

How do the attitudes and beliefs of healthcare professionals and older people impact on the appropriate use of multi-compartment compliance aids by older people living at home.

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Submitted in accordance with the requirements for the degree of Doctor of Philosophy.

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February 2008

The candidate confirms that the work submitted is her own and that appropriate credit has been given where reference has been made to the work of others

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Acknowledgements

I would like to thank all the older people and healthcare professionals who freely participated in the interviews. Also I am grateful to the pharmacists and other healthcare professionals who assisted in the recruitment.

A special thank you is extended to my supervisors, Professor Theo Raynor, Dr Peter Knapp and Professor José Closs whose patience and guidance was much appreciated.

Finally I would like to thank my family, in particular my husband, Jim Nunney, for all their help and support, without which this thesis would never have been completed.

Abstract

Compliance with medication regimes is a widely researched topic within the field of healthcare. Older people are considered to be a greater risk of non-compliance due to multiple morbidities. Multi-compartment compliance aids are frequently issued to older people in an attempt to improve their medicines management.

This thesis aims to determine whether the attitudes and beliefs of both the older people who use MCAs and the healthcare professionals who request their use, influence the use of such devices by older people living in the community.

A preliminary study which investigated the use of MCAs in primary care is described. The findings suggested that over 100,00 people in the UK may be issued with a MCA despite little evidence for their efficacy.

The literature review undertaken for this thesis concludes that very few studies have been undertaken in this area and those which have are mainly of poor quality. The results from these studies failed to conclusively support the use of these devices and further rigorous conducted studies are needed.

The main study comprises qualitative, in-depth semi-structured interviews with older people, who are using a MCA and healthcare professionals. The interviews were analysed using a grounded theory approach.

The study revealed that older people find MCAs easy to use and convenient although a minority of the participants did experience difficulties using the device. Maintaining independence and remaining in control was important for all the older people and this influenced their attitudes towards using their MCA.

The healthcare professionals concurred with the observation that MCAs were convenient to use and despite a minority stating that MCAs assisted older people to remember to take their medication, the majority acknowledged that this was not the case. The healthcare professionals agreed that the decision to issue a MCA could be seen as paternalistic however there remained a belief that the issue of a MCA would assist the older person take their medication correctly.

The thesis concludes by providing details of a proposed method for undertaking a holistic, patient-centred, multi-disciplinary assessment of older people's medicines management abilities

Publications and Presentations

The work described in the section of this thesis named below formed the basis of the following publication.

Chapter 2. Multi-compartment compliance aids in primary care: A preliminary study.

NUNNEY, J.M. D.K.RAYNOR, 2001. How are multi-compartment compliance aids used in primary care? *The Pharmaceutical Journal* **267** (7176), pp.784-789

The following presentations have been made as a result of the work described in this thesis.

Posters

Chapter 2. Multi-compartment compliance aids in primary care: A preliminary study.

NUNNEY, J M. D.K.RAYNOR.

Multi-compartment compliance aids in primary care: building an evidence base. British Pharmaceutical conference. Cardiff, 1999.

Chapter 3. Review of the literature relating to the use of multi-compartment compliance aids by older people.

NUNNEY, J.M. D.K.RAYNOR, P.R. KNAPP.

What is the evidence for the use of multi-compartment compliance aids by older people living in the community?

Health Services Research and Pharmacy Practice Conference. London 2003

Chapter 6 & 7. Interviews with older people and healthcare professionals.

NUNNEY, J. D. K. RAYNOR, P. KNAPP. S.J.CLOSS.

Multi-compartment compliance aids: Who gets the benefit? Who takes the risk? British Pharmaceutical Conference. Manchester 2007.

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List of Abbreviations

Abbreviation	
AF	Atrial fibrillation
MCA	Multi-compartment compliance aid
PCT	Primary Care Trust
HA	Health Authority
INR	International Normalised Ratio
GP	General Practitioner
RPSGB	Royal Pharmaceutical Society of Great Britain
UKCC	United Kingdom Central Council for Nursing
SOP	Standard Operating Procedure
PMR	Patient medication records
ADR	Adverse drug reaction
“prn”	To be taken when required.
BP	Blood pressure
USA	United States of America
UK	United Kingdom
HRT	Hormone replacement therapy
NSF	National Service Framework
ICT	Intermediate care team
MDS	Monitored dosage system

Chapter 1: Introduction

1.1 Background to the thesis

This thesis describes research undertaken to investigate whether the attitudes and beliefs held by older people and healthcare professionals influence the use of multi-compartment compliance aids (MCAs) by older people living in their own homes. Multi-compartment Compliance Aid is the term I have used to describe containers designed to hold all of a patient's solid medicines in individual compartments. These compartments are usually labelled with the day of the week and a time of day. Further description of these devices will follow later in the chapter. My interest in the use of multi-compartment compliance aids first developed during a research project, undertaken in 1997 (Raynor *et al.* 2000). In this project we investigated the ability of community pharmacists to provide compliance support to older people, who were living in their own homes. Although the number of participants in this study, who were issued with multi-compartment compliance aids, was small the question of the suitability of these devices was raised. In 1998 I was successful in obtaining a Galen Award from the Royal Pharmaceutical Society of Great Britain and this allowed me to carry out a preliminary study, which I describe in Chapter 2. The preliminary study indicated that a large number of patients were being issued with multi-compartment compliance aids, despite the evidence for their use being unclear. This conclusion led me to ask why healthcare professionals recommend the use of MCAs for older people living independently in the community. When considering the answer to this question

I hypothesised that the attitudes and beliefs held by the healthcare professionals concerning older people and their medicines may contribute to the appropriate issue of

these devices. Equally important, older people who are recipients of these devices may also have attitudes and beliefs which may influence their use of them.

