Improving compliance behaviour after discharge: the role of a hospital pharmacist

Jane Robson

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This thesis demonstrates that compliance is problematic in the elderly population studied and requires intervention if treatment failure is to be avoided. Non-compliance risk level was measured by use of a questionnaire and was found to be different for each of the subjects interviewed. Four different risk factors were identified as problems for over 50% of the subjects interviewed. Lack of understanding of regime, general dissatisfaction with prescribed treatment, poor provision of information from health professionals, and polypharmacy. However, no two subjects had identical combinations of problems and therefore generalisation into categories was not possible. Correlation between the categories was low.

The most commonly required interventions were provision of individually tailored verbal information or standardised written information on discharge, attempting to simplify the medication regime and finding solutions to various physical problems. All elderly hospital inpatients should be offered these interventions as routine services. In particular, it is essential that hospital pharmacists provide medication information to patients and attempt to achieve concordance as the study suggests that this is not a priority to hospital doctors. Polypharmacy should be avoided by regular prescription review, however, polypharmacy cannot always be avoided for patients with multiple disease states.

Hospital pharmacists have a vital role in solving compliance. However, primary care must therefore be involved in any decision to implement interventions. General practitioners and community pharmacists have the greatest opportunity amongst health professionals of being able to effect change in compliance behaviour. Many changes to the boundary divides between primary and secondary care must be bridged by means of cross-sectoral posts in order to ensure that compliance and concordance are achieved.

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Declaration

None of this material has been previously submitted for a degree in this or any other university

Statement of copyright

Chapter 1: Introduction

Compliance is a problem that is often overlooked when prescribing medication for patients unless it is the direct reason for a patient's admission. This is mainly because of a perceived lack of time and an ambiguity as to who holds the responsibility to assess compliance. Although absolute compliance in itself is almost impossible to measure, many authors have described factors that have been shown to affect patients' compliance with prescribed medication (Griffith, 1990). This study hoped to show that a pharmacist's interventions to ameliorate or remove the effect of these factors has a positive benefit on medicine taking. It was hoped that by using specific interventions patient care would improve and non-compliance risk would decrease.

Whilst many authorities describe the potential benefit to be realised by utilising pharmacists in discharge planning and compliance checking; there exists little soundly based research evidence. This evidence is difficult to attain whilst the patient is still in hospital because the quality improvements can only be measured after discharge. Following-up patients after discharge from hospital is therefore required to reassess their compliance risk and assess the benefits gained from interventions made prior to discharge.

In this thesis the current situation in the National Health Service is discussed regarding the responsibility of ensuring patients take their medication in the most effective manner. The current opinions of health care professionals regarding compliance and concordance are discussed, as are the various problems that can be encountered. After describing the objectives of the study and the methods employed, the research findings will be presented.

A number of interesting ideas which have arisen through the course of this research are then discussed in detail and illustrated with case studies. These include the problem of polypharmacy, why subjects don't want to know information that health care professionals may feel is essential, and how health care professionals' opinions

of the necessity of compliance differs from the patient's. The results and implications are then discussed and concluding recommendations given.

Current situation in the NHS

The general situation at the hospital designated as NT in which the study was conducted has been a common situation in many hospitals in England. There has been a division of labour amongst healthcare professionals with a sharp segregation between the various roles of doctors, nurses and pharmacists. This has resulted in a situation where compliance has been overlooked somewhat.

Prescribing decisions have been made in an environment where the issues of compliance or concordance were left very much to the individual prescriber and could be ignored if they wished. It can be assumed that some prescribers would consider the likelihood of poor compliance — especially in the elderly age group because of the high risk of non-compliance in this group (Department of Health, 2001). However, no formal assessments have been made by any professional as a routine part of patients' admission to hospital.

The second problem is that the supply system for medicines crosses a number of professional boundaries, with each professional responsible for his section alone.

1. The doctor is responsible for prescribing
2. The nurse is responsible for administration on the ward and ordering
3. The pharmacist is responsible for dispensing activities and prescription monitoring
4. The nurse is responsible for handing the medicines and any information to the patient on discharge

This can result in problems being overlooked as each health professional assumes one of the others will take responsibility for finding a solution. Conversely, each may attempt to solve the problem in isolation, which may result in duplication of effort, or in the implementation of solutions which are incompatible. This has been further complicated by the third problem; namely, each professional has many duties

and therefore insufficient time to assess each patient individually. Better team working with sharing of responsibilities and improved interdisciplinary communication may improve this situation.

Certain groups have been targeted as needing special attention within hospital NT, for example newly diagnosed diabetics, patients with cancer and those with chronic obstructive pulmonary disease (COPD). Most other patients are assumed to be able to cope unless an obvious problem appears or the patient has had a compliance-related admission. Previous studies have suggested that many of these patients have unmet needs such as complex regimes, forgetfulness and confusion (Anonymous 1997b; Ley, 1982; Parkin, 1976; Royal Pharmaceutical Society of Great Britain, 1997).

It is essential that the problem of non-compliance is addressed and this thesis suggests that the pharmacist is the most appropriate person to address this problem. Firstly, pharmacists are therapeutics specialists. They arguably have greater knowledge of side effects and drug interactions which may precipitate poor compliance than other practitioners. A greater knowledge of drug formulations and brand names is also helpful when discussing drug histories with patients.

A hospital pharmacist-led review of compliance-risk status may also be of benefit, as all patients need to obtain further prescriptions from a community pharmacist after discharge. This allows continuity of care within the same profession as community pharmacists arguably have more time to spend discussing compliance problems than general practitioners, especially as they are seen as a free advice service for those patients who 'do not want to bother the doctor'. Community pharmacists can also continue to supply any medication aids that are identified as being necessary in any compliance review.

Meeting these needs is an essential part of The NHS Plan published in July 2000. The implications for Pharmacy have been further described:

> 'making sure that people can get medicines or pharmaceutical advice and, as far as possible, in a way, at a time and at a place of their choosing; second more support in using their medicines. Extra help

> for those who need it to get the best out of their medicines - help which will mean fewer people being ill because they are not using their medicines properly, and which will cut the amount of medicine which is simply wasted; third, giving the patients the confidence that they are getting good advice when they consult a pharmacist.'
>
> (Department of Health, 2000: 3-4)

In the context of this thesis, the above summary incorporates improving discharge dispensing and the timeliness and relevance of information given to patients, ensuring that they are assessed for problems with compliance and, as far as possible, solutions for those problems found.

The primary/secondary care gap

The responsibilities of a pharmaceutical care practitioner are to determine the patient's wishes, preferences and needs concerning their own health and treatment, that is concordance, and to ensure that provision is made for continuing care, including when the patient crosses the primary/secondary care interface. This concept is described as seamless care (Binyon, 1994). Jackson et al have defined seamless care as follows:

> 'The process by which a patient is moved from one care environment to another with the assurance that all their health care requirements, including information, can be communicated in a safe, timely, efficient and user friendly way'
>
> (Jackson, 1993: 58)

A Department of Health Executive Letter - EL (91) 127 (Anonymous, 1991a) discussed the issue of seamless care. As well as the obvious need for good communication between hospital doctors and general practitioners, this Executive Letter also recommended that there should be liaison with the community pharmacist to ensure continuity of supply of the drug.

Unfortunately, seamless care within prescribing and therapeutics is not the norm in today's National Health Service. One of the causes of this is that patients are not registered with community pharmacies, a scenario that is normal in some other countries, for example in the USA. The result is that patients can, and do, chose to

visit a number of different pharmacies, reducing the potential for continuity of care. Although community pharmacies keep Patient Medication Records (a record of all medications dispensed for that patient) if patients have prescriptions dispensed at other pharmacies these records will be incomplete.

If a patient visits the same pharmacy each month with a prescription the pharmacist can become acquainted with that patient and identify potential needs in a manner which is not so obvious if prescriptions are dispensed at a number of pharmacies. Also many of the interventions required to meet these pharmaceutical needs (e.g. large print labels, compliance aids – see later for a fuller list of interventions) require forward planning and/or financial outlay and therefore rely on the patient visiting the same pharmacy each time.

Another consequence of the informal relationship between patients and their community pharmacies is that when patients are admitted to hospital the community pharmacist is not advised of this admission, with the result that valuable information regarding compliance is not passed on to the hospital pharmacist and the clerking doctor. A similar problem can occur at discharge with the hospital pharmacist carrying out a number of interventions, but with this information not reaching the community pharmacist. It is not yet routine for community pharmacists to be informed of changes to prescriptions and compliance needs, however, this has been recommended (Anonymous, 1993; Department of Health, 2001).

Much work still needs to be done within the concept of seamless care before we can claim that the patients within the hospital are obtaining total pharmaceutical care.

Need for research into pharmacy generated quality improvements

Whilst many authorities describe the potential benefit to be realised by utilising pharmacists in discharge planning and compliance checking (Milliken, 1997) there exists little soundly based research evidence. Healthcare is currently attempting to become evidence based (Muir Gray, 1997). This paradigm dictates that all therapeutic interventions should not be based on historical practice or the opinion of

one consultant, but be underpinned by sound, reproducible and relevant evidence. Much time and effort is being put into collecting and analysing this evidence and identifying new areas of research.

Similarly the Royal Pharmaceutical Society of Great Britain has identified compliance and concordance as areas requiring research in order to inform evidence based practice (Anonymous, 1997a). Clinical pharmacy, that element of pharmacy practice concerned with prescription monitoring, prescribing advice and patient centred problem solving, has undergone rapid development in the last ten years. However, much of this development has been on an *ad hoc* basis, with common practice stemming from what was originally an interim solution to a newly identified problem. For example, compliance aids were introduced to allow patients to be reminded whether they had taken a dose of medicine. However, many health professionals currently view them as a solution to all compliance problems. This is discussed in greater depth later in this thesis but illustrates how appropriate research is required to assure those who purchase clinical pharmacy that its functions improve patient care.

Objectives

The aim of the study was to investigate the role of a hospital pharmacist in improving compliance behaviour after discharge from hospital. In order to meet this aim there were a number of objectives:

1. To identify the various ways compliance can be measured.
2. To describe how a valid measure of compliance can be used to improve patient care.
3. To design a practical tool to measure an improvement in patient care.
4. To discover whether all elderly in-patients require an assessment of compliance when in hospital, or whether generalisations for sub-groups can be made.
5. To identify changes to current levels of service required in order to implement the conclusions of the study.
6. To determine whether the hospital pharmacist is the best health care team member to undertake the activities identified in this project.

Chapter 2: Literature review

In this literature review the traditional relationship between the prescriber, generally a doctor, and the patient will be discussed. This will be contrasted with a discussion of the new relationship which health professionals are being encouraged to develop with patients.

In order to identify appropriate practice with regard to identifying and improving medication use, the literature review includes a discussion of the following:

- Patient and prescriber focused therapeutics
- The relationship between compliance and concordance
- The failure to achieve concordance
- The professionals' view of medication compared with the patients'
- Why patients do not take medication as directed
- Measuring compliance
- Sufficient compliance
- Improving compliance
- Compliance in the elderly

A critique of the ethics of using a control group in health care studies will also be included.

Management of therapeutics in secondary care

Prescriber focused therapeutics

Medication is an important armament in the treatment of many morbid conditions. Since ancient times, healers have been giving their clients or patients chemicals or extracts of plant materials with the intention of palliation or complete cure. In many cases these concoctions had little more than a placebo effect. They had little therapeutic effect and any improvement was probably due to a blind faith in the healer. Often, as in the case of digitalis, use of such substances could cause more

damage or even be fatal. Occasionally, however, some substances could bring true benefit in certain circumstances and these substances became the forerunners of today's medicines.

Even in these ancient times, it was acknowledged that to gain maximum benefit from a cure the paste or mixture needed to be applied or taken in a certain way. These ranged from the unlikely direction to take the concoction at midnight at the time of the full moon, to more understandable directions such as taking after a meal or before bedtime. Even at this early stage the importance not just of taking the right amount of a substance, but also of taking it in the correct manner and at the right time, was recognised. So too was the importance of obeying the healer who was thought to have superior knowledge and experience of treating the condition. If a cure failed, it was obviously the fault of the patient, the healer was always right (Herxheimer, 2000).

In modern years the number of available concoctions, or as we more regularly call them, medicines, has grown dramatically. In 1952 The National Formulary contained details of approximately 1600 preparations on 106 pages (Anonymous, 1952). By comparison the British National Formulary for September 2000 contained over 4000 preparations on 557 pages (Anonymous, 2000b). This number is rapidly changing, as exemplified by the fact that a new edition of the BNF is published every six months. Many of the substances we now use are extremely potent and can still cause more harm than good, some still can be fatal. However, the knowledge of the safe and effective use of medicines, therapeutics, has also developed and guidelines for their use are available. This has reduced the harm of most medicines and allowed doctors to prescribe these medicines and predict the risk of taking them and the likely benefit. For most newly marketed drugs this risk benefit ratio is relatively well understood, although a few problems still do occur and medicines which cause more harm than good are still marketed, for example, Centoxin®. However, the belief that the doctor knows best and any therapeutic failure is due to the patient not taking the medicine properly, has until recently been all pervasive. This concept is called compliance.

Compliance with prescribed medication can be described as follows: whether or not a patient follows the doctor's instructions (Pharmacy Practice Research Resource Centre, 1998). Compliance has also been described as:

> 'The consistency and accuracy with which a patient follows the regime prescribed by a physician or other health professional'
>
> (Dirckx, 1997: 181)

A completely compliant person would follow the prescriber's instructions exactly and observe the following points, with regard to medication: taking the prescribed dose; in the appropriate way; at the appropriate times; observing cautions relating to drug, food and alcohol interactions.

Patient focused therapeutics

The current view within pharmacy is that the ideal situation is not a patient who complies with their medication but one who acts in concordance with a therapeutic plan (Clark, 1998; Royal Pharmaceutical Society of Great Britain, 1997). Marinker illustrated the difference between these two terms well. In the case of prescriber focused therapeutics and compliance he suggested:

> 'What the doctor brings to the consultation - scientific evidence and technical skill - is classed as the solution. What the patient brings - "health beliefs" based on experience, culture, personality, family tradition, and so on - is seen by the doctor as the impediment to the solution. The doctor's task is to overcome the impediment'
>
> (Marinker, 1997: 747)

His description of a practitioner interested in concordance is as follows:

> 'The clinical encounter is concerned with two sets of contrasted but equally cogent health beliefs.....The patient's task is to tell the doctor his or her health beliefs and the doctor's task is to enable this to happen. The doctor must also convey his or her (professionally informed) health beliefs to the patient. The intention is to form a therapeutic alliance - to help the patient make as informed a choice as possible about the diagnosis and treatment. Although the alliance is reciprocal, the most important determinations are made by the patient.'
>
> (Marinker, 1997: 747-748)

The concept of concordance came to prominence as evidence showed that compliance was affected by the quality of the patient/doctor interaction. The aims of concordance is to build a bridge between the prescriber's evidence and/or experience-based recommendations and the experiences, beliefs and values of the patient (Misselbrook, 1998b; Anonymous, 1998b) and to reach an agreement regarding treatment (Sanghani, 1998). Such an agreement has been termed a therapeutic alliance. This reinforces the concept that patients don't refuse to comply because they are unintelligent, but because they have their own models of the problem and the appropriate response (Misselbrook, 1998b). The aim of concordance is to optimise the benefits of medicines usage in line with the patient's desires and capabilities (Department of Health, 1999a).

The importance of implementing this new concept was discussed in a recent report from a working party of the Royal Pharmaceutical Society of Great Britain (RPSGB, 1997) of which Marinker was chairman. Informed consent must be obtained from the patient and opportunities to withdraw that informed consent need to be available (Ley, 1982). The concept of concordance has been further developed in the NHS Plan (Department of Health, 2000).

> 'A key theme of the NHS Plan is empowering patients to take an active role in managing their own care. Patients are not passive recipients of prescribing decisions. They have their own beliefs about medicines, how they work and how they are best used. Moreover, medicines taking has to fit within their normal daily lives'
>
> (Department of Health, 2000: 15)

Concordance marks a shift away from the paternalistic model seen in prescriber focused therapeutics in which the prescriber tries to convince the patient to do what he is told (Misselbrook, 1998b), towards one in which the patient takes the lead role in deciding whether to take medication (Anonymous, 1998b). In reaching a therapeutic alliance, the patient can decide to ignore evidence based medicine but the doctor should not allow this to impair the concordant relationship (Anonymous, 2000a). This is essential in chronic conditions because ownership of the responsibility to treat the disease is required to ensure continuation of treatment and successful disease management (Mazucca, 1982).

Non-concordance is descriptive, not judgmental, and implies an inability to come to an understanding between doctor and patient (Royal Pharmaceutical Society of Great Britain, 1997). The causes of non-concordance are multifactorial and can occur equally on both sides. Non-compliance implies error on the part of the patient in not following the doctor's, or other health professional's, instructions (Marinker, 1997). However, the semantics becomes difficult when assessing whether the patient is actually taking his medication in the manner in which it was initially prescribed. Equally concordance cannot be measured, but an indication of whether it has been achieved could be that the patient is satisfied with the consultation and follows the therapeutic plan (Dean, 2000).

Compliance and concordance

Compliance vs. non-compliance

All patients who fail to take a dose at exactly the correct time and in exactly the correct way could be classed non-compliant. Non-compliance has been defined as:

> 'Any non-trivial deviation from the prescribed medication regimen (as judged by us). It can be intentional or unintentional, and includes dosage errors (underuse and overuse), interruption of treatment, failure to take drugs at specific times, taking them at incorrect intervals, and/or the addition of other drugs.'
>
> (Col N, 1990: 842)

It has been estimated that only 50% of patients with chronic diseases take their medicines at therapeutically effective doses (Marinker, 1997). However, other studies show that this rate varies from 10-90% for different populations (Aronson, 1992; MacDonald, 1977; McGavock, 1998; Misselbrook, 1998c; Parkin, 1976). Rather than poor compliance being deviant behaviour, Professor Marinker argues that it is normal behaviour (Anonymous, 1997a). There are many reasons why patients do not comply with medication regimes. They include physical and psychological difficulties, for example, confusion, forgetfulness and ignorance as well as deliberate refusal or lack of faith in the treatment or doctor (Anonymous 1997b; Cochrane, 1992; Ley, 1982; MacDonald 1977; Parkin, 1976; Royal

Pharmaceutical Society of Great Britain, 1997). In one study 103 of 315 (32.7%) elderly patients admitted to an acute care hospital admitted to non-compliance within the previous year. 81% reported underuse, 17% overuse and 2% misuse. 54% of non-compliance was intentional and 46% unintentional (Col, 1990). These mediating factors are discussed in more depth later.

It is generally recognised that if we continue to give patients expensive drugs, it is essential to ensure that the patient takes them correctly as this might improve efficacy of care and substantially enhance the benefits of treatment (Haynes, 1996). There are obviously many benefits from adhering to a therapeutic regime, the main one being successful treatment of the condition in question. It has been estimated that 4-35% of patients misuse their drugs to such an extent that they endanger their health (Wandless, 1977). The consequences of poor compliance may be damaging for the patient and distressing for their families, 6-12% of hospital admissions may result from problems with medicines (Department of Health, 2000; Col, 1990). Fifty percent of all cases of end stage hypertension, 70% of end stage glaucoma, 40-60% of end stage diabetes and 91% of all deaths due to organ transplant rejection may be caused by non-compliance (McGavock, 1998).

The cost of such non-compliance also includes increased doctor consultation time, increased frequency of laboratory tests, decreased work-force productivity and potentially premature death (Grymonpre, 1998). A third problem arising from non-compliance is the potential wastage resulting from supply of medicines which are not subsequently used. Unused medicines worth in excess of £100m are returned to pharmacies each year (Department of Health, 2000). Compliance may therefore ensure that scarce NHS resources are maximised.

Adherence has a similar dictionary definition to compliance but has been defined as 'the extent to which the patient fulfils the intention of the prescriber' (Pharmacy Practice Research Resource Centre, 1998). It does not carry the same connotations of patient inferiority and has therefore been preferred by some authors. In assessment of whether the drug therapy is being used optimally by the subjects in this study, the term compliance will be used, as adherence can be included in 'sufficient compliance' (see later in this chapter).

Various strategies have been suggested to improve compliance rates with varying success. However, Ley (1982) suggested:

> 'In some ways perhaps the wisest method of increasing patients' compliance is to discover the features in the particular situation which are contributing to non-compliance and then do something appropriate about them.'
>
> (Ley, 1982: 244)

In this study, it is hoped to discover what contributing factors certain individuals have and attempt to measure the effect of appropriate remedial action.

The relationship between compliance and concordance

Compliance is a submissive and disempowering action. Compliant patients, by definition, submit to the wishes of others. By stressing compliance we ignore the health beliefs, opinions and values of the patient and require compliance with the beliefs, opinions and values of the prescriber. These beliefs may be professionally informed and evidence based and still oppose those of the patient. The task of the prescriber is to impose his beliefs on the patient.

Concordance is a state of agreement between prescriber and patient. The patient is empowered and given an opportunity to share his health beliefs, opinions and values (Anonymous, 2000a). Those beliefs are considered of equal value to those of the prescriber and both parties attempt to appreciate the position of each other. A compromise plan is arrived at which reflects both sets of beliefs, etc. and which the patient agrees to follow. A failure in concordance occurs when either the doctor or patient does not come into the encounter with honesty and openness. Concordance can improve compliance (Anonymous, 2000a) but it does not solve all compliance problems (Misselbrook, 1998). Concordance should however reduce wastage of drugs, as the patient will not be given a prescription if they declare a decision not to take it.

Within concordance is the possibility of irreconcilable disagreement, in which the prescriber does not feel professionally that he can compromise any further yet the patient still refuses to follow his advice. The most important determinants are those that are made by the patient and the outcome is dependent on his final decision (Department of Health, 1999a). If the patient has made an *informed* decision concordance has been conserved.

Once the decision to prescribe medication is made the patient can either take the medicine as prescribed, he is therefore compliant, or he can take it at variance to those directions, i.e. non-compliance. This non-compliance may be due to 1) a failure in concordance: the doctor did not discuss the decision fully with the patient, 2) the patient changing his mind about the concordant decision or 3) some other unforeseen difficulty. The achievement of compliance and concordance are related but not always linked. The following scenarios describe this relationship:

- A situation where the doctor and patient achieve concordance and the patient follows the resultant agreement is equivalent to the patient exhibiting full compliance.

- A situation where the doctor ignores concordance and imposes his wishes on the patient, but they are followed exactly by that patient, is also an example of compliance.

- An encounter in which concordance is achieved but the patient subsequently changes his mind and does not follow the agreed plan is an example of intentional non-compliance.

- If the patient chooses to follow an agreement achieved either through concordant or non-concordant means, but fails to do so by accident, he is unintentionally non-compliant.

- An encounter in which the patient through lack of honesty or openness agrees to a therapeutic plan that he does not intend to follow is an example of both non-concordance and non-compliance.

A pharmacist attempting to improve this non-compliance has two options: either to refer the patient back to the prescriber in order to achieve concordance, or to remove the difficulty that is a barrier to compliance. The physician's responsibility in developing concordance is described elsewhere (Marinker, 1997). The problems of a patient changing his mind about an agreement and other difficulties with concordance can be loosely linked together under the terms intentional and unintentional non-compliance. It is these problems which are studied in this thesis.

The professional view versus the patient's view

We have discussed the desirability of the patient taking medication in the correct way and the benefit of involving the patient in making the decision how to treat their medical condition. One of the major problems with achieving concordance, however, is the wide divide between the views and beliefs of the doctor and those of the patient (Misselbrook, 1998).

No matter how patient-focused a health professional is, his brief is to diagnose disease and whenever possible cure it or reduce the severity of consequences and improve the quality of life. The health professionals' standpoint is best described in the Hippocratic Oath:

> 'I will follow that system of regimen which, according to my ability and judgment *(sic)*, I consider for the benefit of my patients, and abstain from whatever is deleterious and mischievous. '
>
> (Adams, 2000)

In these days of expensive medicines, there is pressure to use the most effective, appropriate, safest and economically efficient drug possible. Doctors are inundated with guidelines, meta-analyses and reviews from bodies such as NICE (National Institute for Clinical Excellence), the Cochrane Group, SIGN (Scottish Intercollegiate Guidelines Network), etc. NHS hospitals, and to and increasing extent, Primary Care Trusts, are required to produce formularies to restrict the

doctor's choice to only those preparations for which evidence of their efficacy exists and which the NHS can afford (Anonymous, 1994). They key phrase is evidence based medicine. Patients should not be given a therapy of unproven value when there is alternative with stronger evidence of efficacy. The pressure of conforming to evidence based medicine may pressurise the doctor to prescribe what is recommended in the guideline without reference to the patient's wishes.

The patient by contrast is often only concerned in their own health and whether they personally will benefit from treatment. Some may decide to refuse all treatment if they do not believe that their health is at risk or if they believe that the risks of treatment are greater than the risk of no treatment (Misselbrook, 1998b). It is difficult for a lay person to assess objectively the risk benefit ratio attached to any treatment. This is further complicated when made personal. For example, warfarin is used to treat deep vein thrombosis, both to reduce pain and inflammation in the affected leg but also to prevent the high risk of myocardial infarction and stroke. However, the risk of serious haemorrhage following warfarin therapy is also high. The patient must decide not only how likely each of these endpoints may occur; namely frequency, but also how serious to them is each of these endpoints, i.e. severity, and how much they would be willing to suffer to prevent each of them, i.e. sacrifice. It is the balance between these three variables of frequency, severity and sacrifice that must be calculated by the patient before an informed decision can be made. Evidence based medicine only considers the first two of these and assumes that the third, sacrifice, is linearly related to these two. Experience, however, tells us that no two individuals have an identical view of sacrifice and so no two patients will approach concordance in the same way.

Some patients will find this responsibility too hard to bear and may abdicate responsibility to the doctor. The fear of rejection and the anxiety of accepting responsibility for deviating from evidence based medicine may be too great to accept responsibility (Department of Health, 2000). The patient may even have a fear of not being taken seriously. When a patient does not wish to make a decision the prescriber must try to understand what underlies this reluctance in order to achieve concordance.

The choice which patients make is also dependent on their social context. If they know someone who has taken a particular medicine previously, their response to it will colour the patient's opinions. If it worked, the patient will generally want to try the same thing. If it failed or the friend or relative developed a troublesome adverse drug reaction then they may wish to avoid it. There will also always be a small proportion of people will want the newest drug on the market in order to be different.

With the increase in access to the Internet, more patients are accessing information about their condition and the best way to treat it. This may result in a well-educated patient who is better equipped to make an informed decision. However, such information is not of a uniform standard (Anonymous, 2000a) and it is often much easier to find sites of a poor or anecdotal nature and much harder to find unbiased sites. This may result in the doctor being presented with unreliable information and being asked to interpret it without the time to assess the quality thereof.

Sanghani (1998) describes a hypothetical scenario in which a recently diagnosed hypertensive male is given a betablocker - a treatment of reliable efficacy. The patient returns to the doctor describing an adverse reaction, which he finds particularly troublesome. Before visiting his doctor this patient carried out an intensive literature search and discovered a number of facts about hypertension. He discovered that the risk of any repercussions of untreated hypertension within ten years is low, that only a proportion of hypertensives suffer such repercussions and in the absence of other risk factors there is no way to predict whether he will thus suffer. Although the doctor explains the various options available and the likely side effects associated with them, the patient decides he is willing to take the risk and refuses all treatment.

This scenario describes complete concordance - the patient is much better informed than average and the decision made was arrived at after serious consideration of all risks and potential benefits. However, the end result is that of a patient who has not received evidence-based treatment, as the published evidence indicates that hypertension must be treated.

Sanghani then proceeds to ask a number of questions:

> 'What if in seven years' time the same patient dies following a massive myocardial infarction and his wife asks the GP why he did not insist that her husband take medicine?.....
> But what if the life insurance company now refuses to honour its policy because the husband had clearly acted against the best medical advice?'
>
> (Sanghani, 1998: 84)

Concordance may improve the relationship between the patient and the doctor, but it introduces many difficulties to the doctor, for example, time restraints, communication skills, and choice of information to convey, and places a great deal more responsibility onto the shoulders of the patient. The doctor must try to reconcile the conflicts between wanting the best for the patient whilst respecting their health beliefs and remaining faithful to evidence based medicine (Anonymous, 2000a; Misselbrook, 1998b).

Problems in practice

Why patients do not take their medication as directed

We have already shown that frequently patients don't take medicines in the manner directed and this is for a number of reasons (Misselbrook, 1998a). An understanding of the reasons why patients do not take their medication as directed could allow amelioration of this effect. 20-50% of patients do not comply with the medicines they have been prescribed (Misselbrook, 1998c). The reasons for non-compliance can be divided into two categories: patient's ability, which accounts mainly for unintentional non-compliance, and patient's motivation, which may account for intentional non-compliance (Anonymous, 1997b).

Unintentional non-compliance can be caused by a number of factors, the most common being forgetfulness (Hughes, 1998; Moriskey, 1986). This can be complicated by other problems and may be a consequence of ageing or other disease states such as dementia, however, age does not consistently correlate with forgetting, except possibly for patients over 65 years-of-age (Ley, 1982). Secondly, unsafe storage or administration can lead to forgetfulness; for example, tablets decanted into

other bottles can result in patients having no written instructions of how to take their medicines.

Complicated regimes in both the number of drugs (polypharmacy) (Hughes, 1998; Ley, 1982) and number of daily doses (Moriskey, 1986; Parkin, 1976; Sweeny, 1989) can lead to confusion and forgetfulness. Physical problems can also cause difficulties in compliance. Opening child resistant closures and removing tablets from blister packs (Hughes, 1998; Lorenc, 1993; Sweeny, 1989) and using inhalers and other dosing devices (Johnson, 2000) can limit a patient's ability to take their prescribed medication at the correct time as they may require assistance with accessing the dose, assistance which is not immediately available. Liquid medication also appears to cause more non-compliance than solid dosage forms (Sweeny, 1989), possibly because patients perceive them to be less important.

Poor vision often means that the patient cannot rely on the label to remind them of the directions they need to follow. Poor memory therefore increases the risk of non-compliance in these patients (Lorenc, 1993; McGavock, 1998; Sweeny, 1989). Label clarity may be further compromised if the print is too small or of poor quality, for example if the printer is running out of ink.

Concordance, and the theory behind empowering patients to take responsibility for their own treatment, has been discussed. A breakdown in concordance may reduce compliance, which is one reason for its desirability. A patient who receives insufficient information or who does not understand what they have been told, is less likely to remember what the information was and will not have the ability to put it into practice (Col, 1990; Eisen, 1990; Lorenc, 1993; McGavock, 1998). Lack of satisfaction with the doctor (Anonymous, 1999; Anonymous, 2000a; Ley, 1982) and lack of faith in medication (Griffith, 1990) may also contribute to non-compliance.

Patients may decide not to take medication because of fear of becoming dependant, scare stories, unwillingness to use 'artificial chemicals' and worry about side effects and what to do if they occur (Anonymous, 1997b; Britten, 1998; Lorenc, 1993; McGavock, 1998; Misselbrook, 1998b; Sanghani, 1998). The balance between guilt and social stigma also affects an individual's propensity to comply (Griffith, 1990;

Misselbrook, 1998b). Interestingly, however, evidence shows that experiencing side effects does not decrease compliance, but physicians and patients both believe that it does (Ley, 1982). It appears that the fear of side effects may have a greater effect on compliance than the actual occurrence of side effects (Misselbrook, 1998b). In one study, a third of patients had concerns about adverse effects (Anonymous, 1997b).

Patients living alone with low levels of social support and little follow-up from health professionals have reduced compliance (Col, 1990; Ley, 1982; Moriskey, 1986). There is also evidence that women of high parity, the very young, adolescents and the elderly and low-income groups comply with treatment to a lesser extent (Griffith, 1990). For working adults, the inconvenience of fitting complicated regimes into the working day and the expense of prescription charges may reduce their willingness to comply (Misselbrook, 1998b). Non-compliance can also occur when patients accidentally continue to take drugs which have been discontinued or changed because old supplies have not been discarded. This is particularly a problem for patients with multiple conditions and on discharge from hospital (Parkin, 1976).

People do not automatically react to risks and benefits in a logical manner, following the option of least harm and maximum benefit. Decisions made by patients are also informed by their health beliefs. Approximately 50% of subjects in one study believed that medicines were overused and 17% believed they did more harm than good (Anonymous, 1997b). However, 85% believed that medicines were necessary for good health. There is some evidence that patients are more keen to take medicines for symptomatic, troublesome, acute problems than for enduring problems (Britten, 1998), however, other studies showed lower rates of compliance with treatment for acute illness than for long-term medication (Lorenc, 1993). It is difficult to generalise whether a patient will take a particular medicine, as duration of illness does not correlate with compliance (Griffith, 1990; Ley, 1982; Lorenc, 1993). It does appear that the reasons for complying are different for chronic and acute conditions (Lorenc, 1993), with non-compliance in acute conditions being related to the low importance attributed to taking tablets and low motivation. In chronic conditions, the fear of addiction appears to be more inhibitory.

The decision to comply depends on the patient's perception of the severity of their illness and their vulnerability to its effects (Griffith, 1990; Ley, 1982; Misselbrook, 1998b). If a patient believes there is no hope of a cure or that the prescribed treatment is not working, they are less likely to take the medicine as prescribed, even if they understand the need for treatment (Col, 1990; Hughes, 1998). A patient may not take a medicine if they feel it is unnecessary (Col, 1990; Sanghani, 1998) but the judgement of necessity is made on the basis of different fundamental premises in each case.

Some patients have a mistrust of conventional medicines in general. In one study, 9.4% of patients who reported non-compliance blamed this on dislike of medicines in general (Col, 1990). For some people this reluctance to take conventional medicines is a matter of religious belief in which they may eschew all medicines, for example the Christian Scientist, or specific medical practices, for example the Jehovah's Witness. For others, their trust in faith healing may reduce their reliance on conventional medicines. Others may prefer alternative therapies such as aromatherapy, herbal medicine, acupuncture and homeopathy, among others. It is interesting to note that both aromatherapy and herbal medicine work on the same principles as conventional medicine as the premise is to introduce a chemical into the body to effect a cure. It is also worth noting that these therapies also rely on compliance on the part of the patient to ensure efficacy.

Health beliefs are generally thought to be determined by the knowledge and attributes of the patient (Griffith, 1990). For patients where these align with those of the prescriber, compliance is more consistently achieved. For patients whose health beliefs are opposed to those of the prescriber, compliance is unlikely. Although memory is necessary for compliance to be achieved, it is not sufficient and does not account for deliberate non-compliance and rejection of advice (Anonymous, 1992; Parkin, 1976). Patients may deliberately not comply for fundamental reasons that are personal to them and do not allow contradiction.

There are many different reasons for patients not taking medicines as prescribed and in some patient groups with certain conditions, compliance is much rarer than non-compliance. It is therefore arguable that non-compliance is normal behaviour and compliance is an abnormal and deviant activity, which is why it is so difficult to obtain.

Measuring compliance

The reasons for the desirability of compliance and why patients fail to agree to take medicines or follow an agreed therapeutic plan have been discussed earlier. In order to be able to address some of these problems it is necessary to assess to what extent they affect the patient's likelihood of complying with treatment (Paes, 1998). The issue of sufficient compliance will be described later. In this section the emphasis will be on the various methods of measuring compliance, and a discussion of the many difficulties encountered in trying to make such a measurement.

Assessing patients' ability and likelihood of complying with a therapeutic regime is as complex as it is important. It has been shown that doctors frequently make inaccurate estimates of their patient's compliance (Aronson, 1992; van Berge Henegouwen, 1999) and prediction without an objective measure is not possible (Misselbrook, 1998c). Problems of estimating compliance rates are caused because observable patient characteristics do not correlate consistently with non-compliance (Moriskey, 1986). To overcome this difficulty, many methods have been used such as structured verbal and written questionnaires, pill counts, blood and urine tests, measures of outcomes and using mechanical measuring devices (Aronson, 1992; Ley, 1982; Paes, 1998).

As has been discussed earlier, rates of non-compliance have been estimated at anywhere between 4 and 93%. It is likely that this variation is due at least in part to methodological variation (Griffith, 1990; Paes, 1998; van Berge Henegouwen, 1999). It is also the case that different research instruments may measure different kinds of behaviour or different aspects of compliance (Paes, 1998) and there is conflicting evidence regarding which measure provides the best estimate of overall behaviour (Grymonpre, 1998).

Pill counts have been used to assess compliance (Parkin, 1976; Smith, 1983) but a number of limitations are associated with this method. The patient can 'cheat' by removing a number of dosage units prior to counting (Hughes, 1998). Nothing can be concluded about the patient with no tablets left in the container as there is no way of knowing if these were actually taken. Over consumption, erratic drug use and drug holidays, that is when the patient decides not to take any medication for a short period of time and then resumes normal dosing, cannot be measured (Paes, 1998) and may lead to an overestimate of compliance rate. Finally, decanting of tablets into other containers and use of previously dispensed supplies can reduce the accuracy of this measure (Grymonpre, 1998).

A more workable and informal method of using pill counts can be used for patients who get their medication filled by a community pharmacist on a weekly basis in a compliance aid such as a Medidos®. It would be less obvious to the patient that a check was being made but the community pharmacist, by seeing the number of doses left in the box, can assess whether the patient is using it correctly. However, pill counts can only be used for discreet dosage forms (tablets, capsules, suppositories) and for medicines that are taken regularly (Grymonpre, 1998). Pill counts do not take into account when the tablets were taken, for example, with food or in the morning, which can be essential for some medicines to have effect. For full compliance to be achieved this aspect of the doctors instructions must also be followed and so some other method of assessing this aspect of compliance is required.

Electronic measuring devices provide more information than tablet counts in that they give some indication of timing of doses, if a patient does not take any tablets and then pours a number away at just before the count is to occur this will be obvious. However, there are a number of limitations with this method. The first is the cost. Any recording device, whether it is a small computer chip or a radioactive device will be more expensive to obtain than a simple tablet bottle lid. Also, special reading devices will be required to access the records held within the cap. This precludes the use of such devices in all environments except research. The container may look different to other containers and this may alert the patient to the fact that

some record is being made. Electronic measuring relies on the fact that each time the bottle is opened a dose has been removed which is the correctly prescribed dose and that this dose is subsequently taken (Aronson, 1992). As this is not necessarily always the case, the results may not reflect actual compliance behaviour.

To assess whether a dose has actually been taken there has been some attempt to design biological markers which can be measured in blood, urine or faeces. Some drugs such as digoxin, phenytoin, theophylline have well understood pharmacokinetics and the plasma concentration can be measured directly to give an estimate of under or overdosing. This method is often expensive and is unsuitable for many drugs. It may be affected by changes in renal and hepatic function and the presence of concomitant diseases and interacting drugs (Aronson, 1992). In addition, if the patient is aware of the likelihood of a blood level measurement, they may improve their compliance for a few days prior to the test (Anonymous, 1991b). However, for suitable medicines with appropriate professional interpretation this is the most accurate measure of compliance (Grymonpre, 1998).

In some disease states, it is possible to directly associate improvement in symptom control with compliance, for example in diabetes, hypertension and obesity (Ley, 1982). However, the result must depend on continued treatment for the assessment to be valid or there is the risk of a patient complying for two or three days prior to the appointment and giving the impression of long term compliance. This can been seen in all aspects of medicine and usually occurs when the desire to please the prescriber is strong, but is less strong than the patient's ability, or desire, to comply.

In some conditions, failure of therapy may be due to the wrong treatment being prescribed or a worsening of the condition and so a poor result may not be directly related to compliance. However, if a patient is not improving a change in medication may improve compliance if the cause of non-compliance was a side effect or ineffectiveness.

The frequency of prescription renewals has been used by some as a measure of compliance (Grymonpre, 1998). This measure has a number of limitations in that it does not take into account whether the medication has been taken. This is explained by understanding that ordering a prescription does not necessarily coincide with the previous supplies being exhausted (Hughes, 1998). A further difficulty with this method is that it relies on patients picking up prescriptions from the same Pharmacy each time as data from several different Pharmacies is much harder to collate (Moriskey, 1986). Information from prescription writing by the general practitioner cannot be used for this purpose as 10-20% of prescriptions are not filled despite being collected from the surgery (Aronson, 1992; Beardon, 1993; Col, 1990). Studies have shown that the data from pill counts is not comparable with the results obtained from refill data as the former measures short term compliance and the latter long term compliance and may be affected by many factors over time (Grymonpre, 1998; Paes, 1998).

Self report has been used to measure compliance. Patients generally do not volunteer the problem of non-compliance but a carefully constructed questionnaire can help (Moriskey, 1986). Most patients are aware that they occasionally forget to take medication and sensitive non-judgmental and non-threatening questioning can reveal this problem and the cause. However, patients generally have difficulty remembering erratic behaviour and over-consumption (Paes, 1998) and so cannot give accurate estimates of the frequency of such behaviour. There is a risk of overestimating the level of compliance (Haynes, 1996).

Diaries have also been used as a measure of compliance (van Berge Henegouwen, 1999), especially in clinical trials. However, the act of having to write down what was taken and when may have the effect of improving compliance and so may not be a valid measure.

Measuring absolute compliance is generally inaccurate (van Berge Henegouwen, 1999), almost impossible and extremely time consuming. It is more appropriate to define a scale of compliant behaviour as full compliance is not always necessary; rather, sufficient compliance that results in a therapeutically effective regime is required.

Sufficient compliance

Most patients are neither non-compliant nor compliant, but have degrees of compliance, which vary with time and are dependent on personal processes (Griffith, 1990). With antihypertensive medication, it has been shown that blood pressure only falls significantly when patients take more than 80% of medication as directed. For other conditions and treatments, the rate may be higher or lower.

