whether the patient receives any advice on their medications or not. Please note that it is very important to record the information when the prescription is handed out as it is quite easy to forget the details afterwards.

As far as choosing the time is concerned, it should be a two-hour session either in the morning or afternoon. It is essential that your pharmacist is unaware of you recording this information at the time. I should emphasise that the pharmacist has consented to this condition. The following is the instruction on how to fill the forms. In the case of any query please do not hesitate to ask your pharmacist.

How to complete the forms

1. The first column indicates the prescription number. All you have to do is to put the numbers in sequence as the prescriptions are given out. The first three rows are already numbered. This will show the total number of prescriptions dispensed within the two-hour you have collected the data.

2. The second column is to show who gave the dispensed medications out. If it is handed out by pharmacist please write pharmacist or P, if it is handed out by other staff please enter staff or S as appropriate.

3. The last column refer to any advice or information provided for the patient on their medications when collecting their prescription.

The advice or information can be on one or more of the following issues:

- How many times a day the medication should be taken?
- What is the medication for?
- Is the medication taken before or after food?
- How should the medication be stored, e.g. in the fridge, in a dark place?
- Does the patient have to avoid alcoholic drinks?
- Has the pharmacist shown the patient to use the medication e.g. inhalers, oral syringe?

If there is any other information given to the patient with regard to their medication and

Appendix 3.4: (Continued....)

not listed above still mark the box as yes. For example if your pharmacist asks whether the patient had the medication before, and on the receipt of a positive reply do not provide any information please ensure you mark the last column as yes.

On the collection of medicines if no advice is offered please write No in the appropriate space. Please listen carefully when pharmacist is handing the prescription out to enable you to record as to whether any advice was given or not.

Thanks again for your participation.

Yours faithfully

Zoe Aslanpour

Appendix 3.4: (Continued....)

Name of the Pharmacy..... Date:..... Time.....

Prescription number	Prescription handed out by (Pharmacist=P OR Staff=S)	Information provided for the dispensed medications Yes/No?
1		
2		
3		

Appendix 4.1: Invitation letter to pharmacists to attend the standard setting meeting

THE SCHOOL OF PHARMACY
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Date:

Dear Pharmacist

If you recall a few months ago, I visited you as an observer to collect information on pharmacist- patient interactions as part of my project "Audit in Community Pharmacy". The cooperation of colleagues in a wide range of community pharmacies enabled me to file sufficient data to establish the current level of counselling on Prescription Only Medications (POM).

Setting standards against which practice is assessed, is the initial stage of an audit cycle. It is important that the standards are appropriate, workable and take into account the practicalities of pharmacy practice and the views of community pharmacists.

The final stage of the project will be to discuss a set of standards developed from the observational work and assess their practicalities.

We are inviting you to take part in this. It involves:

- Attendance at a meeting at the School of Pharmacy to discuss the appropriateness of the proposed standard, on either *Wednesday 13, or Thursday 14 of March from 2- 6pm*
- To take part in pilot study to assess the feasibility of the standards.

A fee of £80 will be paid for the locum cover and your further participation in data collection at the pilot stage. It should be noted that any payment from this establishment is taxed at source.

I hope you will agree to take part. I will telephone you in few days time to answer any question you may have. At the meantime please do not hesitate to contact me if there is any query.

I look forward to speaking to you soon.

Yours sincerely

Zoe Aslanpour

Appendix 4.2: Confirmation letter to pharmacists attending the meeting on setting standards and schedule of the meeting

**THE SCHOOL OF PHARMACY
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Dear pharmacist

I would like to confirm that the meeting will be held on 17 of March 1996 between 10 am and 2 pm at The School of pharmacy, University of London, Brunswick Square.

The objectives of this gathering is:

1. To discuss the findings of the observational study on the level of counselling of POMs in community pharmacies and explore the ways to improve it
2. Examine practicality of the scoring system proposed in setting an acceptable standard for counselling aspect.

A summary of the findings of the observational study is enclosed for your information. There is a short commentary on the results which you should read before attending the meeting . This includes some points on which the discussion will be focused. The gathering will be quite informal and only a small number of colleagues are invited. Your contributions as a pharmacist who has been involved in the project will be very valuable.

Enclosed is the meeting agenda and a map of the venue. If you need any more information please do not hesitate to contact me.

I look forward to seeing you on the day.

Yours sincerely

Zoe Aslanpour

Appendix 4.2:(Continued....)