1.2 The Aim of the Study

The aim of the study was to discover how the attitudes and beliefs of older people and healthcare professionals affect the use of multi-compartment compliance aids (MCAs) by older people living in the community.

There follows in this introductory chapter brief consideration of a number of key issues, which are of relevance to the work which was undertaken to take forward this study. In some cases this will be an introduction to a topic which is thought necessary to make prior to the description of the preliminary study in Chapter 2.

1.2.1 Attitudes and beliefs

In order to discuss the findings of the study, it is necessary to determine what is meant by both “attitudes” and “beliefs”. Attitudes are defined in the Shorter Oxford English Dictionary as:

Settled behaviour or manner of acting, as representative of feeling or opinion.

Attitude of mind: habitual mode of regarding anything.

Beliefs are defined in the Shorter Oxford English Dictionary as:

Mental assent to or acceptance of a proposition, statement, or fact, as true, on the ground of authority or evidence.

There is a difference therefore between attitude and belief as defined above. Attitudes can be based on a person’s individual opinion and continue through habit whereas beliefs are based on evidence.

Attitudes and beliefs have been further explored by Ajzen (1988) who states that a person’s attitude towards something may be influenced by their underlying belief.

Therefore if a person believes that medication is dangerous, then they will have a negative attitude to medication compliance. In contrast a favourable attitude to medicines might be implied by the belief that pharmaceutical research has led to many new and effective treatments.

1.3 What are Multi-compartment Compliance Aids?

A brief definition of MCAs has already been given at the beginning of this chapter. MCAs usually hold seven days supply of a patient's medication and comprise two distinct types:

Re-usable aids (e.g. Dosett® , Medidos®). These are made of rigid plastic with separate compartments for days of the week and times of the day. Patients access their medication by sliding open or lifting a cover. The aid is not tamper proof-sealed when it leaves the pharmacy. Re-usable aids can also be purchased in pharmacies or obtained by mail-order from a number of outlets. They can be filled by the patient or carer themselves or in the pharmacy.

Disposable aids (e.g. Nomad® and Venalink®) sometimes known as a monitored dosage system (MDS). These are made of much less robust materials but have similar divisions for days of the week and times of day. They are sealed by transparent film or a foil backing sheet, making them tamper proof when they leave the pharmacy. The patient accesses the medication either by piercing the film or the foil backing.

When the preliminary research was undertaken, approximately one third of MCAs issued from pharmacies were of the re-usable type (see Section 2.4.2 for further discussion). Currently the majority of devices issued are of the disposable type, which leave the pharmacy sealed and are therefore tamper evident.

1.3.1 What is the evidence for the use of MCAs?

Prior to undertaking the preliminary study, I had undertaken a brief review of the literature relating to the effectiveness of MCAs. This literature review indicated that the evidence for using these devices was inconclusive. I therefore decided as part of this current research to undertake a thorough review of all the available literature relating to MCAs and older people. The method and results of this review are contained in Chapter 3 of the thesis.

1.4 What is meant by the term compliance?

The Shorter Oxford Dictionary defines compliance as

acting in accordance with a desire, condition etc.

At a basic level compliance with medication could be defined as taking the correct drug, in the correct quantity, at the correct intervals. However the most frequently cited definition is that provided by Haynes (1979) who defined it as

“ the extent to which a person’s behaviour (in terms of taking medications, following diets, or executing lifestyle changes) coincides with medical or health advice” p.1.

The earliest reference to compliance with medication is often stated to have been made by Hippocrates and in the early twentieth century, Franz Kafka wrote in his short story ‘A Country Doctor.’ Published in 1919

“To write prescriptions is easy, but to come to an understanding with people is hard.”

Perhaps this is an early reference to shared decision making or concordance?

The literature on compliance with medication really starts in earnest in the 1950s, when new powerful drugs such as antibiotics were first developed. A journal article in the early 1970s, (Stimson 1974), reviewed a number of studies of compliance with medical instructions and concluded that these studies had all used an ideal image of the patient as a passive and obedient recipient of medicines. Those patients who failed to take their

medication as instructed were seen as 'defaulters'. Stimson noted that the studies were all undertaken from a medical perspective and aimed to discover what made a patient a defaulter. Ahead of his time, he argued that this problem should be considered from the patient's perspective and went on to carry out a study in which patients were interviewed about their consultations with their doctor. His conclusions were that we must consider the social context in which our patients live, fall ill and use medication.

MCAs may be issued because the recipient is seen as a 'defaulter'. How does the older person view the issue of a MCA? Do the healthcare professionals, who request the issue of a MCA for an older person in their care, consider the older person's perspective? These are all questions which I wish to try to answer in my research study.

1.4.1 Adherence.

More recently, researchers and health care professionals have used the term adherence instead of compliance, this is because the term compliance is seen to suggest that the patient is in a passive role simply obeying the instructions of the health professional. The term adherence was substituted for compliance with the implication that the patient had a more active role and was more involved in the process. Throughout this thesis, I will use the term compliance, both terms refer to the same thing, and much of the literature referred to uses this term.