Absolute compliance, that is taking the prescribed dose at exactly the correct time on all occasions, is only desirable if treatment is appropriate and optimal (Webb, 1999) and follows not only evidence based medicine, but is the most appropriate treatment for the individual. It is assumed that a fully compliant patient will benefit significantly, through the lowering of risk status. Non-compliance is only clinically important if therapeutic outcomes are not achieved (Moriskey, 1986).

It is worth remembering that estimates suggest that 5% of beds in the UK may be occupied by patients suffering from iatrogenic problems (Wandless, 1977). If treatment is inappropriate or is causing significant side effects it is important that the patient does discontinue it, but under the guidance of a doctor. It is arguable that in cases of sub-optimal therapy, although compliance may be improved, it may not be necessary or desirable. In most studies investigating rates of compliance, the degree of value to the patient of the medication has not been defined and so it is difficult to assess the importance of drug defaulting to the therapeutic goal.

Improving compliance

Patients fail to comply with therapy plans for many different and individual reasons and so the options for improving compliance must be as varied. The most effective way of improving compliance is to discover the cause and to rectify it (Ley, 1982). Unfortunately, poor methods of measuring compliance have made it harder to attempt to improve compliance (Anonymous, 1991b). The aim of treatment must be to maximise the extent of compliance whilst minimising the amount of discomfort or cost to the patient. Compliance can only be ensured if the patient is directly

observed or if a doctor or nurse administers the dose (Anonymous, 1991b). In all other scenarios, compliance relies on the patient having the motivation and ability to comply. As recently as 1996, Haynes was of the opinion that the effort expended by health professionals to improve compliance was insufficient:

> 'Although adherence and treatment outcomes can be improved by certain - usually complex - interventions, full benefits of medications cannot be realised at current levels of adherence. It is time that additional efforts be directed towards developing and testing innovative approaches to assist patients to follow treatment prescriptions.'
>
> (Haynes, 1996: 383)

Simplifying the regime (Anonymous, 1991b; Eisen, 1990; Lowe, 1995) and aligning dosing times with daily activities (Sweeny, 1989) can improve compliance. Appropriate provision of information can also help compliance (Lorenc, 1993; Smith, 1983; Sweeny, 1989). Regular medication review to reduce polypharmacy (Smith, 1983), drug interactions (Hughes, 1998) and adverse drug reactions can also reduce the risk of non-compliance. As has been discussed already, achieving concordance may also improve non-compliance.

Providing medicines in appropriate containers, which can be used or opened without difficulty, is essential to improve compliance (Lowe, 1995). Allowing patients to practise taking new medicines independently in hospital before discharge has also been used to decrease unintentional non-compliance and highlight difficulties (Lowe, 1995; Wandless, 1977).

Monitored dosage systems (MDS) (Sweeny, 1989) and diaries (van Berge Henegouwen, 1999) have been used to help reduce forgetfulness. It is generally understood amongst nurses in NHS hospitals that MDS such as the Medidos® improve compliance, however, there may still be a problem if filling of the container is unsupervised (Sweeny, 1989).

We must remember that although much non-compliance is unintentional, and if we can find the cause a great deal can be done to avoid the problem or reduce its effects, non-compliance is still deliberate for some patients. Concordance may reduce some of this intentional non-compliance but a significant proportion may be insoluble.

Compliance in the elderly

Studies of the elderly provide evidence of large differences in individual responses to medication and compliance (Abrams, 1990; Hudson, 1997). Despite this, there are a number of problems that are more common to elderly patients than younger patients, each of which can decrease compliance (Col, 1990). For example, the elderly are more likely to have multiple disease states and therefore multiple drug therapies (Reid, 1997). Patients over 65 are prescribed two or three times as many drugs as younger patients (Royal College of Physicians Working Party, 1997). They also suffer increased rates of adverse drug reactions and drug interactions (Nolan, 1989). Polypharmacy may be necessary to treat the patient's multiple conditions, but it may introduce non-compliance and other problems. In one study, half of the elderly patients studied hoarded medicines that were not required (Sweeny, 1989). We have already discussed the problems this can cause with patients continuing treatment that may interact with new treatment or cause overdose.

Half of all elderly people make errors in compliance, and one third of these may lead to damage to health (MacDonald, 1977). These errors are greatest in those patients who are over 85 years of age, living alone and/or do not cope well at home, and those whose memory is poor or who are confused (Parkin, 1976). The main causes of non-compliance in this age group are forgetfulness, polypharmacy, complicated drug regime, confusion, adverse drug reactions, poor doctor/patient communication, and inconvenience of taking medicines (Cochrane, 1992; Cantrill, 1992; Gainsborough, 1990; Ley, 1982; Parkin, 1976; Raynor, 1993; Royal College of Physicians Working Party, 1997; Smith, 1983).

The elderly as a whole are prescribed more medicines, have greater problems with compliance, and therefore have most to gain from any intervention. This group will therefore be used as the client group in this study.

The ethics of randomised controlled trials in health care research

In choosing a research methodology, it is generally recognised by researchers that randomised-controlled trials have high internal validity because they exhibit high statistical control over systematic and random errors (Daly, 1992; Kerlinger, 1992a). A judicious choice of control parameters can reduce the effect of many independent variables whilst allowing a small number of dependent variables (those which the researcher is attempting to affect) to change with specific interventions. The researcher is therefore able to conclude with greater certainty that any measured differences between the control and active groups are due to the interventions made. The same is true for health research, where ethics will allow. To measure specific effects of a particular treatment, all other conditions and non-specific effects must be kept equal for two groups of patients with the same disease (Kleijnen, 1994).

The randomised-controlled trial is a powerful research tool because of its two main components: randomisation and control. Randomisation in healthcare is the random allocation of patients to one of two or more different treatment groups. The important point is that there is equal probability of any one patient being allocated to any particular treatment group. For a study to have high internal validity, the patients in each group should be similar in relevant characteristics before treatment (Anonymous, 1985). The only reliable way to do this is to assign patients to treatment groups randomly (Kerlinger, 1992a) and this can also reduce the effects of regression to the mean (Yudkin, 1996). However, randomisation can fail if the investigator has prior knowledge of the group allocation. This lack of concealment can lead to selection bias, for example, delaying entry of a subject until the desired treatment group allocation is available (Schulz, 1996).

Including a control group in a study is important in clinical trials. Indeed, randomisation is not possible unless there are a minimum of two groups or phases. The full benefit of randomisation cannot be realised unless one of the groups is a control and the other receives the experimental intervention. Well-designed control conditions take many forms but have two things in common: the outcome is

considered to be predictable apart from non-specific effects and comparison between the control and study group outcomes yield useful information about the effect of the study intervention. In fact, some authors argue that studies without control groups seldom provide useful information on efficacy (Anonymous, 1985).

The ideal randomised-controlled trial is also double-blinded. That is, neither the subject, nor the investigator measuring the outcomes, is aware which treatment arm the subject is in. This reduces observer bias which otherwise could lead to an exaggerated estimate of treatment effect (Schulz, 1996). Observer bias may occur because the patient or investigator expects the experimental treatment to have a greater effect than the control. Even objective measures may be affected (Anonymous, 1985). This may be an extension of the placebo effect.

The 'John Henry' effect may occur in studies that are not blinded from the subject (Baumgartner, 1994). When subjects in the control group know which study arm they are in, they will be aware that they are not supposed to respond better than the experimental group. Their response maybe to try harder to outperform the experimental group. Alternatively, the control group may stop trying, leading to a reverse 'John Henry' effect.

In some studies, double blinding is possible by use of a suitable placebo. In other studies a 'double-dummy' is needed, a technique by which the patient receives two drugs or interventions – one of which is experimental and the other is the control. However, it is rarely possible to achieve a double-blind trial in healthcare research (Anonymous, 1985; Newell, 1992; Schulz, 1996). A partially blinded study may be appropriate, with the patient blinded to treatment arm, but not the investigator. Such studies should be treated with caution, as observer bias is a potential hazard.

The area in health research where the use of the randomised-controlled trial is most appropriate is in drug trials. In the case of a new class of drug or procedure in development, the randomised placebo-controlled trial is considered most appropriate. In fact, all new drugs that enter Phase III clinical studies must be compared against a placebo product, or the market leader ('gold standard'), in a suitable sample of patients (Harman, 1999).

A placebo is an intervention designed to simulate active medical therapy but believed to be ineffective for the target condition (Turner, 1994). In placebo-controlled trials, one group of subjects (the control group) receives appropriate conservative therapy (mainly symptomatic relief) plus placebo, but is not allowed any alternative active treatment; the active group receives the drug under research. The outcomes of the two groups are compared. In a well-designed trial, any difference can be attributed to the specific effect of the active treatment (Kleijnen, 1994).

It is important to ensure that the study is truly placebo controlled, that is both sets of subjects receive a similar intervention (for example, a lactose filled capsule rather than one containing the active drug) to ensure that any placebo effects are taken into account. Otherwise these are not placebo-controlled trials but are comparing treated patients to untreated patients, which may not give the same results (Turner, 1994). Using a placebo in the control group controls for non-specific effects of treatment (placebo effect), and allows the specific effects of the active treatment to be measured. Failing to control for placebo effects can lead to erroneous claims of efficacy for any type of treatment. Placebo effects are effects that are attributable to factors other than the specific effect of treatment, and can include the healing setting, the apparent attitude of the physician and even the colour of tablets (Turner, 1994). The placebo effect is well recognised and has been used as a treatment modality in its own right (Chaput de Saintonge, 1994).

In placebo-controlled trials, strict selection criteria must be adhered to, which usually exclude a large proportion of the population (children, the elderly and pregnant women) in an attempt to limit the effect of any non-specific effects that may be introduced through sampling (Anonymous, 1985). This may limit external validity. However, if the sample population is representative of the total population under investigation, then a well-designed study will have high external validity.

The Declaration of Helsinki states:

> 'In any medical study, every patient – including those of a control group, if any – should be assured of the best proven diagnostic and therapeutic method.'
>
> (World Medical Assembly, 1989)

It therefore follows that in conditions for which a proven therapeutic method exists, the new drug or therapeutic entity should be compared with the 'gold standard'. In such a comparator-controlled study, the researcher can ensure that all subjects receive active treatment of some kind. The efficacy of the new drug is therefore compared with the best treatment currently available.

Comparator-controlled studies are designed to reduce the effect of independent variables either by use of a simple control design, as described for placebo-controlled trials, or by crossover design. In a crossover study, one group of subjects receives the 'gold standard' for a fixed period of time and subsequently receives the alternative (experimental) treatment. There is often a 'washout' period between these two phases to reduce any residual effect from the first phase. Occasionally a second crossover phase is utilised to investigate any errors that arise due to treatment order. A second group of subjects (randomly assigned or matched) encounters the same treatment phases but the experimental treatment is administered first. This type of crossover design confers the benefits of limiting both intra- and inter-individual variations without compromising patient care (Anonymous, 1985).

Often randomised-controlled trials have limited applicability to the clinical context of patient management, as the results may not be applicable to patients who differ from the study population. As Sackett (1997) explains:

> 'Randomised controlled trials carried out in specialised units by expert care givers, designed to determine whether an intervention does more good than harm under ideal conditions, cannot tell us how the experimental treatments will fare in general use, nor can they identify rare side effects.'
>
> (Sackett, 1997: 1636)

In circumstances where controlled trials are not possible to achieve, the investigator must attempt to limit the effects of extraneous random variables. He must ensure that the measured effect was caused by the investigation intervention and not by anything else.

In an attempt to adapt the concept of randomised controlled-trials to an individual patient's care, some authors have suggested using an 'n-of-1 trial' (Anonymous, 1998). In these trials patients alternate between placebo and standard treatment, and the investigational drug. The patient and, ideally, the investigator, need to be blinded with regard to medication phase. Consequently, these trials are not suitable for drugs with characteristic side effects or those needing a long washout period. The patient receives the drugs in random order and the outcome of treatment is measured. This type of study is therefore unsuitable for conditions that are self-limiting and drugs with a long lag time before response is seen. The results from such studies may be useful for a physician to make difficult treatment decisions for an individual patient. However, the results are patient and drug specific and cannot be extrapolated to other patients or drugs.

In some cases, the *intervention* is environmental (that is not made intentionally by the researcher; such as the effect of air pollution on rates of childhood asthma). In these circumstances, matched controls are used. Matched controls are subjects with similar baseline measures (background, family medical history, etc. – independent variables), but with differences in the dependent variables the researcher is interested in (for example, exposure to air pollution during childhood). When these differences are compared, matching controls for the effect of the independent variables, and hopefully a true representation is seen. However, if more than three characteristics need to be matched, it becomes extremely difficult to achieve. Also, the means of the two groups may be quite different before the *intervention* occurred, which may lead to type 1 or type 2 errors (Woodward, 1992).

A single group study, where all subjects receive the same intervention, can cause the researcher many difficulties. Unless strict inclusion and exclusion criteria are enforced, the inter-individual variations can introduce a large number of dependent and co-dependent variables, thus rendering any measurements meaningless.

However, excessively strict selection criteria may result in a group so selective that the conclusion, despite having unquestionable validity, cannot be applied to other groups under similar but subtly different circumstances.

Single group studies are at risk of a number of threats to internal and external validity. In fact, one group 'one shot' studies, in which all subjects are given the same intervention and tested once after that intervention, have been described as 'scientifically useless' (Kerlinger, 1992b). In such studies, patients are not selected randomly and therefore there is a risk of selection bias. Even without deliberate selection bias, the background of the patients may cause differences in outcomes that are not representative of the wider population. There is no way of knowing if the results are due to the intervention or due to some other variable.

In health research, however, where patient welfare is at stake if an inappropriate methodology is used, single group studies may be unavoidable. Such instances include research into conditions that are relatively rare, such as some congenital defects, in which suitable subject numbers would not be available to assign any to a control group. Another situation occurs when the current recognised method of treatment has no basis in evidenced-based therapy but there is no clearly defined alternative and the use of a placebo situation would be unethical.

Pre-test/post-test studies with the same subject are often used to try to overcome some of the limitations of single group studies. These are slightly better than 'one shot' studies because the majority of independent variables associated with the subjects' characteristics are controlled. However, these trials still introduce risks to validity, namely, maturation, measurement, testing and regression to the mean (Baumgartner, 1992). The problem is not that these factors may operate, but that without strict controls we do not know if they have operated or the extent to which they affect the final measures (Kerlinger, 1992b).

Chapter 3: Research methodology

3a: Research design and rationale

Introduction

This study was carried out in an attempt to assess the effect and appropriateness of pharmacist introduced interventions for subjects who have demonstrated risk of non-compliance. It was intended to use the results of the study in order to discover whether all elderly patients require an assessment of compliance when in hospital, or whether generalisations for sub-groups can be made. It was hoped that any changes to current levels of service required in order to implement the conclusions of the study would be identified. As changes to service levels require resources it was essential to determine whether the hospital pharmacist is the best health care team member to undertake the activities identified in this project. Ethics committee approval was sought and gained to carry out the research within the hospital. A copy of the letter can be found in Appendix I.

In designing this research project, it was necessary to undergo a number of stages: Firstly a suitable client group needed to be identified. Secondly, a suitable research tool needed to be designed to assess levels of compliance and non-compliance. In order to achieve this it was necessary to identify the various ways compliance can be measured. Once this was achieved, it was necessary to describe how a valid measure of compliance can be used to improve patient care and to use this to design a practical tool to measure an improvement in patient care.

It was necessary in designing this tool to identify potential problems with compliance and decide on the most suitable interventions to apply in order to address these problems. A method of assessing the response to these interventions was required. It was also necessary to attempt to ascertain whether interventions instigated by the hospital pharmacist were continued in the community. The resulting procedure then had to be applied to a sufficient sample size in order to assure statistical significance.

Monitoring compliance

In order to measure whether a hospital pharmacist can improve patient compliance, compliance must be measured. The various options available to assess compliance have been discussed during the literature review. In this section, consideration will be given to those which were most appropriate for use in the current research protocol. As has already been described, assessing absolute compliance is almost impossible (Van Berge Henegouwen, 1999).

Various measures have been used to assess compliance in previous studies (Anonymous, 1991b; Aronson, 1992; Beardon, 1993; Col, 1990; Eisen, 1990; Grymonpre, 1998; Hughes, 1998; Lowe, 1995; Lorenc, 1993; Moriskey, 1986; Parkin, 1976; Smith, 1983; Sweeny, 1989). These have included pill counts, incorporating recording devices into the lids of containers, measuring prescription renewal intervals, measuring blood levels of drugs or inert markers, assessing therapeutic control and self-report. The limitations of each of these have been discussed earlier (see Chapter 2).

Not all of these measures would be appropriate for the current study. The first three measures would require close collaboration from the subjects' general practitioners and community pharmacists. Detailed knowledge of prescriptions dispensed prior to admission would be required, information which would be difficult to access as contacting 23 surgeries and 29 community pharmacists would be required. Measuring blood levels is not possible for all drugs and even if it were possible it would not feasible for the vast array of medicines prescribed to the study population. Similarly biologic markers would not be feasible as each subject would require a separate marker for each drug taken because patients do not comply consistently with all prescribed medicines. In addition, although some of these subjects would have suffered deterioration of therapeutic control because of non-compliance, we could not assume that all deterioration was thus caused.

The final option for assessing compliance is self report. This is the simplest tool to use, can be used in all settings and can be carried out with no prior arrangements being made. However, the responses require careful assessment to avoid observer bias and to identify when a subject is giving the answer they think the investigator wants to hear. Self report can be qualitative - a description of why and when problems occur and what the subject does in order to rectify them, or quantitative - an estimate of how many doses the subject takes each day.

It has been shown that the way questions are worded (Aronson, 1992) and the relationship between the questioner and the subject can affect the results (Paes, 1998). This can be deliberate with the subject telling the investigator what they think he wants to hear (Col, 1990; Hughes, 1998) in order to avoid being reprimanded, or an involuntary response to a leading question.

If a patient denies non-compliance, no conclusion can be made, however, if a patient admits to a problem a solution can be attempted. Also, self report cannot reliably distinguish between a patient who sometimes forgets and one who regularly forgets (Paes, 1990). In one study (Grymonpre, 1998) there was no difference in mean percentage compliance when measured by self report or refill data and both gave a higher percentage compliance than pill counts.

The limitations of self report can be great, however the strengths in the current situation are many. Self-report will, by necessity, describe actions prior to administration and not during the current stay. It does not rely on any prior information being known and if a standard questionnaire is used, allows comparison of different subjects and of the same subject before and after an intervention.

Self-report alone cannot accurately assess absolute compliance, however, if worded sensitively such a questionnaire would be able to identify possible risk factors which may cause non-compliance. Absolute compliance is generally not necessary to know for an individual but their risk of non-compliance would be useful to know. An appraisal of these risk factors could identify those subjects at greatest risk of non-compliance and indicate the type of intervention required to improve compliance.

Other measures such as pill counts only measure one type of non-compliance. In a carefully worded questionnaire, it is possible to obtain information on all causes of non-compliance. It was therefore decided that the method of measuring compliance utilised in this study was to be a questionnaire. The design of this questionnaire will be discussed later in Chapter 3b.

Client group & sample size

The client group was chosen to be elderly patients who were admitted as acute medical in-patients to the two acute Medicine for the Elderly wards at hospital NT. All patients were included except those who fall into the following categories: living independently but not self administering; resident in residential or nursing accommodation; included in previous pilot projects. The justification for these inclusion and exclusion criteria is discussed below. Patients were included with any medical or psychological condition except those which would make them unsuitable for self-medicating at home.

The aim of the study was to investigate the role of the hospital pharmacist in improving compliance behaviour following discharge; therefore, the client group must include hospital patients. Many patients have contact with a hospital as day cases, out-patients or as in-patients. However, it is only the latter for whom there is adequate opportunity for a pharmacist to have input into their total care. They generally remain in hospital for a minimum of 2-3 days, which allows sufficient time for a pharmacist to assess their therapy and interview them during the daily clinical pharmacy visit. This also allows time to remedy some of the identified problems before discharge.

Out-patients may be given a prescription to present at the outpatient pharmacy. However, during busy periods the pharmacist may only be able to spend a few minutes with each patient, which may not be sufficient to elucidate any important problems. Patients also may not be willing to spend extra time with the pharmacist if this service was offered because of the long waits which they have usually experienced. Also, patients often do not bring all the information which would be

required to assess compliance behaviour to these clinic appointments. For these reasons, this group would not be a suitable client group.

Patients who visit the hospital as day cases would be a more appropriate client group. They potentially would have more time to be interviewed by a pharmacist but at hospital NT there is currently no opportunity for a pharmacist to visit these patients. Also, these patients are generally admitted for surgical procedures and therefore may be unavailable for interview for a large proportion of their hospital stay.

There is one disadvantage to using in-patients as the client group; in-patients do not generally self medicate whilst they are in hospital. This presents the difficulty of measuring compliance in an artificial situation. On wards where self-medication is offered, this would still be an artificial scenario as not all in-patients are suitable for self-medication and the nurses could therefore unintentionally provide prompting. However, the situation is the same in most day case wards, and out-patients are unlikely to need to take their medication at the precise time they present at the pharmacy. This therefore is a relative disadvantage of studying compliance in the hospital environment rather than one specific to in-patient care.

In-patients on an acute medical ward would make an appropriate client group for a number of reasons. Firstly, in a surgical ward the surgeons usually concentrate on the surgical procedure, wound healing and subsequent rehabilitation. Medication is not usually altered except for the possible addition of antibiotics, analgesics, laxatives and anti-inflammatory drugs on discharge. On acute medical wards often a change in medication is the main intervention made by the physician. Many studies have shown that a change in drug treatment after a stay in hospital can significantly affect compliance (Binyon, 1994; Cochrane, 1982; Parkin, 1976; Royal College of Physicians Working Party, 1997). The need for interventions to improve compliance is therefore greater on medical wards.

Another problem with surgical patients is that the length of stay can be variable, ranging from an overnight stay for minor procedures to several months for some orthopaedic operations. On acute medical wards, the length of stay is usually in the range 2–14 days. This is long enough to be assessed by the pharmacist but not too long for the patient to become institutionalised.

As has been shown previously, the elderly as a whole have greater problems with compliance and therefore have most to gain from any intervention. The age group 70-85 was therefore chosen as the age range for the client group. The lower end of the age bracket was chosen as most authorities class this as the lower age range for categorisation as elderly (Royal College of Physicians Working Party 1997). The upper age range was chosen because the majority of patients over 85 do not self-medicate, either because they live in nursing or residential accommodation, or have carers giving them their medication (Dryden, 1999). This group therefore has less chance of benefiting from a pharmacist's intervention.

Sample size

The study period was chosen to cover an eight-month period between October 1999 and June 2000. The sample size required to have sufficient power to show a benefit was calculated to be 113 patients. This was calculated from previous data, supplied by medical records, in the following way. The study wards held 26 acute medical patients with an average length of stay of 14 days. This would give a total of 416 patients admitted over the eight-month period. On the study wards two day case patients were admitted each week and would not be included (see above) leaving a total of 352 patients. Due to the case mix of the patients admitted to the study wards 10% of patients lie outside the 70-85 age range and 50% of the study population would be residing in residential or nursing accommodation and therefore not suitable for inclusion into the study. This leaves a population size of 160 patients. Using standard tables for calculating sample sizes (Bland, 1995) a sample size of 113 would give a proportion to within ± 0.05 of population proportion at 95 percent confidence interval.

Because of the large sample size compared to the population size, it was decided that random sampling would not provide sufficient data. A variation on systematic sampling was therefore employed (Kerlinger, 1992a). All patients admitted to the study wards were identified. Of these, all patients who met the criteria for interview (see below) were identified and alternate patients (chronologically by date of admission to the study wards) were included in the study. It has been estimated before that between 20-50% of elderly patients have compliance problems (Misselbrook, 1998c), a sample size of 113 should therefore identify 23-29 patients with compliance problems.

Inclusion and exclusion criteria

The inclusion and exclusion criteria can be separated into two stages: those subjects suitable for investigation and those subsequently found suitable for follow-up and inclusion in the final results. These are shown in Table 3i.

The reason for choice of age group and ward has been discussed above. The reason for the arbitrary time limit of remaining on either ward for three or more days was two-fold. Firstly, acutely ill elderly patients often have acute confusion which resolves relatively quickly, hence subjects were assessed on their usual ability to comply and not the artificial level on admission. Secondly, some interventions may take 24 hours or more to apply. As the pharmacist may not see the patient until the second day of admission, it may take until the third day to implement any interventions.

Subjects who were not self medicating at home were excluded because in these cases compliance with the doctors wishes was not dependant on the patient's ability but on that of the carer, the same was applicable to subjects in nursing or residential homes. Any pharmaceutical input would not have had any impact on the outcome after discharge. Also, measuring the compliance of such subjects would be irrelevant to patient care and would not be representative.

Table 3i: The inclusion and exclusion criteria for the study

SUITABILITY FOR INTERVIEW	
Inclusion criteria	**Exclusion criteria**
• Age 70-85 • Admitted to one of two acute Medicine for the Elderly wards at Hospital NT • Remaining on either ward for 3 days or more • All admissions who fit the above criteria except those who fit the exclusion criteria	• Living in nursing or residential accommodation • Included in pilot phase • Admitted to hospital more than ten days prior to transfer to study wards • Having any condition that would render self-administration impracticable e.g., end stage Alzheimer's, massive CVA, paralysis or lack of use of both hands, AMT <5/10, etc.
SUITABILITY FOR FOLLOW-UP	
Inclusion criteria	**Exclusion criteria**
• Meets criteria for suitability for interview • Able to understand and answer compliance questionnaire • Have an identified compliance problem and agree to further follow-up	• Not self-administering medication at home • Completely deaf or do not understand written or spoken English • Due to religious or other beliefs refuses to take western medicines • Unavailable for interview at 10-14 days post discharge • Discharged to short stay residential care before going home • Not prescribed any medication • No compliance problems (total score ≥ 40) • Intervention not administered by pharmacist or no intervention possible • Patients deemed unsafe to self-administer medication as a result of applying the baseline questionnaire.

The chosen research tool was an investigator lead questionnaire. Subjects were therefore only included if they had a sufficient understanding of spoken words and showed adequate ability to understand and answer the questions asked. As compliance was being assessed primarily on the answers to a number of questions, lack of understanding or confabulation would cause unreliability in the results.

Excluding completely deaf patients and those who did not understand written or spoken English may exclude a particularly needy group; however, resources for interpreters were not available during this study and the responses of a subject who did not completely understand the question could not be assessed as reliable. Written questionnaires could have been given to completely deaf subjects in order to assess compliance risk, however, this introduces all the complications of written questionnaires. Also, a number of supplementary questions were often required to prompt subjects with partial memory and to help decide on the most appropriate intervention. This may not have been possible for a significant number of completely deaf subjects. Excluding these subjects was neither desirable nor strictly ethical on the basis of pharmaceutical need, but was expedient in the carrying out of the current study.

As the aim of the study was to investigate the effect a hospital pharmacist might have on compliance, subjects were only followed-up if they had an identifiable problem with compliance. If a subject had minor or no problems with compliance there would not be any need to improve their compliance and also it would be very difficult to measure any improvement.

Also excluded were any subjects that had been enrolled into previous pilot projects. Bias may have been introduced by enrolling these subjects as they had already had the input of a hospital pharmacist. This may have either changed their activity at home or may have changed the answers given to questions. In addition, they would have been known to the investigator, which could have introduced investigator bias.

Subjects who had been in previous wards for longer than 12 days prior to transfer to the study wards were excluded. This was because the interview could take place more than a fortnight after admission to hospital, long enough for an elderly patient with good compliance to forget how they had managed with their medication at home and might result in inaccurate answers to questions. Elderly patients rapidly become institutionalised in hospital causing errors in assessment of compliance ability (Hodkinson, 1981). Also, it is arguable that patients who have been in hospital for a long time may take longer than the study period (three months) to return to their pre-admission state. There appears to be no evidence of whether this

is the case but this group was excluded on the basis that such changes in ability or behaviour may also be shorter lived and hence introducing the risk of erroneously attributing any improvement to the intervention made by the pharmacist.

Subjects who were not prescribed any medication prior to admission or on discharge were excluded from the study. Compliance is only an issue with subjects prescribed medication and any assessment method would require a subject to have taken medication. An assessment of compliance problems was therefore not possible for this sub-group of subjects.

Subjects who were lost to follow-up or unavailable for interview 10-14 days post discharge were excluded. This interview was designed to identify any problems the patient encountered in continuing interventions after discharge. Interventions that were in place within the first fortnight post-discharge were likely to be continued. Those not initiated immediately were unlikely to be started before the final reassessment.

Subjects refusing entry into the study

Refusing follow-up

The proportion of males and females refusing entry into the study were the same (24%) but the reasons for refusal were subtly different. Whereas women were generally worried about the perceived risks involved in being followed-up after discharge and the possible inconvenience, the men were more likely to give the reason that they were unlikely to benefit from any follow-up, and neither was anyone else. Although the figures are too small to be significant this may reflect either a general fear of strangers in elderly women or be indicative of a lack of interest in medication in men.

For example, Mrs. LG (37LG061012), Mrs. ML (39ML090414) and Mrs. MM (37MM020233) all accepted the intervention offered. However, Mrs. LG refused to sign the consent form because she 'wanted a quiet life' and Mrs. ML refused because she didn't want bothering at home. Mrs. MM refused to sign the consent form

because she didn't want bothering at home and was obviously nervous of inviting the investigator into her house.

This fear of asking someone into the home or not wanting to be bothered after discharge may reflect a desire to retain independence. In addition, although not usually vocalised by the subjects, a fear of being checked up on may also have caused this reluctance. When consent was requested, an explanation was given that the suitability of the interventions was being investigated. However, some element of assessment of the subject was involved and they may have felt they were being examined. Subjects were advised that a friend or relative was welcome to be present at the follow-up interview and in fact both Mr. LO (37LO090524) and Mrs. GM (39GM031015) had one of their children in attendance at this interview. Although every attempt was made to interview the subjects at a hospital appointment, this would not always have been possible. In finality, however, only two subjects were followed up after discharge, one by interview at home and one at a hospital outpatient appointment.

It was difficult to persuade the male subjects to agree to sign the consent form, as most did not see any benefit in signing. For example, Mr. ED (39ED070821), Mr. JT (39JT060219) and Mr. GR (39GR240107) all accepted the interventions offered. However, Mr. ED refused to sign the consent form because he didn't want bothering at home. Mr. JT refused because he didn't want to get involved, as he did not see any possible benefit. Mr. GR refused to sign the consent form because he did not see any possible benefit to him or others. The importance of compliance was not always clearly understood by these subjects and they frequently denied having any problems with non-compliance and therefore could not perceive how they might benefit or how anyone else could benefit from the study.

Other compliance studies have shown a lower rate of refusal of entry into follow-up studies. In one study (Kravitz, 1996) 86% of subjects agreed to follow-up and in another discharge follow-up study (Parkin, 1976) 93% agreed to be enrolled. In neither paper was any reason for refusal given. Subjects in both groups included mainly younger patients.

Eisen et al (1990) identified 756 patients who fitted their inclusion criteria, however, only 192 agreed to participate, a refusal rate of 75%. Although these subjects were not all elderly (69% in one arm were 65 years of age or under) and only represented patients with one condition (hypertension) it is representative of some of the difficulties involved in recruitment. In this study 48% of refusing subjects were 'not interested' in taking part in the study and 34% could not commit to keeping to the terms of follow-up (six monthly appointments). The subjects refusing entry were not divided into male and female for the purposes of describing reason for refusal and so this cannot be compared. Interestingly a similar but smaller study by Lorenc et al (1993) reported a one hundred percent agreement rate for enrolment into the study. However, this was qualified by the statement 'To the author's knowledge all patients approached at the surgery agreed to be interviewed'. It is possible that refusing patients were not reported.

Refusing interventions

A small number of subjects in the current study refused all interventions. It was not always apparent why although it may be related to their desired level of control. A subject who is afraid of losing their independence may refuse assistance, if the intervention is perceived as diminishing their control rather than enhancing their ability to remain in control.

In order to help with compliance, Mrs. SW (39SW080425) filled her own Medidos® each week. She was found to be at moderate risk of non-compliance however, she refused all offers of help for her poor manual dexterity because she did not feel that she was in need of any input. Similarly, Mrs. ID (39ID151114) lived alone but receive a visit from a home carer three times a day. This assistance did not involve reminders of when to take her medication. She was found to be at high risk of non-compliance but she was independent and was unwilling to accept any new intervention. Mrs. JR (39JR240413) also lived, alone but received support from her daughters. She was found to be at moderate risk of non-compliance however, she refused all interventions.

A lack of willingness to accept an intervention may also reflect the lack of importance the subject assigns to complying with medicines. This may be caused by a number of factors, but if this results in complying being assigned a low priority then the subject may not bother trying to take his medicines at the correct time. An intervention may therefore be viewed as an imposition attempting to rectify a problem that is inconsequential. This was the case for Mr. JP (37JP231209), who was found to be at moderate risk of non-compliance but refused all interventions as he was not interested in trying to take his medication correctly and could not see any possible benefit.

There is an argument that diagnostic and evidence based interventions should be viewed as a treatment necessity and not at the whim of patient choice. They should be seen as part of the treatment and not an afterthought. However, if they are a treatment modality they must be subject to the constraints of concordance and therefore patient choice is once more important.

All healthcare studies must be undertaken without undue pressure on the subjects to agree to involvement and after serious consideration. In research using healthy volunteers, recruitment can continue until the required numbers are reached. However, if benefit to patients is of interest, authentic patients must be used as subjects and be given free and fair opportunity to refuse entry. It is unethical to coerce subjects or offer inducements that may bias the findings. It is therefore possible in any similar study to fail to enrol sufficient subjects.

Subjects enrolled for follow-up

Twenty-four subjects were deemed suitable for enrolment into the study as originally designed. However, due to loss of subjects, due to death, early discharge or not self-medicating, and refusals of entry, only seven subjects were enrolled and only five were followed up after discharge. Only two were successfully contacted at three months.

Subjects lost to follow-up

Two subjects were not available for follow-up at two weeks despite many attempts to contact them. Both subjects lived alone but had different levels of social support. Both, in common with most of the subjects interviewed, only visited one pharmacy to get their prescriptions dispensed. They were not significantly different to any of the other subjects interviewed except Mrs. EW (39EW130709), who did want to be more involved in decisions about her treatment. Both were happy to sign the consent form and no obvious reason for their unavailability at two weeks was found.

Mrs. DR (39DR150919)

- 81 year old female who had been admitted with a chest infection and fall. She lived alone in a warden controlled flat and with home carers visiting three times a day. This support did not include reminders on when to take her medication. She always got her prescriptions dispensed from the same pharmacy.
- Mrs. DR reported that her GP always gave her sufficient information about her medication but she had not so far been given any information whilst she was in hospital. She reported being happy with her level of involvement in making decisions about her treatment.
- Despite having an AMT of 9/10 she was found to be at moderate risk of non-compliance because she was able to explain what she was taking and the reason why only with some difficulty and some omissions, she was unsure if her medicines were effective and she was unable open child resistant closures or remove tablets from blister packs. Because of rheumatoid arthritis, she could not manage to remove screw caps from small bottles.
- She agreed to receive a number of interventions to improve her compliance, namely, a compliance sheet, counselling, large bottles and avoidance of blister packs. She consented to be followed up at home but a number of unsuccessful attempts were made to contact her after discharge.

Mrs. EW (39EW130709)

- 91 year old female who had been admitted with falls. She lived alone and had refused help in the past; she was usually fully independent. She always got her prescriptions dispensed from the same pharmacy.
- Mrs. EW reported that her GP only gave her information about her medication when prescribing a new drug and she had not so far been given any information whilst she was in hospital. She reported wanting to be more involved in making decisions about her treatment.
- She was able to explain satisfactorily what she was taking and the reason why.
- Despite an AMT of 10/10 she was found to be at moderate risk of non-compliance because she was unsure whether she still needed some of the medication she was prescribed although she thought they were working.

She also wanted more involvement in making decisions about her treatment.

- Mrs. EW agreed to receive a number of interventions to improve her compliance, namely a concordant interview and compliance sheet. She agreed to be followed up at home but a number of unsuccessful attempts were made to contact her after discharge.

Key issues from 1st follow-up

Five subjects were interviewed at two weeks post discharge and Table 3ii shows the data obtained from these subjects.

Table 3ii: First follow-up

	Mrs. MC	Mrs. MM	Mrs. DW	Mrs. GM	Mr. LO
Prescription from GP	Yes	Yes	Yes	Yes	Yes
Prescription changed since discharge	Yes	Yes	Yes	Yes	Yes
Pharmacy changed	No	No	No	No	No
Interventions continued	Yes	Yes	Yes	Yes	No
Interventions helped	Yes	Yes	Yes	Yes	Unsure

All subjects had had changes to their prescription in the intervening two weeks but had continued to get their prescriptions from the same Pharmacy. All subjects had remembered to get a new prescription within a week of discharge, as their discharge medication would have run out after one week.

Four subjects had received the same interventions when a new prescription had been dispensed. These included continuing on a new inhaler, updating the compliance reminder chart, counselling on medication, providing large print labels and giving screw caps on medicine bottles. For Mr. LO (37LO090524) neither intervention had been continued by the community pharmacy (updating reminder sheet and counselling on medication) and this subject was not sure whether they would help in improving compliance. The time taken to follow these subjects up was on average eleven minutes.

Three subjects were successfully contacted at two weeks but subsequent follow-up was not possible. All three lived alone but had some limited help in the form of daily visits. Interestingly, one of these subjects, Mrs. DW (39DW070422), used two different pharmacies for her prescriptions. This may indicate the fact that she had experienced a good service from both of these pharmacies and therefore could not choose between them, or she may not have felt that she would benefit from only visiting one pharmacy and visited whichever one was most convenient at the time.

Mrs. DW (39DW070422)

- 77 year old female who had been admitted with chest pain. She lived alone but was mobile about the house with her daughter helping out occasionally. She had two pharmacies at which she usually got her prescriptions dispensed.
- Mrs. DW reported that her GP always gave her sufficient information about her medication and she had so far been given appropriate information whilst she was in hospital; she reported being happy with her level of involvement in making decisions about her treatment.
- She was able to explain satisfactorily what she was taking and the reason why, despite a complicated regime.
- Despite an AMT of 9/10, she was found to be at moderate risk of non-compliance because she was unable to read standard labels and had a complicated treatment regime (11 drugs on admission).
- Mrs. DW agreed to receive a number of interventions to improve her compliance, namely, counselling, a compliance chart and large print labels. She agreed to be followed up at home but although she was successfully contacted at two weeks a number of unsuccessful attempts were made to contact her at three months post discharge.

Mrs. MM (37MM210420)

- 80 year old female who had been admitted with an exacerbation of chronic obstructive pulmonary disease. She lived alone with a home carer only providing assistance with shopping. She always got her prescriptions dispensed at the same pharmacy.
- Mrs. MM reported that her GP never gave her any information about her medication and she had not so far been given any information whilst she was in hospital, however, she reported not wanting to be involved in making decisions about her treatment.
- She was able to explain satisfactorily what she was taking and the reason why, despite having a complicated regime.
- Despite an AMT of 10/10 she was found to be at high risk of non-compliance because she was unsure if she was happy with her medication or whether it was working, she had an inappropriate inhaler, which she thought was not working, as she was still breathless and she had a complicated treatment regime (five drugs on admission).

- Mrs. MM agreed to receive a number of interventions to improve her compliance, namely, counselling, a compliance sheet and changing her inhaler device. She agreed to be followed up at home. Although she was successfully contacted at two weeks, she was later admitted to a nursing home before her final follow-up.

Unfortunately, Mrs. MM (37MM210420) was admitted to a nursing home, which caused her exclusion from the study. She was found to be at high risk of non-compliance and this may be an indicator of a patient's ability to cope with the other activities of daily living. However, other subjects found to be at high risk of non-compliance have successfully returned home with home carers providing support and so this event may simply reflect deterioration in her general medical status.

Mrs. MC (39MC080527)

- 72 year old female who had been admitted with decreased mobility. She lived alone but used a pendent alarm when necessary, with home carers visiting three times a day. She always got her prescriptions dispensed at the same pharmacy.
- Mrs. MC reported that her GP only gave her information about her medication when she was prescribed a new drug and she was unsure whether she had been given any information whilst she was in hospital; however she reported being happy with her level of involvement in making decisions about her treatment.
- She was admitted taking seven different medicines with four different frequencies but she was able to explain satisfactorily what she was taking and the reason why.
- Mrs. MC was fairly happy with her medicines but was not sure if she needed a change in her Parkinson's Disease treatment; she also did not think her antidepressant was working. Despite this she did not want to change it and refused to have her sleeping tablets reduced, despite understanding the risk of dependence.
- Despite an AMT of 9/10, she was found to be at moderate risk of non-compliance because of a complicated treatment regime which she was unhappy with or whether it was effective.
- Mrs. MC agreed to receive a number of interventions to improve her compliance, namely, a compliance sheet and counselling. She agreed to be followed up at home. Although she was successfully contacted at two weeks, she was later readmitted to hospital before her final follow-up.

Most of the subjects agreeing to follow-up were satisfied with the level of involvement they generally had in the decision making process with regard to medical treatment. Their willingness to take part in the study was therefore not related to a desire to have greater involvement. An interesting common factor for all

subjects who agreed to sign a consent form is that they all had a Abbreviated Mental Test Score of greater than the average for the sample. Each had a score of 9 or above. This may have meant that they had a greater understanding of what was going to be involved after discharge, possibly related to an increased ability to understand the information provided to inform the subjects of what would be involved in the post discharge follow-up. The consent form (see Appendix I) was designed to be easily read and had a Flesch Reading Ease Score of 74.4 (80% of people can read). All subjects who refused entry claimed to have understood the information and an opportunity was given to allow discussion and questioning to allay any fears. However, subjects who do not fully understand what is involved in a study will be less likely to volunteer.