Details of the Community Pharmacists Meeting on the Counselling of Prescription Only Medications (POM) in Pharmacies

Date:

Time: 10am till 2pm

Venue: Room 102, The School of Pharmacy, University of London, Brunswick Square, WC1N 1AX

AGENDA

Morning

10- 12.30 Discussion on findings of the observational study

12.30- 1 Refreshment

Afternoon

- 1 - 2
1. Presentation of the proposed scoring system for setting standards on counselling of POMs in an audit cycle.
 2. Briefing the participants on how to conduct the pilot study in their own pharmacies.

Appendix 4.3: Questionnaire on provision of oral counselling for dispensed medications in community pharmacies

A Questionnaire on the Results of Observational Study

Let us see whether you can predict the findings of the study and if so how closely?
(Please remember that the results reflect an average practice in our sample of 51 community pharmacies.)

1. What percentage of the prescriptions were handed out by pharmacists?

- A.30% [] B.50% [] C.70% [] D.90% []

2. What proportion of the patients received counselling on the medications dispensed?

- A.27% [] B.39% [] C.49% [] D.65% []

3. What was the population ratio of the following groups in our sample?

Children: Middle age: Elderly

- A.1:4:4 [] B.2:1:2 [] C.1:1:1 [] D.4:1:1 []

4. What was the ratio of counselling offered to the following groups of patients?

Children: Middle age: Elderly

- A.2:3:2 [] B.4:3:2 [] C.8:2:1 [] D.6:2:1 []

5. What was the ratio of patients who received counselling when collecting medications from the pharmacist verses other member of staff, e.g. counter assistant?

- A.3 to 1 [] B.4 to 1 [] C.1 to 1 [] D.1 to 2 []

6. What was the highest counselled group of medications?

- A. Antibiotics [] B. Central nervous system [] C. Respiratory []
D. Musculoskeletal []

7. What group of medication received the least counselling?

- A. Cardiovascular [] B. Skin [] C. Eye preparations []
D. Endocrine []

8. What was the most frequently advised issue during verbal counselling by pharmacists?

- A. Dose [] B. Indication [] C. Time intervals [] D. ADRs []

9. What was the least counselled issues?

- A. Dosage in relation to food [] B. Dose [] C. ADRs [] D. Indication []

Appendix 4.4: Form used by pharmacists to set standards for the content and extent of oral advice on dispensed medications

Repeat Medications/ New Medications**

Please indicate issues you consider essential in setting up a standard for oral counselling of Repeat/New dispensed medications.

In your opinion, what is the minimum number/s of issues that constitutes a workable and acceptable standard?

Please specify which issues by putting a tick in front of the issue/s:

Indication

Dosage: Interval
 Maximum
 Timing in relation to food

Demonstration (when applicable e.g. inhalers, dermal patches)

Storage

Adverse Drug Reactions (side effects)

Interactions: With other POM
 OTC
 Food/Drink

Contraindications (e.g. existing conditions, age, pregnancy)

Other information (please specify)

** (Pharmacists were given two separate forms one for Repeat and one for New items)

Appendix 5.2: Instruction on completion of data collection forms used by pharmacists to self report their oral advisory activities after implementing the standards

The initial stage of the audit process

It is paramount that the collected data reflects a true picture of counselling practice as it happens daily. The aim is to improve the practice through setting a *workable* standards. Unless the collected data reflects the *true* level of current practice, an unrealistic standard may be set which may not be achievable.

Data collection in the pharmacy

Data should be collected for one hour every day for 5 days for each prescription handed out by the pharmacist only. For the data to be representative of your practice the timing of data collection should be different on each of the 5 days. For example data can be collected from 10- 11 am on Monday, 1-2 pm on Tuesday, 9- 10 on Wednesday, 4-5 on Thursday and 11- 12 on Friday.

Use of the data collection form

Table 1: R information

In this section please record information on the prescription form. Give each prescription form a number and write this in the first column.

In the next column, record the items on the prescription form using a new line for each item.

In the third column for each item write R if it is a repeat, N if it is new for this patient. This information may be available from a PMR or it be necessary to ask the patient. Please indicate in this column (by stating PMR or Q) if the information was obtained from a PMR or by questioning the patient. This information is important as different standards will be applied to each.

Table 2: Oral advice given to the patient

In this section record what you discussed with the patient. Please tick the boxes as applicable.