1.4.2 Intentional and Unintentional Non-compliance.

The distinction between intentional and unintentional non-compliance was described in research undertaken in the early 1980s, (Cooper, Love and Raffoul 1982). Later studies, (Lowe and Raynor 2000b; Raynor 1992) also distinguished between intentional or deliberate non-compliance and unintentional non-compliance.

Intentional non-compliance

Intentional non-compliance is said to occur when a patient makes their own decision not to take their medication exactly as instructed. The reasons why patients consult a healthcare professional and then decide not to take their medication according to instructions are complex. Patients may be unhappy with the medical advice they have been given and are therefore reluctant to take the medication. The side effects of drugs may prove too severe or reduce the patient's quality of life to such an extent that the patient decides to stop taking the medication. Patients may worry about becoming dependent on medication and take 'drug holidays'. Sociologists suggest that patients may be stigmatised by taking medication (Conrad 1985). Patients' health beliefs have also been identified as significant when considering compliance (Horne and Weinman 1999). This intentional non-compliance requires considerable understanding on the part of the healthcare professional when trying to assist patients to take their medication as directed.

Unintentional non-compliance

In unintentional non-compliance, patients wish to take their medication correctly but are unable to do so because of reasons beyond their control. The reasons why patients are unable to comply include the following categories:

Inability to understand instructions

- Lack of knowledge about their medication
- Difficulty in accessing the medication
- Poor memory
- Inability to swallow or administer the medication themselves.

Therefore strategies to improve unintentional non-compliance can be targeted at the patient's individual problem. These strategies could include better education about the medication, clearer information on how to take the medication and easy-to-open containers. Reminder charts and other memory aides may also be beneficial (Raynor, Booth and Blenkinsop 1993).

1.4.3 The prevalence of non-compliance.

There is a large amount of literature on the topic of compliance with medication. A meta-analysis of empirical articles, published in English language journals over a fifty year period, found that the average non-compliance rate was 24.8%, (DiMatteo 2004). This study undertook the meta-analysis on 569 studies, which gives an indication of the amount of literature devoted to this particular topic.

Individual studies have quoted figures of between 25% and 60%, (Blackwell 1972; Stewart and Cluff 1972). A more recent study, (Degli Esposti *et al.* 2002) investigated 16,783 patients with hypertension whose average age was 56 years. Of these patients 65% discontinued their anti-hypertensive treatment during the period of the study.

It is important to consider what is meant by these figures for it seems unlikely that 50% of patients take their medication exactly as directed 100% of the time, while the other 50% fail to take their medication as directed. In a journal editorial (Kravitz and Melnikow 2004) the authors question the assumption that 75% compliance means that patients disregard a quarter of all recommendations received or that 25% of patients never adhere. The authors state that beyond quibbling over the mathematical statements, important issues are raised concerning the conceptual and mathematical models used to link compliance and outcomes.

Evidence obtained by electronic monitoring of medicine taking, has suggested the following patterns of behaviour. Approximately one sixth of patients take their

medication as close as is possible to perfectly, one sixth take almost all the doses but with some errors in timing, one sixth miss the occasional day's doses and have some timing errors: one sixth take drug holidays three or four times per year, with occasional omissions of doses; one sixth take frequent drug holidays and omit doses on a regular basis, and one sixth take few or no doses whilst giving the impression of good compliance. This pattern of behaviour was described as the 'rule of sixes', (Urquhart 2002). It is not clear whether this behaviour is generalisable to all patients, however it does indicate the variety of compliance behaviour which may occur.

Another problem which arises is due to the difficulty of measuring the level of non-compliance. This is frequently carried out by self-report and/or pill count. Both of these methods may not give the true result. Studies which use a clinical outcome measure, for example improvement in blood pressure control, are often seen as being more robust; however in their review of measurement, correlates and health outcome of medication compliance Vik and colleagues (2004) state that many factors apart from compliance may influence clinical outcomes and therefore these should not be used alone to provide a measure of compliance.

1.4.4 Predictors of non-compliance.

The ability to predict which patients may be at risk of poor compliance with their medication regime could be very useful to a healthcare professional. Identifying particular groups of patients as more prone to non-compliance would mean that strategies could be targeted at particular groups of patients. Various studies have investigated risk factors which might influence non-compliance. A literature review article (Balkrishnan 1998) identified 14 studies which investigated the relationship between elderly patient's non-compliance with medication and various demographic, social, behavioural, economic and medication related variables. Age is often suggested

as a predictor of non-compliance with those over 65 being seen as at greater risk, however Balkrishnan (1998) stated that this was not an important predictor in most published studies. In fact many research studies indicate that older age is an indicator of better compliance, (Degli Esposti *et al.* 2002; Park *et al.* 1992). A study of elderly people with hypertension in the USA (Monane *et al.* 1996) found that not only was age not a risk factor but also that the 'oldest old' that is those aged 85 years or older were most likely to achieve compliance of 80% or over. Conversely Park *et al.* (1992) identified the 'old-old' as less compliant than the 'young-old'. A postal survey of community based men and women aged over 60 years in Australia (Cohen *et al.* 1998) found significant positive associations between non-compliance and being male, taking more than two drugs daily, not having had an explanation about the drug and taking the drug more than twice daily. Although many factors have been investigated, it remains impossible to identify with any certainty which patients generally are more at risk of poor medication compliance.