The fact that each of these subjects had a high AMT but were at moderate risk of non-compliance also demonstrates the limitations of using the AMT to exclude patients with no compliance problem. Confusion level and memory affect compliance. However, compliance can also be affected by knowledge of medicines, which depends on concordance and also the patient's interest in and attitude to their medication. Physical ability to access dosage forms and packaging can also affect compliance. None of these factors are included in the AMT questionnaire and therefore cannot be predicted by it.

Key issues from 2nd follow-up

Two subjects were successfully enrolled into the study and followed up at three months. These subjects, one male and one female had no obvious characteristics that would allow one to predict that these would complete the study.

Mrs. GM (39GM031015)

- 84 year old female who had been admitted with congestive heart failure. She lived alone but her son reminded her when to take her medicines. She was unable to name the pharmacy where she got her prescriptions dispensed.
- Mrs. GM reported that her GP never gave her any information about her medication and she had not so far been given any information whilst she was in hospital. However, she reported being happy with her level of involvement in making decisions about her treatment.

- She was able to explain satisfactorily what she was taking and the reason why.
- Despite an AMT of 10/10 she was found to be at high risk of non-compliance because she was unable open child resistant closures or remove tablets from blister packs; she also had difficulty using her aerosol inhaler, both in actuating the inhaler and co-ordinating her breathing with pressing the canister. She also was unsure if she still required her medication and felt it was not working. She also had a complicated regime (8 drugs on admission).
- Mrs. GM agreed to receive a number of interventions to improve her compliance, namely, counselling, changing inhaler device, providing screw caps and avoiding blisters. She agreed to be followed up at home and successfully completed all phases of the study.

Mr. LO (37LO090524)

- 76 year old male who had been admitted with a fall. He lived alone with no assistance. He always got his prescriptions dispensed at the same pharmacy.
- Mr. LO reported that his GP always gave him sufficient information about his medication and he had so far been given sufficient information whilst he was in hospital. He reported being happy with his level of involvement in making decisions about his treatment.
- He was able to explain satisfactorily what he was taking and the reason why. He was admitted taking three different medicines, but was discharged with nine; various doses were altered and he was prescribed new medication for constipation, pain, osteoporosis prophylaxis, epilepsy and insomnia.
- Despite an AMT of 10/10 he was found to be at moderate risk of non-compliance because he admitted to occasionally forgetting to take his medicines and had no special method of remembering when to take them. He also admitted that sometimes, when he felt better and thought he no longer needed his medication, he stopped taking it without informing his GP. He also had a complicated regime.
- Mr. LO agreed to receive a number of interventions to improve his compliance, namely, a compliance chart and counselling. He agreed to be followed up at home and he successfully completed all phases of the study.

Both subjects had had further changes to their prescription but were continuing with the same Pharmacy. The interventions made for Mrs. GM were continued and were still found helpful. Mr. LO still had not had his interventions continued but he now felt that counselling had been helpful and asked to be reminded of what his medication was for and when was best to take it.

The home circumstances of both subjects had not changed and there had been no change in their AMT. Approximately 30 minutes was spent reassessing the compliance risk of these two subjects. The results of the compliance questionnaire are shown in Table 3iii. Individual categories are scored out of five and the total is a mark out of 45. A mark of four or five for an individual category indicates that the subject is at low risk of non-compliance from that risk factor.

Mrs. GM showed an improvement in all areas of compliance risk and the overall risk of non-compliance reduced from high to moderate risk. At follow-up she was happy with her medication and felt that her new medicines were effective. The interventions made to overcome her physical impairment were effective and she was no longer at risk from her poor manual dexterity. Although still happy with the information supplied she reported not being told very much about her medicines by her general practitioner and her treatment regime was still very complicated. It is interesting that almost all improvements were due to the action of her community pharmacist following the letter sent on discharge.

Table 3iii: Second follow-up

	Mrs. GM		Mr. LO	
	Baseline	**Follow-up**	**Baseline**	**Follow-up**
Storage and administration	5	5	3	4
Understanding	5	5	5	5
Satisfaction	3	5	4	3
Drug efficacy	3	4	5	2
Adverse drug reactions	5	5	5	5
Information supplied	2	3	5	5
Physical problems	1	4	5	1
Disease related problems	5	5	5	5
Complexity of regime	0	0	0	0
Total	29	36	37	30

Key: 4-5 = Minimal or no compliance risk due to this factor
≤3 = Compliance risk due to this factor

Mr. LO showed a deterioration of compliance risk but remained within the moderate risk bracket. The main problem was deterioration in his eyesight, which accounted for the physical problems and resulted in the need for large print labels. The second biggest problem was ineffectiveness of his medication. Again this appeared to stem from deterioration in his condition and an appointment had been made with a doctor

to identify the need for a new dose. Neither of these could have been anticipated before discharge. It is possible to assume that had these problems not occurred his non-compliance risk score might not have reduced. However, Mr. LO did have a slight improvement in his method of administration in that he now appeared to have some method of remembering to take his medicines and was less likely to stop them without advising his doctor.

3b: Research instruments

Questionnaire design

As has already been discussed, it was decided after a literature search that compliance risk (rather than absolute compliance rate) would be measured by means of self-report. To ensure that responses were consistent an investigator administered questionnaire was decided upon as the method of choice.

A number of other options were available in carrying out self report of compliance. A qualitative approach could be used, asking subjects to answer general questions regarding whether they remember to take their medicines and what problems they encounter. This could be administered by means of a written questionnaire or a structured interview. A written questionnaire of this type relies on the subject volunteering information of a variety that can be used and compared. We have already described how patients are reluctant to volunteer information on non-compliance, often believing that health professionals wish to hear that they are complying. If a patient fails to admit to non-compliance, nothing can be said about the risk that they are under.

A semi-structured interview would be more useful as the investigator can guide the subject to talk about the issues which are appropriate but allow them to volunteer information that is important to them. Semi-structured interviews are useful tools for defining the main areas of a study and can yield a large amount of information. Because of the open ended nature of the questions used, the data obtained can be extremely difficult to analyse and requires specialised techniques which are time consuming to administer. The information gleaned from such an interview is mainly of a general nature, describing issues that are important and problems that patients may have. They are less useful when trying to quickly diagnose individual problems and find a solution, and they are not very suitable for large samples. It is also difficult to apportion causal relationships between changes in responses and

interventions made. For this purpose, quantitative methods are required in the form of a carefully designed questionnaire.

Questionnaires can also be subject or investigator-administered. The former can be used to provide large amounts of information cheaply but there is a risk of low rate of return, often as low as 40 - 50% (Kerlinger, 1992c). There is also the problem of wide variations in subjects' comprehension limiting the range of questions that can be asked, and the risk that different subjects will interpret a particular question in different ways, limiting the ability to compare answers between subjects. Re-applying self-administered questionnaires is also less reliable as the subject may be less honest, sometimes unconsciously, with the second questionnaire, giving the 'correct' answers if they believe they can identify where changes are required. Anonymity of response can improve the candour with which subjects reply to questions, but as the answers in this study need to be applied to make specific interventions, anonymity was not possible.

Investigator lead questionnaires are easier to administer, as the investigator can anticipate difficulties and ensure that the subject understands the questions. These yield a very high rate of return as only subjects who refuse to be interviewed are missed. It is important to ensure that the information asked of each subject is the same if comparison between subjects is to be valid and to reduce the risk of investigator bias. However, the investigator can try to ensure that understanding is of a minimum level and does not bias the results. Long questionnaires can be very time consuming to apply and so they need to obtain responses as efficiently as possible. In addition, lengthy questionnaires would not have suited the client group as some could not concentrate for long periods and the questionnaire could cause fatigue. In view of the nature of this study, an investigator-administered questionnaire was chosen as the best choice of research tool.

Designing a questionnaire is a difficult and time-consuming process. Many authors have attempted to describe the requirements for a valid questionnaire (Stone, 1993; Tully, 2000). The first requirement is to decide what information is needed. Extraneous questions add nothing to the results gained and can cause subjects to lose interest and miss later questions. The questions must be clear, unambiguous and as

easy to answer as possible. Questionnaires with many different methods of answering questions (tick boxes, ranking, Likert scales, open questions) can be confusing. However, these are less of a problem in investigator-administered questionnaires where the investigator can ask the question and only prompt with the options if the initial response doesn't fit with the selection identified. It is important that any question including a selection of possible responses is omnicompetant, that is there are no possible responses that fall outside the range of responses offered. This can be achieved by use of the response other and asking the subject to give details. However, if too many respondents chose 'other' this may be a sign that the question was poorly devised.

The combination of open and closed questions is particularly important to ensure that the subject is allowed to volunteer information that hasn't been anticipated, but is guided when specific information is required. Biased and leading questions must generally be avoided. The educational level aimed at must be carefully assessed to ensure that the level of the wording is neither too high so that most subjects will not understand what is required, nor too low which can cause the more intelligent and erudite responder to feel patronised and frustrated.

Choice of questions

Nine areas of compliance risk were chosen to form the basic structure of the compliance risk questionnaire following a literature review. These included: physical problems, complexity of medication regime, practice of storage and self-administration, attitude to medication, efficacy, adverse drug reactions, information needs, comprehension of prescribed regime and the presence of age or disease related problems.

a) *Physical problems*

Physical problems can reduce compliance by introducing difficulties in accessing the dose and in reading directions.

b) *Complexity of regime*

Polypharmacy and complicated regimes have been shown to reduce compliance.

c) *Practice of storage and self-administration*

Unsafe storage and self-administration can lead to confusion when deciding whether to take a particular medicine and can reduce the usefulness of the information provided on the original container.

d) *Attitude to medication*

A subject's satisfaction with medication can indicate the likelihood that they will take it and highlight potential problems.

e) *Efficacy*

Lack of efficacy can indicate non-compliance but can also cause non-compliance by reducing the subject's faith in their medication.

f) *Adverse drug reactions*

These can occasionally cause non-compliance. However, it is useful to know whether the subject perceives the adverse reactions to be problematic and worth changing practice for.

g) *Information needs*

Lack of information about medication can lead to unintentional non-compliance. In addition, a failure of concordance can reduce faith in their medication.

h) *Comprehension*

A good working knowledge of what medicines a subject is taking, and the reason they are prescribed, can indicate a higher possibility of compliance.

i) *Age/disease related problems*

Some conditions such as rheumatoid arthritis, depression and dementia, may increase risk of non-compliance.

Abbreviated Mental Test

The Abbreviated Mental Test (AMT) is a measure of confusional state. It is a series of questions, which are designed to be asked of elderly patients who are in hospital or nursing/residential care. These are listed in Table 3iv below. Patients score one point for each item that they correctly answer out of a total of ten possible marks. A score of seven to ten is normal.

Table 3iv: The questions asked in the Abbreviated Mental Test (and scores)

• How old are you?	(1)
• What time is it? (*To the nearest hour*)	(1)
• I am going to give you and address to remember (*e.g. 42 West Street*). Can you repeat it?	
• What year is it?	(1)
• Where are you? (*Hospital/ward*)	(1)
• Can you tell what these two people do? (*E.g. doctor and nurse*)	(1)
• What is your date of birth? (*Day and month will suffice*)	(1)
• When was World War I? (*1914-1918 or some variation*)	(1)
• Who is the current monarch? (*Queen Elizabeth required*)	(1)
• Count backward from 20 to 1	(1)
• What was the address I asked you to remember?	(1)
(Maximum score =	10/10)

The purpose of using the AMT in the current study was for:

a) The selection procedure - patients with chronic confusion as measured by an AMT of less than 5/10 were excluded
b) In determining requirements for interventions - subjects with an AMT of 5-7 were offered a Monitored Dosage System

The AMT is an abbreviation of a longer test - the Roth-Hopkins test (Roth, 1953 - see Appendix V), in which the patient is given a score out of 34. This test has been validated and has been shown to correlate well with brain changes in senile dementia (Blessed, 1968). This longer test is more discerning than the abbreviated test. However, being longer, ill elderly patients often lost concentration and therefore found the test unacceptable (Hodkinson, 1973). The shorter test achieved more consistent co-operation from patients (Hodkinson, 1972).

The shorter test was designed by looking for correlation between different questions in the longer Roth-Hopkins test and looking for questions asking for the same type of reasoning. These duplicate questions were then grouped together to shorten the test without loss of discriminatory power. The shorter test was shown to be able to quantify changes in mental state and hence predict ability to cope, however it did not show an ability to discriminate between confusional state and dementia and therefore was not appropriate for diagnosis (Hodkinson, 1972). The shorter test was compared with the Roth-Hopkins test and the slightly shorter Tooting Bec questionnaire (Denham, 1972). The AMT was shown to have high correlation with the other two tests (0.82-0.90) (Qureshi, 1974).

The Abbreviated Mental Test has therefore been shown to be a useful tool for assessing patient's ability for independent self-medicating in so far as a low AMT score (less than 5/10) would indicate potential problems with ability to comply with medication instructions. These subjects were therefore excluded from the study. Scores of greater than seven, however, would not sufficiently predict an absence of problems because the lack of sensitivity to differentiate between the relative abilities of the intellectually more capable and in such cases the test may give an overestimate of ability. All subjects with an AMT of 5/10 or greater were therefore classed as potentially at risk and enrolled for interview.

Pilot phase and final design

The pilot phase included two discrete stages: investigating the scale of compliance problems and trialing the draft questionnaires. The first stage lasted 3 months and patients were assessed for suitability for interview by using the inclusion and exclusion criteria described earlier. The baseline data for these subjects are described in Table 3v.

Table 3v: Subject characteristics for pilot phase

	Female	**Male**
Number interviewed	39	22
Age range	73-100	71-95
Mean (SD)	85 (6.10)	82 (6.97)
Number with compliance problems	26	13

64% of subjects had compliance problems which warranted an intervention to ensure safety in medicine taking. This is similar to figures found by other authors. The assumption that a non-compliance rate of at least 50% would be found during the active phase was therefore justified. Rates of non-compliance were similar in males and females. More females were interviewed which reflects the greater proportion of females in the elderly population (Guralnik, 2000).

The questionnaire used in the current study was designed after a literature search which suggested some questions which may give an insight into compliance problems (Aronson, 1992; Grymonpre, 1998; McGavock, 1998; Moriskey, 1986). This questionnaire was piloted to ensure that the questions covered all possible areas of compliance problems as described earlier (see pages 64-65). The presence of a risk factor was sufficient to imply the need for an intervention. However, the evidence to state which risk factors are more important than others is not available, with the exception of an Abbreviated Mental Test Score of less than five being accepted as a reason to avoid self-administration. It was therefore decided to equally weight all these issues when making the decision to intervene.

The questions asked in the pilot questionnaire are shown in Appendix II. This contained a list of open questions which allowed the subject freedom to volunteer as much information as they wished. This questionnaire successfully categorised the areas requiring investigation and formed the basis of all subsequent drafts. Each draft questionnaire was trialed with five to ten subjects to ensure clarity and ability of subjects to understand what was required.

The open nature of the questions in the pilot questionnaire resulted in a variation in response, with some subjects giving too much information and others insufficient. This necessitated many supplementary questions, some of which may have been leading, and resulted in no two interviews being comparable. In the first draft (see Appendix II - first draft) an attempt was made to design a questionnaire that accurately assessed a subject's risk of non-compliance. It contained both open and closed questions. This was more appropriate because closed questions are simpler to answer and easier to quantify as the possible responses are limited, whereas open questions allow the more intelligent subjects to verbalise their responses in the manner they wish.

There were a number of limitations with this questionnaire. The range of responses to the closed questions were not omnicompetant. The question order resulted in related questions being separated by unrelated questions. Some questions were still ambiguous and some used words in a different context to that understood by the average subject. For example, the word 'medicines' is understood by pharmacists and doctors to mean all forms of pharmaceuticals including tablets, injections, etc. However, to many subjects this was understood only to mean oral liquids. This word was therefore changed in subsequent drafts to 'medication'.

The questionnaire was revised on three more occasions before the final questionnaire was designed. The intermediate drafts attempted to score responses to allow a quantitative estimation of compliance risk. Each question was scored out of five in such a way that a score of four or five indicated no or low risk and one to three indicated high to moderate risk. In questions describing attitude and opinions, a Likert scale was used. In other questions, for example that measuring the subject's knowledge of medication prescribed immediately prior to admission, a simple

scoring system was implemented where a proportion of the marks were available depending on the level of accuracy which the subject attained.

In drafts two and three this scoring was not successful as there was either ambiguity or overlap, with different problems of equal clinical significance being given different weighting. Also, the ordering of questions was still slightly confusing. However, equal weighting was accorded to each possible risk factor and so scores from questions investigating different aspects of the same risk factor were combined to give a score out of five as above.

In the fourth draft the questions flowed in a logical order. The scoring system also appeared effective. However, on assessing responses from subjects it was apparent that some questions, although interpreted by a health professional as covering different issues, were interpreted by subjects as asking for the same information and so added no new information. There were also a few questions which asked for extraneous information which was not useful and simply extended the length of the interview. Such questions included 'How long have you been taking the medicines prescribed for you?' 'How are you getting on with your medication?' These questions were removed and the scoring system re-applied giving the final questionnaire, which is shown in Appendix III.

In assessing the individual subjects and their risk of non-compliance, ten figures were considered: the scores for each of the nine categories described on pages 64-65 and the sum of these scores (out of 45). The total score was used to decide which subjects could be included in the study. A score of 40-45 indicated low risk of non-compliance, as the subject would have to score four or five in the majority of categories to achieve this score. These subjects were excluded from the rest of the study as no intervention was required. A score of 30-39 was classed as moderate risk and a score of less than 30 high risk. This figure of 30 was chosen as a cut-off because patients scoring less than 30 would have exhibited moderate or high risk in the majority of categories. For many of the subjects scoring less than 30, the interventions required would have been very complicated. These subjects were generally excluded as self-administration would not have been safe and social services assistance was usually recommended.

The individual category scores were used to indicate which intervention was required. An intervention was made for any category scoring three or less, with the proviso that such interventions were limited to three per subject. Once the questionnaire was designed, the protocol was decided on as shown in Appendix VI.

Interventions

The aim of this thesis was to assess the success of a number of hospital pharmacist-lead interventions on compliance. It was therefore necessary to define a limited number of interventions that would be appropriate for the majority of compliance problems and study the effects of these interventions. The interventions used had already been shown to have an effect on compliance and these are described below.

A simple solution such as ensuring the treatment regime is as simple as possible, with once or twice daily dosing, improves compliance (Anonymous, 1991b; Eisen, 1990; Lowe, 1995). An attempt was therefore made to simplify the medication regime whenever a subject was found to have a complicated regime, that is five or more drugs or a frequency greater than twice daily for any drug. The aim was to discontinue any medication no longer thought appropriate and change preparations to once or twice daily if possible. The effects of polypharmacy and complicated regimes is described in more detail in Chapter 8.

Patients who are given sufficient (as determined by the patient), high quality information, which is easily understood and followed, have a higher chance of compliance than those given insufficient information (Lorenc, 1993). Patients receiving this information will have a better understanding of what to do and so will be less likely to forget their instructions, the aims of therapy cannot be achieved unless the patient understands and follows instructions (Lorenc, 1993; Sweeny, 1989). Talking to patients about their treatment also gives them an opportunity to ask questions and verbalise fears of treatment (Smith, 1983). If these fears are not expressed then a potentially major risk to compliance may be ignored.

A pharmacist counselling patients on discharge has been shown to improve compliance (Sweeny, 1989). Therefore, all subjects were counselled about their medication on discharge if they had the following risk factors: complicated regime; unsafe storage/self-administration practices at home; drug apparently ineffective (with measurable therapeutic effect) or outcome not explained sufficiently to the subject in the past; presence of subject identified adverse drug effects; subjects voicing the opinion that they had been given insufficient information or the information given previously had not been understood. If the information that had been previously given was not understood or quickly forgotten the subject was given a medication reminder leaflet (see Appendix II). This could be taken home and used as a daily reminder of which medicines to take and when. The information that patients require is discussed in Chapter 7.

A Monitored Dosage System (MDS) (Sweeny, 1989) was supplied for subjects who continued to be confused when they should take their medicines despite verbal and written guidance; those who frequently forgot whether they have taken a dose or not, and those who demonstrated unsafe administration methods. Effort was made to ensure that any MDS supplied could be filled safely by a carer or by the subject's community pharmacist. This necessitated communication with the subject's community pharmacist and general practitioner.

Concordance in the consultation is important to many subjects and may affect willingness to comply (Department of Health, 2000). Subjects who felt they required more information, and wanted that information from their doctor, were therefore referred to their hospital doctor for a more concordant interview. Subjects were also referred if they were dissatisfied with their medication and had not communicated this fact to their doctor. These two scenarios cover both aspects of concordance breakdown.

A simple but effective intervention was to produce large print, colour coded or Braille labels. These would be suitable for people with impaired vision, as inability to follow instructions on a medicine bottle is a well-known risk factor for non-compliance (Griffith, 1990; Lorenc, 1993). These large print and colour coded labels were relatively easy to produce using a word processing package and were

attached to containers in addition to the standard pharmacy label which contained all the legally required details. Braille labels are harder to produce but are available in limited form from the Royal National Institute for the Blind.

Physical problems have been shown to impair ability to comply (Hughes, 1998; Lorenc, 1993; Sweeny, 1989). Subjects with specific difficulties were given alternative devices, for example inhalers, or containers to allow self-administration of medicines at home.

If a drug is ineffective, or has serious side effects alternative treatment is required, regardless of compliance risk. However, these problems can impede compliance (Col, 1990; Misselbrook, 1998b) and so subjects with these risk factors were referred to doctor for alternative treatment.

Subjects who were deemed unsafe to self-administer because of physical or mental impairment which put them at high risk of non-compliance, were excluded from the study. If no carer in the form of a friend or relative could administer medicines on a regular basis referral to social services for home or residential care was recommended

It was decided that each subject would receive no more than three interventions. The reasons for this were many. Firstly, subjects with multiple problems and therefore requiring multiple interventions are often not capable of safely self-administering their own medication at home, these subjects would therefore require assistance from an outside agency and were excluded from the study. Other subjects with more than three problems may have an overlap in requirements allowing the number of interventions to be limited to three or less. For example, counselling a subject on what their treatment is for and when to take it can help solve problems with complicated regimes, lack of understanding, unsafe storage or administration practices, and lack of understanding of whether the medicine is working. In addition, implementing more than three interventions would make it more difficult to determine which intervention helped with any improvement in compliance which may be seen.

The appropriate interventions were identified and these were implemented prior to discharge. Subjects at this stage were asked for consent to continue in the study and relevant information was sent to their general practitioner and designated community pharmacist. See Appendix VII for the consent form.

Study phase

After the pilot phase recruitment was undertaken as described earlier. The pilot phase had predicted a population size of 160 subjects who would meet the inclusion criteria. A sample size of 113 subjects was therefore aimed at. However, during the course of the study only 51 subjects were found to be suitable for interview. The reason for this lack of suitable subjects was probably due to the case mix during the study period. Although there did not appear to be any difference in the age or level of sickness between the pilot and active phase groups, an increase was seen in the number of patients living in nursing or residential homes. These patients would not be suitable candidates for inclusion in the study.

Of the 51 subjects who were interviewed, only eleven were suitable for follow-up and analysis, of which nine were lost to follow-up, four before discharge, due to death or early discharge, two in Stage 1 and three in Stage 2. Table 3vi shows the reason for exclusion of the other subjects.

Table 3vi: Reason for exclusion from follow-up

Reason for exclusion	**Number of subjects (% of total)**
No interventions	10 (20)
Refused entry into study	13 (25)
Recommended intervention already implemented	5 (10)
Subject not self-administering	3 (6)
Referred to Social Services or discharged to a residential/ nursing home	8 (16)
Referred to doctor (intervention unsuccessful)	1 (2)
Total	40 (79)

Thirteen (25%) subjects interviewed refused entry into the study. Four of these refused to accept the interventions that were recommended because they did not agree that any intervention was required. The other nine subjects accepted the offered intervention but refused follow-up. These refusals were for two main reasons: the subject did not want to be contacted at home; or they felt their problems were minor and their results would not be useful in helping future patients. The reasons for refusal have been discussed in Chapter 3a. There was no significant difference between the subjects who refused entry and the other subjects interviewed (see Table 3vii).

For five subjects (10%) the recommended intervention had already been implemented and a further three subjects (6%) were not self-medicating at home. These subjects should not have been interviewed, as they did not meet the inclusion criteria. However, they had no record in their nursing notes of any assistance by a third party. Also, on questioning they did not volunteer this information until after the questionnaire was completed and an intervention was suggested.

Eight subjects (16%) were excluded because they were discharged to a nursing or residential home or had a Social Services worker visiting daily to administer medication and so would not be responsible for self-medicating after discharge. Of these, six were deemed unsuitable for self-medication as a result of the interview and so were excluded in response to a successful intervention. One subject was excluded as he was referred to the doctor for a concordant consultation, which the doctor refused to give. No intervention was therefore made and so follow-up was inappropriate.

Only 10 subjects (20%) were excluded because of unsuitability of any intervention. Four of these had no compliance problems at all and so no intervention was required. Of the remainder, most had potential problems that could not be solved, mainly problems with complexity of drugs, which could not be simplified because of multiple disease states. Another common risk for these subjects was lack of information. However, although these subjects claimed that they had not been given any information they did not want any information. In all other categories these subjects scored high marks and the significance of these risks on their compliance

ability was therefore questionable. There was a slight difference between the subjects for whom interventions were identified and those without (see Table 3viii) but this was not statistically significant. Subjects who did not require an intervention were slightly older and slightly more likely to be male. As would be expected the average AMT was higher in the group not requiring interventions, implying a lower level of confusion.

Table 3vii: Comparison of subjects refusing enrolment

	Refused entry	Not refused entry
Average age	83.0	83.6
Number male (%)	4 (33%)	13 (33%)
Average AMT	8.5	8.0
Average total score	32.9	33.1

Table 3viii: Comparison of subjects with and without interventions

	Intervention	No intervention
Average age	83.3	84.1
Number male (%)	12 (46%)	5 (62.5%)
Average AMT	7.9	8.6

Eleven subjects (22%) were successfully interviewed, interventions implemented and plans were made for follow-up. However, six of these were not contacted at 10-14 days (two died, two discharged early before signing consent form, one unable to contact after discharge, one admitted to nursing home after discharge). Three could not be contacted at 2-3 months (one admitted to a nursing home and two unable to be contacted). Two subjects were successfully followed-up after discharge. These subjects are discussed in more detail in Chapter 3a.

In view of the unsuccessful attempt to follow subjects up after discharge, it was decided to analyse the results of the interviews and try to assess whether any useful trends emerged.

Subject characteristics

The relevant characteristics data for all subjects interviewed in phase 1 of the study are shown in Table 3ix. There were twice as many females as males interviewed, this is representative of the proportions of males to females in the elderly population (Guralnik, 2000).

Table 3ix: Baseline data for phase 1

	Male (mean; SD)	Female (mean; SD)
Age	70-97 (85; 6.97)	67-98 (82.7; 6.10)
Number	17	34
Self-medicating	15	33
Reminder for medicines	4	4
Number of drugs on admission	1-9 (5; 2.49)	2-11 (5; 2.13)
Number with less than 5 drugs on admission	4	14
AMT (x/10)	3-10 (8; 2.33)	1-10 (8; 1.88)

The majority of subjects were over 75 with only four (three females and one male) being 75 or under. This reflects the situation that the lower age range was extended late in the data collection phase in order to capture more subjects suitable for interview.

The average number of medicines taken by the subjects was 5 (95% CI 4.0-6.0). Polypharmacy is problematic in the elderly and is discussed in more detail later.

There was a wide range of scores for AMT in the group, with some subjects being obviously unsafe to self-administer medication (1-5/10) and other showing no signs of confusion whatsoever (9-10/10). This shows the importance of treating elderly people as individuals and not extrapolating the needs of one individual to the needs of the whole population.

3c: Scientific and ethical basis for study design

The decision was made to not have a control group but enter all subjects into the active arm and allow them to act as self-controls, measuring before and after scores for each subject and comparing the difference. The absence of a control group is unconventional and reduces the power of the study to show significance, however, any difference in compliance after an intervention, if present, would be expected to be large and the study therefore should be sensitive enough to identify this difference. Also, the use of a control group in the presence of a large expected difference may be considered unethical in clinical practice.

Randomised controlled trials offer the best defence against many threats to internal validity (Kerlinger, 1992a). However, in order for a trial to have this description, an appropriate control scenario must be found. In the current study, a placebo arm (Turner, 1994) would have been difficult to achieve. The interventions would need to be subject-specific and not general. Each subject would receive those interventions that he required, as determined by interview. These interventions included counselling on inhaler technique, producing large print labels and supplying a Monitored Dosage System. This wide variety of interventions would be difficult to imitate in a placebo group. How does one produce placebo large print labels? Even if placebos for the various interventions could be found, such methodology would cause the study to become very complex. In effect it would become a group of individual studies, and with each intervention being compared to it's own placebo. In such a study, a sufficiently large sample for statistical significance would be difficult to achieve.

One could deliberately not carry out any interventions, but that would cause two problems, one scientific and one ethical. The scientific problem is that rather than a placebo-controlled trial this would now become a 'no-treatment' controlled trial. A difference may be seen between the groups, but there is no guarantee that it is due to the intervention; it may be due to a placebo effect (Chaput de Saintonge, 1994;Turner, 1994). However, it is possible that scientifically, a comparison with a 'no-treatment' group may be justified.

The implications of the ethical problem, however, are more far reaching. In effect, we are suggesting giving each subject an interview, identifying a need for a number of interventions, and then failing to meet this need. Although there is no direct evidence for the effectiveness of these interventions, that is the reason for the study, many pharmacists believe they are important and routinely implement them (Sweeny, 1989; Aronson, 1992). There is a distinct possibility that the interventions will affect patients' compliance behaviour and potentially affect the therapeutic outcome of their treatment. To deliberately fail to make these interventions, after a need has been identified, is therefore unethical.

In any randomised-controlled healthcare trial, the investigator must believe that there is no advantage of one treatment over the other. If this is not the case then the investigator should refuse to undertake the trial because of personal and professional ethical standards (Newell, 1992). Otherwise, they would be knowingly allocating patients to a treatment, or lack of treatment, which they know to be inferior. If pharmaceutical practitioners believe that the drug treatment that the patient is prescribed is appropriate and essential for their medical condition it follows that non-compliance with such treatment may lead to unnecessary morbidity or mortality (Working Party, 1997). Therefore withholding such an intervention cannot be ethically justified.

In some research scenarios, previous studies have shown alternative therapies to be very effective in the condition under review. In such a situation, it would be deemed unethical to deny any patient treatment by assigning them to a placebo group (World Medical Association, 1989). Comparator-controlled studies are therefore utilised in this situation, with the best, or the most predictable, therapy acting as a control. In the current study such a comparator intervention would need to be the best possible alternative (gold standard) or an intervention with a known or predictable response for all patients. There is no evidence available of the existence of such an intervention or its objective effect on patient care (Grymonpre, 1998). If such a comparator were arbitrarily assigned it would not be possible to predict the effect of this intervention on compliance behaviour. Any comparison with the study intervention would therefore be meaningless.

In order to limit the ethical dilemmas described so far, the control group could be assessed for compliance risk only once, either in hospital or at the out-patient visit. This would render irrelevant the question of whether interventions were made or not as no record of their effect could be made. This baseline measure could therefore be compared with the 'after' measure of the second group. This would be ethically appropriate. This would furnish some interesting measurements but would not answer the question posed by this study. The only information we could gather would be general data on the compliance behaviour of elderly patients who are admitted to hospital. In such a study, this group would not be a true control arm but an extension of the active arm, giving evidence only of the extent to which the active group were representative of elderly patients in general with respect to compliance risk at baseline. As only subjects with potential compliance problems would be included in the study, it would furnish information of limited value.

One final alternative would be to assess compliance risk and pass on details of the required intervention to the subject's general practitioner or hospital doctor. This appears to be a good option; ethical considerations are met without the researcher needing to make an intervention. It will be seen, however, that there are a number of major problems with this option in practice.

The first problem is that a general practitioner may ignore any advice given to him, and the patients in his care will be put at potential risk. This will result in a true control group, albeit an unintentional placebo-control group. Alternatively, the general practitioner may follow the recommendations given, which may affect the results and cause rejection of the hypothesis in error (type 2 error). Although the investigator would not make an intervention, the subject would still receive the recommended intervention. These two alternatives may result in there being three groups: the active group proper; a pseudo-placebo control group; and the pseudo-active group who receive an intervention from their general practitioner. Data from the latter group would show the difference between a doctor and a pharmacist following the same advice, and the study may show whether a doctor is likely to follow a pharmacist's advice, but these are not the questions under investigation.

A second scenario is possible. The general practitioner, on receipt of the advice might contact the hospital pharmacist for assistance with the interventions. This places the researcher in a difficult professional position. Should the pharmacist refuse, a response of doubtful ethical value; or should the pharmacist agree and withdraw the subject from the study? This problem is even more likely to occur if the information is given to a hospital doctor as they may see it as the pharmacist's responsibility to carry through their own advice. Such a study is likely to have a high exclusion rate, which may lead to selection bias.

A similar difficulty might occur from a different source. The ward nurses frequently ask pharmacists for assistance with discharge problems. It is probable that they will contact the pharmacist to make interventions on behalf of control group patients leading to the same ethical dilemma as stated above. It appears, therefore, that in the current study it would not be ethically appropriate, or scientifically feasible, to introduce a control group of any kind.

Matched controls are sometimes used when a randomised controlled design is not possible to achieve. However, the methodology of matched controls would not be appropriate for the current study. It may be used to answer the question 'Do interventions made by a pharmacist help patients who need such an intervention more than those who don't?' This is a question that hopefully would be answered in the affirmative, but not one relevant to the current study.

Single group studies are difficult to administer fairly and with internal validity (Kerlinger, 1992b). However, in many health care research situations they are the only possible option to satisfy ethical considerations. A pre-test/post-test methodology has been used in the current study into the effect of certain interventions on baseline measurements. Randomisation and control was not possible in this study. However, a number of controls have been introduced in an attempt to improve internal and external validity.

Maturation effects occur because over any period of time natural ageing or development occurs which may affect the reliability of results. The only way to correct for this is to use a control group and compare any general trends. This is not possible and so great care is required in interpreting results.

One factor called *history* describes the possibility of some unforeseen occurrence between the pre- and post-tests. This could result in changes in the post-test that are not specific effects of treatment, and thus reduce the reliability of results obtained. A subject may be re-admitted to hospital between the two interviews, new medication could be prescribed or the Community Pharmacist may fail to carry out specific recommendations. These could all cause *history* type errors and so the post-test interview will cover each of these scenarios.

The act of taking the pre-test may affect the scores of the post-test, as similar questions will be asked. This may lead to a reduction in internal validity, because it would not be known with certainty that the intervention made the observed changes. Also external validity is threatened if the pre-test changes response so that the sample is no longer representative of the population. The latter problem is not relevant, because the same interview would be used to determine required interventions if the results of the study are favourable. Any effect of *testing* would therefore be common to the whole population. It is possible that the results could not be extrapolated to patients whose compliance risk was assessed in some other manner. The former problem causes difficulties, however, because the study is looking at whether patient specific interventions are effective, and some diagnostic method for deciding on the interventions to implement is essential. However, if the act of carrying out the interview (talking to subjects) improves compliance, then this would give evidence that counselling patients on discharge would be an appropriate intervention. Unfortunately, the reliability of evidence that other interventions are appropriate may be compromised.

The *experimental setting* can affect subjects' responses and can render the results inapplicable to other settings. The interview setting would be the same for all subjects in the study, and would be the same as that which would be used for other patients once the study is complete. *Experimental setting* will not therefore threaten external validity.

Another threat to any uncontrolled trial is *regression to the mean.* This occurs with any variable that fluctuates within an individual, either genuinely or due to measurement error. A single measurement may be higher or lower than an individual's mean value. This is particularly a problem for studies where subjects are selected because of a single high, or low, value. The probability of any subsequent value being closer to the 'true' mean is high, and so apparent improvements may occur because of *regression to the mean*, rather than as a result of the experimental intervention. Randomising subjects to active or control groups will exclude *regression to the mean.*

Another method of reducing this effect is to select subjects on the basis of one measurement, but assess the effect from another. If *regression to the mean* has taken place between score one and two, the effect is eliminated. However, this is only helpful if the correlation between the first and second scores is the same as between the first and third. In the current study, it would be difficult to control for this effect and care must be taken in interpreting the results. It is worth noting, however, that compliance is more likely to worsen after discharge, rather than improve. This is because medicines often have changed and so a new routine is required, and patients may continue to take old medication or take the new medication incorrectly. The effects of *regression to the mean* may therefore be minimised.

Changes in *measurement* between different subjects can reduce internal validity. The same investigator will score all subjects, to reduce inter-observer variability, and each will be given exactly the same questionnaire. Great care will be taken to implement similar interventions in the same manner to reduce intra-observer variability.

Selection bias can threaten validity. If subjects are not chosen at random, the results may be skewed (reduced internal validity). If the selection is too strict, extrapolation to the wider population may not be possible (reduced external validity). The current study is investigating the compliance behaviour of all elderly patients admitted to two Medicine of the Elderly wards. All suitable patients will be enrolled and only rejected if they do not exhibit any compliance problems. The sample population will therefore be identical to the total population of elderly patients who were admitted to the study wards during the study period, and who were shown to have compliance problems. It is agreed that this population may be different to the population at, say, a period six months later, but this cannot be controlled for.

Experimental mortality can introduce a further problem with the validity of the results. This is when high dropout rates result in a sample that is no longer representative of the population. This is not problematic with a pre-test/post-test study. However, the effect of *multiple treatment interference* may be problematic. The effect of prior treatment may affect the response to current experimental treatment. A check on background and experiences can control this threat. Questions about such prior treatment will be asked in the pre-test interview to enable the effect of such differences to be assessed. Also in a pre-test/post-test study, all possible independent variables associated with the subject's characteristics are controlled.

The important question to ask about any research is: 'Is the question appropriate and would the results be both interesting and useful to patient care?' The current study confronts an area of practice with little evidence of best practice, which should not be condoned in these days of 'evidence based healthcare' (Sackett, 1996). The methodology used may not reach the standard of internal validity of which propounders of the randomised controlled-trial boast. However, given the current ethical and practical limitations, a pre-test/post-test methodology has sufficient sensitivity to disprove the hypothesis that a pharmacist can improve compliance behaviour, if the claim is erroneous. The study would have external validity because all suitable subjects will be included, not just a sample.

Chapter 4: Summary of findings

Introduction

Fifty-one subjects were interviewed and a summary of their general characteristics is shown in Table 4i. These include age, gender, Abbreviated Mental Test score (AMT), total non-compliance risk score, number of medicines prescribed at the time of admission and whether they were enrolled, excluded or refused entry into the study.

Only seven subjects were enrolled into the study. Thirteen refused entry into the study or refused the interventions offered. The remaining 31 subjects were excluded.

This chapter will form a general summary of the results obtained in this study. The rate of enrolment will be described. The non-compliance risk of the subjects interviewed will be presented and the extent to which each of the individual risk factors contributed to this. The interventions utilised in the study will also be presented. The key findings from the follow-up stages described. Each of these issues will be discussed in greater depth in the remainder of the thesis

Enrolment into study

As described above, only seven patients from the 51 interviewed were enrolled into the study. The key findings for the two follow-up stages will be described at the end of this chapter. In this section the reason for refusal and exclusion will be presented.

Four subjects refused some or all of the interventions offered. These included providing verbal advice on discharge by the investigator or doctor and large print labels and reviewing medication regime. These subjects all had a non-compliance risk score of less than 35 but had an Abbreviated Mental Test Score of eight or nine. Interventions were refused either because the subject did not want to lose

Table 4i: Subjects' characteristics

GENDER	PATIENT NUMBER	AGE	RISK SCORE/45	AMT/10	DRUGS ON ADMISSION	STATUS
Female	39AT150420	80	42	10	3	Excluded
	39DH190712	88	42	9	3	Excluded
	39AE240716	84	41	10	3	Excluded
	39EH230708	92	41	8	3	Excluded
	39DS020916	84	39	9	5	Excluded
	39GE110815	85	39	8	4	Excluded
	39EO111219	81	38	6	6	Excluded
	39JG070221	79	37	8	2	Refused
	39DP200120	80	37	10	7	Excluded
	39LH181217	83	36	8	6	Excluded
	39JR240413	87	36	9	3	Refused
	39MW151117	83	35	9	5	Excluded
	37MM020233	67	34	9	4	Refused
	39MC080527	72	34	9	7	Enrolled
	39DW070422	77	34	9	11	Enrolled
	37AP050312	88	33	8	4	Excluded
	37DT071022	78	32	10	4	Excluded
	39ED070821	79	32	10	7	Refused
	39DR150919	81	32	9	3	Enrolled
	39LP170702	98	32	8	2	Excluded
	39SW080425	75	31	8	10	Refused
	39AG231221	79	31	9	7	Excluded
	37LG061012	88	31	5	11	Refused
	39EW130709	91	31	10	3	Enrolled
	39ER150215	85	30	5	4	Excluded
	39ML090414	86	30	9	5	Refused
	39CW060123	77	29	9	10	Excluded
	37MM210420	80	29	10	5	Enrolled
	39GM031015	84	29	10	8	Enrolled
	39ID151114	86	29	8	6	Refused
	39AS291109	91	29	8	5	Excluded
	39DT280515	85	27	6	6	Excluded
	39MB290624	76	26	7	8	Excluded
	37PN120316	84	26	1	5	Excluded
Male	39SH101120	80	40	9	5	Excluded
	39NW190130	70	38	8	5	Excluded
	37LO090524	76	37	10	3	Enrolled
	39JT060219	81	36	8	4	Refused
	39AB270916	84	36	8	6	Excluded
	39GR290503	97	36	9	6	Excluded
	39JF070716	84	35	9	7	Refused
	37JP231209	91	34	9	6	Refused
	37KJ090117	83	33	8	5	Excluded
	39JP011015	85	33	10	5	Refused
	39WR030922	78	32	9	9	Excluded
	39GR240107	93	32	9	1	Refused
	39JH010211	89	29	3	5	Excluded
	39JR260810	90	28	6	6	Excluded
	37NT070508	92	27	4	7	Excluded
	39TH040114	86	26	10	9	Excluded
	37GW281024	76	19	3	7	Excluded

independence or because they could not understand the possible benefit to treatment outcomes.