Indication

Dosage

Supplementary information:

dosing interval

maximum dose

timing in relation to food/meals

demonstration eg. Inhaler, patches etc

Storage

ADRs and interactions

Q patient for side effects: tick this box if you asked the patient if they have experienced any side effects (repeat prescriptions only)

S/E: tick this box if you provided information possible side-effects (new or repeat)

POM-OTC: advice regarding interactions with OTCs

Food/drink: advice about interactions with food and drink

Contraindication

Extra information: please write details of any other issues raised

Please remember to enter the pharmacy name, date and time.

Appendix 6.1: Letter sent to pharmaceutical advisors seeking support for conducting a peer audit of oral counselling on dispensed medications in community pharmacists

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Dear Pharmaceutical Adviser

In recent years audit has become mandatory for many health care professionals including pharmacists in Scotland. The Royal Pharmaceutical society of Great Britain has been actively promoting the audit to improve the standard of pharmaceutical services. One of the key elements for a successful audit is setting standards based on the current level of practice which are workable and acceptable to the practitioner. To achieve this active involvement of community pharmacists is essential.

I am a research pharmacist based at School of Pharmacy, University of London and this study is a further development of my PhD project. The study focuses on the **counselling on dispensed medication**, with the aim of establishing a set of universally acceptable standards as an integrated part of an audit cycle, at Health Authorities level. A few weeks ago I contacted Mr Ashfaq Khan who expressed an interest in the study and asked me to write to you with the details of the project.

The time span of this part of study is between 8 to 10 weeks. There will be two separate weeks allocated for the data collection with a meeting scheduled in between. This provides the participants pharmacists with the opportunity of discussing their findings and form a consensus on the standards felt appropriate to adopt. On the completion of the study there will be a final meeting where the pharmacists are presented with the findings (anonymously) and the level of standards achieved during the second week of data collection. I endeavour to take the minimum of your time and I will be personally responsible for running of the study.

The findings and analysis of data will be made available to each Health Authority and their participation will be acknowledged in the future publications. Bearing in mind that the measuring tools and methods utilized in this study can also be adopted for improving other aspects of community pharmaceutical services in the future. In order to achieve universally accepted standards it is paramount that procedure is tested and data is gathered in different settings. The study is taking place in a number of different Health Authorities and there are already three recruited in London area.

As a Health Authority your participation includes publicising the project and encouraging community pharmacists to take part and help with the venue for the future meetings. In addition other health authorities have kindly offered to pay a nominal fee to pharmacists for their participation in this audit project.

I hope you too feel the need for documentation of this pharmaceutical service and its improvement as highlighted recently by the Royal Pharmaceutical society. I will telephone you in few days time for a further discussion. At the mean time please do not hesitate to contact me if you need any more information. I look forward to speaking to you soon.

Yours Sincerely
Zoe Aslanpour

Appendix 6.2: Letter sent to pharmacists in Barnet to invite them to take part in a peer audit of oral counselling on dispensed medications

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Date

Dear pharmacist

Audit has increasingly become an important part of professional activities in health care. In the last few years it has been **mandatory** for many health care professionals including pharmacists in Scotland and it is likely to become so for the rest of us.

I am a community pharmacist based at the School of Pharmacy, University of London. In collaboration with Barnet Health Authority and as part of my PhD, I am running a project on "*audit of oral counselling on dispensed medicines*". The aim of this project is to establish a set of universally acceptable standards for this service through implementation of an audit cycle. This improves and harmonises the provision of counselling in community pharmacies and documents the importance of this unremunerated service to the public.

The study is designed to take a minimum of your time. Your participation involves collecting information on your oral counselling of dispensed medications for **three hours a day**, for 5 days. Only minimal recording will be required by ticking the appropriate boxes on the data collection form which is provided for you. You will also be requested to attend two meetings. The initial meeting takes place after the first week of data collection to set standards based on the group findings and the second one is to monitor changes in practice and to review the standard. All the data will be treated anonymously.

I am aware that community pharmacists are busy and work long hours, however in order to develop a workable standard participation of practitioners like yourself is essential. I hope you agree to take part. A nominal payment will be made by the health authority for your participation.

On Tuesday 17 of September there will be a local branch meeting at the postgraduate centre, Barnet General Hospital, where I will be talking about the project and recruiting pharmacists. If you are unable to attend this meeting but still would like to take part please telephone me on 0171- 753 5860. At the meantime if you require any more information please do not hesitate to contact me.

I look forward to seeing you in the meeting.

Yours sincerely

Zoe Aslanpour