1.4.5 Strategies to overcome non-compliance.

Much of the research on non-compliance with medication is directed to developing strategies to overcome it. Having discovered that the prevalence of non-compliance with medication is high, then developing strategies to overcome this problem are seen as a priority. Ten years after his original work on compliance, Haynes published a critical review of interventions to improve compliance with prescribed medication (Haynes, Wang and Da Mota Gomes 1987). Haynes concluded that although considerable knowledge had been gained, none of the methods aimed at improving compliance were fully effective. This review of the interventions to improve compliance with medication has been updated at regular intervals and will be discussed again in later chapters. Research to identify strategies has continued but no single method can be said to be completely effective.

1.5 Concordance.

Focusing on compliance with medication is now seen as paternalistic in nature. I will be discussing paternalism in more detail in later chapters. In an attempt to move away from paternalism, a number of new approaches have been suggested. A ‘patient-centred’ approach was first discussed at the end of the 1960s (Balint 1969). A review of the literature on ‘patient-centeredness’ (Mead and Bower 2000), attempted to develop a model of the doctor-patient relationship, which is defined by this term. Another concept which has come to the fore recently, is that of ‘shared decision making’, (Charles, Gafni and Whelan 1997). Charles and her colleagues aimed to define the key characteristics of shared decision making. At the same time, the Royal Pharmaceutical Society was producing a report ‘From Compliance to Concordance: Achieving Shared Goals in Medicine Taking.’ (1997). This report suggested that a better terminology was ‘concordance’; which emphasised a partnership between the patient and the health professional. In the report, concordance is expressed as follows:

“The clinical encounter is concerned with two sets of contrasted but equally cogent health beliefs – that of the patient and that of the doctor. The task of the patient is to convey her or his health beliefs to the doctor, to enable this to happen. The task of the doctor or other prescriber is to convey his or her (professionally informed) health beliefs to the patient; and the patient, to entertain these. The intention to assist the patient to make as informed a choice as possible about the diagnosis and treatment, about benefit and risk and to take full part in a therapeutic alliance. Although reciprocal, this is an alliance in which the most important determinations are agreed to be those made by the patient.” p. 12

Within the profession of pharmacy, the term ‘concordance’ has become the preferred terminology, whereas, in other parts of the world, ‘shared decision making’ has been the expression of choice. Later in this thesis, I intend to discuss concordance in relation to the use of MCAs and also to consider the health professionals’ views on this.

1.6 Why investigate the use of MCAs by the older population?

Although the incidence of non-compliance with medication occurs across all ages of the population, anecdotal evidence suggests the decision to issue a MCA is generally taken for older people only. Non-compliance is well documented in patients with other conditions, for example, patients with HIV whose medication regime is complex and who suffer from a high risk of side effects. For example MCAs have been issued to patients with HIV; however, more use is made of other strategies, for example, electronic reminder systems, telephone reminders and education sessions (Bartlett 2002; McPherson-Baker *et al.* 2000). The preliminary study, which I discuss in Chapter 2, indicated that the majority of patients issued with an MCA by the community pharmacists were aged over 65. Therefore I wished to investigate if the MCAs were being issued because the patient was older, rather than because they were having problems with their medication and the MCA was deemed to be the most appropriate solution.

1.6.1 The Ageing Population

The 2001 census shows that in the previous 50 years the population of the United Kingdom has aged considerably, both in terms of actual numbers and as a proportion (Office for National Statistics 2001). In particular, the ageing population can be seen from the increase in people aged 85 and over. In 1951, there were 0.2 million, (0.4% of the population), while the 2001 census shows that this has grown to over 1.1 million, (1.9% of the population). The ageing population reflects longer life expectancy, largely because of improved living standards and health care.

1.6.2 Level of medication usage in older people.

The dispensing statistics produced by the Department of Health (2007b) reveal that elderly people, i.e. those aged 65 and over, receive 58.6% of all prescription items

dispensed in the community at a total cost of £4,401.8 million. The number of prescribed items of medication per head of population received by the elderly was 21.2 in 1996 rising to 40.8 in 2006. Therefore the level of medication usage in the over 65 age group is rising steadily, allied to this is the fact that the population is also aging. Medication costs for elderly people represent a significant burden on the NHS and that a significant proportion of this medication is not taken, is a cause for concern. This may explain why so many research studies look at ways to improve compliance with medication.

1.7 A brief description of the study

The study undertaken in order to address the aim set out in section 1.2 of this chapter consists of the following parts:

A preliminary study which aimed to assess the scale of dispensing of medicines in MCAs in a health authority area; the level of service provided by community pharmacists, and the needs of the patients receiving their medication in MCAs.

A review of the literature relating to the use of MCAs in older people. This review aims not only to investigate the evidence base for the use of MCAs, but also to identify other literature pertaining to the use of these devices.

In-depth semi-structured interviews with older people (aged 65 and over) who are using MCAs with the aim of investigating the interviewees' attitudes and beliefs concerning the use of MCAs.

In-depth semi-structured interviews with healthcare professionals who may recommend the use of MCAs for older people in their care. The aim of these interviews is to examine the attitudes and beliefs which the healthcare professionals hold concerning the use of MCAs and the older people who are issued with these devices.

1.8 A brief description of the layout of the thesis.

This chapter has set the scene of current thinking concerning compliance with medication, concordance and the use of MCAs. I have indicated the rising level of medication usage among the elderly population and discussed the increase in the numbers of people aged over 65 years in the population of the United Kingdom.

Chapter 2 describes the preliminary study of MCA use in one health authority area. It relates how the findings from this study provided the background for the main study.