A further nine subjects refused enrolment into the study. The reasons for this were many and included a fear of inviting strangers into their houses, wanting 'a quiet life' and because they felt follow-up would be an imposition. Some subjects also felt that there would be no benefit from enrolling in the study.

31 subjects were excluded from the study. The reasons included subjects at low risk of non-compliance or if it was not possible to implement the intervention identified (20). Interventions were not possible if the patient was discharged before the intervention was implemented, another party had already implemented the required intervention or if no solution could be found. Subjects who were not self-medicating on discharge (6) were also excluded as non-compliance risk would be difficult to assess at follow-up. In addition, subjects for whom referral to Social Services was one of the interventions recommended (5) were also excluded as they would be prompted when medication was due.

Total scores – Non-compliance risk score

The total scores for the compliance questionnaire for the 51 subjects interviewed ranged from 19-42. No subject scored a maximum mark of 45. The scores were divided into three ranges representing low, moderate and high risk of non-compliance. The distribution of scores in these three ranges is shown in Table 4ii.

Table 4ii: Non-compliance risk score

	Male (%)	**Female (%)**
Low risk (40-45)	1 (6)	4 (12)
Moderate risk (30-39)	11 (65)	22 (65)
High risk (<30)	5 (29)	8 (23)
Average score	32.41	33.35
Standard error	1.27	0.79

Only five subjects (10%) had low risk of non-compliance that did not require any intervention. A quarter of the subjects (25%) were at high risk of non-compliance, some of which were not judged safe to self-medicate on discharge. Most subjects (65%) had a moderate risk of non-compliance, most of which could be helped by simple interventions.

The rate of high or moderate risk of non-compliance in the study population was found to be 90%. This is high but has been seen by other researchers (Aronson, 1992; Parkin, 1976) although usually rates of 50% are quoted (MacDonald, 1977). The high rate may reflect two possibilities; firstly, that the study population is in some way unrepresentative of the general population and therefore has a higher rate of non-compliance. A claim for an increased rate of non-compliance in the elderly compared with younger populations seems to be defensible. The second possible reason for a difference in rate is that what is being measured is not comparable with previous studies.

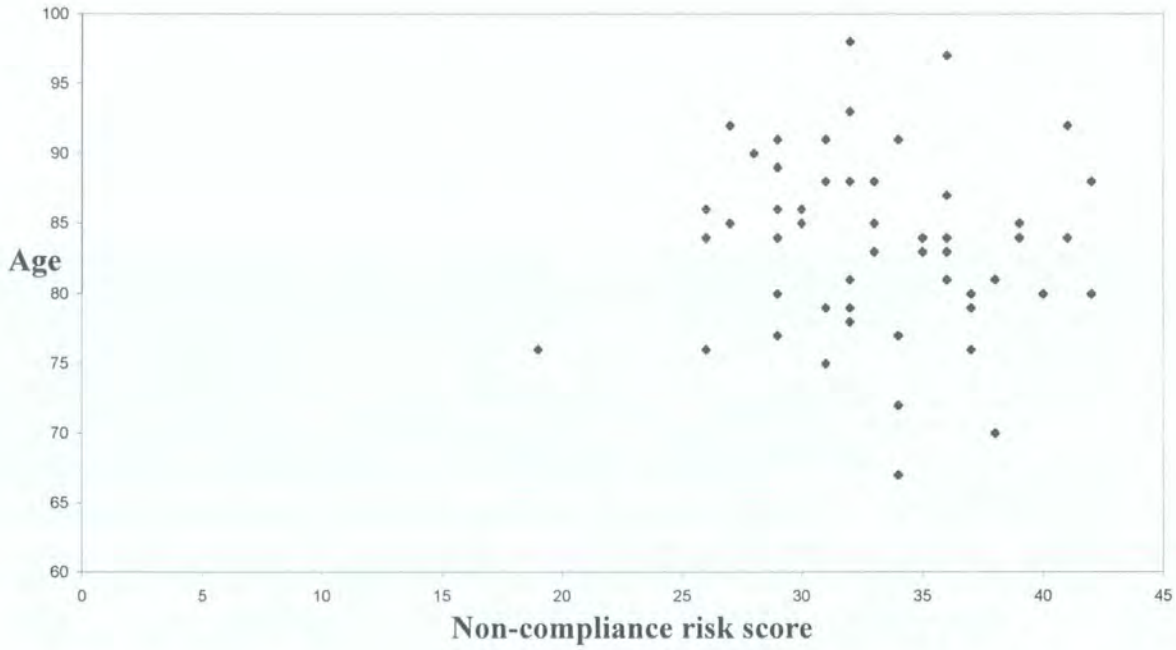
Previous authors have discussed rates of non-compliance and measured these in a number of different ways. Each of these studies measured different aspects of non-compliance and measuring one cause necessarily affects other causes. In this study, an attempt was made to assess non-compliance due to all causes. As measuring this directly was not possible, the presence of risk factors was assessed. It was not possible to state that any risk factor present was definitely responsible for non-compliance; however, subjects with many risk factors are likely to have a higher rate of non-compliance. It is to be expected that elderly patients with multiple disease states and physical deterioration will have more risk factors than would a younger person without these problems (MacDonald, 1977).

The vast majority of subjects had problems which caused them to be at risk of non-compliance. This has been predicted by other authors (Cochrane, 1992; Cantrill, 1992; Gainsborough, 1990; Ley, 1982; Parkin, 1976; Raynor, 1993; Royal College of Physicians Working Party, 1997; Smith, 1983) and was the main reason why an elderly population was chosen to be the sample group. The magnitude of this risk, however, did not correlate with sex or age, with all ages having a similar range of total scores. This is understandable, as the elderly population is not a homogenous

population and ageing and its effects progress at different rates in different individuals. One would expect that a range of scores would be obtained, as each individual would attempt to deal with each situation in a different manner. Also, individuals with differing mental and physical abilities would achieve variable success at dealing with the problems caused by attempting to take medication in the manner prescribed.

The total scores, and hence risk of non-compliance did not appear to correlate with age, which is shown in Figure 4i. All age groups appeared to be on average at moderate risk of non-compliance.

Figure 4i: Distribution of non-compliance risk scores with age



In addition, there appeared to be no correlation between total score and gender, with both males and females having a similar range of scores. There appears to be some slight correlation between total scores and AMT score. This is partially understandable as AMT is responsible for 2.5 (6%) of the total scores. The correlation does not appear to be significant at low AMT scores but may be significant at higher scores as shown in Table 4iii. An interpretation of this could be that an AMT of less than seven would indicate a high risk of non-compliance and an

AMT of greater than seven is compatible with a moderate or low risk status. The clinical significance of this is debatable; however, this is the result that the questionnaire was designed to test.

Table 4iii: Correlation of AMT with total scores

AMT	Average total	95% CI
<5	25.25	21.0-29.5
5-7	30	26.5-33.5
>7	34.24	33.0-35.5

This discovery was interesting and showed that the questionnaire was sensitive to test for level of confusion. One might be tempted to say that rather than spending such a long time asking the subjects all the questions in the questionnaire, the much shorter AMT could be used to identify patients at high risk of non-compliance. Whilst this appears to be borne out by this study, the practical use of this test is limited. A knowledge of whether a patient is at high risk of non-compliance on its own does not give any indication of the cause of the problem or what solutions may alleviate this problem. This is therefore useful tool to identify at-risk patients, but would not provide sufficient information to help identify required interventions.

Risk factors for non-compliance

The main causes of non-compliance in the study population were complexity of prescription (71%), lack of information (71%), dissatisfaction with medicines (41%), poor understanding of regime (41%) and physical and sensory problems (35%). These are reported in this section and the possible causes and solutions discussed. Each of these will be discussed in greater depth in subsequent chapters (5-8).

Complexity of prescription

The majority of subjects (71%) had complex prescriptions at the time of assessment. Thirty had five or more medicines prescribed, with one subject being prescribed 13 different medicines. Twenty-eight subjects had been prescribed medicines that were to be taken three or four times a day, also 32 had three or more different direction on

their medicines (maximum five). Having a complicated prescription did not correlate with any other risk factor.

There are many causes of complicated prescriptions. However, the main adverse cause was a failure of the doctor to review the prescription regularly. The intervention that was used to remove this factor was simplification of the prescription. However, often this was not possible because the subject suffered from multiple disease states or was optimally controlled. In these cases a compliance chart was given to the subject to help them understand when to take their medicines, and Monitored Dosage System was supplied to avoid the need for the patient to calculate which medicines were to be administered and when. If none of these solutions were appropriate, the subject was referred to social services.

Although frequently no solution was possible for these subjects, asking about complexity of treatment regime was useful in identifying patients at risk of non-compliance.

Information supply

Thirty-six (71%) of subjects were at risk of non-compliance because they reported not being given information about their medicines. However 30 (83%) of these, and 86% of the total population, reported being happy with the level of involvement they had in the treatment decision making process. There was no correlation between reports of information supplied and any other variable. However, subjects who claimed to have been given sufficient information also had high Abbreviated Mental Test Scores, which may mean that they had a better ability to recall what they had been told.

Subjects who reported having insufficient information had their medicines explained to them by the investigator on discharge or were referred to the doctor for a concordant interview. Only one subject who had this risk factor was followed-up in the study. This patient did show a slight improvement in this risk factor, but this was difficult to assess.

As most subjects reported that they did not want any further involvement in making treatment decisions this risk factor appears not to be worth investigating in this population in terms of assessing compliance risk. However, to assess a patient's desire for concordance, and whether it has been achieved, this is essential.

Satisfaction with medicines

Dissatisfaction with medication was found to be a compliance risk factor for 21 subjects (41%). This was as likely to be a risk factor for men and women, 35% men and 42% women claimed to be unhappy with their treatment. Nineteen of these subjects also complained of not having been given any information about their treatment, however, 15 of them knew why they had been prescribed. All of these subjects were found to be at moderate or high risk of non-compliance.

The reason for the dissatisfaction with medication was not always easy to identify. 52% of these subjects claimed that a lack of efficacy was the reason for this dissatisfaction; other reasons included inability to use inhaler devices. However, some subjects reported a non-specific unhappiness with the treatment prescribed. It was difficult to find a solution to such dissatisfaction, as the subject could not explain what was wrong or how to improve matters. In contrast, some subjects could explain what solution they wanted but this was inappropriate medically.

The required interventions to improve satisfaction with medication was dependent on the cause. An attempt to change the prescription was made in three cases and in three more the doctor had already changed the prescription before medication review by the investigator was possible. Three subjects were referred to a hospital doctor because a breakdown in concordance appeared to be to blame. A further three subjects were found to be at high risk of non-compliance and so were referred to a social worker for home care. The remaining nine subjects were offered more information about their treatment and why it had been prescribed. Only one subject was followed up and this patient received counselling prior to discharge. On reassessment at three months she was found to be happy with her medication, although other interventions may have contributed to this improvement.

Asking patients whether they are happy with their treatment may provide more problems than solutions, however, it is important to know why patients do not want to take their medication and so this risk factor was an important one to investigate.

Understanding of regime

Twenty-one (41%) subjects exhibited difficulty in describing what medication they were prescribed or in explaining why it had been prescribed. Most of these subjects (81%) also reported not being given any information about their treatment. The complexity of regime did not appear to correlate with an ability to describe that regime; patients with this risk factor were prescribed an average of six medicines on admission as compared to five for those subjects who could adequately explain what they were taking and the reason. This risk factor also did not correlate with any other variable. Although the ability to describe a treatment regime without prompting does not directly equate with ability to take medication correctly when the directions are available on the label, patients who do not know how many times a day they need to take medicines of any kind will be more likely to forget to read the label for a prompt. This risk factor is therefore useful to consider when assessing compliance risk.

A number of different solutions to this problem were implemented. Ten subjects were given extra information about their treatment in the form of a medication reminder chart or counselling. One subject was provided with a Monitored Dosage System in order to decrease the effect of this risk factor. A total of nine subjects were not self-administering on discharge, five of them in response to advice from the investigator. The final subject wanted to talk to a doctor and not a pharmacist and so the relevant referral was made. None of these subjects were followed up and so the efficacy of these interventions is unknown.

Physical and sensory problems

A total of 18 subjects (35%) had physical or sensory problems which inhibited their ability to safely self-medicate. Unsurprisingly this did not correlate with any other risk factor.

The majority of these subjects (67%) experienced difficulty in opening child resistant closures (CRCs). Similarly, 44% were unable to remove tablets or capsules from blister packs. Other problems included inability to read labels, inability to manipulate small bottles due to reduced manual dexterity, difficulty with measuring liquids onto a spoon and various problems with using inhaler devices.

The solutions to these difficulties had to be tailored to the problem. Subjects were offered screw caps and doses decanted from strips into bottles and alternative inhaler devices. Large print labels were offered and one subject was provided with a Monitored Dosage System. However, six subjects could not have their problems satisfactorily solved and so Social Services were involved to provide care after discharge. Only one subject with this risk factor was followed up. She was provided with a different inhaler because she was unable to use the original one. At three months she was still able to use the device recommended by the investigator.

Efficacy

Thirteen subjects (25%) complained that at least one of their medicines was ineffective. In 54% of cases the accused medication was found to be subtherapeutic on admission and was changed. The majority of subjects also claimed to be unhappy with their medication (85%) and had not been given sufficient information (92%). Also five of the subjects who disagreed with their doctor as to whether their medication was effective did not know why they had been prescribed, so it is difficult to understand how they could tell whether they were effective or not.

The reasons for subjects reporting a lack of efficacy were that the medication was not working, the subject erroneously understood them to be ineffective or because they had inappropriate expectation of outcomes. In order to reduce these problems a number of interventions were made. Medication review was instigated to ensure treatment was optimal, inhaler devices were changed if subjects found difficulty in using them. Subjects who did not understand accurately what the medication could achieve and how it worked had this explained to them by the investigator or they were referred to the doctor. Subjects whose non-compliance had caused a lack of

efficacy were provided with home care after discharge if other interventions were insufficient.

Knowing whether a subject thought their treatment was ineffective did not allow adequate assessment of compliance unless further information was available, especially as a number of subjects claimed to be unhappy with medication that they claimed was effective. Combing this factor with general satisfaction with medication would therefore make the assessment more sensitive.

Storage and administration of medicines

Only seven subjects (14%) reported problems with administration practice. Four had no method of remembering when to take their medication, one had a method that did not overcome her forgetfulness and two took most of their medicines incorrectly. The reasons for administration problems appeared to be either forgetfulness or a lack of understanding of the importance of taking medicines correctly.

Four of these subjects had many other problems and so were referred to Social Services, the other three were provided with medicine reminder charts and the investigator explained how the medicines should be taken safely. One of these subjects was followed up and his method of remembering when to take his medicines improved.

This risk factor equated with a report of how often medicines were forgotten and what was done to remember when to take them. This is very similar to self-report of compliance and so it was not surprising that few subjects reported this risk factor. It's usefulness in assessing non-compliance risk is therefore limited.

Adverse drug reactions

Eleven subjects reported adverse drug reactions but only two reported that they changed the way they took their medication. Adverse drug reactions only affect compliance if the patient reacts to them in an inappropriate way. The solutions offered to these subjects were changing treatment where appropriate and explaining

the likelihood of side effects and appropriate action. As described in earlier chapters, adverse drugs reactions do not affect compliance as much as doctors think. This is borne out by the current study and so investigation of this risk factor may not be appropriate.

Confusion level

Four subjects had an AMT of less than 5/10 (incompatible with self-care) (Hodkinson, 1972). A further five had scores of five or six (caution with self-care). The remainder of the sample population scored seven or more which is classed as normal for an elderly person and they were therefore classed as being not confused.

All four subjects with AMT scores below 5/10 were also assessed as being at high risk of non-compliance. Most of these subjects lived alone but had some level of support with their activities of daily living. In two cases, this did not include help with taking their medicines and so they were at high risk of non-compliance with little practical support.

The five subjects with AMT scores less than 7/10 all were found to be at moderate or high risk of non-compliance. Although a 'normal' AMT score was not predictive of low risk of non-compliance, a low AMT had sufficient sensitivity to predict a subject at moderate to high risk. AMT therefore would not be appropriate as a sole diagnostic tool for non-compliance as too many factors would be omitted such as physical problems and efficacy of medication. However, it would continue to play a necessary, but not sufficient, role in screening those patients who would be at greatest risk of non-compliance. This is especially the case for patients who score less than 5/10, who could not be safely left to self-care and no further questioning would be required to predict that outside assistance would be required to ensure safety.

Interventions

Eleven different types of interventions were identified for a total of 39 subjects (76%). Twelve subjects did not require any pharmacist administered interventions. Four of these were at low risk of non-compliance and two had already obtained a change in treatment prior to interview – this was their main non-compliance risk factor. Four of the remaining subjects already had appropriate interventions initiated prior to admission and two were discharged to nursing homes on the advice of a nurse. The interventions are shown in Table 4iv.

Twelve subjects did not have any interventions implemented, although suitable interventions were identified by means of the baseline questionnaire. Two subjects died before discharge and two others were discharged early and so no interventions could be made. Two subjects refused all interventions. The remaining six subjects had medication review identified as the only intervention required; however, as treatment was optimal for these subjects, this was not possible.

Table 4iv: Interventions made during the study

Intervention	Interventions identified*	Interventions actioned (%)
Change inhaler	3	3 (100)
Compliance aid	2	2 (100)
Compliance sheet	16	12 (75)
Counselling	19	14 (74)
Decant blister strips into bottles	6	6 (100)
Large bottles	1	1 (100)
Large print	4	3 (75)
Refer to doctor	2	2 (100)
Refer to Social Services	5	4 (80)
Screw caps	4	4 (100)
Simplify medication	10	1 (10)

* Subjects could have up to three interventions.

The majority of subjects had problems which could simply be solved by using a compliance reminder sheet (see Appendix II) or by counselling. Fourteen subjects required interventions because of physical or sensory difficulties, three subjects required two or three different interventions, with four (8%) requiring larger print labels and six (10%) unable to remove tablets from blister packs. Only two subjects

(4%) required Monitored Dosage Systems such as a Medidos®. Five subjects (12%) had such complex needs that referral to Social Services was required to remove the need for self-medication. For some of these subjects this included supplying a Medidos®. For only one subject did medication review by the pharmacist result in simplification of medication and hence reduction of compliance risk. As the majority of problems had not been identified prior to interview by the investigator (79%) this study supports the hypothesis that pharmacists have a role in identifying non-compliance risk factors.

If interventions are to be effective they must be continued. Many of these interventions required continued input from a Community Pharmacy. Forty-three subjects (84%) routinely had prescriptions dispensed by the same Community Pharmacy and could identify that Pharmacy. Of the remaining eight subjects, five did not require any interventions and one was admitted to a nursing home on discharge. Two more subjects were referred to social services for administration of medicines and so appropriate Pharmacies were identified before discharge. The implications of these interventions are discussed in more depth in Chapter 6.

Key findings from follow-up

First follow-up

Seven subjects were enrolled into the follow-up phase of the study. The first follow-up occurred two weeks after discharge. The aim of this was to ensure that interventions identified during the in-patient stay had been continued. Only five subjects were available for the first follow-up interview. The other two subjects could not be contacted despite many telephone calls and two letters.

All five subjects successfully followed up had received a prescription from their general practitioner after discharge once the hospital supply had run out. All of them had had changes to their prescription which increases the risk of non-compliance. All of the interventions implemented in hospital had been continued except for one subject. His community pharmacist was contacted once more to ensure that the

interventions were continued. He was unsure whether the interventions had been helpful, but the other subjects all agreed that they had been helpful. The interventions implemented for these subjects are shown in Table 4v.

Table 4v: Interventions implemented for subjects followed up

Subject	Problems	Interventions identified*
39MC080527	Unsure if medication appropriate, thinks one medicine is inappropriate, complex prescription	Compliance sheet, counselling
37LO090524	Occasionally forgets medication, stops taking them when feels better, complicated regime	Compliance sheet, counselling
39DW070422	Unable to read labels, complicated regime	Compliance sheet, counselling, large print labels
37MM210420	Not sure if happy with medication, unsure if working, inhaler unsuitable, complicated regime	Compliance sheet,
39GM031015	Unsure if still needs medication, or if working, poor manual dexterity, complicated regime	Counselling, change inhaler device, screw caps, decant blister strips into bottles

The fact that Mr. LO (37LO090524) had not had his interventions continued illustrates the importance of communication between primary and secondary care if interventions to improve non-compliance risk are to be effective.

Second follow-up

Unfortunately three more subjects were lost to follow-up at three months. Mrs. DW (39DW00422) could not be contacted, Mrs. MM (37MM210429) was admitted to a nursing home and Mrs. MC (39MC080527) was readmitted to hospital. However, two subjects were successfully followed up at three months. The data for these two subjects are shown in Table 3iii.

Mr. LO (37LO090524) was originally at moderate risk of non-compliance, but had deteriorated over the three months. However, his main problems were due to a deterioration in health which caused him to be unhappy about his treatment which he felt was no longer effective. In addition his eyesight had deteriorated. Although his risk of non-compliance had not improved, the deterioration appeared to be unrelated

to the interventions which had been initiated in hospital. In fact, his administration of medicines had improved to the point where it was no longer a risk factor for non-compliance.

Mrs. GM (39GM031015) had been assessed as being at high risk of non-compliance and improved in all risk factors over the three months except she still had polypharmacy and still reported receiving little information from her general practitioner. At the second follow up she was assessed as being at moderate risk of non-compliance. Her community pharmacist had continued all interventions and she was happy about them all.

No conclusion can be made about the potency of the interventions implemented to improve compliance risk status. However, both of the patients followed up found it easier to take their medicines correctly and were happier to report problems to their general practitioner and pharmacist. Compliance may not have dramatically improved but concordance had been, in part, achieved.

Chapter 5: Compliance risk in study population

Although a broad range of non-compliance risk scores was seen (19-41), individual subjects had different reasons for reaching these totals. These are described in detail below. Table 5i shows the cumulative data for each of the categories investigated. The solutions to these problems (interventions) will be mentioned briefly but discussed in greater depth in Chapter 6. At this point the discussion will concentrate on the frequency with which these problems occurred in the study group and the possible reasons for these problems.

Administration

Only seven subjects (14%) exhibited potential problems with administration. The data for these are shown in Table 5ii. These subjects did not have any assistance in remembering when to take medicines prior to admission.

Table 5ii: Subjects exhibiting problems with administration practice

Number	Gender	Age	Total score	AMT	Administration problem
37GW281024	Male	76	19	3	No method of remembering when doses due
37LO090524	Male	76	37	10	Occasionally forgets medicines No method of remembering doses due. Sometimes stops taking when feeling better
29CW060123	Female	77	29	9	Sometimes forgets afternoon medicines
39ED070821	Female	79	32	10	All medicines taken morning and evening regardless of prescribed dose. Not always careful to follow doctor's advice
39DT280515	Female	85	27	6	No method of remembering doses due
39JH010211	Male	89	29	3 ½	Patient took all medicines at breakfast and bedtime regardless of prescribed dose
39JR260810	Male	90	28	6	Occasionally forgets - too lazy No method of remembering doses due

Table 5i: Summary of baseline data

PATIENT NUMBER	AGE	SEX	AMT	TOTAL	S&A	U	A	E	SE	I	P	D	C	STATUS
37MM020233	67	F	9	34	4	5	3	5	5	2	5	5	0	Refused
39NW190130	70	M	8	38	5	4	5	5	5	4	5	5	0	Excluded
39MC080527	72	F	9	34	4	4	3	3	5	3	5	5	2	Enrolled
39SW080425	75	F	8	31	4	3	4	5	5	4	1	5	0	Refused
37GW281024	76	M	3	19	3	0	3	3	5	2	1	2	0	Excluded
39MB290624	76	F	7	26	4	3	2	5	4	2	1	3	2	Excluded
37LO090524	76	M	10	37	3	5	4	5	5	5	5	5	0	Enrolled
39CW060123	77	F	9	29	3	3	2	4	5	3	4	5	0	Excluded
39DW070422	77	F	9	34	4	5	5	4	5	4	1	4	2	Enrolled
37DT071022	78	F	10	32	4	1	3	3	5	2	5	5	4	Excluded
39WR030922	78	M	9	32	4	5	3	5	5	2	4	4	0	Excluded
39ED070821	79	F	10	32	3	2	4	4	5	3	1	5	5	Refused
39AG231221	79	F	9	31	4	3	5	5	5	3	1	5	0	Excluded
39JG070221	79	F	8	37	4	4	5	5	5	2	5	5	2	Refused
37MM210420	80	F	10	29	4	4	3	3	5	2	4	4	0	Enrolled
39AT150420	80	F	10	42	4	5	4	4	5	5	5	5	5	Excluded
39DP200120	80	F	10	37	4	5	5	5	5	3	5	5	0	Excluded
39SH101120	80	M	9	40	5	2	5	4	5	5	4	5	5	Excluded
39DR150919	81	F	9	32	4	3	4	3	5	3	1	4	5	Enrolled
39JT060219	81	M	8	36	4	4	5	4	5	4	1	5	4	Refused
39EO111219	81	F	6	38	4	2	5	5	5	5	5	4	3	Excluded
39LH181217	83	F	8	36	4	5	4	5	5	4	4	5	0	Excluded
37KJ090117	83	M	8	33	4	4	4	4	5	2	5	5	0	Excluded
39MW151117	83	F	9	35	4	4	2	2	5	3	5	5	5	Excluded
39AE240716	84	F	10	41	4	4	5	4	5	4	5	5	5	Excluded
39DS020916	84	F	9	39	4	5	5	5	5	3	4	3	5	Excluded
39AB270916	84	M	8	36	4	5	4	4	5	4	5	5	0	Excluded
39JF070716	84	M	9	35	4	5	3	3	5	2	5	5	3	Refused
37PN120316	84	F	1	26	4	0	3	4	5	3	1	1	5	Excluded
39GM031015	84	F	10	29	5	5	3	3	5	2	1	5	0	Enrolled
39GE110815	85	F	8	39	4	5	2	4	5	4	5	5	5	Excluded
39JP011015	85	M	10	33	4	5	2	1	5	4	5	5	2	Refused
39ER150215	85	F	5	30	4	5	4	4	5	2	1	4	1	Excluded
39DT280515	85	F	6	27	3	4	1	1	5	3	5	3	2	Excluded
39ID151114	86	F	8	29	4	3	4	4	5	2	1	5	1	Refused
39ML090414	86	F	9	30	4	3	4	4	5	2	1	5	2	Refused
39TH040114	86	M	10	26	4	3	3	3	2	3	4	4	0	Excluded
39JR240413	87	F	9	36	4	5	3	2	5	3	5	4	5	Refused
37LG061012	88	F	5	31	4	0	5	5	5	3	5	4	0	Refused
39DH190712	88	F	9	42	4	5	5	5	5	3	5	5	5	Excluded
37AP050312	88	F	8	33	4	4	2	4	5	2	5	5	2	Excluded
39JH010211	89	M	3	29	3	0	5	5	5	3	1	2	5	Excluded
39JR260810	90	M	6	28	3	1	4	5	5	4	1	3	2	Excluded
39EW130709	91	F	10	31	4	5	3	4	5	2	4	4	0	Enrolled
37JP231209	91	M	9	34	4	5	3	5	5	2	5	5	0	Refused
39AS291109	91	F	8	29	5	0	4	4	5	2	4	5	0	Excluded
39EH230708	92	F	8	41	4	5	4	5	5	5	5	5	3	Excluded
37NT070508	92	M	4	27	4	3	5	5	5	2	1	2	0	Excluded
39GR240107	93	M	9	32	4	2	4	5	5	3	1	5	3	Refused
39GR290503	97	M	9	36	5	1	5	3	5	2	5	5	5	Excluded
39LP170702	98	F	8	32	4	5	3	5	5	2	1	5	2	Excluded

Key:

S&A - Storage and administration; U - Understanding; A - Attitude to meds; E - Efficacy; SE - Side effects; I - Information; P - Physical problems; D - Disease based problems; C - Complexity; Max for each = 5. TOTAL - non-compliance risk score, Max = 45

Four subjects did not have a routine for taking their medicines which might remind them to take them or ensure that they knew whether a dose had been taken. Two subjects took all medication twice a day, regardless of the prescribed frequency. Another subject attempted to take her medication according to the directions she understood to be correct, but as this meant that one dose was due immediately after a mid-afternoon nap, it was frequently forgotten. One subject described being too lazy to remember when to take medicines and one admitted to not always paying much attention to what the doctor had said.

Two of these subjects also had little faith in their medication and this was mainly due to a perceived lack of efficacy. The other subjects did not have any obvious reason for being careless with their medication. Four of these subjects were found generally to be at high risk of non-compliance and were subsequently discharged to a nursing or residential home. Of the other three subjects, two were followed up and one refused entry into the study.

Although Mr. LO (37LO090524) knew why he was prescribed his medicines in general terms, he was unsure of the need to continue to take them even when he felt well. This meant that he occasionally stopped medicines that the doctor had intended him to continue; this would place him at risk of further exacerbations and potential treatment failure. In addition, he sometimes forgot to take his medicines when he had intended to take them. This could result in a lengthy treatment free period of which his GP was unaware, risking dose or treatment changes when the cause was non-compliance and not necessarily lack of efficacy. Mr. LO did not use any particular method to remember when to take his medicines, such as linking them to mealtimes or other fixed times throughout the day. If this had been the case, his rate of forgetfulness may have reduced.

In one study, 39.6% of patients who had reported non-compliance blamed it on forgetfulness (Col, 1990). Forgetfulness includes forgetting to take one or more doses; forgetting whether a dose has been taken, which may lead to overdosing; forgetting to get a prescription filled, which may lead to delays in continuing treatment; and forgetting what information the doctor or pharmacist gave them, potentially leading to administration errors. Patients generally do not report isolated

incidents of forgetting to take their medicines (Paes, 1998), possibly because they have forgotten such occurrences or because they feel they are not significant. Mr. LO reported missing doses and so this could be interpreted as happening relatively frequently.

Mr. GW (37GW281024) claimed that he never forgot to take his medicines and always followed his doctor's instruction as to when and how he should take his medicines. However, he could not remember anything about his medicines (name, dose or frequency) and claimed never to have been given any information about them. It is therefore difficult to imagine how perfect compliance could be achieved. However, his inability to explain his medicine regime may have been related to his acute confusion, which was responsible for his current admission. It is also possible that he might have overestimated his ability to comply as he was found to be at high risk of non-compliance due to many risk factors.

The main problem that affected Mrs. CW (39CW060123) was remembering when to take her afternoon medicines. This is because she thought that were due at 3pm. However, she usually had a short sleep after lunch and often omitted them because she either slept too long or forgot to take them when she woke up. This problem was encountered because a lack of understanding of when was an appropriate time to take her medicines was coupled with an attempt to take them at a time devoid of any other natural reminders, for example, meal times (Sweeny, 1989).

Sometimes patients do not fully understand why the doctor issues certain guidance and therefore they do not feel it is necessary to follow that information. In addition, some medicines may seem to be of greater importance to a particular patient than others, less care may therefore be taken about the apparently less important medication; Becker (1975) supports this. Concordance can improve this type of non-compliance. However, Mr. JR (39JR260810) tried to follow what the doctor had told him but occasionally found it just too much of an effort to take his medicines, he therefore didn't see the point in trying to remember when to take them.

There was no correlation between the subjects' ability to store and administer their medication safely and any other variable. For all ages and both genders, the risk due to such difficulties was similar. Although the data implies that subjects with an Abbreviated Mental Test score (AMT) of greater than seven would be at low risk compared with other subjects, this was not statistically significant (see Table 5iii). Only two of the subjects with problems with storage and administration had an AMT consistent with inability to self-medicate. This may be evidence that only some problems with storage and administration are caused by poor memory and comprehension. Others are caused by a conscious decision to take medication in a certain way, which happens to be unsafe. This decision may be based on a misunderstanding of the directions given or an attempt to fit medicine taking into the activities of daily living. Either situation would be exacerbated by a breakdown in concordance.

Table 5iii: Safety with storage and administration compared with AMT

Storage and administration score*	Average AMT (SE)	95% CI	Range
3	6.7 (1.3)	4.1-9.3	3-10
4	8.3 (0.3)	7.7-8.8	1-10
5	8.8 (0.4)	8.1-9.5	8-10

* No subject scored less than 3

Most subjects reported having adequate methods for remembering when to take their medicines. This may have been because these subjects did not wish to admit to having problems, giving instead the response that they felt the investigator wanted to hear. The questions in this section amounted to self report of compliance, which has been shown to underestimate the problem (Haynes, 1996). Therefore, it could be argued that these questions could be removed from the questionnaire with no reduction in overall sensitivity. This case may be strengthened by noting that six subjects with low scores for storage and administration also scored low in a number of other areas and so they would still be classed as at-risk of non-compliance. However, one subject would have been classed as being at low risk of non-compliance if these questions had not been asked.

Understanding

Twenty-one subjects (41%) had a poor understanding of their regime, either not being able to recall what they were taking or what condition they were prescribed for. Ten of these subjects (48%) were assessed as being at high risk of non-compliance and five were referred to a nursing or residential home after discharge. Two more subjects were not self-administering before admission and a further two already received their medication in a Monitored Dosage System. This may explain why they had little or no knowledge of their regime as all necessity to remember was removed. Six of these subjects refused follow-up. Seventeen subjects (81%) who had low scores in understanding also complained that they had not been given sufficient information about their medication. Understanding did not correlate with number of drugs on admission, with patients having this risk factor having on average six medicines compared with five for those who could explain their medication regime.

Forty-one percent of subjects were at risk of non-compliance because of a lack of understanding of their required medication regime. If a patient is unable to remember what they are taking or when to take it, they will find difficulty in remembering whether they need to take a certain medicine at a particular time and so they may not even pick up the container to check the label (Hughes, 1998; Moriskey, 1986). Patients who cannot understand why they are taking their medicines also may not take them because they do not realise the importance of complying. This may be illustrated by the case of Mr. JR (39JR260810), who could only explain why half of his medicines were prescribed. He was admitted taking six different medicines but could not name any of them. He was unable to say when he took any of his medicines but knew what three of them were prescribed for. He reported that occasionally he forgot his medicines because he was 'too lazy to remember'. He had no special method of remembering to take them but claimed that he always tried to follow the doctor's instructions on how to take his medicines.

Some subjects were prompted on a regular basis when to take their medicines. They therefore had less need to remember what medicines they had been prescribed or when they should take them. This may have been the reason why they were unable to provide this information. Of course a subject who was having difficulty remembering when to take a medicine may therefore be provided with a reminder that they otherwise may not have been given. It is difficult to tell without much more in-depth investigation which event preceded the other. This is discussed in greater depth later in this chapter (see Rate of self administration).

Mr. GR (39GR290503) was admitted taking six different medicines but was only able to name two of them. Although he knew both the doses and frequencies for these drugs, he was unable to say when he took any of his other medicines and did not know why he had been prescribed any of them. He was not self-administering his medicines. It was not possible to determine why he remembered these two medicines and not the others. As he did not know the reason why he was taking any this could not have affected his attitude to them.

Some subjects received their medicines in a Monitored Dosage System, usually filled by carers or community pharmacists. Unless the subject was responsible for filling the system, there would be no necessity to remember what they medicines they were taking. They would only need to remember when to look in the container and remove doses in the relevant section. These subjects therefore might find it difficult to remember what they were taking unless they read the information supplied with the aid regularly, a practice that is unnecessary for safe use of these devices.

Mrs. AS (39AS291109) lived alone and was generally independent, however, she had a home carer who visited three times a day and her community pharmacist filled a Dosett® for her each week. She was admitted taking five different medicines but could not name any of them. She was unable to say when she took any of her medicines and could only say why she was prescribed one of them; this was probably because she did not see them individually and therefore could not identify them. Mr. GW (37GW281024) was another subject who took his medication from a Monitored Dosage System (in his case a Medidos®). However, he had his medicines dispensed in bottles and boxes, as normal, and his sister subsequently put them in the

Medidos® for him. This may explain why he knew slightly more details about his medicines than Mrs. AS.

The subjects described above all had external assistance with taking their medicines and so many of them should have been excluded from the study because of this assistance, as personal non-compliance would not have been a significant issue for therapeutic success. The reliability and accuracy of the outside assistance would be much more important. However, some subjects did not receive any assistance with their daily self-administration of medicines, and so understanding of their regime would therefore be crucial in affecting their ability to comply with the doctor's instructions.

Mr. GR (39GR230107) had only been prescribed one drug and so his regime could not have been any simpler. He was unable to remember the name of the drug but was committed to taking it. He had forgotten what the medicine was for and was unable to remember whether he had ever been told why he was taking it; he was unsure how much information his GP had given him or what he had been told whilst he was in hospital. This is common, as patients routinely forget 31-71% of what the doctor tells them on the first telling (Griffith, 1990; Hughes, 1998; Ley, 1982) and 50% of patients cannot remember anything they have been told about how to take their medicines (McGavock, 1998).

Forgetting what the doctor told you does not necessarily lead to non-compliance if the directions are clear on the label and the patient has sufficient understanding to be able to follow them. Mr. GR was disadvantaged as he could not read the instructions on the label. Although not knowing what his medication was for may not have caused non-compliance as he was committed to taking it, it could have caused difficulties if new medication had been initiated whilst he was in hospital.

Many subjects had difficulty explaining why all of their medicines were prescribed. This was not reflected in the level of information they claimed to have been given, with the majority stating that they received good information from their family doctor and only one subject, Mrs. DT (37DT071022), voiced a desire to be more

involved in making decisions about her treatment. Her desire for information about new medication could stem from a need to be in control. She was not unhappy that she did not know what she had been prescribed in the past, but possibly wanted to ensure that new medicines were chosen carefully. Understanding why you are taking a medicine is not necessarily essential if compliance can be achieved without it. However, the likelihood of compliance may be decreased if the patient does not understand why compliance is important. This will be discussed in greater detail in Chapter 7.

There did not seem to be any correlation between total scores, age or AMT and understanding of regime. Females tended to have a slightly higher understanding of their medication, but this was not statistically significant. Half of the subjects identified with this risk factor were otherwise found to be at high risk of non-compliance and so would have been identified without this question. However, as 53% of those who had a moderate to high risk of non-compliance because of problems with understanding were self-administering, accounting for 20% of the total sample size, questioning subjects' understanding of their medication regime is therefore a useful tool in assessing compliance risk.

Satisfaction with medication

Twenty-one subjects (41%) were at risk of non-compliance due to dissatisfaction with their medicines. This dissatisfaction was generally non-specific with the subject being unable to explain why they were unhappy and what solutions they thought were necessary. Nineteen (90%) of these subjects also reported lack of satisfaction with the information they had been given by their doctor. Only half of them (11) reported a lack of efficacy as the reason for their dissatisfaction with their medication. Fifteen (70%) could satisfactorily explain why they had been prescribed. This implies that understanding why something has been prescribed does not necessarily lead to an agreement of its necessity. Only eight subjects with this risk factor were deemed to be at high risk of non-compliance, although none were calculated to be at low risk.

Men and women appeared to have similar attitudes to their treatment and age did not appear to affect this score. Subjects with higher non-compliance risk scores were more likely to score highly with regard to satisfaction with medication, however a number of subjects at very high risk of non-compliance reported being completely happy with their medication and scores in this area were not a good predictor of compliance risk. There was no correlation between satisfaction with medicines and the Abbreviated Mental Test scores.

For half of these subjects, a belief that their medication was not working seemed to be the main reason for their dissatisfaction with their medication. In most cases the hospital doctor confirmed the lack of efficacy and changed their treatment. It is not known why these subjects had not reported that their medicines were not working to their general practitioner. However, it is possible that they had voiced these concerns but specialised advice appeared to be necessary. It would be hoped that the perceived lack of efficacy had not been ignored in primary care.

Some subjects understood what was wrong and why they required a change in therapy, for example, Mrs. AP (37AP050312) complained of breakthrough pain before her next dose of analgesics were due; the main reason for admission was a review of her analgesia. This type of problem is likely to encourage over-use of medication as the subject may decide to take extra doses to ensure that they last long enough. She had discussed this with her general practitioner and so concordance was achieved; the risk to compliance was therefore greatly reduced.

Often, however, the patient's interpretation of what is wrong and the possible options for remedying it is often not the same as the doctor's interpretation (Col, 1990; Sanghani, 1998). A claim that medication is not working may mask a number of alternative problems. Incorrect use of medication or devices, drug interactions and insufficient knowledge of what the medication is prescribed for could all present in this way, as well as the dose being insufficient or the medication inappropriate.

Mr. JP (39JP011015) illustrates the difficulty between reconciling a patient's clinical need and his or her attitudes to medication. He had a clear need for a complete review of his analgesia as his leg pain was uncontrolled. However, he did not want to be addicted to analgesics and frequently missed doses. It is often claimed that if a patient understands why he is taking his medication, and he identifies with the need, then he will be compliant (Mazzuca, 1982). However, Mr. JP shows that patient's have more than one method of evaluating the need for a medicine. If the fear of side effects or dependence is greater than the perceived need for treatment, then a patient may still be reluctant to comply with the regime, even if this results in hospitalisation (Anonymous, 1997b; Lorenc, 1993; Misselbrook, 1998b). Concordance may help to improve the success of this subject's treatment, as he believed that his muscle relaxant was more appropriate and possibly safer than his analgesic. Increasing the dose of his muscle relaxant, whilst at the same time providing him with a stronger pain killer, to be used only when he felt he needed it, may have improved his satisfaction with his treatment. This is an example of where the doctor can unwittingly cause non-compliance by not listening to the patient's opinions and desired outcomes of treatment.