Chapter 3. describes a structured review of the literature on MCAs. This includes a critical analysis of the investigative studies on MCAs and discusses the implications of their findings. Also described and discussed are other journals articles and reports which aim to support the appropriate and effective use of these devices.

Chapter 4. describes the underlying methodological theory which was used in the main study. Notably this covers the choice of qualitative research and grounded theory.

Chapter 5 describes the methods used in all parts of the study and details how the analysis of the data was undertaken.

Chapter 6 describes the findings of the older peoples' interviews and then discusses them.

Chapter 7 describes the findings from the healthcare professionals' interviews and discusses them, comparing them across the groups of different healthcare professionals.

Finally in **Chapter 8** I compare the findings across all the groups interviewed and discuss them. This is followed by a discussion of the implications for practice and future research.

Chapter Two: Multi-compartment compliance aids in Primary Care: A preliminary study

2.1 Introduction

This chapter describes a preliminary study which was undertaken in the local health authority area, and which provided the impetus to the main study described in the thesis. The aims and objectives of the research are stated, followed by a discussion and justification of the methodology for this study. The study consists of three distinct parts: a self-administered pharmacy questionnaire, an administered pharmacist's questionnaire and an administered MCA users' questionnaire. These three parts of the study are described and discussed in later sections of this chapter. The conclusions drawn from the results of the study are then discussed. Finally I describe how the findings of this preliminary study influenced the procedures followed in the main study.

2.2 The aims and objectives of the study

The aims of the study were to:

Ascertain the current scale of dispensing of medication in MCAs to patients living in their own homes in the local health authority area.

Investigate how local pharmacists provide this service.

Assess patients already receiving medicines in MCAs with regard to their ability to use the aid correctly and their need for the MCA.

The objectives were to:

Determine the number of patients living independently in the community in the local health authority area, who receive their medication in MCAs.

Explore the methods by which a random sample of community pharmacists undertook the dispensing of medication in MCAs.

Identify from where the requests for the dispensing of medicines in MCAs for patients living in their own homes, originate.

Assess a sample of patients who already receive their medication in MCAs for their:

Ability to use the MCA.

Understanding of their medication regime.

Satisfaction with the MCA.

Need for such an aid.

2.3 Method

This study was intended to provide a snapshot of the situation regarding the supply and use of MCAs within a particular health authority area at a particular point in time.

The study consisted of three distinct phases:

A self-completed questionnaire, which was sent to every registered pharmacy in the local health authority area. The questionnaire was to be completed by the pharmacist

A structured questionnaire administered by the research pharmacist, to a randomly selected group of pharmacists who had already completed the first questionnaire.

A structured questionnaire administered by the research pharmacist to those patients of the pharmacists above, who used MCAs.

2.3.1 Research method used

The methods used to undertake this preliminary study fell within the quantitative research paradigm. Quantitative research as the name implies is concerned with quantities and involves the collection and analysis of data (Bowling 2002). Quantitative research is understood to be experimental in nature, with the experiment designed to test a theory. The data is usually numerical, reliable and statistically defined. The researcher in quantitative research stands aside from his experiment and is independent of it. The results obtained should provide proof or otherwise of the hypothesis and are considered generalisable and reproducible. This contrasts with qualitative research when the researcher acknowledges their position in the social world and their influence on both data collection and interpretation (Temple 1997). Quantitative research aims to produce data which is reliable, replicable and generalisable. Quantitative research is considered to lie within the positivist framework of sociological theory. Positivism aims to discover laws using quantitative methods based on observations and verifiable facts (Bowling 2002). In another definition, research within the positivist paradigm is seen as linear, progressing logically from previously established to new knowledge (May 1994) In Section 4.2. I discuss in more detail the differences between the two research paradigms.

Quantitative research methodology can be experimental, for example randomised controlled trials, or it can be descriptive, for example, cross-sectional surveys. Surveys are widely used within pharmacy practice research and can comprise a quick and relatively easy way of obtaining information about pharmacy related issues.

The majority of surveys gather descriptive data which may aim to give details of services provided, or describe particular populations.

The method chosen for this preliminary study was determined by the questions asked. I wished to discover how many MCAs were in use in a designated area. Who was most likely to have requested the issue of a MCA to a patient? How the community pharmacists responded to such requests and what procedures they had in place for dispensing medication in MCAs. Finally, I wished to determine if the patients who had their medication issued in a MCA could use it and what knowledge they had concerning their medication. All these questions are best answered by survey methods.

Surveys can be defined as a method of collecting information from a sample of a population which the researcher wishes to investigate, by means of personal interviews. Surveys can be either descriptive or analytical. Descriptive surveys are usually designed to obtain information at one moment in time and are therefore also cross-sectional in nature. Analytical surveys, on the other hand, are designed to obtain evidence concerning cause and effect and are usually longitudinal in design. In this preliminary study the survey was designed to obtain a snap-shot of what was happening in a specific area at one moment in time and was therefore descriptive and cross-sectional.

2.3.2 Data collection methods.

Questionnaires are the usual method of data collection when undertaking survey research and can be either structured or semi-structured. Structured questionnaires have the advantage of being quick and easy to administer. However the questions need to be easily understood by the respondents and the structured nature does not allow for the respondent to elaborate on his/her answer. Semi-structured interviews allow the interviewer to be more flexible in their approach, for example asking the questions in a different order. Respondents can have the opportunity to elaborate on their answers and to raise other relevant issues.

The reliability and validity of the questionnaire used is very important. Reliability refers to whether another researcher could reproduce the work and obtain similar results. Validity is concerned with the accuracy of the data obtained. In survey work the validity refers to the ability of the questions asked to provide answers which are relevant to the study objectives (Smith 2002). In order to validate a survey instrument it is necessary to test either all or part of it. The same population must be used to validate the instrument as will be used in the research study. The questionnaire used in part 1 of the preliminary study was based on one previously used by the health authority for a similar survey.

In this preliminary study two types of questionnaire were used. Part 1 of the study used a self-administered structured questionnaire which was posted out to the respondents. The advantages of postal questionnaires are that they can investigate a wider population quickly and cheaply, and because the questionnaire is self-administered there is no interviewer bias. However the questionnaire must be clear and easy to understand and the data obtained is not considered as reliable as that obtained by face-face interviews (Bowling 2002).

Parts 2 and 3 of the study used structured, administered questionnaires. Administered questionnaires give the researcher the opportunity to clarify a reply or to follow up responses, although the structured nature of the questionnaire precludes any further exploration of the replies given.

2.3.3 Research Ethics Approval

Approval was obtained from the both local research ethics committees in the area where the research was undertaken

When the preliminary study was undertaken, Research Ethics approval was only required for the patient interviews. The patients were required to give informed

consent, that is, they had to be able to read, understand and sign the consent form. Therefore consent could not be obtained from those patients who had some cognitive impairment.

2.4 Part 1: The postal pharmacy questionnaire

2.4.1 Method

A short questionnaire was designed which aimed to answer the following questions:

Did the pharmacy dispense in MCAs for patients living independently in the community?

If the answer to question 1 was **yes**, how many patients were receiving their medication in MCAs?

Which device(s) did they use?

If the answer to question 1 was **no**, what was the reason for this?

The pharmacists were also asked if they were willing to contribute further to this research. A copy of the questionnaire can be found in Appendix 1. The questionnaires were posted to all 152 contracted pharmacies in the local health authority area using a list provided by the health authority. A letter accompanied the questionnaire, which gave details of the research and a stamped addressed envelope was provided.

2.4.2 Results

The initial response rate was 53%, which increased to 80% after a repeat mailing.

The results from the 123 completed questionnaires received were entered onto an Excel® spreadsheet.

95 (77%) of the pharmacies reported dispensing medicines in MCAs to patients living in their own homes.

The total number of patients receiving their medicines in MCAs was 1328.

The average number of patients per pharmacy was 11 (range 1 to 70). (see Table1).

Nomad®, Dosett® and Medidos® were the most frequently used MCAs. (see Table 2).

819 (62%) of the patients were using a sealed device rather than a refillable one.

Table 1: Number of patients receiving medication in a MCA per pharmacy dispensing in MCAs.

No. of patients	No. of pharmacies dispensing in MCAs (n=95)
1 - 10	53
11 - 20	22
21 - 30	13
31 - 40	3
41 - 50	2
51 - 70	2

Table 2: Number of patients using each type of MCA

Type of MCA	No. of patients (%) (n=1328)
Nomad®	694 (52%)
Dosett®	363 (27%)
Medidos®	116 (9%)
Venalink®	85 (6%)
Manrex	40 (3%)
Other	30 (2%)

There were 28 pharmacies (23%) which did not dispense in MCAs to patients living independently in the community. The pharmacists were asked to state a reason and these are listed in Table 3.

Table 3: Reasons for not dispensing in MCAs

Reason	No. of pharmacies (n=28)
No demand	11
No remuneration	6
Would dispense if given 7 day scripts	1
Pharmacy not suitable (insufficient space)	1
No reason given	9

2.4.3 Discussion

The brief literature review which had been undertaken prior to the commencement of this study had not identified any articles reporting surveys of this nature. Therefore the prevalence of the use of MCAs by people living independently in the community was previously difficult to determine. The health authority in whose area the study was undertaken had commissioned a survey themselves approximately three years previously. The results of this study had not been published, but the paperwork was still on file and available for investigation. The figure for the number of MCAs in use at the time of the health authority survey was 320, with an average of four patients issued with MCAs per pharmacy. The health authority survey had been carried out in a similar way to the study discussed in this chapter and the response rate had been 62%. Therefore the results detailed above show a sharp increase in the number of MCAs in use, with the average number of patients using an MCA per pharmacy almost tripling. This was much higher than anticipated, however it was not possible to identify a reason for this from the answers to the pharmacy questionnaire.

The figure from the RPSGB for registered pharmacy premises was 11,901 at the time of the study. Therefore it was possible to suggest that there might be 100,000 patients in the country receiving their medication in a MCA, assuming that the mixed inner city, suburban and semi-rural nature of this northern city was comparable with the rest of the UK.

These figures raise the question of why are so many MCAs in use when the evidence for their effectiveness appears to be very limited. The questionnaire was not designed to seek out reasons for the willingness on the part of the pharmacists to dispense in MCAs and therefore it was not possible to answer this question at this point.

The respondents were asked about the devices which they provided for patients. The sealed, disposable Nomad® device was the most frequently issued, with the refillable Dosett® the next most popular. The questionnaire did not ask for reasons for these choices and therefore it is not possible to state why these devices were chosen. However those pharmacies who also provided services to nursing and residential homes, where the sealed monitored dosage systems e.g. Nomad® are mostly used, may use the same device for their community patients.