Occasionally subjects had a clear understanding of what was needed which was completely irreconcilable with the opinion of the doctors. Mrs. MC (39MC080425) had Parkinson's Disease, but this was well controlled and she had no obvious symptoms of deterioration that could be treated by adjusting her dose. However, she was very clear that she wanted a dosage change, although the reason was not possible to elucidate. Interestingly, she felt her antidepressant was ineffective and the doctors tried to adjust the dose to improve its efficacy, however, she resisted this change. Concordance in this case may have resulted in a more satisfied patient but may also have resulted in inappropriate treatment. This illustrates a difficulty in reconciling concordance with evidence based medicine.

Mrs. DT (39DT280515) was generally unhappy with her medication and blamed this on lack of efficacy; but although she knew why she was taking them, she was unable to explain what she meant by saying they were not working. She felt she needed a change in medication because her antihypertensives caused dizziness. It is difficult in the elderly to differentiate between a lack of efficacy, deterioration in clinical

status and an adverse effect of medication. As we discuss below, few subjects complained of side effects of drugs although this is often quoted as a cause of non-compliance (Anonymous, 1997b; Col, 1990; McGavock, 1998). It is apparent that although the terms adverse effect and lack of efficacy have specific technical definitions which reflect both the problem and the means of solving them, to a patient these may be alternative ways of saying that their condition is uncontrolled. It is not known why Mrs. DT's general practitioner did not identify the problem with her medication. It may have been that she did not tell him, but this could also identify a problem with monitoring and medication review for this subject.

The responses of Mrs. JR (39JR240413) to questions regarding her treatment were interesting. Although she claimed that she was very happy with her treatment she wanted a change and thought they were not working. Obviously, she did not perceive that these questions were related and so gave conflicting information. This could be a problem with the question being ambiguous, or it could reflect the complex nature of patient's attitudes to medicines and compliance. The question regarding happiness with medicines was intended to detect any non-specific dissatisfaction with medication, which may or may not have had an effect on a subject's willingness to take it. It was hoped that subjects would admit to dissatisfaction when perhaps they had no concrete reason for their desire to change their medication and a lack of efficacy was not the problem. For some subjects, like Mrs. JR, this question appeared to be interpreted as a criticism of their general practitioner and so they answered in the affirmative only to contradict themselves in subsequent questions.

An alternative reason why subjects may give apparently contradictory answers to similar questions may be because they are too similar. The subject may view them as developments of one theme and so if they claim to be completely happy with their medication they may feel free to show a small degree of dissatisfaction later. Conversely, a subject who voices unhappiness may contradict himself in subsequent questions in an attempt to reduce the severity of his initial response. This illustrates the importance both of asking relevant questions in a variety of ways and the necessity of taking such answers as a whole.

Most subjects who were unhappy with their medicines or wanted a change in treatment also claimed to have been given little or no information about their medicines, although this was not statistically significant. However, only three wanted to be more involved in making decisions about their medicines. This may therefore reflect a number of possible scenarios. Firstly, subjects given little information about their medicines may therefore have less trust in their medicines because they have not been involved in the decision making process. Alternatively, one may infer that subjects who are dissatisfied with their medicines also have less faith in what their doctor has said and so do not remember whether any information was supplied. It is not possible, within the confines of the present study, to decide whether either of these is active here or whether the coincidence between these two risk factors is accidental.

Mrs. PN (37PN120316) reported being happy with her medication but thought she needed a change, in this case because the nurses had not given her any medication. Why she was under the impression that her medication had been stopped is not known as the nurses had been administering them. It is possible that different brands were being supplied and so she was endorsing a change she thought she had already received. It is not possible to understand exactly what she meant, but this may illustrate the difficulties caused by brand changes and therapeutic substitution on admission to and discharge from hospital (Lowe, 1995; Parkin, 1976).

Becker's health belief model states that the likelihood of patients following a regime is related to their motivation and incentive to do so (Becker, 1975). For example, treatment for minor acute conditions may not be complied with once improvement occurs because of the low-risk nature of the condition (Moriskey, 1986). The decision to comply with medication for chronic conditions, however, is made on the basis of the understanding of his vulnerability to sequalae. In contrast, a patient may forget to take medication for chronic conditions if they do not feel any day to day benefit, whereas medication for acute conditions with clear symptomatic control may be forgotten less frequently.

Efficacy

Thirteen subjects (25%) believed they required a new medicine or a dose change because of lack of efficacy. In seven cases (54%) the doctor agreed and therapy was changed during the admission. Of the remaining six subjects, five did not completely understand what they were taking and what it was for. As described above eleven (85%) of these subjects were also dissatisfied with their medication. All except one of these subjects also reported a lack of information from their doctor.

There was no difference in belief that their medicines were effective between males and females and there was no correlation with age or Abbreviated Mental Test scores. There was no significant trend in the relationship between efficacy and non-compliance risk score.

Efficacy describes whether a medication achieves the desired outcome. In some instances, the subject's view of efficacy was the same as that of the doctor but often this was not the case. Many subjects claimed they simply did not know whether their medicines were effective because they did not know what to look for. It has been shown that if patients see a clear endpoint, or symptoms are controlled, then compliance improves (Britten, 12998; McGavock, 1998). There is therefore an argument for educating patients in understanding how to tell whether a certain treatment is effective.

For many drugs efficacy is measured by blood tests or a lack of certain physiological markers, which may not be observable by the patient unless the doctor clearly explains what these test results mean. However, for many medicines such tests are infrequently carried out, so this positive feedback is not available for the patient. This may cause them to incorrectly judge that a particular drug is ineffective and either discontinue an apparently useless medicine or increase the dose until some effect is felt - risking toxicity. This error is made because of limited understanding of pharmacology, but may also be complicated by exaggerated beliefs in other medication which are based on prior experience, not necessarily their own, or misguided attribution of efficacy. It is interesting to note that the majority of subjects who reported being unsure of efficacy also reported not being given any

information by their GP. This may reflect the fact that all information had been forgotten although it had been given initially. In other words if a patient cannot remember what he has been told, it is just as likely that he will forget that he was ever told it. However, it is also possible that no information was given to him. If this is the case, it is to be expected that the patient will have a poor understanding of what is expected of the medication.

Interestingly, asking whether a patient is happy with his medication and whether they are effective may be insufficient to identify problems. Mr. WR (39WR030922) reported being 'very happy' with his medicines and was well controlled on his current medication; he was admitted for a completely separate reason (fractured right hand). However, he said he wanted a nebuliser in place of his inhalers, not because they were not working, or because he found difficulty in using them, but to ensure they continued to work. It was not possible to elucidate why he felt he might need such a change but may have been related to prior knowledge he had of a friend or relative who had been given a nebuliser. This may therefore reflect the effect of social context on compliance (Ley, 1982).

It is possible that Mr. WR might have been given a nebuliser in the past and found it effective or he may have known someone who had been prescribed one. He would have also seen the patients in the beds near him, some of which were using nebulisers, and he may have been worried that his breathing might deteriorate and become as bad as theirs. Unfortunately, on further questioning all he would say was that he thought it might prevent him from being ill. He did not divulge whether he had ever used one in the past or where he had got the idea. Elucidating the reasons behind a patient's satisfaction, or otherwise, with medication is complicated by the number of factors involved: past experience, social pressure, efficacy of medication, perceived susceptibility to illness and a number of others. Overcoming these difficulties depends on the patient being able to explain why they are dissatisfied, something which patients often find difficult.

Adverse drug reactions

An adverse drug reaction is an unwanted event, which can be directly attributed to medication use. Eleven subjects (22%) claimed to have adverse effects from their medication. However, only two blamed adverse effects for a change in the way they took their medication. Mrs. MB (39MB290624) claimed that one of her medicines made her dizzy and so she now took it at night so it affected her less; the change was appropriate and had been recommended by her doctor.

Mr. TH (39TH040114) claimed that one of his medicines caused breathlessness and another caused diarrhoea and so he stopped both of these. He was the only subject for which adverse drug reaction was a risk factor for non-compliance. The decision that Mr. TH made may have been appropriate; however, as he had not contacted his general practitioner, he was at risk of stopping a drug to which he may have erroneously attributed the adverse effect he described. It was also possible that all of these symptoms, which had been attributed to certain medicines as adverse effect, may have been a presentation of a new illness and therefore should have been investigated. This shows the importance of regular medication review and monitoring in the elderly.

As described above, many patients have difficulty in differentiating between illness, lack of efficacy and adverse drug reactions. Those that do report adverse effects may be erroneously attributing them. As most subjects claimed that adverse effects did not affect the way they took their medicines it appears not to be a significant cause of non-compliance. Other authors support this (Ley, 1982). However, it is also important for the prescriber to select drugs with the safest side effect profile and the maximum efficacy. In some medical conditions this is difficult, as all treatments carry high rates of problematic side effects, such an example would be schizophrenia. However, where a choice is available, for example hypertension, the treatment with the least number of side effects should be selected. If a patient complains of adverse reactions or this limits compliance, an alternative treatment should be selected whenever possible.

Asking about side effects does not appear to give any extra benefit when trying to calculate a patient's risk of non-compliance. It is essential, however, in the therapeutic management of disease, as reports on adverse effects may mask new diagnoses or sub-therapeutic treatment.

Information needs

Thirty-six subjects (71%) were judged to be at risk because of the level of information they had been given about their medication by their general practitioner or hospital doctor. Of the 15 subjects who were judged to have been given sufficient information from health professionals, seven were assessed as being at low risk of non-compliance. These accounted for 54% of all subjects who did not require interventions. Of the remaining eight subjects, three were not self-administering on discharge and three refused entry into the study.

Although 36 subjects were judged by the investigator to have received insufficient information about their medication, 30 of these were happy with the level of information the had been given, that is they were happy to continue to trust their doctor and had no wish to attempt to achieve concordance. Table 5iv shows these details.

Table 5iv: Satisfaction with information supply

	Information given* (n=15)	**Information not* given (n=36)**
Sufficient information from GP	14	21
Sufficient information from hospital	8	0
Happy with information supply	15	30

* As judged by the investigator

Very few subjects in this study (eight) recalled being given any information about their medicines, even about medication changes, during their hospital stay. However, most subjects (68%) recalled their general practitioner or community pharmacist giving them sufficient information. A quarter of the subjects who reported receiving information from their general practitioner (nine) stated that this was normally only when they received a prescription for a new drug.

There was no correlation between information supply and non-compliance risk score, gender or age of subject. Fourteen subjects from the 15 judged to not be at risk from this non-compliance factor had an Abbreviated Mental Test score (AMT) of eight or above, however, this wasn't statistically significant (see Table 5v). It could be suggested that the reason behind this apparent correlation is due to prescribers offering more information to those patients who appear to be better able to understand it, which could include those with a higher AMT. However, it could also be explained by the fact that subjects with a lower AMT may not give reliable responses if memory is required to give that response. In other words, a subject with a low AMT may describe not being given any information, when they have actually forgotten that this information was given.

Table 5v: Distribution of AMT scores with information supply

	Information given (n=15)	**Information not given (n=36)**
Mean AMT	8.4	8.0
Standard deviation	1.25	2.27

The desire which subjects had for information and the possible implications are discussed in Chapter 7. Although most subjects reported low levels of information supply, the majority of subjects were happy with this level and their involvement in the decision making process. There may be a number of reasons for this, which will be discussed in more detail later.

Physical and sensory problems

Physical problems showed potential to affect compliance in 18 subjects (35%). The range of these problems is described in Table 5vi. Although physical ability increased generally with non-compliance risk score, this was not statistically significant. Physical ability did not correlate with any other measure such as safety of storage and administration practice or Abbreviated Mental Test score.

A third of subjects had physical problems that caused difficulties with compliance. Some subjects had already successfully solved a number of these problems. However, many subjects still required further assistance because their difficulties had not been identified by anyone else and the subject was unaware that any assistance was available. The range of solutions that can be offered are described below and include different sized print on labels, dispensing medicines in different containers and providing compliance devices such as the Haleraid® for inhalers and the Autodrop® for eyedrops. Community pharmacists could easily identify these problems by asking simple questions and the pharmacist could offer solutions. Some Health Authorities provide leaflets describing what is available to enable patients to volunteer this information proactively (Southern Derbyshire Community Health Services, 1992). Better advertising of these solutions should be available in primary care.

Table 5vi: Physical problems encountered

Physical problem	Frequency*
Unable to open CRCs	12
Unable to remove tablets from blisters	8
Unable to read any print	3
Unable to read standard print	5
Unable to remove lids from small bottles	1
Difficulty measuring liquids onto a spoon	1
Unable to actuate inhaler	2
Unable to co-ordinate breathing with actuation of inhaler	1

* Subjects could have more than one physical problem
CRC = child resistant closures

Three subjects were unable to read print of any size or density. One of these was registered blind, the other two had impaired vision but had not been registered as partially sighted. Being unable to read labels is an obvious potential cause of non-compliance (Lorenc, 1993; McGavock, 1998; Sweeny, 1989) as a patient who is unable to read labels will not benefit from the regular daily reminder of the dose and time of day which medicines must be taken. For one subject, Mr. GW (37GW281024), this did not pose a particular problem as his sister arranged all his medicines for him and so there was no need for him to read the labels. The other

two subjects, however, were at significant risk of non-compliance and because of this a daily prompt and other assistance was required.

Five more subjects were unable to read labels of a standard print size (10-12 points), but could read larger labels (18-24 points). Being unable to read standard print labels put a subject at a similar risk to being completely unable to read labels. However, large print labels or using a magnifying glass can be used to allow these subjects the possibility of using the label as a reminder (Lorenc, 1993; Sweeny, 1989). Other patients with severe visual impairment may benefit from use of Braille labels, however, not all visually impaired people can read Braille, and careful selection is required. Other limitations of Braille labels are the lack of facilities to produce these in a Pharmacy. This means that information is restricted to that produced by organisations such as the Royal National Institute for the Blind, which generally only included details of number of tablets and frequency. It is important to provide information in a form that the patient understands; however, the European Council Directive 92/27/EEC states that labels and manufacturer's information leaflets must be written in English and conform to certain standards (Appelbe, 1997). For foreign nationals and patients with difficulty in reading English, additional information may be supplied which is easier to understand and follow.

Two subjects found difficulty in actuating inhalers, and one of these, Mrs. GM (39GM031015), also found difficulty in co-ordinating her breathing with pressing the canister. Aerosol inhalers have been very useful in the treatment of asthma and chronic lung diseases. However, they are very difficult to use, with few people accurately timing the dose to the breath (Johnson, 2000). Pressing the canister is also difficult for patients with poor manual dexterity. An inability to use these devices correctly can mean that although the dose is taken at the correct time, an insufficient amount is deposited in the lungs and so the patient does not receive the expected benefit. Both of these subjects had difficulty using their inhalers and required alternative devices to ensure they received maximal benefit (Lowe, 1995).

Manual dexterity can cause many other problems with unintentional non-compliance. Inability to remove tablets from their packaging is potentially a cause of non-compliance (Hughes, 1998; Lorenc, 1993; Sweeny, 1989). This can cause doses to be missed whilst the patient is waiting for assistance in removing them or they may decant the doses into another container, losing all the benefit of having a labelled container and potentially reducing the shelf life of the product. Many elderly people encounter difficulty in removing tablets and capsules from blister packs. Eight subjects in the current study encountered this problem. Social Services home carers are not allowed by their contract to remove doses from blister packs and so only a verbal reminder was available to them. In order to be able to take their medicines these subjects would therefore have to decant them into other bottles that may have the wrong label or out of date instructions leading to confusion and non-compliance. An alternative would be for the Pharmacy dispensing medication to decant them at the time of dispensing.

Similarly, medicine bottles can be problematic for elderly people to open if child resistant closures are used. Twelve subjects encountered this difficulty. Although these closures reduce the risk of young children accidentally gaining admission to the contents of a medicine bottle, they can also effectively prevent a patient from being able to take their medicines. If a screw cap is not provided at the time of dispensing, then the patient may decant their tablets into a bottle for which they have a screw cap, with all the attendant risks described above. One subject, Mrs. SW (39SW080425), solved this problem by decanting her medicines straight into a Medidos, a safe and effective container to allow her to accurately take her medicines. Other subjects did not have such safe solutions. A quarter of subjects could not open child resistant closures and others preferred screw caps; it would be appropriate therefore to ask all elderly patients whether they would require screw caps on their bottles.

A number of subjects had significant physical problems, which could impinge on their ability to comply with medication. These problems did not occur in any particular age group or correlate with any other compliance risks. Also, the range of problems, although predictable if a detailed knowledge of the subject's medical condition was known, they could not necessarily be predicted without such

knowledge. There did not appear to be any single physical problem that required intervention for the majority of subjects. It is important therefore to identify individual physical problems when assessing a patient's compliance risk. This question was a useful tool and identified the pharmaceutical needs of some subjects who would otherwise have been missed.

Complexity of regime

Most of the subjects (36 = 71%) were at risk of non-compliance due to the complexity of their medication regime. A complex regime was defined as one with five or more drugs and in which the maximum frequency for any drug was greater than twice a day. The data are shown in Table 5vii. These figures are different to those shown in Table 3ix as this table relates to pre-admission data, whereas Table 5vii relates to data after a medication review had taken place and represents drugs on discharge.

Table 5vii: Complexity of regime

Number of drugs (≥ 5 = at risk)		**Maximum frequency of doses (≥ tds = at risk)**	
Mean (S.D.)	5 (2.5)	Once daily	7
Range	1-13	Twice daily	16
Number of subjects at risk*	30	Three times a day	11
		Four times a day	17
		Number of subjects at risk*	28

* 22 subjects had both risk factors

The number of drugs prescribed and the frequency of doses were equally likely to be the cause of the increase in non-compliance risk. Thirty-two subjects also had three or more different directions as to when medicines should be taken, for example in the morning, at night, twice a day, etc. One subject had five different sets of directions for a total of ten different medicines.

71% of subjects studied were at risk of non-compliance because of the complexity of their regime. There was no correlation between age, gender of subject or non-compliance risk score and complexity of regime. As complexity did not correlate well with the non-compliance risk score, measuring complexity would not allow assessment of the subject's full range of compliance problems. Use of this measure is therefore essential, but not sufficient, for assessment of a subject's complete compliance picture.

In many cases complexity of regime increased or remained the same at discharge compared to pre-admission levels. This reflects the difficulty of rationalising medication regimes for patients with multiple conditions and complex requirements. Assessing risk of non-compliance due to polypharmacy is important but it is often not possible to reduce this risk factor unless treatment is subtherapeutic prior to review. This issue is discussed in greater depth in Chapter 8.

Correlation between categories

As has been described earlier there was little correlation between any of the categories investigated or the total compliance risk score. This lack of correlation could reflect two scenarios. Firstly the questionnaire could be poorly designed and therefore the information gleaned would be contradictory with no possibility of correlation. Although some of the questions did cause difficulty with a few subjects most questions appeared to be understood and answered fully and honestly. The first question regarding any assistance subjects received in taking their medicines was occasionally misunderstood. In each case, however, the true answer was found before the interview was completed and this did not significantly affect the non-compliance risk score, but rather affected the interpretation of results and identification of appropriate interventions.

The information given by the subjects was occasionally contradictory, especially in two particular areas. Firstly, many subjects claimed to be happy with their medication but felt it was not working or that they needed a change. Similarly, some subjects felt their medicines were effective and did not need any alteration, but still they were not satisfied with their medication. This apparent contradiction has been

discussed earlier in this chapter and could be explained by the complex way in which patients rationalise the need for medication. The second apparent contradiction came with questions regarding information supplied by the doctor and the perceived need for further information. This will be discussed later and does not necessarily reflect a contradiction.

A second explanation of the lack of correlation is based on the fact that compliance is complex and mediated by many factors (Griffiths, 1990). In order to assess a subject's risk of non-compliance it was necessary to investigate each of these factors. Assuming that each of these risk factors is discrete, a lack of correlation could be a sign of a well-designed questionnaire. No claim can be made regarding the exhaustive nature of the questionnaire although this was attempted. Lack of correlation would indicate that the questions were not overlapping or ambiguous, ensuring that each problem is accurately assigned to the correct risk factor. Correlation would be expected in some isolated cases where the subjects have a number of risk factors. For example, a subject who is confused would score low in the Abbreviated Mental Test (AMT) and the understanding of medicines category. However, a subject who was not clinically confused could score highly in AMT but still be unable to recall the medicines they were prescribed.

Rate of self-medication

Of the subjects enrolled into the first stage of the study three were not self-administering at the start of the study and a further seven were discharged to nursing or residential homes, or received significant input from Social Services on discharge. These subjects accounted for 20% of the total interviewed. However, a significant number of patients were not interviewed because they stated that they were not responsible for self-medicating at home. This was particularly prevalent in males who generally stated that their wives reminded them to take their medicines and frequently counted them out ready to be taken. It is not possible to state whether this behaviour is common to all males, or even to males from North Eastern England; however, a clear trend emerged with male subjects more frequently denying responsibility for their medication. Other sources do not appear to describe such a

phenomenon with regard to medicines. However, there may be some evidence to suggest that women are more compliant than men are in behavioural circumstances, and this may be extended to the lifestyle issues of compliance with medication (Ward, 1984). Also, it is claimed that women take on a nursing role more readily than men do (Stone, 1987).

Many of the women interviewed wanted to be in control of their treatment and appeared to feel that giving up responsibility of self-administration to another person was a sign of weakness. This could be a problem for those women who encountered difficulties with taking their medicines but did not want to ask for help. Such people may be at higher risk of unintentional non-compliance. Intentional non-compliance could be lower in this group, except when the subject disagreed with the doctor's opinion as to the appropriateness of the therapy prescribed.

A number of the men interviewed relied on their wives to remind them when it was time to take their medicines. For some men, like Mr. JP (39JP011015) this reflected a joint effort and was of little concern as the reminder enabled both of them to comply to a greater extent; his wife reminded him when to take his medication although he was responsible for getting it out. However, other men were more like Mr. SH (39SH101120) who completely relied on his wife to remind him when to take his medication and get it out for him. He took little interest in his own medication, to the point of not really wanting to know why he was prescribed them or when he should take them.

If a patient is not responsible for their medicines at all, that is another person not only reminds them when to take them but also removes them from the container and hands them to them, they will have great difficulty in remembering when to take them. Mr. SH knew what more than half of his medicines were but could not remember when he took most of them. As his wife was completely responsible for his medicines, this was not problematic. This may be an example of a man abdicating responsibility of his medicines to his wife; or may be indicative of his difficulty in self medicating. It was not possible to ascertain whether his forgetfulness caused his wife to take on this administration role, or whether her

assistance removed the need for him to remember, thus causing him to become dependent on her.

Dependence on a spouse to remember when to take medication can potentially cause problems if, as is usually the case, the wife is also elderly and may become confused herself. Also if the wife is admitted to hospital or she dies, this will result in the husband having to take responsibility for administering his own medication, a practice in which he has become inexperienced and may therefore become unintentionally non-compliant. Alternatively, he may be intentionally non-compliant because he does not appreciate the necessity of complying. It is interesting to note that although elderly women tend to have a number of caregivers providing assistance with transport, shopping, etc., men tend to rely on their spouse for more intensive tasks such as personal care and house keeping (Tennstedt, 1989). The reciprocal problem was not often seen in widowed women, possibly because they had taken on the mother role earlier in their marriage and so their willingness and ability to cope may have been greater. It does appear that in old age people tend to continue with those roles they traditionally carried out in earlier life. The attitude of caregivers also appears to differ with the gender of the person requiring care (Tennstedt, 1989). Women tend to outlive men (Guralnik, 2000) and this may affect the way women continue with normal life after bereavement.

The subjects in this study had a high level of social support. A total of 34 subjects (69%) described having a relation or a Social Services home carer visiting regularly to provide help with domestic issues. Three of these were not self-administering and a further eight received a reminder if medicines were forgotten. It was unclear why these subjects claimed to be independent when they had high levels of support with taking medicines. The remaining subjects (n = 24) were independently self-medicating.

Patients who are at high risk of non-compliance and also confused will require Social Services or family input into their care to ensure that medicines are taken appropriately. However, if independence is reduced because of a regular reminder then there is a possibility that all ability to manage to take their medicines independently will be lost. This can be seen in other aspects of life. Patients who

have been long-term in-patients in hospital can become institutionalised and therefore find minor tasks, which previously they completed with little difficulty, have now become very difficult (Hodkinson, 1981). It is important therefore for patients to retain as much independence as they wish and are capable of achieving.

Only 17 subjects in the present study had no regular assistance and therefore were also independently self-medicating. Living alone in a socially isolated situation is often reported to impair compliance as social reinforcement improves faith in medication (Col, 1990; Ley, 1982; Moriskey, 1986). A lack of accountability to others may also reduce the perceived need to comply with medication or treatment regimes. In the current study this did not appear to be the case, however the sample size may be insufficient to detect this phenomenon.

Three subjects received a measurable beneficial effect from their social input in that the carer had already implemented an appropriate intervention before admission to hospital. In each of these cases, the intervention was providing a Monitored Dosage System ready filled each week. This represented only a small proportion of the study group and many more subjects had not received any assistance with their medication or received a detrimental intervention. However, this illustrates an important point, namely that input can be from many sources and to ensure seamless care this input must be investigated and assessed.

Few sources have quoted rates of independent responsibility for self-medicating in elderly people. This appears to be because most studies into compliance automatically exclude those patients not self-administering, on the basis that compliance with medicines does not rely in this situation on the patient's ability but on the carer's. In the current study, patients who were recorded as not self-administering or who admitted to receiving considerable assistance with their medicines were excluded and so accurate rates of self-administration were not available except for those interviewed. In one study (Lowe, 1995) 94% of subjects were self-medicating. However, patients dependent on another person for administration of medicines on admission were excluded before the study commenced.

Law et al (1976) quoted rates of self-medication of 85% in their study of patients over 75 in one general practice. This is much higher than seen in the current study and may reflect a difference in the samples tested. Possibly the intervening 25 years has affected rates of self-administration, with fewer older people needing to be self-reliant. This theory is not supported in the published literature, but it is possible that as life expectancy has increased more opportunities for assistance have been developed. It is also possible that the sample population studied in the current study included more frail, elderly patients, and so more of them were in need of greater assistance. This is impossible to verify, as the data presented by Law et al (1976). does not include age distributions, with all subjects simply described as being over 75. It would be defensible to suggest, however, that as the population studied by Law et al was a general practice population, this may have included a greater proportion of fit elderly patients than the hospital population. The general practice population will include patients requiring hospitalisation but also patients who are fit, well, and in no need of such care. Such a population may require less input into taking their medicines because of fewer complications and possibly a smaller number of medicines taken.

Chapter 6: Enhancing compliance amongst elderly in-patients - the contribution of hospital based pharmacists

This study was carried out because a number of authorities have described the benefits a hospital pharmacist can confer if certain activities occur at discharge (Haynes, 1996). Although the study did not provide any concrete evidence that the interventions used did improve compliance it is interesting to consider which interventions were used most and what sort of benefit could be expected for the subjects.

The problems encountered by the subjects in this study, and the interventions implemented to overcome these risks to compliance are shown in Table 6i. Thirty-nine subjects required eleven different interventions. Each intervention implemented is described below with examples of their potential to improve compliance.

Medication reminder leaflets

A medication reminder leaflet (also called compliance reminder charts) such as the one shown in Appendix II was the most appropriate intervention for 16 subjects. This accounted for 40% of subjects who required an intervention. For eight of these subjects, the principal need for these reminder leaflets was a complicated regime.

Mrs. CW (39CW060123) lived alone but coped well and only had a home carer assisting with washing and cooking. Mrs. CW reported that her general practitioner always gave her sufficient information about her medication but she had so far not been given any information whilst she was in hospital. At interview she was taking ten different medicines with five different instructions on how to take them; she was unable to explain what she was taking but knew the reason why. She claimed that she never forgot to take her morning medicines as she took them with her breakfast, however, she occasionally forgot to take her afternoon medicines. Treatment failure could result from taking doses too infrequently.

Table 6i: The causes of non-compliance risk and the solutions implemented

NUMBER	AGE	GENDER	AMT	TOTAL	PROBLEMS	INTERVENTIONS IDENTIFIED	ACTIONED?
37MM020233	67	F	9	34	Wants more Information, unhappy with medication.	Compliance chart, counsel	yes
39MC080527	72	F	9	34	Unsure if medication appropriate, thinks one medicine is ineffective, complex prescription	Compliance sheet, counsel	yes
39SW080425	75	F	8	31	Poor manual dexterity, unsure what taking or why, complicated regime	Compliance chart, counsel, MDS	yes
37GW281024	76	M	3	19	Unable to explain medication, wants a change, doesn't know if working, poor manual dexterity, unable to read, confused, complicated regime	Refer to Social Service	yes
37LO090524	76	M	10	37	Occasionally forgets medication, stops taking them when feels better, complicated regime	Compliance chart, counsel	yes
39DW070422	77	F	9	34	Unable to read labels, complicated regime	Counsel, compliance chart, large print labels	yes
37DT071022	78	F	10	32	Wants concordance, unable to explain what taking or why, unsure if still needs medication or working.	Refer to doctor - concordance	yes
39ED070821	79	F	10	32	Takes medicines BD regardless, not careful to follow instructions, doesn't know what taking or why, poor manual dexterity, complicated regime	Counsel, compliance chart, screw caps, no blisters	yes
39JG070221	79	F	8	37	Wants concordance	Counsel, compliance chart	yes
37MM210420	80	F	10	29	Not sure if happy with medication, unsure if working, inhaler unsuitable, complicated regime	Counsel, compliance chart, change inhaler device	yes
39DR150919	81	F	9	32	Could explain what taking and why with difficulty, doesn't know if working, poor manual dexterity	Compliance sheet, counsel, large bottles, no blisters	yes
39JT060219	81	M	8	36	Poor manual dexterity	Screw caps, bottles not blisters	yes
37PN120316	84	F	1	26	Unable to remember anything about medication, poor manual dexterity, confused	Refer to Social Services	yes
39GM031015	84	F	10	29	Unsure if still needs medication, or if working, poor manual dexterity, complicated regime.	Counsel, change inhaler, screw caps, no blisters	yes
39JP011015	85	M	10	33	Wants to stop taking some medication, ineffective	Compliance sheet, change treatment	yes
39DT280515	85	F	6	27	Unhappy with medication, doesn't think they are working, confused, depressed, complicated regime	Refer to Social Services	yes
39ML090414	86	F	9	30	Unable to open CRCs, complicated regime	Bottles not blisters	yes
37LG061012	88	F	5	31	Unable to explain what taking or why, complicated regime, confused	Monitored Dosage System	yes
39JR260810	90	M	6	28	Blind, unable to explain what taking or why, confused	Refer to Social Services	yes
39EW130709	91	F	10	31	Unable to explain what taking or why, wants concordance, unsure if still needs medication	Counsel, compliance chart	yes
39GR240107	93	M	9	32	Unable to explain why takes medication, unable to read labels	Counsel, compliance sheet, large print labels	yes
39NW190130	70	M	8	38	Complicated regime	Simplify regime (*simplification not possible)	no*
39MB290624	76	F	7	26	Poor manual dexterity, unable to read labels, unable to explain what taking or why, unsure if happy, complicated regime	Compliance chart, counsel, large print labels (*discharged before interventions implemented)	no*

NUMBER	AGE	GENDER	AMT	TOTAL	PROBLEMS	INTERVENTIONS IDENTIFIED	ACTIONED?
39CW060123	77	F	9	29	Unable to remember what taking, forgets afternoon medicines, complicated regime	Counsel, compliance chart (*died before discharge)	no*
39WR030922	78	M	9	32	Wants a new medication, complicated regime	Simplify medication (*regime optimal)	no*
39AG231221	79	F	9	31	Can't use inhaler, complicated regime	Haleraid, counsel (*discharged before signing consent form)	no*
39EO111219	81	F	6	38	Unable to explain what taking or why, confused, complicated regime	Counsel and compliance chart (*discharged to nursing home)	no*
39LH181217	83	F	8	36	Complicated regime	Simplify regime (*not possible)	no*
39AB270916	84	M	8	36	Complicated regime	Simplify regime (*not possible)	no*
39JF070716	84	M	9	35	Unsure if needs medication, didn't know if working, complicated regime	Simplify regime (*not possible), counsel (*refused))	no*
39GE110815	85	F	8	39	Unsure if happy with medicines, thinks she needs a change	Review medication (*regime optimal)	no*
39ID151114	86	F	8	29	Unable explain what taking or why, unable to read labels, complicated regime, wants concordance	Counsel, large print leaflets and labels (*refused intervention)	no*
39JR240413	87	F	9	36	Thinks need a change in medication, ineffective	Review regime (*optimal, refused intervention)	no*
37AP050312	88	F	8	33	Unhappy with medication, wants a change, not working, couldn't remember what taking	Review regime (*optimal), counsel, compliance sheet (*discharged before intervention possible)	no*
37JP231209	91	M	9	34	Not sure if still needs medication, complicated regime	Refer – concordance (*refused intervention)	no*
39EH230708	92	F	8	41	Complicated regime	Simplify regime (*optimal)	no*
37NT070508	92	M	4	27	Poor manual dexterity, confused, complicated regime	Refer to Social Service (*died before discharge)	no*
39AT150420	80	F	10	42	None	None	n/a
39DP200120	80	F	10	37	Complicated regime	None (doctor already solved)	n/a
39SH101120	80	M	9	40	Unable to explain what taking or why	None (not self-administering)	n/a
37KJ090117	83	M	8	33	None	None	n/a
39MW151117	83	F	9	35	Unsure why taking medication, feels she needs a change, not working	None (doctor already solved)	n/a
39DS020916	84	F	9	39	Rheumatoid arthritis of hands	Screw caps (*already implemented)	n/a
39AE240716	84	F	10	41	None	None	n/a
39ER150215	85	F	5	30	Poor manual dexterity.	Bottles not blisters (*daughter supervises)	n/a
39TH040114	86	M	10	26	Unable to explain what taking or why, unsure if needs a change or if working, complicated regime	None (Monitored Dosage System already in use)	n/a
39DH190712	88	F	9	42	None	None	n/a
39JH010211	89	M	3	29	Unable to explain what taking or why, poor manual dexterity, confused	None (referred to Social Services)	n/a
39AS291109	91	F	8	29	Wants more information, unable to explain what taking or why.	None (Monitored Dosage System already in use)	n/a
39GR290503	97	M	9	36	Unable to explain what taking or why, not sure if working	None (not self-administering)	n/a
39LP170702	98	F	8	32	Poor manual dexterity, doesn't want to take medication	None (discharge to nursing home)	n/a

Patients often have difficulty deciding what time of day each of their medicines should be taken and in which order. Also, medicines are often labelled 'as directed' or with instructions such as 'Take one tablet once a day'. It is much better to put full instructions on the label, including whether a once daily drug is taken in the morning or at night. Unfortunately, if the prescriber has not put this information on the prescription it cannot be put on the label. This information can be clearly marked on the medication reminder leaflet allowing the patient to understand quickly what they need to do. Patients with polypharmacy may be unsure how many different medications they need to take each time and reading each label may not help. Problems can occur if a container is left in a different room to the rest of the prescribed medication as that label will not be read and, unless the patient remembers to go and find it, it will be omitted. With a medication reminder leaflet the patient can use the chart to decide which medicines are required, and he is given an extra reminder if the number of tablets counted out is less than that indicated on the chart.

Some subjects wanted more information about their medicines but did not want to be more involved in making treatment decisions. This is discussed in greater depth in Chapter 7. Using a medication reminder leaflet can most efficiently provide this information. The example shown in Appendix II demonstrates that in addition to the time of day each medicine should be taken being clearly indicated, the chart contains a column into which other useful information can be added. An example of such information could include the reason for the prescription, i.e. the condition the medicine is prescribed to treat. Other useful information could include how to determine whether the medication is effective, the main adverse affects that are likely to be encountered and the action to take if they occur. The information included is by necessity brief and relatively standardised. However, it can provide the patient with the basic information they need and allow them to make informed requests for further information they may feel they require.

Mrs. CW (39CW060123) and Mrs. ED (39ED070821) both made errors in administration of their medication, which were caused by a misunderstanding of when they should be taken. Mrs. CW tried to take one particular medicine at 3pm but often forgot to take it, as that time of day was inconvenient for her; teatime

would have been a more appropriate administration time. Mrs. ED took all her medicines twice a day because she found it too complicated to read all the labels on the containers. Many people, especially the elderly, have difficulty reading labels on medicine bottles. This is exacerbated if too much information is fitted onto the label. Having the information clearly laid out as shown in Appendix II reduces the confusion by arranging it under useful headings.

There has been controversy over whether medicine reminder leaflets should be supplied to patients. The argument is such that all the information that a patient requires should be on the medicine label, a second reminder is therefore not necessary. Also, if the instructions change on a new prescription then it is important to change the reminder sheet, otherwise the patient will continue to take their medicines incorrectly. These criticisms are sound and the usefulness of a reminder sheet depends on its continued accuracy. It is important that someone takes the responsibility to update the information. Patients could be encouraged to take the chart with them each time they visit a doctor to ask them to enter changes. They could also ask the community pharmacist to update the form each time they get a new prescription. However, this is only completely safe if the patient always visits the same Pharmacy and their Patient Medication Records are updated regularly.

Medication reminder leaflets are relatively simple for hospital pharmacists to complete and there is a possibility that with the development of information technology capabilities, these could be produced automatically using a pharmacy dispensing programme. Because of the potential benefit which medication reminder leaflets provide, they should be offered to all patients with complicated regimes or those who appear confused about their medicines. They should also be available for other patients who request one. As this would include the vast majority of elderly patients, they should routinely be provided for this population.

Provision of verbal information

Nineteen subjects were provided with individually tailored verbal information on discharge. This included advice on what had been prescribed, the reason for the prescription, and when the medicines should be taken. This conversation, which lasted ten minutes on average, allowed the subject to ask questions regarding their treatment and offered an opportunity for last minute worries to be addressed.

This subject is discussed in greater depth in Chapter 7. A chance to discuss the prescribed medication should be offered to all patients who have had a change in medication and those for whom non-compliance is suspected. This would include the majority of patients discharged from hospital and should be a routine service offered prior to discharge.

Physical needs

35% of subjects had physical problems, which could affect compliance. These needs were specific to individuals and broad generalisation cannot be used in order to improve compliance for all patients. For example, most subjects in this study who had physical needs had difficulty in opening child resistant closures (CRC). It would be defensible to generalise and give all elderly people screw caps. However, many people do not have difficulty in opening CRC and routine provision of screw caps may result in grandchildren or great grandchildren being put at risk because of the easy accessibility of medication. Similarly, removing tablets from blister packs and dispensing them in bottles would greatly assist some patients. However, doing this can potentially reduce the shelf life of the medicines and can remove the useful reminder of the days of the week often printed on the back of such blister packs.

The difficulties introduced by an inability to open a container of tablets, capsules, liquids and many other dosage forms are relatively obvious. If a dose cannot be accessed it cannot be taken. The risks of patients decanting doses into other containers has been discussed earlier and therefore decanting should be carried out at the time of dispensing.

Physical problems with using other devices can introduce other risk factors for non-compliance. For example, Mrs. MM (37MM210420) had uncontrolled asthma. As she was still symptomatic, it was clear to her that her treatment was sub-optimal. However, the patient's interpretation of what is wrong and the possible options for remedying it is often not the same as the doctor's (Col, 1990; Sanghani, 1998). Mrs. MM had decided that the device she had been given was not working. This illustrates the importance of giving patients medicines in the correct device or most appropriate form for their needs or expectations (Lowe, 1995).

Mrs. MM's doctor's had recently changed her inhaler device because many patients find a dry powder device (such as a Clickhaler®) easier to use than a metered dose inhaler (a standard aerosol inhaler) as the later relies on the patient's ability to co-ordinate breathing with pressing the canister. Unfortunately, Mrs. MM had not been instructed how to use the new device and was therefore using it incorrectly causing deterioration in her asthma. In these circumstances, demonstration and explanation are usually sufficient to improve compliance. However, Mrs. MM had become convinced that the device did not work properly and the only solution was to swap to an alternative device, with adequate demonstration and explanation.

No two patients will have identical physical needs and therefore there cannot be one universal solution. However, it is also the case that many physical problems can dramatically reduce a patient's ability to comply; ignoring such needs is therefore not an option and it is important to assess all patients for physical needs. This can generally be by means of a simple question, but may involve a more time-consuming trial and error assessment of suitable devices and interventions. For many of the subjects interviewed, the process of identifying and solving certain physical problems potentially reduced non-compliance risk more than any other intervention. It is essential for a hospital pharmacist to address these problems when they occur. However, it is of greater importance that these interventions are continued in the community.

Monitored dosage systems

A great emphasis has been placed on Monitored Dosage Systems (MDS) by some authorities (McGraw, 2000). Many nurses request these for patients who may not have taken medicines correctly in the past, regardless of the cause. However, only one subject in the current study was given an MDS. The criteria for receiving a MDS included confusion when to take medicines despite verbal and written guidance, those who frequently forget whether they have taken a dose or not, and those who demonstrated unsafe administration methods.

The MDS used in the hospital NT was the Medidos®. This is a small wallet that contains seven individual containers, one for each day. These containers can be taken out and carried in a handbag or pocket. Each daily container has three moveable dividers, dividing it into four sections labelled 'Breakfast' 'Lunchtime' 'Teatime' and 'Bedtime'. Solid doses can be placed in the Medidos®, which can provide a reminder of when each medicine is to be taken and reassurance whether the previous dose has been taken. Other MDS such as Nomad®, Dosett®, Redidose®, etc., are based on a similar system, but differ in minor ways making them more appropriate to some patients than others.