Twenty three percent of the respondents stated that they did not dispense medication in MCAs and they were asked to give their reasons (see Table 3.). Lack of demand was the most frequently cited reason, however it is not possible to know if these pharmacies actively advertised this service or simply waited for someone to ask. Those pharmacies which provided the service may advertise the fact to other healthcare professionals, leading to more requests.

Lack of remuneration was the second most common reason given for not providing the service. At the time the study was undertaken, there was no NHS funding provided and although some pilot schemes had been initiated in other parts of the country (Anon.

1996) there were none in this area. The pharmacists usually asked the GP to provide 7-day prescriptions for the patient; this was allowable under the NHS contract in place at that time because the medication would be dispensed weekly and delivered to the patient. However this procedure was unpopular with GPs because it was time consuming and there is also a suspicion held by some GPs that the pharmacist is profiteering. This had led to a breakdown in relationships between some GPs and pharmacists.

2.5 Part 2: Administered pharmacists' questionnaire

2.5.1 Methods

The results obtained from the self-completed questionnaire suggested that it would be valuable to obtain more information from community pharmacists regarding the issue of MCAs. A structured questionnaire administered face-to-face was chosen as the method of data collection.

A structured questionnaire was designed which aimed to answer the following questions:

Who most frequently requested the dispensing of medicines in MCAs for patients living in their own homes?

What method of assessment of the patient did the pharmacist use?

What verbal advice and information ('counselling') did the patient receive?

What procedures were in place in the pharmacy for dispensing in MCAs; and was there a written protocol?

Did the pharmacists have any concerns about dispensing in MCAs?

The questionnaire was piloted with one community pharmacist and as a result minor changes to the questionnaire design were made.

2.5.2 Selection of the pharmacists.

The pharmacists who completed the first questionnaire were asked if they were willing to be involved in further research. Those pharmacists who had expressed a willingness to be involved were listed in a database, along with details of the number of patients receiving medication in a MCA supplied by their pharmacy.

Because the results from the self-administered questionnaire revealed that the number of patients who were receiving their medication in MCAs from individual community pharmacies varied widely (see Table1) and it was decided that the selection of pharmacists would be stratified to reflect the number of patients in their practice who used MCAs. Stratifying the sample ensures that sufficient numbers of pharmacies in each group will be selected in order that comparisons can be made.

The groups chosen were 1-10, 11-20, 21-30 and over 30 patients being given a MCA at that pharmacy. Four pharmacists were randomly selected from the first group, three from the second, two from the third and one from the fourth. This distribution reflected the number of pharmacies within each group. The randomisation was carried out independently of the researcher using a computer programme designed for this purpose.

The selected pharmacies were contacted in the first instance by letter and then telephoned to arrange an appointment. Two pharmacists refused to take part, in both cases a change of pharmacy manager had occurred between part one and part two of the study. These two pharmacies were replaced by two more randomly selected pharmacies from the same group.

2.5.3 Administration of the questionnaire

The questionnaire was administered in the pharmacy at a date and time which were convenient for the pharmacist concerned. It was not always possible to undertake this task in a separate room away from the dispensary, which was a disadvantage, however some meetings were held during the lunch hour while the premises were closed.

The questionnaire consisted of a mix of open and closed questions (see Appendix 1), designed to ascertain the procedure which the pharmacist would follow when requested to dispense a patient's medication in a MCA and the dispensing and delivery procedure operating in that pharmacy. There were also opportunities for each pharmacist to express his or her own opinions on the use of these devices.

The questionnaire took between 30 and 45 minutes to administer and the pharmacists' answers were recorded manually on the questionnaire at the time of the interview. The answers were then transferred onto a database as soon as possible after the interview.

2.5.4 Results from the administered pharmacists' questionnaire.

The ten randomly selected pharmacists represented all types of community pharmacy. The demographic details of these pharmacies are detailed in Table 4 .

Table 4: Demographic details of selected pharmacies.

Pharmacy ID	Type of pharmacy	Pharmacist details	location	Number of patients with MCA
A	Independent One shop	Owner	Small town on HA border	2
B	Independent One shop	Owner	Inner city	5
C	Independent One shop	Owner	Small village on HA border	4
D	Independent One shop	Owner	Inner city	28
E	Independent 3 shops	Employee manager	Outer suburbs	12
F	Independent 5 shops	Employee manager	Inner city	13
G	Independent 2 shops	Owner	Outer suburbs	12
H	Independent 2 shops	Owner	Outer suburb	6
I	Large national multiple	Employee manager	Outer suburb	30
J	Large national multiple	Employee	Inner city	50

Who requests the issue of a MCA?

The first question asked the pharmacists to identify which healthcare professional was, in their experience, the most likely to request the issue of a MCA

The pharmacists were given a card with the names of healthcare professionals or organisations and asked to rank the answers from 1 – 7, with 1 being the most frequent and 7 the least. The results in Table 5 and show that the patient's own doctor was perceived to be the healthcare professional who most frequently requested the dispensing of medication in MCAs for patients living in their own homes. The doctor was closely followed by hospital staff, carers and social services. The pharmacists rated themselves as being the least likely to initiate use of an MCA.