Although MDS are liked by many patients and recommended by many nurses, they are not universally helpful. Firstly, if the patient does not want to take their medication (intentional non-compliance), MDS will not improve compliance as they do not affect motivation. Secondly, if a dose is to be omitted or changed on medical advice it is not always possible to identify the relevant tablet and remove it, unless expert advice is sought. Another problem is that many of these containers are not child-resistant.

Many patients fill their own MDS. This may limit their usefulness, as if a patient is confused about their regime they may fill the box incorrectly. This may also apply to relatives filling these containers. The safest way for these to be filled is by a community pharmacist; however, this is costly and time-consuming for the pharmacy and means that the patient must always get their prescriptions filled at the same pharmacy to allow continuity.

Many MDS are difficult to open for certain people. It is important to ensure that the patient can open the container or there would be no benefit in supplying it. This may be a particular problem for patients who have had a stroke. MDS are often recommended for these people, as short-term memory loss may be present; however, the physical sequalae of a stroke may render such a container impenetrable.

Although these containers can help with most solid dosage forms such as tablets and capsules, they cannot accommodate many other dosage forms including liquids, powders, inhalers, suppositories, eye drops or very large tablets, for example, effervescent analgesics. They cannot be guaranteed to be moisture proof, and so they cannot be used to store medicines that require a desiccant. They are also unsuitable for medicines prescribed 'when required', as the patient may not always need to take them at the same time each day. Unless the vast majority of prescribed doses can be placed in the MDS, there is little benefit to be gained from supplying such a container, as the patient will still need to read individual labels to decide when to take the excluded medication.

Very confused patients, who do not know what time of day it is, will not be helped by MDS as they require a reasonable level of comprehension to know which section to open and will require outside assistance from a relative or carer to ensure medication is taken appropriately. It is worth noting at this point that occasionally the carer will require an MDS to ensure they give the patient the appropriate medication at the correct time. Most patients with poor vision will not be able to use MDS as they rely on visual prompts on the most part. Although a small number of visually impaired people may derive some benefit from MDS, other interventions such as large print labels, Braille labels, different sized containers, etc., may be more appropriate.

If a patient is identified in hospital as requiring a Monitored Dosage System then it is essential that they are supplied on discharge as the first few days following discharge often present the greatest risk to non-compliance due to changes in treatment. Also a small number of subjects in the current study were using an MDS prior to admission. It is essential that these patients are identified early and the device brought into

hospital to be filled ready for discharge. Neglecting to do this and subsequently dispensing medication in bottles and boxes can mean that these patients are at a greatly increased risk of non-compliance on discharge from hospital.

There are a few patients for whom MDS may greatly improve their ability to take their medicines. This includes those with complicated regimes that cannot be simplified, those for whom other solutions are inappropriate and patients with short-term memory loss and confusion. These patients must be identified and offered these devices, despite the time-consuming nature of filling these devices. As nurses frequently recommend MDS inappropriately, a pharmacist should assess all patients who potentially require these devices for their suitability. It is essential that safe and appropriate continued filling of these devices is available after discharge.

For many patients Monitored Dosage Systems will not offer any improvement in compliance and may introduce more difficulties (McGraw, 2000). This emphasises the importance of patient focused interventions and not offering one solution for all patients.

Simplifying the regime

Chapter 8 will discuss the finding that simplifying complicated regimes of individual subjects was often not possible. However, it is essential to ensure that patients have the best possible regime. This combines treating each condition with the most effective medicines, avoiding medicines which can cause troublesome side effects, ensuring unnecessary medicines are removed and making the final treatment regime as simple to take as possible. Medication review should occur for every patient and not just those for whom non-compliance is suspected. This should be carried out by all health professionals each time the patient is assessed. However, the hospital pharmacist has an important role to play.

Other interventions

A number of other interventions were implemented for individual subjects. Although they appeared to be accepted well by the subjects, it is not possible to state whether compliance was improved, although they did eliminate or reduce the effect of at least one risk of non-compliance. These interventions were tailored to individual subjects and would not have been appropriate for all subjects. For example, clear printing on labels is important for the majority of people, but large print would only be appropriate for patients with poor but extant visual capabilities. The blind would not benefit from large print and those with no visual impairment may find the duplication of information confusing and the flagging of labels, which is often required when using large print labels, problematic. If other interventions are required then these should be tailored for individual patients, as broad generalisation of requirements is not possible.

Continuation of interventions

In order for patients to benefit from interventions initiated in hospital, they must be continued in the community. The role of primary care in improving compliance is discussed in Chapter 9.

The appropriateness of pharmacy generated interventions

90% of subjects were identified as being at moderate or high risk of non-compliance and required some type of intervention. The ward nurses and doctors appeared to identify those patients who required referral to Social Services quite easily as this was often on the basis of the subject's Abbreviated Mental Test, which was routinely assessed for all confused patients. Similarly, subjects with severe physical disabilities were readily identified and referred to Social Services or to the pharmacist. The other risk factors for non-compliance did not appear to be considered by the other health professionals and so were not solved without the pharmacist's intervention.

Although there is an absence of evidence that these interventions had a positive benefit on the subjects' ability to comply with their medication, the interventions used have been justified earlier. It is possible that the subjects interviewed would have continued with the same practice regardless of the intervention, but it is the case that the problems identified were real and therefore required some solution.

All of the interventions, except providing verbal information or medication reminder leaflets, needed to be implemented by a pharmacist or member of the pharmacy department. This is because they involved alterations in dispensing techniques, a role for which responsibility exclusively rests with a pharmacist. A ward nurse could discuss the medication with subjects on discharge. Similarly creating medication reminder leaflets is not exclusively the domain of pharmacy. However, there is an argument that a pharmacist may have a better ability to give appropriate information about medicines on discharge than a nurse as the pharmacist has greater knowledge and training with regard to medicines. It is definitely the case that pharmacists are in a better position to answer less routine questions, which may be asked during counselling sessions.

Potential benefit to subjects

The rationale for using the particular interventions that were used in the current study has been discussed earlier (see Chapter 3b). It is hoped that if appropriate interventions were offered and implemented then the subjects would improve their ability to comply with medication. They would have a more acceptable regime, which contained medication they understood and were able to take correctly. The likelihood of forgetting to take a dose would be reduced. All this would improve the therapeutic outcome and reduce morbidity, and possibly even mortality.

However, this depends on the patient being prescribed appropriate treatment. If subtherapeutic or incorrect medication is prescribed, or if essential medication were omitted, then fully complying with a treatment regime would not confer the full benefits described above. Evidence based medicine combined with concordance and reduction of barriers to compliance should improve the outcome of medicines use.

Improving the efficiency of the intervention process

Using the questionnaire to identify non-compliance risks and implementing the required interventions was costly in terms of the pharmacist's time. The interview took an average of 22 minutes to implement. Using a shorter questionnaire could successfully reduce this element of the costs incurred, but possibly at the expense of the sensitivity of the questionnaire.

An alternative solution could be to improve multidisciplinary team working. The ward nurses could be asked to select certain patients for further questioning by the pharmacist. This referral could include useful information such as home circumstance and confusion level. If the criteria for selection and referral were carefully designed then this information could effectively be used to screen out those patients without any problems, and those not self-medicating. This would reduce a lot of the background fact-finding that this study required of the investigator before the decision to include or exclude the subject from the interview stage. This information is often readily available to the nurse, even if not clearly documented in once easily accessible place.

The most costly interventions in terms of time taken were producing large print labels and leaflets and filling MDS. Amending the pharmacy computer software to enable automatic printing of supplementary large print labels and medicine reminder leaflets could reduce this aspect of large print label production. This is possible with some dispensing programmes and should be investigated further. However, the limited number of patients this will benefit may not justify the expense of a software upgrade.

Supply of MDS were the most expensive intervention both in cost of intervention (a Medidos® costs approximately £6) and in time taken to implement the intervention. We have already described how these are often inappropriate for many patients and should be limited to those patients for whom need and potential benefit is proven.

Making appropriate interventions for patients at risk of non-compliance is an essential aspect of pharmaceutical care and should be carried out by hospital pharmacists whenever possible. Involving the patient themselves and other health professionals is important and can improve the outcome of the intervention and reduce the time taken to investigate the problems and implement appropriate solutions.

Chapter 7: Factors affecting concordance - Patients' need for medication information

Introduction

Many patient advocacy groups, for example the Patients' Association, have demanded the right for patients to be given sufficient information about their medicines (Anonymous, 1997a). It is this right that concordance is based on; all health professionals are encouraged to provide good quality information to patients in order to increase a patient's ability and intention to comply with a medication regime (Sweeny, 1989). As has been discussed previously, patients who are given sufficient high quality, easily understood information have a greater chance of compliance than those patients who are given insufficient information (Lorenc, 1993). Talking to patients about their treatment also gives them an opportunity to ask questions and verbalise fears associated with treatment (Smith, 1983). If these fears are not expressed then a potentially major risk to compliance may be ignored.

In this chapter the problem of reported levels of information supply will be discussed and contrasted with the subjects' apparent lack of enthusiasm for being involved with making treatment decisions. The implications of this for achieving concordance in the population investigated will be considered followed by a more general discussion of the failure to achieve concordance in the wider population. The chapter will conclude with some suggestions for improving compliance and achieving concordance.

Reported level of information supplied

Thirty-six subjects (71%) were judged to be at risk because of the level of information they had been given about their medication by their general practitioner or hospital doctor. Fifty-eight percent of the subjects who were judged by the investigator to have been provided with insufficient information, reported being given sufficient information from their general practitioners. In total 68% of the study population reported being happy with the information supplied by their general

practitioner. However, all apart from eight subjects (43 = 84%) claimed not to have been given any information about their medicines from the hospital doctors or other staff.

The higher reporting rate of general practitioners supplying information over hospital doctors is interesting; it is generally assumed that GPs have too many patients to see and insufficient time to see them all. A figure of seven to ten minutes per patient is often quoted (Sanghani, 1988); the corollary of this is that there would be insufficient opportunity to give their patients good quality information. Attaining concordance in such a restricted time period is near impossible (Anonymous, 2000a; Dean, 2000). In the hospital setting the situation may be slightly improved in that outpatient appointments may be under less pressure of squeezing in emergencies and a longer time may be available for discussion. However, the time allocated is still limited and may not be sufficient to address each of the patient's concerns.

Conversely, hospital in-patients would be expected to have greater opportunity to ask the doctor questions, as a longer period of time is spent clerking the patient and discussing the case on consultant ward rounds. There is often the possibility of discussing an issue and making a decision the following day, after the patient has had opportunity to consider all the implications of the suggestion. Also, the need for new information would be greater for an in-patient than for a patient visiting their general practitioner as medication is likely to be altered to a greater extent during a hospital admission. Therefore, it might be expected that more information would be provided in hospital. The opposite was seen in this study with hospitals giving less information to the subjects questioned. This may reflect the pressure on junior doctors' time, with the result that discussing issues with the patient is not possible. It may also be an indictment of consultant ward rounds in which patients are discussed as cases, rather than being a discussion involving the patient. However, in-patients may be acutely unwell and therefore unable to make these important choices. In addition, a patient who is considering different options may be blocking a bed, which may be required by another patient who is more unwell.

Patients may feel their family general practitioner is someone they know well, possibly building a relationship over many years, and is therefore viewed as a helpful source of information. Hospital doctors may be new to them, consequently they may feel inhibited about asking 'too many questions'. In addition, the hospital may be seen only as a place where diagnoses are made and treatment prescribed; any changes will be explained to them by their GP on discharge. Such an expectation may inhibit the asking of questions. In addition, a hospital doctor may explain their actions but, because the patient is unwell or uncomfortable about requesting clarification, this information may not be understood. Details of a new diagnosis may attract the patient's attention and cause them to miss advice regarding treatment.

In other studies, only 50% of patients were shown to get detailed information from their doctor (Hughes, 1998) and patients often do not understand what they have been told (Anonymous, 1992). In the current study, it was not necessary to objectively determine the quality of the information supplied by various doctors. Firstly, it is not possible to measure the information given in a confidential consultation unless recordings are made and assessed. Secondly, and more importantly for the current study, it is the subjects' recall of this information that affects compliance and therefore their subjective report of information supplied was of more use in assessing non-compliance risk. However, the responsibility for non-compliance may lie with the doctor or pharmacist if insufficient information has been given to the patient in a manner understood by the patient (Parkin, 1976; Sweeny, 1989). There is here an opportunity for hospital pharmacists to share the task of explaining medication and discussing patients aspirations and attitudes to prescribed medicines. This will be discussed in more detail later in the chapter.

Reported desire for medication information - does this meet concordance

Despite the above, only six subjects were unhappy with the information they had hitherto received and wanted to be more involved in the decision making process. This point does not seem to be discussed in the published literature. Most papers describing how the provision of information to subjects improves compliance take no account of the patient's desire to be given this information. Some authors

describe how patients' information needs can vary with time and circumstances and that health professionals have not always been good at identifying patients' needs (Entwistle, 2000). However, this same author described how health professionals tend to underestimate people's information needs, a point that does not seem to be borne out by the current study. Many more subjects were assessed as being in need of further information than would have been identified by means of self-report of a desire to have more information or in satisfaction with the information supplied.

All six of the dissatisfied subjects were female. This may reflect the level of independence seen in females as described earlier. For example, Mrs. DT (37DT071022) lived with her son but was self-caring. She was satisfied with the level of information given by her GP but she had difficulty remembering what she was taking and why it was prescribed. She wanted to have greater involvement in making decisions about her treatment. Mrs. JG (39JG070221) lived alone and was very independent and so also wanted to remain involved in the decision making process. This could be achieved by encouraging her to ask her general practitioner more questions about her treatment but also by explaining her wishes to her general practitioner direct. A discussion with the hospital pharmacist could also help her decide what she needed to know in order to facilitate concordance. Mrs. AP (37AP050312), however, was also very independent but she reported that she had not been given any information, and despite reporting subtherapeutic outcomes, she did not want to be involved in making decisions regarding her treatment.

Men are traditionally seen as needing to be in control and taking a greater interest in the technical aspects of a solution - how it works and how to improve its efficacy. However, the current data appear to suggest that in the particular elderly population studied the men did not want to be involved in making decisions about their own treatment. None voiced a desire to have greater involvement in making treatment decisions. This implies that they wished to don the health role of the helpless patient, and to be looked after, rather than acting as equal partners in the decision making process. This may have implications for concordance in the elderly male population.

Neither the reported level of information supplied to subjects, or satisfaction with the information supplied, correlated with overall compliance risk. For example, both Mr. AB (39AB270916) and Mr. WR (39WR030922) were calculated to be at moderate risk of non-compliance. However, Mr. AB reported being given sufficient information by both his general practitioner and hospital doctor; Mr. WR reported that he had not been given any information from either source. Both gentlemen were satisfied with the level of involvement they had in making decisions regarding their treatment and were not judged to have this risk factor.

Perhaps the desire for information shown by patient advocacy groups does not reflect the true desire for information in the elderly population. Although 71% of subjects in the current study were classed as being at risk of non-compliance because of lack of information, only one sixth of these felt this was problematic. In addition, understanding of regime was not affected by the level of information supplied, which implied either that the information supplied was of insufficient quality to improve understanding, or subjects could not remember what information had been given. The latter could be caused by a lack of understanding of the importance of remembering or by general forgetfulness, as described by McGavock (1998). He reported that 50% of patient's couldn't remember what they were told by a doctor.

It is interesting to note that there may be some correlation between the level of information supplied, or with satisfaction with that information, and attitude to medication, although this was not statistically significant. This could be explained because subjects who have been given sufficient information about their medication may be more likely to expect that medication to work. Similarly, subjects who are happy with their medication and feel it is appropriate and efficacious may not feel the need for further information. Conversely, subjects with a low faith in their medication, regardless of efficacy, may have no interest in knowing about that medication. It may be that these two areas can be considered as contrasting aspects of the same issue.

Being involved in making decisions regarding treatment was defined in this study as taking an active role, with the doctor, in deciding what treatment is appropriate and in reviewing whether it continues to be required. However, a number of subjects wanted to know what they were taking and why, but when asked whether they wanted to have greater involvement in making treatment decisions they said they were happy to trust their doctor.

A patient wanting to leave all decisions regarding treatment to their doctor is incompatible with concordance. Some subjects in this study may have had some prior involvement; however, the majority claimed not to be involved and to be satisfied with that. This may be due in part to fear, as they often come into a consultation with no prior knowledge and therefore would find it difficult to assist with devising a treatment plan. In the current study, the reason for this lack of enthusiasm with respect to involvement with decision making was not possible to identify. Many subjects did say that they would rather leave all decision making to the doctor. This may have been out of a desire not to upset the doctor or to end the consultation quickly, without any intention of carrying through the treatment course. However, most of these subjects did want to comply with their treatment, even if outside influences and other problems caused them to unintentionally fail. This was a case of intentional non-concordance rather than intentional non-compliance.

It is also possible that these subjects said they did not want to be involved because a treatment decision had already been made and they did not want to cause a problem. If this were the overriding rationale behind the stated position, a difference would be found between those who were satisfied with their medication and those who wanted the doctor to review it. This did not appear to be the case, and so this hypothesis does not seem to be active here. The subjects' judgement as to the efficacy and appropriateness of certain medicines differed from the doctors. This may reflect the fact that in general, members of the public who are not medically trained have limited ability to assess the risks and benefits of certain medicines and an otherwise competent individual may be prevented therefore from making an informed decision. However, it may reflect the fact that because the doctor did not discuss their medication with them they had no way of knowing how to interpret the results they see. Work should be carried out on developing simple but accurate information on

the relative merits of different medicines. As this task is so vast it would probably be best undertaken by the Medicines Information Pharmacists Group, a national organisation which co-ordinates medicines information within the National Health Service.

Health professionals need to supply certain information to patients; however, this need does not necessarily coincide with their patients' desire for that information. Unless elderly patients can be encouraged to take a more active interest in their medication then concordance may be difficult to achieve in this group.

Other barriers to concordance in the elderly population

Concordance was introduced as a concept because it was shown that patients who agree with the therapy prescribed and who feel in control of their condition are more likely to comply with the prescribed treatment (Conrad, 1985). Also, making such fundamental decisions about medical treatment can be seen as a basic human right. However, there are many situations when concordance is limited or impossible to achieve. The general application of such a concept is therefore restricted and may prove only to be of theoretical value. In the first instance, concordance itself is innately difficult to achieve because it involves a significant paradigm shift. Concordance tries to remove the paternalistic imposition of compliance with the doctor's wishes, and replace them with an agreement between the prescriber and the patient. Secondly, there may be accidental or unintentional barriers to achieving concordance.

In the current study, the first barrier to concordance encountered was that of communication between the subjects and the medical professionals. The hospital doctors generally failed to give subjects any information about their medication. This may have been because the prescriber did not agree with the concept of concordance and failed to give the patient sufficient information to be able to make an informed decision or did not allow the patient to be involved in the decision making process at all. Whether either of these were active in this situation or whether an oversight occurred, it was not possible to assess.

The doctors may have felt that the information they supplied was of a sufficiently high quality to be useful to the subjects but poor communication skills inhibited their ability to convey this information. Both the quality of the information supplied, and the specific facts that are conveyed, are important in achieving concordance; this has previously been discussed. Communication skills must be developed if doctors are to be able to communicate sufficient information of a suitable quality to enable patients to make the important decisions expected of them in achieving concordance (Anonymous, 2000a). However, the need for further development of the knowledge base of doctors on therapeutics, diagnosis, etc., and the limited time available within the undergraduate degree, may limit the extent to which teaching of communication skills to medical students can develop. A further problem imposed on the consultation is time restriction; this has been discussed earlier in this chapter. A lack of opportunity to discuss medicines will, by definition, reduce the ability to achieve concordance.

Doctors are by definition professionals in healthcare. They are highly trained in diagnosis and selection of appropriate therapies. The majority of patients, however, will have no prior knowledge of appropriate treatment and the relative benefits of individual medicines over others. It remains difficult for these two parties to agree together to follow the choice of the less expert party, as the patient may encounter difficulty in understanding the intricacies of the differences between proposed treatment options without a detailed explanation.

Six of the subjects interviewed had a very low AMT score (5/10 or less), that would generally be associated with an inability to make decisions about appropriate treatment. Concordance would not be possible with these subjects, as they would not be able to have a sufficient grasp of the issues involved to make an informed decision. This raises the interesting question of whether treatment should be withheld from such patients until they are in a position to undertake concordance. Alternatively, would concordance be required in order to make a decision to withhold treatment? The prescriber must take into consideration whether ethically the good of giving a specific treatment to a patient, who cannot be considered

competent to make an informed decision, overrides an infringement of the patient's human rights to choose whether to accept or refuse treatment.

The approach we have termed prescriber focused therapeutics is generally accepted to be justified for patients who are not expected to regain competency. Concordance is especially problematic for patients with dementia or those with learning disabilities. Patients who have been sectioned under the Mental Health Act can be forcibly given medication which has been prescribed to reduce the risk of self-harm or danger to others. In this situation an act of parliament has exempted these patients from the benefits of concordance. However, it is worth considering whether patients with similar conditions, who have been shown to exhibit diminished responsibility but have not been sectioned, should be involved in making decisions about their treatment. It is possible that such a decision would not be an informed, logical decision.

Circumventing the obligations of concordance can also be justified for patients for whom treatment is the only means of regaining competency, for example an elderly person with a urinary tract infection that is causing confusion. In conditions such as coma and patients who are heavily sedated in theatre or in an Intensive Care Unit, it would not be possible to discuss the various treatment options prior to commencement of therapy. A similar difficulty occurs with acute life threatening situations, for example in an Accident and Emergency department. However, if the patient is expected to recover competency spontaneously, should treatment be imposed before they have an opportunity to make an informed contribution? Many may argue that this situation is ethically unsound.

It is in these circumstances that the doctor must decide whether making a decision without reference to the patient is appropriate or whether the next of kin should take the place of the patient in making treatment decisions. Although this may allow concordance to be achieved it is still possible that if the patient regains consciousness that they may disagree with the decision made. This therefore introduces the interesting dilemma of who takes the responsibility for the decision if it has been made as a result of concordance: the doctor or the next of kin? This is especially pertinent if the action taken was contrary to evidence based medicine.

Most hospitals have formularies, a list of medicines available for prescribing within the hospital, often with prescribing guidelines. These formularies are decided on by individual hospitals but the NHS executive prescribes their existence (Anonymous, 1994). The National Institute for Clinical Excellence (NICE) also imposes decisions on prescribers. In a fully concordant consultation the prescriber would recommend a number of medicines but the patient would have the freedom to choose any of these, an alternative treatment not recommended but which they felt was more appropriate, or no treatment at all. Hospital formularies limit this choice to one or two (occasionally more) medicines within each class. On rare occasions no drugs from a particular class may be offered. It is generally hoped that these formularies take into account evidence based medicine, unfortunately this still limits concordance as the patient is not given a free selection of all possible treatments and a patient who wishes to use an alternative therapy may be refused.

In addition to these prescriber-based limitations, there are a number of patient-centred barriers to achieving complete concordance. The patient may not want to be involved in making a decision or may agree to something, out of a desire not to upset the doctor or to end the consultation quickly, without any intention of carrying through the treatment course. Additionally, the patient's ability to assess the risks and benefits of treatment with certain medicines may limit concordance. The patient may have been given sufficient and appropriate information and may understand why treatment is required and some of the potential adverse effects, but still be unable to judge the appropriate action to take. Risks are interpreted differently by doctors and patients. The patient's understanding of the severity and risk of deterioration and possible consequences of the condition under treatment will affect their ability to make decisions, making objective judgement difficult. The effect of feelings of vulnerability to disease and adverse effects has been discussed in previous chapters. These fears and attitudes must be taken into account by the prescriber when making therapy decisions but are relatively simple to identify. More difficult to address in trying to achieve concordance is a patient's understanding of the benefits of treatment.

Some patients will want a complete cure and will not accept failure; others would be happy with minor symptomatic improvement. These two scenarios could be quite easily explained to a patient and they could decide which they were willing to accept. However, other grey areas of medicine are much more difficult for patients to contend with. A doctor or pharmacist may have the ability to deal with statistical probabilities of therapeutic success but these may be too complicated for a patient with no scientific or medical background to understand as they often need to combine a number of risks and benefits.

Many decisions can be simplified into an understandable risk, for example, a 50% chance of a complete cure. However, in order to achieve concordance a full grasp of the implications is required. For example, Drug X may not provide a complete cure but may control symptoms in 50% of cases and prevent deterioration; however, in 20% of cases it has to be stopped because of severe side effects. Drug Y may have a cure rate of 10% but provide adequate control in a further 55% of cases but also has a withdrawal rate due to adverse effects of 20% and requires regular blood tests to avoid other toxic effects due to a narrow therapeutic range. Such scenarios are common but are difficult to interpret.

Concordance cannot be achieved once and then forgotten, it is a process which should continue throughout the course of the disease. However, patients may not be able to make informed decisions if they do not understand how to interpret the success or otherwise of a specific medicine. This inability to interpret outcomes may be due to a lack of clarity in those outcomes. For example, the outcome of a course of steroid inhalers is often not clear to a mild asthmatic as no immediate benefit is felt from using them. Evidence based medicine may indicate the appropriateness of such treatment but this would be less clear to the patient.

The majority of the subjects in this study did not want to be involved in making therapy decisions for reasons which were not always vocalised. Making the subject take part in this consultation process could then be seen as an imposition. Most of the subjects did not want to be kept completely without information, but they did not want to have to use this information to make a decision that they did not feel capable

of making. There are also many other difficulties in achieving concordance. It is an ideal to aim for but is often limited.

How should information be offered?

To achieve concordance

In order for patients to take full part in concordance, a number of issues must be addressed: the various treatment options must be discussed with the patient and they must be assisted in assessing the risks and benefits involved and interpreting outcomes. Unless patients are offered a concordant consultation it is not possible for concordance to be achieved. The prescriber follows a decision making process that results in the prescribing of particular medicines; within concordance the patient must be involved at an early stage, i.e. from the moment of diagnosis.

If a patient wants a concordant consultation then the health professional must make every attempt at accurately but simply describing why treatment is necessary, the various treatment options available, and the merits and risks of each. Time must be provided for the patient to decide which option to take, which may involve a second appointment at a later date. At this point providing written information for the patient to take away and consider may be appropriate. This can take the form of product information leaflets, material provided by self-help groups or other information provided by the doctor.

If a patient decides that they do not want to be involved in making decisions about their treatment, the health professional must respect their decision, but still provide appropriate information about the choice that they have made. It is the responsibility of the prescriber to ensure that the reasons for this lack of willingness to participate are investigated; some of these reasons have been discussed above. However, patients often do not comply because of their attitude to medication (Griffith, 1990). Barriers to compliance may include a feeling of invulnerability to the disease and the inconvenience of taking tablets (Misselbrook, 1988b). The health professional must try to understand what the patient believes and attempt to explain the relative risks and benefits of treatment compared with non-treatment.

Decreasing fear, frustration or resentment towards illness can improve compliance (Lorenc, 1993). Sometimes these opinions have been formed with reference to outside influences such as the media, friends and relatives and previous experience (Lorenc, 1993). Increasing family member understanding and support can improve compliance (Moriskey, 1986). To meet these problems concordance is the only solution. It is worth remembering that in some studies up to 85% of patients strongly believed that medicines were necessary for good health (Anonymous, 1997b). However, this figure may vary depending on social background.

New prescribers (Department of Health, 1999b) such as nurses and pharmacists may find concordance difficult to achieve as they will generally be prescribing from a limited formulary. The limitations that are imposed by formularies have already been discussed. Nurse prescribers may find involving the patient in the prescribing process easier than many doctors, as nursing roles have traditionally been more patient-centred than doctor's roles. However, these nurse prescribers may not have sufficient depth of knowledge of the medicines they prescribe to be able to explain them satisfactorily to the patients they care for. Prescribing pharmacists should have greater capability to explain the various treatment options to patients than nurses. Hospital pharmacists in particular are trained in evaluating the appropriateness of treatment decisions and are experienced in explaining prescribed medicines to patients. Ensuring that concordance is achieved when making treatment decisions may therefore be easier for a pharmacist.

The main focus of concordance centres on the initial consultation between the prescriber and the patient. Until pharmacists become independent prescribers, there will be little scope of developing this role (Anonymous, 2000a). However, hospital pharmacists are being encouraged to be pharmaceutical care practitioners (Hepler, 1990) and are expected to assess and meet pharmaceutical needs. Concordance will flounder if all members of the healthcare team are not actively delivering the same message. The pharmacist therefore has an important role in maintaining a concordant relationship with the patient (Sanghani, 1998). A pharmacist needs to be a professional who understands medicines and their risks but are accessible when the public requires advice (Anonymous, 2000a). Hospital pharmacists can also act as a

reference source for prescribers and help identify those patients with whom concordance was not achieved.

During a consultation, certain types of questions must be asked of the patient and particular information given to the patient in order to enable the patient to answer them. The patient should be asked primarily if they want any treatment at all, with the proviso that in certain conditions, such as schizophrenia, the necessity for treatment must override the patient's wishes. However, in general, in order to answer this question the patient must have explained to them all the possible consequences of refusing and accepting treatment. The prescriber must respect the various fears and aspirations of the patient and understand that these are specific to that patient, with large inter-individual variation. These dictate that the most appropriate treatment option may be different for each patient presenting with the same condition.

Once the decision to treat is made then a number of treatment options should be described to the patient. The benefits and risks of these options must be explained and the patient assisted through the decision making process. Once treatment has been initiated then it should be reviewed regularly. For concordance to be continued then the patient must be given opportunity to continue with the same medication, change to an alternative medicine, or stop treatment. The patient must also be given assistance in interpreting outcomes as patients often attribute outcomes erroneously; this can be addressed and an appropriate review made. This phase in concordance in particular is suitable for a pharmacist to provide assistance: patients may give valuable feedback when picking up repeat prescriptions as an informal discussion may allow the patient to volunteer their true opinion of the treatment.

To achieve compliance

There are a number of reasons why health professionals believe that patients should be given good quality information about their medicines. Firstly, a patient who understands what is required of them will find it easier to comply with the advice. Secondly, a patient for whom the advice makes sense to them, in the light of their own perceptions of the illness, is more likely to follow that advice. Concordance is

based on the premise that patients are more likely to comply if they have been involved in the decision making process; this seems to be born out by experience (Anonymous, 1997b; Mazzuca, 1982). Also, we have discussed how mistaken beliefs about efficacy and side effects can reduce compliance and addressing these mistaken beliefs may improve the patient's willingness to comply and is an essential part of pharmaceutical care (Sanghani, 1998). However, in one study of patients with infections who were given information about adverse events there was no improvement in either compliance rate or outcome (Haynes, 1996).

The content of the information supplied is important because giving extraneous details may confuse the patient and cause them to forget details that are more important. Previous authors believed that general information about medicines should include details of the regime and the importance of following it (Lorenc, 1993); more general information about the condition such as disease progression and complications (Sweeny, 1989); and a description of possible side effects with advice on what to do if they occur (McGavock, 1998). Concordance also dictates that alternative treatment options and the relative merits or demerits of each should also be given (Misselbrook, 1998b).

Providing all the information described above can be complicated and time consuming. Even simple medicines, which can be bought without a prescription, can have multiple adverse effects, be dangerous when taken with other medicines and require close monitoring for some patients. The choice of what information to give and what to omit poses a dilemma. It is also important to consider that if a patient has been newly prescribed three or more different medicines, as may be the case in a newly diagnosed asthmatic or a patient who has recently suffered a myocardial infarction, then the amount of information required could be prohibitively long. Patients with no underlying levels of confusion, and prescribed simple regimes, will probably be able to cope with a greater proportion of the available information for each medicine than clinically confused patients with complicated regimes could cope with. It is probable that the greater the variety of verbal directions given for a regime then the harder it will be for the patient to be able to follow it without other written reminders.

When deciding what information to give to a patient then a number of factors must be considered: the level of involvement with decision making that the patient wants; the most important things you need to convey to the patient; the patient's level of understanding; the patient's desire for further information and any time constraints imposed on the patient and the health professional.

Considering the latter point first, if the patient has an ambulance waiting or has another engagement, for example, needing to pick up children from school, there is little point in spending lots of time discussing their medicines with them when handing them out. This is a scenario that often presents to hospital out-patient dispensaries and on discharge from hospital. Patients in a hurry are unlikely to remember what they have been told because they will be preoccupied with getting away as soon as possible. Similarly, a patient in such a situation is unlikely to give feedback, which is important in determining whether they have understood the information given or whether they have any unresolved fears and unmet expectations. In this situation it may be better to provide written information and an opportunity to discuss any issues at a later date. This written information could take the form of a medicines information sheet such as that in Appendix II, product information leaflets, which can be found inside the majority of manufacturer's dispensing and patient packs, or other leaflets that can be produced by a pharmacy department.

In the hospital situation it may not be convenient for the patient to return to the pharmacy for further discussion. However, patients can be referred to community pharmacists or practice nurses, or can be provided with a telephone number, which they can use to speak to the pharmacist at a later date. With the development of the Internet it may also be possible for electronic helplines to be created in order to provide this service. The role of the community pharmacist is particularly important. In addition to explaining what the new treatment is for and when to take it, they are in an ideal position to allow the patient to provide feedback on the efficacy of treatment and whether they continue to be satisfied with it.

If the lack of time is on the health professional's side then this poses a more of a strategic problem and must be tackled. It is unacceptable to leave a patient with genuine concerns and worries and not attempt to deal with them. Workload should be rearranged to ensure that patients can be provided with the time and attention they need, to ensure that they receive all the information they require. If a health professional is finding that lack of time is causing such a difficulty, then this may be symptomatic of the low priority that such interaction with patients is held within the organisation or department.

If there is no externally dictated time limit to the consultation it is tempting to provide the patient with all possible information about their medication; however, this may be self-defeating. It is better to give small amounts of important information over a period of no more than, say, ten minutes and repeat it frequently at subsequent consultations. If the information is repeated consistently by all health professionals caring for the patient, he is more likely to remember what is required (Moriskey, 1986). Patients tend to forget 31-71% of what they have been told but this reduces to 18-33% on repeated telling (Ley, 1982). This has been attempted in a number of ways: making a telephone call in the first week after prescribing a new drug (Anonymous, 1997b); the pharmacist counselling patients on discharge or when new drugs are prescribed (Sweeny, 1989); visiting patients at home (Smith, 1983) and involving specialist nurses in conditions such as diabetes. This repetition can also be achieved by providing the patient with written instructions to read in their own time in addition to the verbal instructions given during the consultation (Haynes, 1996; Lowe, 1995; Sweeny, 1989). It is important to remember that the quality of this written information is as important as that of the verbal information if a patient is to be able to follow it. Good quality reminders have been shown to improve both compliance and therapeutic outcome in asthma and infections. In epilepsy, however, such interventions improved compliance without a significant improvement in outcomes (Haynes, 1996).

Patients often do not take their medicines because their faith in the doctor or the treatment that he has prescribed is low. This may be exacerbated if the doctor fails to consult the patient about treatment options and gives insufficient information, thus causing the patient to be dissatisfied with the doctor (Anonymous, 1999;

Anonymous, 2000a; Ley, 1982). A lack of information from the doctor may cause the patient to conclude that the doctor also has little faith in the medication, thus reducing the patient's determination to follow the treatment plan (Griffith, 1990). This is particularly a problem for patients with a high demand for control who may be finding a way of exercising control over his disorder and find difficulty in coming to terms with their illness (Anonymous, 1992; Misselbrook, 1998a). Compliance has been shown to be related to the quality, duration and frequency of the interaction of the patient and doctor (Moriskey, 1986) with short impersonal consultations resulting in the lowest levels of compliance (Griffith, 1990).

It is important to remember that the label on the tablet bottle, etc., is a source of information. Pharmacists must ensure the labels on medicines clearly state the correct instruction in a form easily read and understood. This is easier with printed labels; hand-written labels should never be used. Similarly, labels stating 'Take as directed' are inappropriate as these give no guidance to the patient. Patients dislike these labels (Griffith, 1990) but it is much easier for prescribers to write 'as directed' on the prescription, especially for repeat prescriptions, which may be written by a doctor who does not know the patient. However, it is essential that prescribers put full instructions on the prescription so that the pharmacist can label the container clearly. This should not be difficult in general practice where most records are computerised and details of dose and frequency can be entered when the treatment is initiated and repeated at the press of a button when repeats are required. Efficient use of technology can improve patient care.

The content of the information will vary from patient to patient and with different drugs and combinations of drugs. A patient who has no comprehension problems and who is prescribed only one simple medication will probably only need to be told: what condition the medication is for, how and when to take it and any side effects which it is important for them to watch out for (or common side effects which they can ignore). If the patient wants further information, then questioning about specific concerns is essential. Giving extra information that has little clinical value and of little interest to the patient merely increases the risk of forgetting important information.

When regimes are reviewed, it is important to ensure the patient does not continue with discontinued medicines. Hoarding of these old medicines may lead to non-compliance (Parkin, 1976). This may be removed by asking patients to hand in old medicines on admission to hospital or when they visit their GP. Complications may still occur if patients are reissued the same drug but in a different brand if they do not realise they are the same medication and only one should be taken. Ensuring that the information supplied does not only include advice about new medicines, but also about current and discontinued medicines can prevent therapeutic failure and interactions.

Patients who do not want to receive any information about their medication are a particular concern. One would assume that most patients would want to know whatever information they were offered regarding medical treatment. We have already discussed the special case of patients who have insufficient time to spend discussing their medicines with a pharmacist. However, a small number of subjects in the current study did not want to be given any information. This was generally associated with a high risk of non-compliance: namely, the subject did not want to be told anything because he didn't want to take anything. This may have been symptomatic of the fact that the prescriber had not attempted to achieve concordance. The second group of subjects who did not want to be told anything about their medicines were reliant on a spouse to remember when to take their medicines. For these subjects, talking to the spouse would have been more helpful. However, patients who do not want to be told anything about their medicines may also be afraid that it will be too complicated to understand or give information they do not want to hear ('bad news').

Taking medicines incorrectly reduces their efficacy and may be a cause of toxicity. It is therefore important that patients have a chance of taking them correctly and this often includes giving extra information in addition to that provided on the label. The literature that describes the effect of extra information does not use objective measures and often describes multiple interventions; it is therefore difficult to tell which causes the greatest improvement (Haynes, 1996). It may be that simply spending more time with the patient and showing an interest in their condition and response improves their likelihood of complying. This is known as the Hawthorne

effect (Smith, 1983). Interventions that simply deal with improving knowledge have a success rate of 64%, whereas behavioural strategies have a success rate of 85% (Mazzuca, 1982).

The author suggests that a minimum level of information should be given to all patients. This would include the condition the medication is prescribed for, the frequency and method of administration and the likely length of the treatment course. If there are any other important aspects to treatment (for example regular blood tests) these should be mentioned. This will give the patient the minimum information they require in order to be able to comply. However, as with all patients, they should be asked if they have any further questions about anything to do with their treatment, as sometimes patients do not vocalise their concerns and opinions (Stevenson, 2000).

Patients have a right to know what they are being prescribed and the reason. They also have a right to be involved in the decision-making process. However, they must also have the ability to forgo this right without any loss of respect or increase in preventable risk. Health professionals must try to meet the individual needs of the patients they care for and ensure that where the patient implicitly trusts the health professionals to make the correct decisions then they will find this trust well founded. Hospital pharmacists in particular can play an important role in ensuring that patients are offered the most appropriate treatment and are satisfied with that treatment and the information they have been given.

Chapter 8: Addressing the problem of Polypharmacy

Introduction

Polypharmacy was found to be a problem for most subjects in the study and is problematic for many elderly people (RCPWP, 1997; Reid, 1997). Polypharmacy is used to describe the administration of too many drugs in one prescription (Thomson, 1974), although the exact number of drugs which would cause problems would be different for each patient and is dependant on their ability to cope. Different authors disagree on whether three or five drugs constitute polypharmacy (Anonymous, 1991b; McGavock, 1998; Royal College of Physicians Working Party, 1984) although all agree that more than five drugs constitute polypharmacy.

Parkin (1976) described a study in which 8% of patients taking two drugs did not comply. This rate increased to 42% in patients taking four or more drugs. Sweeny (1989) showed a similar drop in compliance, although patients showed significantly higher rates of non-compliance at all levels, for example, 67.5% for patients taking two drugs. Polypharmacy can lead to non-compliance in two ways (Royal College of Physicians Working Party, 1997; Reid, 1997; Wandless, 1977). Unintentional non-compliance has been shown to be related to the number of drugs prescribed due to forgetfulness and confusion. Polypharmacy may also cause intentional non-compliance; patients with large numbers of prescribed medicines may selectively take those they think are important and omit the rest, or deliberately stop taking a drug they erroneously blame for adverse effects.

Patients taking drugs which have been prescribed as once or twice daily doses exhibit much better compliance than those prescribed three or four times a day doses (Eisen, 1990; Griffith, 1990; Parkin, 1976). For example, Hughes (1998) quotes rates of medication errors of 15% for once daily dosing and greater than 35% for doses of four times a day or more. The knowledge of drugs also decreases, from 75% for a once daily dose, to 40% for four or more times a day. No significant difference has been shown between once and twice daily dosing (Anonymous, 1991b).

Polypharmacy may be the result of a failure to review and discontinue unnecessary medication. However, the reason for polypharmacy can be different in each case and may cause different levels of complication for different individuals. In addition to the detrimental effect on compliance, polypharmacy is potentially problematic because it increases the risk of adverse drug reactions and drug interactions (Hughes, 1998; Ley, 1982).

One example of a patient with polypharmacy was Mrs. LG (37LG061012). This 88 year old woman was admitted taking eleven different medicines. Table 8i indicates the medicines she was admitted taking and the changes made to her treatment.

Table 8i: Changes to medication for Mrs. LG (37LG061012)

Medicine on admission	Reason for prescription	Outcome
Gliclazide 40mg daily	Diabetes	Continued
Aspirin 75mg daily	Anti-platelet	Changed to warfarin daily
Isosorbide dinitrate 20mg three times a day	Angina	Changed to isosorbide mononitrate MR 60mg daily
Atenolol 100mg daily	Angina/hypertension	Continued
Frusemide 80mg daily	Ankle oedema	Continued
Calcichew D3 Forte® 2 daily	Osteoporosis	Changed to Adcal D3® 2 daily
Cimetidine 400mg twice a day	Gastric acid	Changed to ranitidine 150mg daily
Betahistine 16mg three times a day	Unknown, possibly dizziness	Stopped
Mebeverine 135mg three times a day	Unknown, possibly irritable bowel	Continued
Glyceryl trinitrate spray 2 puffs when required	Angina	Stopped
Tramadol 50-100mg when required	Pain	Stopped

Mrs. LG was prescribed 11 different medicines on admission. Her reason for admission was a fractured neck of femur, which was not thought to be drug related. During her admission a number of changes were made to her treatment. Mrs. LG's angina was not completely controlled and so her isosorbide dinitrate was changed to isosorbide mononitrate, a preparation which is slightly more potent, but also has the

advantage of being available as a modified released preparation which can be taken once a day.

Mrs. LG had been prescribed betahistine for a number of years but had no documented requirement for this medicine, it was therefore stopped. Tramadol was prescribed prior to admission because of pain. Treating her fractured neck of femur with a replacement hip reduced her pain and so it could be stopped. This was important to achieve before discharge otherwise Mrs. LG could be discharged on a medicine that could cause drowsiness, confusion and constipation. The reason for pre-admission prescribing of mebeverine was unknown, however, as it has few side effects, the doctors were reluctant to stop it. This could affect compliance therefore this may be classed as mismanagement.

Mrs. LG had had a previous myocardial infarction and on review the doctor decided that she would benefit from warfarin as aspirin would be insufficient to prevent future thrombosis. Cimetidine was prescribed to reduce gastric acid, it would also protect against gastrointestinal bleed which may be exacerbated by warfarin. However, cimetidine inhibits the metabolism of warfarin and can lead to an increased International Normalised Ratio (INR) which is a measure of warfarin efficacy and toxicity; such an increase can lead to uncontrolled bleeding. Ranitidine was therefore prescribed as this does not interact with warfarin. The dose was also altered to a bedtime only, because protection from gastric acid was not required by Mrs. LG during the day as she had no symptoms of dyspepsia.

Certain medicines remained the same throughout Mrs. LG's time in hospital. These included atenolol, frusemide and gliclazide. Calcichew D3 Forte® was changed to Adcal D3® simply because the latter was the hospital formulary choice. This was required to prevent further fractures and the high risk of mortality and morbidity that can follow from hip fractures.

Because of the changes described above Mrs. LG was discharged taking eight different medicines at three different frequencies; there were changes to seven of her medicines. Mrs. LG had an Abbreviated Mental Test score of 5/10 and was confused about her medicines on admission. She could only explain what one was

prescribed for and knew the dose or frequency for only five medicines. It was therefore unlikely that she would be able to take her new prescription safely on discharge and she was supplied with a Medidos®, which would be filled on a weekly basis by her pharmacist.

Polypharmacy can cause significant problems, but cannot always be avoided. Mrs. LG exemplified this. In this chapter, the causes of polypharmacy for the subjects in this study and the possible options to avoid or remedy the problem will be discussed.

New treatment prescribed

The most obvious way that polypharmacy occurs is when a patient presents with a new condition that requires new medication; this often cannot be avoided. Medication is usually required when the consequences of not treating the new condition are potentially serious. For example, a patient with angina who is not offered treatment is at high risk of developing cardiac problems of a more serious nature and may suffer from a fatal myocardial infarction. However, if new medication is prescribed then the risk of non-compliance will increase.

Mr. LO (37LO090524) was a 76 year old male who had been admitted after a fall. He was admitted taking three different medicines, but was discharged with nine. Table 8ii shows the changes in his treatment and the reasons.

Prior to admission, Mr. LO visited his doctor infrequently and this admission saw the diagnosis of a number of new conditions. Dose adjustment was required for the medicines he was taking on admission to ensure effectiveness. All of the new conditions that were diagnosed for Mr. LO were mutually exclusive, so different medicines were required for each condition. For example, during the fall that he sustained prior to his admission to hospital, he fractured a bone in his arm; he therefore required analgesia. This was introduced in a complicated regime, four times a day dosing, but would be possible to stop when his armed healed. Although he was still taking both analgesics at his 14-day follow-up, the codeine had been stopped at 3 months.

Table 8ii: Changes to medication for Mr. LO (37LO090524)

Medicine on admission	Reason for prescription	Outcome
Aspirin EC 75mg daily	Anti-platelet	Continued
Salbutamol inhaler 2 puffs three or four times a day	Chronic obstructive airways disease	Changed to four times a day
Beclomethasone 100mcg/puff inhaler 2 puffs three or four times a day	Chronic obstructive airways disease	Changed to 200mcg/puff inhaler 2 puffs twice a day

Medication added on discharge	Reason for prescription
Lactulose 10ml twice a day	Constipation
Paracetamol 1g four times a day	Pain
Didronel PMO® 1 tablet daily	Osteoporosis
Codeine 30mg daily when required	Pain
Phenytoin 300mg at night	Epilepsy
Zopiclone 7.5mg at night	Insomnia

The reason for the fall was investigated on admission and epilepsy was found to be the cause based on clinical and EEG findings. Mr. LO was also found to have osteoporosis, which increases the risk of fractures. Both of these conditions required treatment to ensure that he did not suffer any further increase in morbidity and so phenytoin and Didronel PMO® respectively were prescribed.

Many patients who are admitted to hospital develop constipation and require laxatives. In addition, Mr. LO was prescribed codeine: an opiate analgesic which causes constipation. Lactulose was added to treat this. Similarly, insomnia is common in hospital and zopiclone was added to aid sleep. Both of these should be short-term therapy and should be stopped soon after discharge. Adequate medication review in primary care should identify when these could be discontinued.

Sometimes non-drug therapies can be offered to patients when new conditions are diagnosed. For example, counselling may help with some cases of anxiety or depression and thus avoid the need for antidepressants. In other conditions physiotherapy, hydrotherapy or an exercise regime may reduce pain and inflammation and negate the need for analgesia. In other cases, dose adjustment of current medication may be sufficient. Ensuring that evidence based medicine is applied to the situation, and the treatment regime is reviewed prior to prescribing a new medicine, then polypharmacy can be avoided in many cases.

Requesting inappropriate medicines

Sometimes, however, patients request medication when the evidence in the medical or scientific literature and the prescriber's experience advises against a prescription. This is particularly a problem with overuse of antibiotics; this may reflect patient demand (Linder, 2001). Many people have come to depend on antibiotics and so request them for viral infections, conditions which are not treatable by antibiotics. Although in this case any resultant polypharmacy is short-lived and ceases when the course is complete, such over-use of antibiotics can cause problems such as the build up of resistance in the bacterial population which may lead to treatment failure in future uses of that antibiotic.

In the study population, nobody demanded unnecessary antibiotics, however a number of subjects did request apparently unnecessary medicines, examples of which follow. The consequences of non-compliance in such a scenario may be greater than in the case of appropriate treatment being added to a patient's regime. In the latter case, if the patient decides to discontinue a particular medicine, or forgets to take one, then the remaining medicines are all required and some therapeutic benefit will be achieved. If a patient requests an inappropriate medicine then it is possible that this medicine will be continued and any discontinuation or forgetfulness will affect another medicine which is possibly more necessary for therapeutic control.

Mrs. MC (39MC080425) was admitted taking seven different medicines with four different frequencies. Mrs. MC was fairly happy with her medicines but was not sure if she needed a change in her Parkinson's Disease treatment. She also did not think her antidepressant was working, but despite this she did not want to stop it and refused to have her sleeping tablets reduced, despite understanding the risk of dependence. Mrs. MC was happy to accept all assistance offered except prescription review. She was worried that in stopping some of her medicines some apparently unrelated symptom would return. She disliked taking seven medicines, but dare not stop any of them. There is little which can be done in this circumstance except

ensuring that the decision has been made by the patient after consideration of the full facts, that is that concordance has been achieved.

Mr. WR (39WR030922) reported being 'very happy' with his medicines but he wanted a nebuliser to replace his inhalers because he wanted to 'make sure everything was OK'. However, he thought his medicines were working and this was not the reason for his desire for a change. Nebulised therapy for asthma is appropriate for patients with severe symptoms. However, this can introduce adverse effects which are not present for standard inhalers. Mr. WR was controlled on aerosol inhalers and was therefore not prescribed nebules. The reason for this decision was explained and he reluctantly agreed to try the inhalers for a further period of time.

There are various methods of reducing the likelihood of patients requesting inappropriate medicines; most of them involve patient education. This can be achieved by introducing concordance into the consultation and by providing advice and information as described in Chapter 7. National advertising campaigns have been used in the case of inappropriate requests for antibiotics and may be effective for other therapies (Anonymous, 2002; Regional Drug and Therapeutics Centre, 1999). However, each patient is different and may request different medicines depending on their experience and that of their friends or relatives. It would not be possible therefore to address all problems of patient demand using national advertising campaigns.

One area in which such advertising appears to have failed is in the area of single component vaccines to cover measles, mumps and rubella as alternatives to the MMR vaccine. Despite scientific and government reassurance that the combined MMR vaccine is safe and effective, public opinion appears not to believe this and views it as propaganda. It is interesting to consider that for concordance to be achieved, as discussed in Chapter 7, then the patient must be able to have a free choice of any medication, including ineffective medication, if that is what they wish. The only limitation is that the patient has been given sufficient information to make an informed decision. It is arguable therefore that the majority of parents requesting single component vaccines have been given sufficient information to be able to make

such an informed decision and concordance would therefore dictate that this is what should be prescribed.

Polypharmacy is difficult to avoid for patients with multiple conditions with mutually exclusive treatments. However, it should be avoided wherever possible by medication review, using alternative therapies and avoiding prescription of unnecessary medicines.

Failure to review medication

Polypharmacy often occurs because new medicines are prescribed and old medicines are not discontinued. We have already commented on the problem of restricted consultation time (Sanghani, 1988). It is not always possible for a general practitioner to review all of a patient's medication during one consultation. Often the patient has limited time but also the GP has other patients waiting to be seen. It is usually only possible to consider the treatment of the presenting complaint and leave other conditions, which are apparently under control, until they require attention. This may mean that a patient is receiving subtherapeutic treatment, which is not reviewed, because the patient does not understand that something can be done. Alternatively, the patient may be suffering unnecessarily with side effects, which could be avoided by using an alternative medication.

Although all the conditions Mr. GW (37GW281024), aged 76, was being treated for were still requiring treatment, his doses and choice of medicines were no longer appropriate. Table 8iii shows the changes instigated to optimise his treatment.

Trifluoperazine has a long half-life and therefore can be given once a day. It was unknown why Mr. GW was prescribed it twice a day on admission. Similarly, prednisolone should be taken as a single daily dose with breakfast to reduce adverse effects. The opposite applied to mesalazine, which should be taken three times a day, Mr. GW had therefore been receiving a sub therapeutic dose. All three of these medicines were prescribed at inappropriate doses and had not been reviewed.

Table 8iii: Changes to medication for Mr. GW (37GW281024)

Medicine on admission	Reason for prescription	Outcome
Trifluoperazine 5mg twice daily	Schizophrenia	Changed to 10mg at night
Cimetidine 800mg at night	Gastric acid	Changed to lansoprazole 30mg daily
Codeine phosphate 30mg four times a day	Pain	Stopped
Prednisolone 1mg four times a day	Inflammation	Changed to 5mg daily
Benzhexol 5mg twice a day	Unknown, possibly an adverse drug effect	Stopped
Mesalazine 400mg daily	Crohn's disease	Changed to three times a day
Calcium carbonate 500mg three times a day	Osteoporosis	Changed to Adcal D3® 2 tablets daily

Cimetidine is not recommended in the elderly because of an increased risk of confusion and the possibility of drug interactions. This was therefore changed to lansoprazole, a safer and more potent gastric acid-lowering agent. Calcium alone is ineffective at preventing steroid induced osteoporosis as vitamin D is also required. Mr. GW's calcium tablets were therefore changed to Adcal D3®, which contains both medicines.

Mr. GW was also taking two medicines for which the indications were not known. Codeine phosphate is an analgesic, but as Mr. GW was not in pain this could be stopped, with a reduction in constipation, drowsiness and confusion. Benzhexol had presumably been prescribed to treat extra-pyramidal adverse effects, but this was not documented. As benzhexol can cause nausea and postural hypotension this was discontinued. Mr. GW did not experience any adverse effects on withdrawal and so he was discharged without it. Although he still had polypharmacy on discharge, his regime was much simpler, with three different frequencies compared with the six he was admitted with. His regime on admission bore all the hallmarks of a prescription that had not been reviewed recently.

Polypharmacy can also occur if a medicine is discontinued but the prescriber forgets to remove it from the patient's repeat prescribing list. This mismanagement is particularly a problem with patients who have recently been discharged from hospital, when changes made in hospital may not be accurately recorded. The patient may receive both the old medication and the new one when they order a new prescription. If the patient understands what they should be taking they may only order the new medication, but is at risk of taking potentially conflicting medication or toxicity due to overdose. This cause of polypharmacy is particularly addressed within the National Service Framework for older people, with patients over 70 years of age and more than four regular medicines receiving six-monthly repeat prescription reviews (Department of Health, 2001).

Mrs. GE (39GE110815), an 85 year-old woman, was admitted to hospital feeling generally unwell and, although was unsure whether she was happy with her medicines, she felt she needed a change. The hospital doctors confirmed this and the changes outlined in Table 8iv were made.

Table 8iv: Changes to medication for Mrs. GE (39GE110815)

Medicine on admission	Reason for prescription	Outcome
Digoxin 125mcg daily	Atrial fibrillation	Continued
Metoprolol 25mg twice a day	Hypertension	Continued
Lisinopril 15mg daily	Left ventricular failure	Stopped
Frusemide 40mg daily	Left ventricular failure	Stopped
-	Anti-platelet	Aspirin 75mg daily added

Mrs. GE had two medicines stopped because she was found to be suffering from postural hypotension. However, aspirin was added because of the increased risk of thromboembolism for patients with atrial fibrillation. Mrs. GE did not have polypharmacy when she left hospital, however, if the information regarding the stopping of two medicines was not transcribed to her repeat prescribing list then she would be at risk of adverse effects. In particular the postural hypotension that necessitated the discontinuation, which could precipitate falls and possible fractures and subsequently lead to further admissions to hospital. It is important that general practitioners record changes accurately as soon as information is received from the hospital.

The failure to review repeat medication on a regular basis, and particularly immediately after a patient is discharged from hospital, can cause many medication errors and precipitate adverse effects. A solution would be to increase patient: doctor contact time by lengthening consultations. However, it is difficult to imagine how the length of time available for consultation with a general practitioner can be extended unless requests for consultations decrease or the number of general practitioners increases. In the meantime, medication review must become a routine part of the service offered by doctors to their patients, which may require a change in attitude and priority for some clinicians.

The role of pharmacists in medication review

Medication review is possible when the patient is not in the surgery and it does not have to be carried out by doctors. In response to the National Service Framework for Older People, many surgeries are employing pharmacists to carry out these reviews. The pharmacist can access a patient's notes and medication record and decide whether the medication is still required or whether the patient should be requested to attend the surgery to discuss changes that could be made. If pharmacists were dependent prescribers they could make the changes themselves. However, in most circumstances the recommendation is given to the general practitioner to action as soon as practicable.

During pharmacist led medication review sessions hospital discharge letters can be reviewed to ensure that changes are made where appropriate. This information would not routinely be available to community pharmacists and therefore if not followed by the doctor then there would not be any possibility of the error being spotted during dispensing. However, there would be opportunity for a hospital pharmacist forwarding the relevant information to the community pharmacist to ensure that the patient has the maximum chance of receiving the correct medication. The hospital pharmacist has often been involved in advising on dose adjustments and treatment changes and would be in an ideal position to share this knowledge with primary care.

In order to prevent adverse effects and prescribing errors, medication must be regularly reviewed, even for patients on apparently stable treatment. General practitioners and hospital doctors can carry this out, but increasingly pharmacists have been recognised as having a role to play in this important area.

Lack of information

If a medicine is stopped in a medicine review or on discharge from hospital, the patient may still be at risk of polypharmacy. If the patient has hoarded medicines in former years and does not completely understand the reason for stopping certain medicines, then they may continue to take ones which should have been stopped (Parkin, 1976). It is for this reason that patients are often asked to bring all the medicines they may have stored at home to the clinic when a medication review takes place. At this time the doctor or pharmacist can identify which medicines are no longer required and dispose of them safely.

It is important when patients are discharged from hospital, or when the regime is otherwise changed, that they have explained to them what the changes mean and whether they should continue taking previously prescribed medicines or dispose of them. This can be a problem on discharge from hospital (Burns, 1992) or when prescribing generically, as the patient may have other medicines at home which may have different brand names on them and which the patient may believe are different medicines and take all of them, putting themselves at risk of overdose.

None of the subjects in this study were obviously continuing medicines that should have been stopped, but this is difficult to assess as often the other sources of information on drug histories are flawed (Audit Commission, 2001). It is often not possible to clearly identify whether the patient is taking a medicine that they should not be prescribed or whether the GP has failed to record the prescribing of that particular drug.

The treatment cascade

Sometimes medicines can cause side effects, and often these adverse effects can require further treatment. It is important for the prescriber to decide with the patient the best course of action. One suggestion is to stop the medicine that caused the side effects; a second is to add a second medicine to treat the effects of the former. The latter should only be considered if the need for the first drug outweighs the benefits of stopping it to prevent the adverse effect. The second medicine has also the possibility of causing side effects, which may need the addition of a third drug. This procedure can continue until it is impossible to distinguish which conditions are primary and which are secondary to a medicine. This is termed the *treatment cascade*. Drug-disease interactions become more likely and the patient may suffer from worse health than if all medication is stopped.

A review by the Royal College of Physicians (Working Party; 1984) describes a situation where polypharmacy, due to both changed clinical need and a treatment cascade, led to hospitalisation. This patient was taking an anti-inflammatory drug for joint pain and a treatment for angina. Unfortunately, worsening renal function meant that the doses of both were too high and heart failure developed. The nature of the adverse reaction was not identified and so a diuretic was added to remove excess fluid. This in turn caused lowering of her potassium, which needed to be treated with supplements. On admission, her regular angina medicine was replaced with an alternative preparation which could be taken as and when she required it. Her anti-inflammatory drug was replaced with a simple analgesic. This reduced all side effects and allowed the discontinuation of the diuretic and potassium supplements.

A similar scenario occurred with Mr. WR (39WR030922), aged 78. He was taking nine different medicines prior to admission. Table 8v shows the alterations made to his medication

Table 8v: Changes to medication for Mr. WR (39WR030922)

Medicine on admission	Reason for prescription	Outcome
Prednisolone 10mg daily	Chronic obstructive airways disease	Continued *Adcal D3® added to prevent osteoporosis*
Clomipramine 50mg twice a day	Depression	Continued
Co-codamol 30/500 2 four times a day	Pain	Changed to 2 at night and Co-codamol 8/500 2 three times a day when required *Fybogel® and senna added to prevent constipation*
Mebeverine 135mg three times a day	Diverticular disease	Continued
Isosorbide dinitrate 20mg four times a day	Angina	Continued
Beclomethasone 100mcg inhaler 2 puffs twice a day	Chronic obstructive airways disease	Continued
Salbutamol inhaler 2 puffs four times a day	Chronic obstructive airways disease	Continued
Glyceryl trinitrate spray 1 puff when required	Angina	Continued
Co-amilofruse 5/40 2 daily	Oedema	Changed to 1 daily

In spite of a confusing combination of medicines, Mr. WR was able to accurately describe his regime in detail without prompting. In fact, his drug history was more accurate and included more useful information than the referral letter sent by his general practitioner. He was also able to explain why he was taking each medicine and reported being satisfied with the efficacy of his medication. During his admission two medicines were changed but three more were added to treat adverse effects of his current medication.

Mr. WR was admitted with a fractured right hand, which was not related to any other clinical condition. However, because fractures can be caused by steroid induced osteoporosis, Adcal D3® was added to reduce the risk of further fractures. Also, the analgesics he had been taking caused constipation, which was controlled only by taking a further two medicines: Fybogel® and senna. As his clinical condition was stable and none of his admission medication was judged to be inappropriate, he was discharged with 12 medicines, three of which were to prevent side effects of three of the other medicines. His only problem with compliance was removing tablets from blister packs because of his fractured hand.

It is important for prescription reviews to include investigation of whether particular medicines are being used to treat the side effects of other drugs. If such a problem is identified then both drugs should be discontinued together. If a patient is prescribed a medicine that can cause nausea then an anti-emetic may be added. This in itself may cause Parkinsonian type symptoms, which may be confused with Parkinson's disease and treated with a dopamine agonist. If the first drug is stopped then there is a risk of the other drugs remaining, but now with no purpose. The above is a real situation which occurred on one of the study wards but to a patient who was not interviewed. On discontinuation of the two drugs that had been used to treat side effects, the patient's clinical condition improved.

Doctors have strengths in diagnosis and prescribing but may assume that new diseases cause new symptoms. In contrast, pharmacists often assume that symptoms are drug related. A teamwork approach between these two parties could ensure that adverse effects are identified and treated appropriately, avoiding the problems of the treatment cascade.

Polypharmacy induced compliance risks

71% of subjects studied were at risk of non-compliance because of the complexity of their regime. However, as complexity did not correlate well with total scores, measuring complexity would not allow assessment of the subject's full range of compliance problems. However, as polypharmacy predisposes a patient to a number of problems both related and unrelated to compliance it is worth considering.

Most of the subjects in the study had no change in the number of medicines they were taking at discharge, and some were prescribed more than they had been on admission. As described above, it is often not possible to avoid polypharmacy. However, more importantly, many of the subjects had medicines changed because they were no longer effective or causing adverse effects. If a patient has the optimal treatment prescribed with no extraneous medicines then the risks of polypharmacy may be reduced to that of non-compliance.

Polypharmacy occurs in many different ways but should be avoided whenever possible. If avoidance is not possible then other measures such as prescription review, counselling and medication reminder sheets should be used when possible to limit the risk to the patient.

Chapter 9: The role of primary care in improving compliance for elderly patients discharged from hospital

Introduction

In previous chapters, compliance has been discussed in general and the role of the hospital pharmacist in particular. This included discussion of the reasons why patients do and do not comply with the medication they have been prescribed and what can be done by a hospital pharmacist to improve the likelihood that medicines that have been prescribed will be taken appropriately by patients. This chapter will discuss how the health professionals in primary care can help with compliance.

For a small number of patients medication review exclusively occurs within the hospital. However, the vast majority of older people are treated in primary care. These people visit their general practitioner for consultations or visit a community pharmacy for advice or for medication for minor ailments. These two professionals, the general practitioner and the community pharmacist, therefore have the greatest opportunity amongst health professionals to effect change in compliance behaviour.

General practitioners influencing compliance

68% of subjects in the current study reported being given sufficient information by their general practitioner. This was higher than the rate of satisfaction with information from hospital doctors, and the reasons for this have been discussed in earlier chapters. Most of the subjects appeared to want to trust their family doctor and were upset if they did not find him approachable or felt that he did not deserve their respect. Because of this they may listen to the advice of their doctor and want to comply with it more. However, they also may not want to upset their doctor by admitting to not wanting, or remembering, to take the prescribed medicines; in this situation concordance may help improve compliance.

In chapter 7 it was suggested that many patients may expect general practitioners to explain to them what happened whilst they were in hospital and why they have been prescribed certain medicines. There is often a delay in this information being supplied to the general practitioner; faster communication between primary and secondary care is therefore essential to reduce prescribing errors after discharge from hospital. This may be achieved by involving hospital pharmacists in this information transfer. Once a solution to the problem of delayed communication is found, it would be very useful for patients to visit their general practitioner soon after discharge from hospital. The doctor could identify any problems or worries that the patient might have regarding their treatment and advise on how to deal with the medication they might have stored at home, but which has been discontinued.

Consultation time with general practitioners is restricted, but spending extra time with patients who are suspected of non-compliance may improve compliance and reduce the number of consultations they require. General practitioners need to learn how to ask the questions that will prompt patients to divulge any difficulties that they may have with particular regimes. They need to try to achieve concordance in each consultation, even if it is retrospective. This means that once a medicine has been tried for a period of time, the GP must assess whether the medication is working, therapeutic effect, but also whether the patient has been able to take it, namely compliance. This assessment must not be judgmental, acknowledging that often the regime or choice of therapy may be causing the difficulties of compliance rather than the patient deliberately choosing not to comply.

Concordance, in the simplest understanding of the term, occurs during the first two stages of the medicine process, namely, the decision to treat and provision of treatment stages. Concordance is achieved if the patient, after being given sufficient information, enters into an agreement with the prescriber to proceed with a course of action, a therapeutic plan, which may include taking medication. Note, however, that this definition combines the writing of a prescription and the handing of the dispensed drugs to the patient into one stage, as this is how a general practitioner would perceive it. In practice, however, these are two separate stages and further input can be made at both stages.

For concordance to be meaningful, however, it must take into account the two further stages in the medicines process: administration and feedback or review. If the patient tries to take the medicine but fails, or decides that the therapeutic plan was flawed, then this information must be taken into account when reviewing the medicines. It is this stage which is so difficult in in-patient hospital medicine as administration of medication occurs within a controlled environment and patient satisfaction and non-compliance with new treatment cannot be assessed accurately. This has been discussed earlier and is the reason why non-compliance risk factors were investigated in the present study. The general practitioner, however, can assess the impact of patient satisfaction and non-compliance and with the patient make a decision that is much more richly informed, and probably more closely adhered to. This is the true fulfilment of concordance.

In the current study, 88% of subjects claimed they did not want to have a greater involvement in making decisions about their treatment. As the majority of these also said they had not had any involvement so far, it could be claimed that most of the subjects did not want to be involved in making treatment decisions. The reasons for this have been discussed earlier; but it is interesting to note that many of these subjects did want to provide feedback on the medicines they had already been prescribed. It may be that, whereas elderly people may be afraid or feel unable to make a choice between a number of theoretical options that they have not yet experienced, they do feel capable of interpreting the success of a particular medication if guided by an health professional. It was apparent that the subjects in the current study expected their opinions to be taken into account by the pharmacist. Whether they would feel the same about voicing opinions to their general practitioner remains to be seen, but general practitioners must develop the skills necessary to draw this information from their patients. Asking patients whether they are satisfied with their treatment and discussing what their aims of treatment are may allow greater involvement in the decision making process and hence achieving concordance.

Sometimes, however, patients will not divulge non-compliance behaviour to their general practitioner (Moriskey, 1986). In this situation he must use other clues to discover whether the patient is taking the medicine appropriately. Lack of response or toxic side effects may provide clues to compliance level achieved. If a patient mentions particular adverse effects, or appears worried about their treatment, this can reveal areas that need further investigation.

Repeat prescriptions are often ordered and produced by the receptionist and signed by a doctor who may not pay much attention to what is being ordered. The problems which can be caused by failure to review repeat prescriptions have been discussed in Chapter 8. However, rates of ordering of repeats could indicate non-compliance and computer systems could quite easily register potential problems. Many prescribing systems have a facility to limit the number of repeats allowed before a review occurs. However, it is essential that this is not overridden or ignored as in this interval many problems may occur without the doctor being aware of them.

A doctor's failure to provide medication review may be blamed on lack of time. However, it may be due to a failure to prioritise. It is easier for a doctor to assume patients are on appropriate treatment and only concentrate on issues raised by the patient. Ultimately, however, if patients are left on inappropriate therapy this may be viewed as mismanagement or even negligence.

For patients over 75 years-of-age, the National Service Framework for Older People (Department of Health, 2001) recommends annual medication reviews and recommends a decrease in the interval to six months for patients with more than four medicines. This hopefully will reduce the number of unnecessary medicines patients receive and allow patients to be more involved in the review process. However, patients with unstable medical conditions, or who have demonstrated compliance problems or adverse reactions to medicines, should be reviewed more frequently. In particular, the doctor should review newly prescribed medicines within two months of initiation, especially if dose adjustment and monitoring may be required.

General practitioners have many opportunities to assess and prevent non-compliance. However, because of their lack of accessibility, they require assistance from other members of the primary care team. The community pharmacist is in an ideal situation to assist with this.

Community pharmacists influencing compliance

Community pharmacists have two main roles: responding to symptoms with advice and supply of over the counter medicines; and the supply of prescription medicines with the necessary information to enable the patient to take it correctly. The pharmacist is therefore in an ideal situation to minimise many of the factors that may cause non-compliance.

The effect that communication with patients has on improving compliance has been discussed in Chapter 7. The community pharmacist is in an ideal situation to be able to explain to patients what is required whilst showing them what has been prescribed. This verbal and visual reinforcement of the information that the general practitioner has given should make understanding and remembering how to take the medicines easier (Haynes, 1996; Lowe, 1995; Sweeny, 1989).

It is often difficult to make an appointment with a general practitioner, but a community pharmacist is always available, when the pharmacy is open, for advice and reassurance. The relationship with the patient can also be used to assess whether there are any problems with the medication a patient has been given. A patient may ask about side effects or complain that the medication is ineffective. A patient who appears anxious when the pharmacist explains how to take their medicines, or who appears to have little interest in what the pharmacist is trying to tell them, may not want to comply with the regime. If a patient routinely visits the same pharmacy, and the same pharmacist, rather than locums, usually runs that pharmacy, the pharmacist may have a good working knowledge of their social situation and may be able to offer advice in tailoring the regime to their routine. This is particularly useful for older people who visit day centres or other such activities.

Patients may be dissatisfied after consultations with a doctor because they feel their wishes have not been respected. Sometimes they are unhappy with the treatment decision. On other occasions they may be satisfied with the treatment decision but dissatisfied with their role in making that decision. Community pharmacists may be able to identify these problems when patients come in to have their prescription dispensed. This dissatisfaction can be reported to the general practitioner, with the patient's permission, providing the feedback part of concordance. The community pharmacist is an important link in this chain, especially because of their accessibility.

All community pharmacies keep Patient Medication Records (PMRs). These are records of all medicines dispensed to an individual patient each time they present a prescription. These records often have the ability to store information on non-prescription medicines bought by the patient, interventions made by the pharmacist, and advice given. Using these records, a community pharmacist may be able to identify patients at risk of non-compliance. For example, if a patient presents with a repeat prescription very early then they may be overusing their medicines, or may be having difficulty with dropped or otherwise spoilt tablets. A patient who leaves a long interval between successive prescriptions may be hoarding medicines at home or they may not be using the prescribed dose. It may be that these patients require a medication review to ensure that they are being prescribed the correct medicines or they may need reminding of what the appropriate method of taking their medicines is. PMRs can also be used to ensure that patients receive the same brand of medication on each occasion to reduce the risk of patients assuming that two different brands of the same medication are different and thus the risk of overdose.

If a patient borrows medicines to tide them over until their next prescription is available, or they frequently report losing medication, this may also indicate problems with compliance; these patients may need more input from the community pharmacist. Similarly, patients who are requesting certain non-prescription medicines, such as laxatives, antiemetics or sore throat and cough remedies, may be showing signs of adverse effects to drugs, which they may not realise are iatrogenic. It is always useful for the pharmacist to be aware of what medicines their regular customers are purchasing.

Another use of PMRs is in identifying patients with frequent or large changes to their prescription. We have discussed how this can affect patients' ability to comply as the more frequent the changes, the harder it will be for a patient to remember what the relevant instructions are for taking it. However, multiple changes are also a sign of poor therapeutic control. It is important for the pharmacist to consider whether non-compliance is implicated in this poor control. The pharmacist can ask the patient why the treatment was changed and whether they were having any problems which may require referring to the general practitioner. Although community pharmacists cannot change prescriptions and currently have no authority to overrule a prescribing decision, they can offer useful advice, both to the patient regarding what feedback the doctor will need when reviewing medication and to the doctor regarding therapy choice. The community pharmacist can also address the general compliance problems presented by complicated regimes.

Hoarding medicines puts patients at risk of non-compliance (Parkin, 1976): doses may change and medicines may be discontinued, but if the patient still has plenty at home they may continue to take the old dose. Many pharmacies run so called *Brown bag* clinics, where patients can bring in all their medication from home and have the pharmacist assess what is still appropriate for use, and dispose of the rest. This can help the pharmacist identify at-risk patients and also reduce their level of risk.

Many pharmacists are getting more involved in medication review for their regular customers. This is similar to a review which the general practitioner may carry out but concentrates on the medicines being used, drug interactions, and the presence of unnecessary medication. Community pharmacists can help reduce polypharmacy and simplify regimes by providing the general practitioner with the results of their reviews.

Any interaction with the patient is lost if a carer or other third party collects the prescriptions for the patient. The obvious loss is the ability to counsel patients on their medication and for them to ask questions. Sometimes, however, these carers can provide some insight into the administration practices of the patient and allow some interventions.

It is important to note at this point that most of the input that a pharmacist can have into compliance is only possible if the patient visits the same pharmacy on the majority of occasions. Fortunately, this appears to be the case for elderly patients and was also seen in the current study with 84% of subjects visiting the same pharmacy each time a prescription is dispensed. In addition, if community pharmacists identify a problem with compliance, it is important that they communicate these problems with the patient's general practitioner. The latter may have already identified a problem and attempted to deal with it, or they may not have realised that there was a problem and may need to review the patient's medication in the light of this information.

Communication between general practitioners and community pharmacists is not automatic. Although patients are registered with a particular general practice, they are free to visit any community pharmacist they wish. It therefore follows that the general practitioner might not know which pharmacy the patient usually visits and therefore cannot share appropriate information with them. It is much easier for a pharmacist to contact a general practitioner as the relevant practice is simple to identify as the surgery stamp must be on every NHS prescription presented for dispensing. In order to rationalise care in primary care and ensure maximum safety for patients, the status of community pharmacists must change. Registration with community pharmacies, similar to that in other countries, must be introduced if they are to provide a clinical service, and not simply a supply service. Registration will also allow service level agreements to be agreed by Health Authorities and remuneration for some services may be possible.

Once non-compliance has been identified, then interventions must be made. These can involve treatment review and subsequent changes being made, but they can also involve providing certain services such as large print labels, Monitored Dosage Systems and medication reminder leaflets. There is a wide variation in the provision of these services among community pharmacies which can leave some patients with no extra assistance because the pharmacy they routinely visit does not offer any non-core services. Registration may allow standardisation of service provision, ensuring that the patient receives the service they require.

With their frequent contact with patients and ease of accessibility, Community Pharmacists are in an ideal position to assess and improve compliance. However, this may be wasted if communication on admission to and discharge from hospital does not occur.

The primary/secondary care interface

When patients are discharged from hospital, they are at special risk of non-compliance, as changes in treatment are frequently not transferred to the repeat prescription list. This problem is exacerbated by poor handwriting on the immediate discharge document, with the typewritten document not received by the general practitioner until several weeks have elapsed. A community pharmacist cannot intervene to reduce this risk unless they are contacted on discharge and the same information relayed to them as to the general practitioner. If this was routinely carried out, the community pharmacist would be in a much better situation to help the patient with advice than is currently the case.

Another problem at discharge is that the interventions initiated by the hospital pharmacist must be continued in the community. The numbers in the current study were low, but four out of the five subjects followed-up at two weeks post discharge had received a continuation of the interventions initiated by the hospital pharmacist. In order to ensure that interventions are continued after discharge communication between the hospital and community pharmacies must occur. The hospital pharmacist must inform the community pharmacist of anything they have been doing for the patient. Also, the community pharmacist must inform the hospital in order to reduce duplication of effort and to ensure that discharge medication is provided in a format suitable for the patient. This is particularly important when Monitored Dosage Systems are used, as often the particular device offered by the pharmacy may be different to that offered by the hospital. Some arrangement or compromise must be found if the patient is not to receive two different devices.

Compliance is a problem that should be considered by health professionals from both sides of the primary/secondary care divide. By working together health professionals can give their patients the most appropriate medicines and enable them be given the best possible opportunity for taking them correctly with the least complications.

Chapter 10: Compliance and concordance – some recommendations

Problems with assessing compliance and concordance

In this study problems were encountered in enrolling subjects into the follow-up phase. These problems occurred because the subjects were afraid to take part or because they were unable to understand why their participation would be useful. This may reflect a more general problem, namely that people want various medical interventions to be proven before offered to patients. However, many would have no desire to take part in those studies. If research governance is adhered to and studies are shown to ask specific, measurable, appropriate and relevant questions which can be achieved given the resources available then the population can be guaranteed that their participation is valuable. What might be helpful would be some sort of public awareness programme in which the general population would have the benefits of research participation explained to them. In this way evidence based medicine may be achievable and the benefits of particular compliance interventions may be proven.

The instrument used within this study appeared, with the provisos described in earlier chapters, to be capable of identifying patients at risk of non-compliance and indicating the appropriate solutions. The Abbreviated Mental Test was shown to be a useful tool in screening patients who would be at high risk of non-compliance, but would not be sufficient to identify those patients at moderate risk or to identify the appropriate interventions

Compliance is problematic in the elderly

The aim of this study was to investigate the role of a hospital pharmacist in improving compliance behaviour in an elderly population after discharge from hospital. This thesis demonstrates that compliance is problematic in the elderly population studied and requires intervention if treatment failure is to be avoided.

All of the subjects interviewed had different levels of compliance risk, although the vast majority did present with at least one risk. It would therefore appear appropriate to assume that most elderly people would have some problems with compliance. Four different risk factors were identified as problems for over 50% of the subjects interviewed. Lack of understanding of regime was evidenced by an inability to describe what medicines the subject had been prescribed prior to admission or explain why they had been prescribed. There was a general dissatisfaction with prescribed treatment for many subjects; this was related to a lack of efficacy in 50% of cases, but many subjects could not explain why they reported being unhappy with their medication.

Provision of information was found to be poor for the majority of patients, with hospital doctors providing much less information regarding treatment regimes than general practitioners. However, the majority of subjects appeared to be satisfied with the amount of information they had received and the level of involvement they had in making treatment decisions. Many subjects had a complex regime which exceeded the National Service Framework for Older People (Department of Health, 2001) standard of four medicines for patients over 75 years-of-age. However, no two subjects had identical combinations of problems and therefore generalisation into categories was not possible.

How a hospital pharmacist can address compliance problems

This study was carried out because a number of authorities have described the benefits a hospital pharmacist can confer if certain activities occur at discharge. Although the study did not provide any evidence that the interventions used did improve compliance, a number of interventions were carried out which may have potential to benefit elderly patients at risk of non-compliance. The most commonly implemented were counselling on discharge, providing a compliance reminder sheet, attempting to simplify the regime and finding solutions to various physical problems.

Many subjects reported that they had not been given any medication information either by their general practitioner, the hospital doctor, or both. However, most of these were happy with the level of involvement they had in making decisions about their treatment. The subjects interviewed often were interested to know what they had been prescribed and the best way to take it. Providing information about medicines is important in improving the ability to comply with a regime. It can improve patients' knowledge of why medicines are prescribed and possibly improve their understanding of whether they are effective and which medicines can cause adverse reactions that they might experience. This was therefore a useful service which the majority of subjects appreciated and found helpful and should be offered to all hospital in-patients prior to discharge.

The majority of subjects reported that they would want their doctor to continue to make treatment decisions for them and they did not want to be involved. They therefore wanted information about their medicines, but not the responsibility of making decisions; this is incompatible with concordance. As increased involvement in making decisions about treatment options has been shown to reduce compliance risk, patients should be encouraged to become more involved. This can be difficult in hospital if the treatment required could make the difference between several days longer in hospital and early discharge. Allowing patients to consider the relative benefits of treatment could lead to bed blocking. Waiting until the next consultant ward round may be too long an interval, causing the patient to forget the questions they wished answering or the reason why treatment was recommended. Achieving concordance in this situation must therefore be multidisciplinary, with all members of staff trained to assist patients with their deliberations. Obviously, the hospital pharmacist would be the best qualified to offer this assistance and should be available to discuss issues with the patient.

Because of the reluctance exhibited, attempts to achieve concordance in this population should concentrate on the treatment review stage, rather than the initial therapy choice stage. The majority of subjects were happy to comment on whether they felt treatment was working or continued to be necessary and so would be capable and willing to increase their involvement in this stage of the process. However, if advances were made in the information available to explain relative

risks to patients then they may be happier to become more involved in the treatment planning process. As recommended earlier, this should be a national initiative with easy to understand information packs being developed for various common conditions. These should be objective and evidence based. However, the pharmacist must take time to understand what level of risk the patient is willing to take; this is time consuming but is worthwhile if the outcome is a patient who is happy to take the treatment as prescribed.

In hospital there is more opportunity for the pharmacist to be involved in concordant interviews; the consultant can recommend a treatment and refer the patient to the pharmacist for more information. However, in general the role of the pharmacist would be to identify where concordance has not been achieved and make the relevant intervention to achieve concordance.

Polypharmacy was found to be a problem for most subjects in the study. However, the majority of these had no change in the number of medicines they were taking at discharge, and some were prescribed more medicines than they had been receiving on admission. It was often not possible to avoid polypharmacy. However, if a patient has the optimal treatment prescribed with no extraneous medicines then the risks of polypharmacy may be reduced to that of non-compliance. Polypharmacy should be avoided whenever possible; if avoidance is not possible then other measures such as counselling and medication reminder sheets should be used when possible to limit the risk to the patient. Of particular concern are the patients who do not want to take medicines but are afraid to stop. These may not be predictable non-compliers as their medicine taking may be erratic. A discussion with the patient to understand their true attitude to medication may allow identification of the underlying problem and medication review may therefore be possible.

Medication reminder leaflets were provided to the majority of subjects. These could be very helpful for those patients who have complicated regimes or who want a more schematic reminder of how medicine taking can fit into the normal daily routine. However, they would be inappropriate for patients on very simple regimes who do not exhibit forgetfulness, and would also be insufficient for patients who are very confused. Medication reminder leaflets should be offered routinely to all elderly

patients: they are cheap to produce and so would not be wasteful for those patients who do not need them. However, the potential benefit for those patients who do use them would be great.

A number of interventions were implemented to address physical problems; these included large print labels, alternative devices and screw caps. These should be offered to all patients who need them, but strict selection criteria should be adhered to as an appropriate solution for one patient could cause a hindrance to another. Also some subjects refused interventions. It is important that these interventions are seen as treatment necessities and not as optional extras which can be accepted or rejected by patient choice except under the auspices of concordance.

The study appeared to confirm the hypothesis that elderly patients have various compliance problems, and that a hospital pharmacist has a role to play in solving these problems. This role should not be exclusive, however, and the role of ward nurses in identifying patients with problems and possibly assisting with some solutions has been discussed. Similarly, in order for hospital initiated interventions to improve compliance risk status, they must be continued after the patient is discharged from hospital. The GP and the community pharmacist have the most opportunities amongst health professionals of being able to effect change in compliance behaviour. They must therefore be involved in any decision to implement interventions.

The solutions suggested above are all achievable within current funding and job descriptions. Compliance assessment and initiating interventions are time-consuming but come within the remit of the hospital pharmacist and other health professionals within the demands of pharmaceutical care. However, for compliance and concordance to be achieved to the maximum extent then links between primary and secondary care need to be improved beyond the limits which are currently achievable. Admission letters, discharge summaries and *ad hoc* communication between hospital and community pharmacists, hospital doctors and general practitioners, are useful but a more structured intervention across the primary/secondary care divide is required.

The role of primary care in concordance and compliance

The relationship between the general practitioner and community pharmacist requires better definition. Both are health professional but whereas the patient is registered with a general practitioner they can chose to visit any community pharmacist in any part of the country. The community pharmacist must refer patients to their general practitioner but the GP in return does not have any requirement to communicate anything with the community pharmacist. In primary care, therefore, the doctor carries out the diagnosis and prescription and the pharmacist provides assistance in monitoring. It is therefore the responsibility of the doctor to provide regular medication review to ensure treatment is optimal. This often does not occur but has been prescribed in the National Service Framework for Older People (Department of Health, 2001). However, if this occurs but is not thorough enough then any resultant non-compliance or morbidity may be thought of as resulting from negligence.

Community pharmacists have an important role in identifying those patients whose treatment is not optimal or who are unhappy with their treatment. Solutions available may be sale of OTC (over-the-counter) medicines, advice or referral back to the general practitioner. It is important that patients at risk of non-compliance are advised of the possible solutions available, many of which have been described earlier. Unless patients are made aware of services such as filling Monitored Dosage Systems or large print labels then they will not be able to take advantage of them.

Bridging the primary/secondary care divide

Many of the problems presented to the hospital on admission are caused by a lack of knowledge of the patient's usual ability to cope with medication and services provided by Social Services or the community pharmacist. Similarly on discharge, information regarding changes made to treatment and interventions to improve compliance are communicated only when the hospital health professional decides it is appropriate or in direct response to a request from primary care. This communication should be more formalised and this could be achieved by employing a primary/secondary care liaison pharmacist.

The primary/secondary care liaison pharmacist post could be funded from the hospital with a remit to ensure that all relevant information for at-risk patients is obtained from primary care and supplied to those who need it most at discharge. Alternatively, this could be an extension of the practice pharmacist role and be funded from general practice. The pharmacist could identify all patients from a particular practice who are admitted to hospital and ensure that an appropriate drug and compliance history is provided to the hospital. On discharge they would liaise with the hospital and community pharmacists and general practitioner to ensure that all relevant information is shared and achieve seamless care. This role could be provided by a hospital pharmacist if more resources were available and provide a useful link between the hospital and primary care.

Errors, due to lack of information regarding drug histories, would be eliminated and patients would not find themselves in the situation of failing to have services continued in the difficult days after discharge. Also, prescription review would be carried out with the maximum available knowledge, ensuring that medicines that had failed in the past were avoided and discontinued medicines were not accidentally reinstated due to lack of repeat prescription review. Polypharmacy could therefore be avoided.

Interventions instigated in hospital must be continued in the community if patients are to benefit. However, patients can change the pharmacy they get their prescriptions dispensed from and so continuity of care can be disrupted. In addition, if the patient cannot remember the name of the pharmacy they routinely visit then communication with that pharmacy is not possible. If patients could register with one particular pharmacy, many compliance problems could be addressed. Firstly, it would be as easy to provide discharge information to the correct pharmacy as it currently is to communicate with a patient's general practitioner. Secondly, pharmacists could be given contracts which reflected the level of service they provided to their patients. The general practitioner is paid a certain fee for the number of patients registered with him and receives extra payment for individual non-standard activities. Pharmacy registration could allow similar remuneration packages, which would allow extension of services such as Monitored Dosage

Systems and enable investment into computer hardware which would enable provision of large print or even Braille labels and leaflets. Many aspects of pharmaceutical care depend on pharmacists taking responsibility for their *patients'* well being, and not just limited service provision for *customers*.

Many patients cannot remember the information they have been given at discharge. If patients are offered a hospital-based pharmacy telephone helpline to contact for further information after discharge, this could reduce some of the worry that may lead to non-compliance. NHS Direct currently provides such a service, but this is impersonal and the health professional answering calls would not know any of the background to the patient's condition or reason for admission to hospital. A hospital pharmacy helpline could access information from the recent admission and could explain the reasoning behind any changes. If required, arrangements could be made for the pharmacist who had cared for that specific patient whilst in hospital to speak to them, ensuring continuity of care. This service could identify treatment failure and be used within concordance to suggest a course of action to the patient's general practitioner, if the patient was in agreement.

Patients with many potential problems after discharge would benefit from a domicilliary visit. The hospital pharmacist, practice pharmacist or community pharmacist could identify patients who are at high risk and visit them to ensure they understand how to take their medicines and were still coping. At these visits it would be possible to check the medicines that the patient may have at home and advise on their suitability for continued use and which should be destroyed to reduce the risk of continuing discontinued medicines. A telephone call shortly after discharge could identify if any problems existed and restrict domicilliary visits to those patients who appeared to warrant one.

With the advent of Training Primary Care Trusts, and the potential for pharmacist involvement in medical undergraduate training, pharmacists would be in an ideal position to train other health professionals in the skills that they would require to ensure concordance and compliance were achieved. Advice on such subjects as how to avoid polypharmacy, common drug interactions and the practicalities of drug review could be provided to other health professionals, especially doctors and

nurses. In this way the burden of reducing compliance and achieving concordance would be shared amongst all health professionals and become a priority for all those caring for patients.

Compliance can be problematic for elderly patients, but with innovative thinking and co-operation across professional and sectoral divides, it can be addressed and the attendant risks minimised.

Appendix I: LREC information sheet and approval

Information sheet

INVESTIGATION INTO THE ROLE OF A HOSPITAL PHARMACIST IN IMPROVING COMPLIANCE BEHAVIOUR AFTER DISCHARGE FROM HOSPITAL

Can a hospital pharmacist improve patient's ability to take their medication when they leave hospital?

You are being invited to take part in a research project, which is part of my Master's degree at Durham University. Here is some information to help you decide whether or not to take part. Please take time to read the following information carefully and discuss it with friends, relatives, your named Nurse or Hospital Doctor if you wish. Ask me if there is anything you do not understand or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this.

The purpose of the study

To try and help you take your medication Pharmacists can do a number of things. For example we can explain what your tablets are for and try to make them easier for you to take. I am doing this study to find out if we could help more.

Why have you been chosen?

You have been chosen because I talked to you about your medication and I felt that there were some things I could do to help you. I would like to talk to you after you leave hospital to see if I have helped you. I will be asking about 100 people in total to take part in the study.

What will happen to you?

If you agree to take part in the study I will ring you or visit you at home 10-14 days after you leave hospital. I will ask you some questions about your medicines and the things I have done to help you. This should take about 30 minutes. I will also meet with you when you return to the hospital for an Outpatients appointment.

What will happen to any information collected about you?

All the information collected about you during the course of the study will be kept strictly confidential. Any published report of the research will not identify you.

Your GP will be informed that you are taking part. If this is a problem for you, you should discuss it with me.

What if you decide not to take part?

It is up to you to decide whether to take part or not. If you do decide to take part, you are free to withdraw at any time and without giving a reason. This will not affect the standard of care you will receive. Your doctor will not be upset if you decide not to take part. I will try to help you in the same way that I would have done if you had chosen to take part in the study.

What risks are there?

You will receive the same service whether you take part in the study or not. Therefore you will not be at any more risk if you decide to take part. The only inconvenience is that I will need to talk to you twice after leaving hospital to discuss your medication. I will try to find a time convenient for both of us.

Will you benefit from taking part?

You may or may not receive any direct benefit from taking part in the study. We hope it will help us to help future patients.

If you want any more information please ask your ward pharmacist when I visit the ward each day. Or you can ring me on extension 4364.

Thank you very much for taking part in my study.

Flesch Reading Ease Score – 74.4 (80% of people can read)

LREC approval letter

NORTH TEES & HARTLEPOOL NHS TRUST

NORTH TEES GENERAL HOSPITAL

North Tees Local Research Ethics Committee

Stockton-on-Tees
Cleveland
TS19 8PE
Direct Line: 01642 624164
Fax: 01642 624951

ELG/LM

8 June 1999

Ms J Robson
Dept of Pharmacy
NTGH

Dear Ms Robson

****13/99-2000 – Investigation into the role of a hospital pharmacist in improving compliance behaviour after discharge from hospital***

Thank you for submitting the above application which was considered by the North Tees Local Research Ethics Committee at its meeting today. The Committee were impressed with the quality of your application and unanimously agreed that the second version of the patient information leaflet should be used.

NTLREC is fully compliant with the International Committee on Harmonisation (ICH) Guidelines for Good Clinical Practice as they relate to the responsibilities, composition, function, operations and records of an Independent Ethics Committee/Independent Review Board. To this end it undertakes to adhere as far as it is consistent with its constitution to the relevant clauses of the ICH Harmonised Tripartite Guideline for Good Clinical Practice adopted by the Commission of the European Union on 17 January 1997.

I would be grateful if you could submit a study report in one year's time. Please advise this Committee if your research does not take place.

Yours sincerely

Leigh Morgan

E L Gilliland – Chairman
North Tees Local Research Ethics Committee

Appendix II – Medication reminder leaflet

Name **Unit No.** **Ward** **Discharge date**

MEDICINE	TIMES TO BE TAKEN							REASON FOR TAKING/ NOTES
	6am	8am	10am	12 noon	2pm	6pm	10pm	
Madopar disp 62.5mg	ONE							Dissolve in a glass of water. Take before getting out of bed. For Parkinson's Disease
Sinemet CR 50/200	ONE			ONE		ONE		For Parkinson's Disease Take with or after food
Citalopram 20mg		ONE						Treats depression
Omeprazole 10mg		ONE						Reduces acid in the stomach
Domperidone 10mg		ONE		ONE		ONE		To stop you from feeling sick
Ropinirole		✓			✓		✓	Take according to pack. Take with or after food. For Parkinson's Disease

Appendix III – Pilot questionnaires

Pilot

- How are you getting on with your medication? _____
  _____
- How long have you been taking them? _____
  _____
- Do you know why you have been given your medication? _____
  _____
- What do you think of your tablets? Are they helping? _____
  _____
- Do you have any problems with your tablets/ any unwanted effects? _____
  _____
- People often have difficulty taking their tablets for one reason or another. What about you? _____
  _____
- Do you have a method of remembering when to take them? _____
  _____
  _____
- Many people find they miss a dose from time to time; is this a problem for you?
  _____
- When ..... do you sometimes take an extra dose? _____
  _____
- Do you find your family doctor or pharmacist helpful when you have questions about your medicines? _____
  _____
- Remembered drug history
  Full recall ☐
  Partial recall ☐
  No recall ☐

TDM results _____

First Draft

1. How are you getting on with your medication?

   Very well ☐
   all right ☐
   With difficulty ☐

2. What medicines have you been taking and when do you take them? Do you take any medication which the doctor has not prescribed for you? (E.g. vitamins, paracetamol, lactulose)

   (Need drug name, strength/dose and frequency)

3. Do you know what you are taking them for?

4. Are you happy with your treatment?

   Yes ☐
   Fairly ☐
   No ☐

5. Do you think your medicines are working? Why?

   Yes ☐
   No ☐

6. Do you feel you still need the same medication which you have been prescribed? What different medication do you think you need? Why?

7. Do you have any problems/unwanted effects from taking your medicines? Do these problems stop you from taking your medicines or change the way you take them?

   Side effects Yes ☐ No ☐

   Change in medicine taking:

8. Do you have a method of remembering when to take them?

9. Do you ever forget to take your medicines?

   Yes ☐
   No ☐

10. Are you careless about taking your medicines?

    Yes ☐
    No ☐

11. When you feel better do you ever stop taking your medicines?

    No ☐
    Yes ☐

12. When you feel worse do you sometimes stop taking you medicines?

No ☐
Yes ☐

13. Has your doctor or pharmacist told you about your medicines?

Yes ☐
No ☐

14. Did your doctor discuss with you what medicines were appropriate before he prescribed them?

Yes ☐
No ☐

15. Would you like to be more involved in making decisions about your treatment?

No ☐
Yes ☐

16. Labelling and container requirements

Container requirements		**Labelling requirements**		**Device requirements**	
None	[ ]	None	[ ]	Volumatic	[ ]
Screw caps	[ ]	Large print size	[ ]	Nebuliser	[ ]
Large tablet bottles	[ ]	Colour coded labels	[ ]	Haleraid	[ ]
Different sized bottles*	[ ]	Other*	[ ]	Other*	[ ]
Compliance aids*	[ ]				
Measuring pot	[ ]	* Give details			
Oral syringe	[ ]				
All items as liquids	[ ]				
Other*	[ ]				

Appendix IV – Data collection documents

Compliance Assessment

Subject code: 39/GM/031015

INFORMATION PRIOR TO ADMISSION

1. Does anyone help you to take your medication at home?

Full help	☐	(Excluded from study)
Reminder only	☑	5
No help	☐	3

2a. What medication have you been taking and when do you take them?

(Need drug name, strength/dose and frequency 1 for each correct and divide by n)

Drug name	Dose/strength	Frequency	Score
Frusemide	40mg	3 daily	3
Digoxin	62.5mcg	1 daily	3
Lisinopril		1 daily	2
Lansoprazole		1 daily	2
Warfarin		daily	2
Mucogel		prn up to tds	3
(ISMN)		1 tds	2
(Terbutaline)	2 puffs	twice daily	2
		Total	3

2b. Do you take any medication that the doctor has not prescribed for you? (E.g. vitamins, paracetamol, lactulose)

Drug	Dose	Frequency
None		

3. Do you know what you are taking them for?

(Score 2 for each correct and divide by n)

Drug	Reason	Score
Warfarin	Clots	2
Frusemide	Water tablet	2
Isosorbide mononitrate	Heart	2
Digoxin	Heart	2
Lisinopril	Heart	2
Terbutaline	Breathing	2

Mebeverine	Stopped	
	Total	2

4. Are you happy with your medication?

Very ☐ 5 Fairly ☑ 4 Unsure ☐ 3
Not very ☐ 2 Not at all ☐ 1

5a. Do you think your medication is working?

Yes ☐ 5 I think so ☐ 4
I don't know ☑ 3 I don't think so ☐ 2
Not at all ☐ 1

5b. Why?

Water tablet and warfarin are working Digoxin seems to be OK Unsure about the others

6a. Do you feel you still need the same medication which you have been prescribed?

Yes ☐ 5 Unsure ☑ 3 No ☐ 1 (go to 6d.)

6b. What different medication do you think you need and why?

Alternative medication	**To replace:-**	**Reason**
Don't know		

7a. Do you have any problem/unwanted effects from taking your medication? (E.g. sickness, diarrhoea, constipation, rash, headache, dizziness etc.)

Side effects: Yes ☐ No ☑ 5 (go to 8a.)

7b. Do these problems stop you from taking your medication or change the way you take them?

Yes ☐ (see below)
No ☐ 5

Change in medicine taking (score: 4 - change appropriate e.g. with food
2 - ↓ dose or miss dose occasionally
1 - stop using)

Drug	Side effect	Change	Score

8a. How often do you forget to take your medication?

Always ☐ Occasionally ☑ Never ☐ (go to 8d.)

8b. Why do you forget?

Don't know

8c. Do you have a method of overcoming your forgetfulness?

Yes ☑ (see below)
No ☐ 1

Method of remembering when to take medication (score 5 - safe and effective
3 - unsafe)

Method	Score
Follow compliance chart written by hospital	5
Put tablets out for next dose and take at mealtimes	5
	5

8d. Why do you never forget your medication?

Reason (score 1 - no method
5 - safe and effective method
3 - unsafe method)

Reason	Score

9. Are you careful to follow the doctor's instructions about when to take your medication?

Always ☑ 5 Sometimes ☐ 3 Never ☐ 1

10a. Have you ever stopped taking your medication because you felt better or worse?

Feel better Always ☐ Feel worse Always ☐ 1
Sometimes ☐ Sometimes ☑ 3
Never ☑ Never ☐ 5

10b. Why?

Antibiotics sometimes make me sick, so I don't always continue the course when I feel like that

11. When you are given a prescription does your doctor or pharmacist tell you any information about your medication?

Always ☐ 5 If it is a new drug ☐ 4 Unsure ☐ 2
Never ☑ 1

POST-ADMISSION INFORMATION

12. Has anyone told you about your medication since you came into hospital?

Yes	☐ 5	Who?	Nurse	☐	Doctor	☐
			Pharmacist	☐	Other	☐
Unsure	☐ 3					
No	☑ 1					

13. Has your hospital doctor discussed with you what medication were appropriate before he prescribed/changed them?

Yes ☐ 5 Unsure ☐ 3 No ☑ 1

14. Would you like to be more involved in making decisions about your treatment?

Yes ☐ 1 No ☑ 5

15. Labelling and container requirements

Container requirements		**Labelling requirements**		**Device requirements**	
None	☐	None	☑	Volumatic	☑
Screw caps	☑	Large print size	☐	Nebuliser	☐
Large tablet bottles	☐	Colour coded labels	☐	Haleraid	☑
Different sized bottles*	☐	Other*	☐	Other*	☐
Compliance aids*	☐				
Measuring pot	☑	* Give details			
Oral syringe	☐				
All items as liquids	☐				
Other*	☐				

Score 5 - no problems
4 - problem patient solves safely
1 - unsolved problem/unsafe solution Score 1 .

16. AMT 10 /10 >7 score 5
5-7 3
<5 1 Score 5

17. Conditions which may affect compliance:

Baseline 5, score –2 for each item

RA ☐
Depression ☐
Confusion ☐
Other ☐
Score 5

18. TDM available none

Normal range score 5 No levels 5
Borderline 3
Outside range 1 Score 5

19. Likely complexity of drugs on discharge:

Number of drugs 6
Maximum frequency tds
Number of different frequencies, directions (e.g. with food) 4

< 5 drugs ☐ 2
Maximum frequency bd ☐ 2
≤ 2 frequencies ☐ 1 Sum to give score Score 0

Final scores

$\frac{1+8+9+10+18}{5}$ = 5

2+3 = 5

$\frac{4+6}{2}$ = 3

5 = 3

7 = 5

$\frac{11+12+13+14}{4}$ = 2

15 = 1

$\frac{16+17}{2}$ = 5

19 = 0

Total 29

40-45 Low risk of non-compliance

30-39 Moderate risk of non-compliance

<30 High risk of non-compliance

Any score ≤ 3 requires an intervention

Time taken to complete: 30min

First follow-up

Subject code 39/GM/031015

INTERVENTION ASSESSMENT

1a. Have you had a prescription from your GP since leaving hospital?

Yes ☑ 1
No ☐ 2

1b. What medication was your prescription for?

Discharge medication	**New prescription**
Warfarin 2mg daily 5pm	✓
Frusemide 120mg daily	✓
Isosorbide mononitrate 20mg bd	Isosorbide 20mg tds
Digoxin 62.5mcg daily	✓
Lisinopril 30mg od	✓
Lansoprazole 30mg od	Stopped
Salbutamol inh 2 puffs qds via Volumatic	✓

2. Which pharmacy did you get your medication from?

Nominated pharmacy Woodlands - Yarm Lane
Current pharmacy Woodlands - Yarm Lane

3a. On discharge form hospital I arranged for you to have some special services. Have they been continued?
3b. Are they helping?

Interventions made	**Continue? (✓)**	**Helpful?**
1. Turbohaler → Inh. via Volumatic	✓	Yes ~~Unsure~~ ~~No~~
2. Screw caps and medicine pots	✓	Yes ~~Unsure~~ ~~No~~
3. Counsel and reminder chart	✓	Yes ~~Unsure~~ ~~No~~

4. Are you having any problems with your medication? Yes ☑ No ☐

Inhaler keeps falling out of Volumatic

5. Interventions required
   1. Explained how to attach inhaler so it doesn't fall out
   2.

Time taken to complete: 10 min

Second follow-up

Subject code 39/GM/031915

FOLLOW-UP INTERVENTION ASSESSMENT

1. Which pharmacy did you get your last prescription from?

   Nominated pharmacy Woodlands
   Pharmacy at 14/7 Woodlands
   Current pharmacy Woodlands

2. What was your last prescription for?

Warfarin 2mg daily
Isosorbide mononitrate 20mg tds
Digoxin 62.5mcg daily
Frusemide 120mg daily
Salbutamol inh via Volumatic prn
Lisinopril 30mg daily
Lansoprazole 30mg daily

3a. On discharge from hospital I arranged for you to have some special services. Have they been continued?
3b. Are they helping?

Interventions made	**Continue? (✓)**	**Helpful?**
1. Turbohaler → Volumatic	✓	~~Yes~~ Unsure ~~No~~
2. Screw caps and medicine pots	Sometimes	Yes ~~Unsure~~ ~~No~~
3. Counsel and gave reminder chart	✓	Yes ~~Unsure~~ ~~No~~
4. Explained how to manage 1.		~~Yes~~ Unsure ~~No~~
5.		Yes Unsure No
6.		Yes Unsure No

Plus compliance sheet

Time taken to complete: 30 min

Appendix V – Roth-Hopkins test

Question	Possible Score
Name	0/1
Age	0/1
Time (nearest hour)	0/1
Name & address (5 minute recall)	
Mr.John Brown	0/1/2
42 West Street	0/1/2
Gateshead	0/1
Day of week	0/1
Date (number)	0/1
Month	0/1
Year	0/1
Place: Type	0/1
Name	0/1
Ward	0/1
Town	0/1
Recognition (2 people)	0/1/2
Date of birth (date and month)	0/1
Place of birth	0/1
School	0/1
Former occupation	0/1
Spouse/next of kin	0/1
World War I (year)	0/1
World War II (year)	0/1
Present monarch	0/1
Present Prime Minister	0/1
Months backwards (Dec-Jan)	0/1/2
Count 1-20	0/1/2
Count backwards 20-1	0/1/2
Total	x/34

(Roth, 1953)

Appendix VI – Individual subject procedure

1. **Baseline measurements**

1.1 Baseline information will be obtained from the patient's medical notes and by contacting the patient's GP and community pharmacist
1.2 Each patient will be interviewed using a structured questionnaire by the researcher (see Appendix IV) at day 3 of admission or transfer to the study wards
1.3 Using this information a number of problems (≤ 3) will be identified for each patient

2. **Intervention**

2.1 Solutions will be sought for each problem identified and actioned before discharge
2.2 Patients with identified problems will be asked for consent to enter stage 3 (see Appendix VII)
2.3 At discharge any relevant information will be sent to the patient's GP and designated community pharmacist (e.g. dispensing, counselling and information needs of the patient)

3. **Reinforcement**

3.1 Each patient will be interviewed by telephone or at home 10-14 days after discharge
3.2 The purpose of this visit will be to ascertain whether pharmacist initiated solutions are being continued and whether they are found helpful by the patient
3.3 Any further interventions will be made as necessary

4. **Outpatient clinic re-evaluation**

4.1 Each patient will be followed up at their first outpatient appointment (unless this occurs at less than 2 months)
4.2 Patients will be assessed for compliance and administration problems and the success of the pharmacist's interventions

Appendix VII – Consent form

Researcher: Jane Robson, Directorate Pharmacist for Medical Rehabilitation

Please initial box

1. I confirm that I have read and understand the information sheet dated May 1999 (version 1) for the above study. ❑

2. I understand that my participation is voluntary and that I am free to withdraw at any time without my medical care and legal rights being affected. ❑

3. I am willing to allow access to my medical records but understand that strict confidentiality will be maintained. The purpose of this is to check that the study is being carried out correctly. ❑

4. I agree to take part in the above study ❑

Name of patient	Date	Signature
Researcher	Date	Signature

References

Abrams, W.B. (1990) Cardiovascular drugs in the elderly, Chest, 98:980-6

Adams (*trans*) (2000) The Oath By Hippocrates. [online] Available from: http://classics.mit.edu//hippocrates/hippooath.html [accessed 25th May 2002]

Anonymous (1952) The National Formulary. London, The British Medical Association & The Pharmaceutical Society of Great Britain

Anonymous (1985) Reading between the lines of clinical trials – I: Design. Drug and Therapeutics Bulletin, 23:1-3

Anonymous (1991a) Responsibility for prescribing between hospitals and GPs. EL(91)127. London, Department of Health

Anonymous (1991b) Helping patients to make the best use of medicines. Drug and Therapeutics Bulletin, 29:1-2

Anonymous (1992) Knowledge and compliance - not linked after all. The Pharmaceutical Journal, 248:186

Anonymous (1993) Communication between hospital and community pharmacists concerning patient's medication and pharmaceutical needs. London, Royal Pharmaceutical Society of Great Britain

Anonymous (1994) Purchasing and prescribing. EL(94)72. London, Department of Health

Anonymous (1997a) Towards achieving shared goal in taking medicine. The Pharmaceutical Journal, 259:860-1

Anonymous (1997b) Why patients fail to take their medicines correctly. The Pharmaceutical Journal, 259:525

Anonymous (1998a) Randomised controlled trials in single patients. Drug and Therapeutics Bulletin, 36:40

Anonymous (1998b) From compliance to concordance. Prescriber, 9:14-16

Anonymous (1999) Poor compliance can be costly. Drug and Therapy Perspectives, 10:14-16

Anonymous (2000a) Achieving concordance. Primary Care Pharmacy, 1:93-95

Anonymous (2000b) The British National Formulary 40. London, British Medical Association & Royal Pharmaceutical Society of Great Britain

Anonymous (2002) NHS Direct – self–help guide Antibiotics [online] Available from: www.nhsdirect.nhs.uk/SelfHelp/info/advice/antibiotics.asp (Accessed 7th June 2002)

Appelbe, G.E. Wingfield, J. (1997) Medicines Act 1968: Containers, packages and identification
In: Dale and Appelbe's Pharmacy law and ethics. (6th Edition) London, The Pharmaceutical Press

Aronson, J.K. Hardman, M. (1992) Patient compliance. British Medical Journal, 305:1009-11

Audit Commission (2001) Strategic challenges
In: A spoonful of sugar: medicines management in NHS hospitals. London, Audit Commission

Baumgartner, T.A. Strong, C.H. (1994) Experimental Research
In: Baumgartner, T.A. Strong, C.H. Conducting and reading research in health and human performance. Dubuque, WBC Brown & Benchmark

Beardon, P.H.G. McGilchrist, M.M. McKendrick, A.D. McDevitt, D.G. MacDonald, T.M. (1993) Primary non-compliance with prescribed medication in primary care. British Medical Journal, 307:846-8

Becker, M.H. Maiman, L.A. (1975) Sociobehaviourral determinants of compliance with health and medical care recommendations. Medical Care, 13:10-24

Binyon, D. (1994) Pharmaceutical care: Its impact on patient care and the hospital-community interface. The Pharmaceutical Journal, 253:344-53

Bland, M. (1995) Determination of sample size
In: An introduction to medical statistics. (2nd Edition) Oxford, Oxford University Press

Blessed, G. Tomlinson, B.E. Roth, M. (1968) The association between qualitative measures of dementia and senile changes in the grey matter of elderly subjects. British Journal of Psychiatry, 114:797-811

Britten, N. (1998) Communication: the key to improve compliance. Prescriber, 9:27-31

Burns, J.M.A. Sneddon, I. Lovell, M. McLean, A. Martin, B.J. (1992) Elderly patients and their medication: a post-discharge follow-up study. Age and Ageing, 21:178-181

Cantrill, J.A. Clark, C.M. (1992) Discharge counselling by pharmacists: The need and the reality Hospital Pharmacy Practice, 2:429-32

Chaput de Saintonge, D.M. Herxheimer, A. (1994) Harnessing placebo effects in health care. The Lancet, 344:995-8

Clark, C. (1998) Concordance is not a PC term. Pharmacy in Practice, 8:83

Cochrane, R.A. Mandal, A.R. Ledger-Scott, M. Walker, R. (1992) Changes to drug treatment after discharge from hospital in geriatric patients. British Medical Journal, 305:694-6

Col, N. Fanale, J.E. Kranholm, P. (1990) The role of medication noncompliance and adverse drug reactions in hospitalisations of the elderly. Archives of Internal Medicine, 150:841-5

Conrad, P. (1985) The meaning of medication: another look at compliance. Socail science and medicines, 20:29-37

Daly, J. McDonald, I. (1992) Introduction: the problem as we saw it
In: Daly, J. McDonald, I. Willis, E. (Eds.) Researching Healthcare: Designs, Dilemmas, Disciplines. London, Routledge

Dean, T. (2000) The changing relationship between doctor and patient. Prescriber, 11(4):13

Denham, M.J. Jefferys, P.M. (1972) Routine mental assessment in elderly patients. Modern Geriatrics, 2:275-9

Department of Health (1999a) Glossary
In: Review of prescribing, supply and administration of medicines - Final Report. London, Crown Copyright

Department of Health (1999b) Proposed policy framework for extension of prescribing
In: Review of prescribing, supply and administration of medicines - Final Report. London, Crown Copyright

Department of Health (2000b) Helping patients get the best from their medicines
In: Pharmacy in the future - implementing the NHS plan. London, Department of Health

Department of Health (2001) Medicines for Older People: Implementing medicines-related aspects of the NSF for Older People. London, The Stationary Office

Dirckx, J.H. (1997) Steadman's Concise Medical and Allied Health Dictionary. (3rd Edition) Baltimore, William and Wikins

Dryden, D. (1999) Health services utilization in the population aged 65 and older. The Alberta Centre for Health Services Utilization Research [online] Available from: www.health.gov.ab.ca/public/document/research/agelit2.PDF (accessed 25th May 2002)

Eisen, S.A. Miller, D.K. Woodward, R.S. Spritznagel, E. Przybeck, T.R. (1990) The effect of prescribed daily dose frequency on patient medication compliance. Archives of Internal Medicine, 150:1881-4

Entwistle, V. (2000) Providing patients with the information they need. Prescriber, 11(4):24-27

Gainsborough, N. Powell-Jackson, P. (1990) Prescribing for the elderly. The Practitioner, 234:246-8

Griffith. S, (1990) A review of the factors associated with patient compliance and the taking of prescribed medicines. British Journal of General Practice, 40:114-6

Grymonpre, R.E. Didur, C.D. Montomery, P.R. Sitar, D.S. (1998) Pill count, self-report, and pharmacy claims data to measure medication adherence in the elderly. Annals of Pharmacotherapy, 32:749-54

Guralnik, J. Havlik, R. (2000) Demographics.
In: Beers, M.H. Berkow, R. (Eds.) The Merck manual of geriatrics. [Online] Available from: www.merck.com/pubs/mm_geriatrics/home.html (accessed 25th May 2002)

Gurwitz, J.H. Col, N.F. Avorn, J. (1992) The exclusion of the elderly and women from clinical trials in acute myocardial infarction. Journal of the American Medical Association, 268:1417-22

Harman, R.J. (1999) The drug development process - 1. Introduction and overview. The Pharmaceutical Journal, 262:334-7

Haynes, R.B. McKibbon, K.A. Kanani, R. (1996) Systematic review of randomised trails of interventions to assist patients to follow prescriptions for medications. Lancet, 348:383-6

Helper, C.D. Strand, L.M. (1990) Opportunities and responsibilities in pharmaceutical care. American Journal of Hospital Pharmacy, 47:533-543

Herxheimer, A. (2000) Why 'Doctor knows best' is no longer appropriate. Prescriber, 11(5):31-35

Hodkinson, H.M. (1972) Evaluation of a mental test score for assessment of mental impairment in the elderly. Age and Ageing. 1:233-8

Hodkinson, H.M. (1973) Mental impairment in the elderly. Journal of the Royal College of Physicians of London, 7:305-17

Hodkinson, M. (1981) The elderly
In: Simpson, J.E.P. Levit, R. (Eds) Going home: a guide for helping the patient on leaving hospital. London, Churchill

Hudson, S.A. Boyter, A.C. (1997) Pharmaceutical care of the elderly (1) Drug use in elderly patients. The Pharmaceutical Journal, 259:686-8

Hughes, S. (1998) Compliance with drug treatment in the elderly. Prescriber, 9:45-54

Jackson, C. Rowe, P. Lea, R. (1993) Pharmacy discharge - a professional necessity for the 1990s. The Pharmaceutical Journal, 250:58-9

Johnson, D.H. Robart, P. (2000) Inhaler technique of outpatients in the home. Respiratory Care, 45:1182-7

Kerlinger, F.N. (1992a) Sampling and Randomness
In: Kerlinger, F.N. (1992) Foundations of Behavioural Research. (3rd Edition) Orlando, Harcourt Brace College

Kerlinger, F.N. (1992b) Research design: Purpose and principles
In: Kerlinger, F.N. (1992) Foundations of Behavioural Research. (3rd Edition) Orlando, Harcourt Brace College

Kerlinger, F.N. (1992c) Survey research
In: Kerlinger, F.N. (1992) Foundations of Behavioural Research. (3rd Edition) Orlando, Harcourt Brace College

Kleijnen, J. de Craen, A.J.M. van Everdingen, J. Krol, L. (1994) Placebo effects in double-blind clinical trials: a review of interactions with medications. Lancet, 344:1347-9

Kravitz, R.L. Callahon, E.J. Paterniti, D. Antonius, D. Dunham, M. Lewis, C.E. (1996) Prevalence and sources of patients' unmet expectations for care. Annals of Internal Medicine, 125:730-7

Law, R. Chalmers, C. (1976) Medicines and elderly people: a general practice survey. British Medical Journal, 1:565-8

Ley, P. (1982) Satisfaction, compliance and communication. British Journal of Clinical Psychology, 21:241-54

Linder, J.A. Randall, M.D. Stafford, M.D. (2001) Antibiotic treatment of adults with sore throat by community primary care physicians. JAMA, 286:1181-6

Lorenc, L. Branthwaite, A. (1993) Are older adults less compliant with prescribed medication than younger adults? British Journal of Clinical Psychology, 32:485-92

Lowe, C.J. Raynor, D.K. Courtney, E.A. Purvis, J. Teale, C. (1995) Effects of self medication programme on knowledge of drugs and compliance with treatment in elderly patients. British Medical Journal, 310:1229-31

MacDonald, E.T. MacDonald, J.B. Phoenix, M. (1977) Improving drug compliance after hospital discharge. British Medical Journal, ii:618-21

Marinker, M. (1997) Personal paper: Writing prescriptions is easy. British Medical Journal, 314:747-8

Mazzuca, S.A. (1982) Does patient education in chronic disease have therapeutic value? Journal of Chronic Disease, 35:521-9

McGavock, H. (1998) Noncompliant patients: causes and solutions. Prescriber, 9:117-20

McGraw, C. Drennan, V. (2000) District nurses and medication compliance devices. The Pharmaceutical Journal, 264:368

Milliken, B. Rea, Y. (1997) A clinical pharmacist's contribution to discharge planning and patient counselling. The Pharmaceutical Journal, 258:777-8

Misselbrook, D. (1998a) Why do patients decide to take their medicines? Prescriber, 9:41-4

Misselbrook, D. (1998b) Managing change from compliance to concordance. Prescriber, 9:23-33

Misselbrook, D. (1998c) How to improve patient compliance with treatment. Prescriber, 10:21-9

Moriskey, D.E. Green, L.W. Levine, D.M. (1986) Concurrent and predictive validity of a self-reported measure of medication adherence. Medical Care, 24:67-74

Muir Gray, J.A. (1997) Evidenced-based Healthcare
In: Muir Gray, J.A. Evidenced-based Healthcare. Churchill Livingstone, London

Newell, D.J. (1992) Randomised controlled trials in health care research
In: Daly, J. McDonald, I. Willis, E. (Eds.) Researching Healthcare: Designs, Dilemmas, Disciplines. London, Routledge

Nolan, L. O'Malley, K. (1989) Adverse drug reactions in the elderly. British Journal of Hospital Medicine, 41:446-57

Paes, A.H.P. Bakker, A. Soe-Agnie, C.J. (1998) Measurement of patient compliance. Pharmacy World & Science, 20:73-7

Parkin, D.M. Henneym C.R. Quirk, J. Crooks, J. (1976) Deviation from prescribed drug treatment after discharge from hospital. British Medical Journal, ii:686-8

Pharmacy Practice Research Resource Centre (1998) Drug therapy and Pharmacy. Pharmacy Practice: setting the resource agenda. London, RPS

Qureshi. K.N. Hodkinson, H.M. (1974) Evaluation of a ten-question mental test in the institutionalised elderly. Age and Ageing, 3:152-7

Raynor, D.K. Booth, T.G. Blenkinsopp, A. (1993) Effects of computer generated reminder charts on patients' compliance with drug regimes. British Medical Journal, 306:1158-61

Regional Drug and Therapeutics Centre (1999) Antibiotic prescribing. Drug Update No. 7

Reid, J. Crome, P. (1997) Polypharmacy: causes and effects in elderly patients. Prescriber, 8:83-6

Roth, M. Hopkins, B. (1953) Psychological test performance in patients over 60. I - Senile psychosis and affective disorders of old age. Journal of Mental Science, 99:439-50

Royal College of Physicians Working Party (1997) Medication for older people. (2nd Edition) London, RCP of London

Royal Pharmaceutical Society of Great Britain (1997) From Compliance to Concordance: towards shared goals in medicine taking. London, RPS

Sackett, D.L. Rosenberg, W.M. Gray, J.A.M. Haynes, B.R. Richardson, W.S. (1996) Evidence based medicine: what it is and what it isn't. British Medical Journal, 312:71-2

Sackett, D.L. Wennberg, J.E. (1997) Choosing the best research design for each question. British Medical Journal, 315:1636

Sanghani, P. (1998) Comfortable with concordance? The Pharmaceutical Journal, 261:84

Schulz, K.F. (1996) Randomised trials, human nature, and reporting guidelines. The Lancet, 348:596-8

Silverman, W.A. Altman, D.G. (1996) Patients' preferences and randomised trials. The Lancet, 347:171-4

Smith, P. Andrew, J. (1983) Drug compliance not so bad, knowledge not so good — the elderly after hospital discharge. Age and Ageing, 12:336-42

Southern Derbyshire Community Health Service (1992) Compliance Aids: A guide for health care professionals

Stevenson, F. (2000) Patients' beliefs about prescribed medicines. Pharmacy in Practice, 10:252-4

Stone, R. Cafferata, G. Sangl, J. (1987) Caregivers of the frail elderly: a national profile. The Gerontologist, 27:616-26

Stone, D.H. (1993) Design a questionnaire. British Medical Journal, 307:1264-6

Sweeny, S.J. Dixon, J.S. Sutcliffe, I. (1989) The impact of the clinical pharmacist on compliance in a geriatric population. The Pharmaceutical Journal, 242:R4-6

Tennstedt, S.L. McKinlay, J.B. (1989) Informal care for frail older persons
In: Ory, M.G. Band, K. (Eds) Aging and health care: social science and policy perspectives. London, Routledge

Thomson, W.A. (1974) Black's Medical Dictionary. (30th Edition) London, A. and C. Black Ltd.

Tully, M.P. (2000) Questionnaire design and interviewing. Pharmacy in Practice, 10:292-4

Turner, J.A. Deyo, R.A. Loeser, J.D. van Korff, M. Fordyce, W.E. (1994) The importance of placebo effect in pain treatment and research. JAMA, 271:1609-14

van Berge Henegouwen, M.T.H. van Driel, H.F. Kasteleijn-Nolst, T. (1999) A patient diary as a tool to improve medicine compliance. Pharmacy World and Science, 21:21-24

Wandless, I. Davies, J.W. (1977) Can compliance in the elderly be improved? British Medical Journal, i:359-61

Ward, A. Morgan, W. (1984) Adherence patterns of health in men and women enrolled in an adult exercise program. Journal of Cardiac Rehabilitation, 4:143-152

Webb, D. Sanghani, P. Tugwell, C. Cross, M. (1999) Concordance: last link in the chain? The Pharmaceutical Journal, 263:782

Woodward, C.A. (1992) Broadening the scope of evaluation: why and how
In: Daly, J. McDonald, I. Willis, E. (Eds.) Researching Healthcare: Designs, Dilemmas, Disciplines. London, Routledge

World Medical Assembly (1989) World Medical Association Declaration of Helsinki. [online] Available from: http://ohsr.od.nih.gov/helsinki.php3 (accessed 25th May 2002)

Working Party (1984) Medication for the Elderly: A report of the Royal College of Physicians. Journal of the Royal College of Physicians, 18:7-17

Working Party (1997) From compliance to concordance: achieving shared goals in medicine taking. London, Royal Pharmaceutical Society of Great Britain

Yudkin, P.L. Stratton, I.M. (1996) How to deal with regression to the mean in intervention studies. The Lancet, 347:241-3