Table 5: The healthcare professionals most likely to request dispensing in MCAs
Ratings from 1 (most frequent) to 7 (the least)

	Pharmacist ID										Mean
	A	B	C	D	E	F	G	H	I	J	
Doctor	3	2	1	6	1	2	7	5	1	1	2.9
Hospital staff	6	3	2	7	2	1	3	2	3	2	3.1
Carer	2	7	5	3	3	6	1	4	2	3	3.6
Social services	5	1	4	4	7	3	6	1	5	5	4.1
District nurse	1	7	3	5	5	7	5	7	4	4	4.8
Patient	4	7	6	1	6	5	2	6	6	6	4.9
The pharmacist themselves	7	7	7	2	4	4	4	3	7	7	5.2

The pharmacists were asked if they had ever been pressurised to dispense a patient's medication in a MCA when they felt that it was inappropriate to do so. Four pharmacists stated that they had been pressurised by other healthcare professionals; however this was not a frequent occurrence. The four pharmacists stated that, in this situation, they would comply with the request and then review the situation at a later date. The remaining six pharmacists stated that this situation had never occurred.

Four pharmacists said that they had been pressurised to issue a MCA by a patient's family. In such cases two pharmacists stated they would ask the relative to purchase a MCA and fill it themselves, one pharmacist would agree to provide the MCA but state their reservations and one pharmacist would refuse.

What procedure is followed once a request is received?

The pharmacists were asked to describe the procedure that they followed when a request to dispense a patient's medication in a MCA was received.

The questionnaire contained a number of subsidiary questions, asked if the pharmacist did not provide the information without prompting. These questions concerned trying an alternative strategy, e.g. regime simplification; assessment and counselling of the patient and concerns regarding the stability of drugs in a MCA. The pharmacists were also asked if they had a written protocol or procedure in place.

The data obtained from these questions is detailed in table 6 below

Table 6: Procedures followed by pharmacist when request received.

Pharmacy ID	7-day prescriptions	Assess patient	Counsel patient	Simplify regime	Stability	Written protocol
A	no	yes	yes	yes	yes	no
B	yes	yes	yes	no	no	no
C	yes	yes	yes	yes	yes	no
D	yes	no	yes	yes	no	no
E	yes	yes	yes	yes	yes	no
F	no	yes	yes	yes	yes	no
G	yes	yes	yes	yes	yes	yes
H	no	yes	yes	yes	no	no
I	yes	no	no	no	yes	no
J	yes	no	no	no	yes	yes

The dispensing procedure

The pharmacists were asked questions concerning the filling of the MCAs, and any concerns they might have regarding the procedure. Details of any delivery service were also sought and the pharmacist was asked if they had a preferred MCA.

Details of the results are given in Table 7 below.

Table 7: Details of the community pharmacists' answers concerning dispensing in MCAs

Pharmacy ID	Who fills MCA	Who checks	Concerns about checking	Collection and delivery	Preferred MCA
A	Pharmacist	N/A	yes	Pharmacist	Manrex Sun & Moon®
B	Pharmacist Qualified dispenser	Pharmacist	no	Pharmacist	Medidos®
C	Pharmacist or Qualified dispenser	Pharmacist	yes	Pharmacist	Venalink®
D	Unqualified dispenser	Pharmacist	yes	Pharmacy assistant	Nomad®
E	Unqualified dispenser	Pharmacist	yes	Pharmacist or driver	Nomad®
F	Pharmacist or dispenser	Pharmacist	some	Driver	none
G	Pharmacist	N/A	N/A	Pharmacist or driver	Manrex Sun & Moon®
H	Pharmacist or Qualified dispenser	Pharmacist	some	Pharmacist	Venalink®
I	Pharmacist or Unqualified dispenser	Pharmacist	yes	Driver	none
J	Qualified dispenser	Pharmacist	no	Driver	Dosett®

Time taken to dispense medication into a MCA.

The pharmacists were asked to estimate how long it took to dispense a patient's medication in a MCA:

on the first occasion.

on subsequent occasions.

Table 8 below lists the estimates given by the pharmacists.

Table 8: Estimated time taken for dispensing in MCAs

Pharmacist ID	Time taken for first dispensing	Time taken for subsequent dispensing
A	Unable to estimate	-
B	10 minutes	5 minutes
C	15 minutes	5 minutes
D	10 – 15 minutes	5 minutes
E	12 minutes	4 minutes
F	10 – 20 minutes	5 minutes
G	15 minutes	5 minutes
H*	30 minutes	20 minutes
I#	20 – 30 minutes	10 minutes
J	30 minutes	7 minutes

*Pharmacist H dispensed 28 days supply at a time and this explains the variation in time taken to dispense.

Pharmacist I had a very comprehensive record system which had to be set up for each new patient and this explains the length of time taken to dispense on the first occasion.

What procedure do you follow if the MCA is returned with tablets still in it?

Receiving a MCA back in the pharmacy which contained medication might indicate problems with compliance. The pharmacists were asked what procedure they would follow if this occurred.

Most of the pharmacists would not take any action on the first occasion, but 3 pharmacists would talk to the patient to see if there was a reason why the tablets had not been taken. All the pharmacists said they would contact the GP if the MCA was returned with doses not taken on subsequent occasions. However those pharmacists using MCAs with disposable inner sections stated that they often did not see any unused tablets because only the outer re-usable parts of the MCAs were returned.

Choice of MCA

Eight pharmacists would decide which MCA to use without reference to the patient, one pharmacist would vary the choice depending on the medication and one pharmacist would choose the MCA which seemed most suitable for that particular patient. The pharmacists were asked if they had a preferred MCA and eight stated that they did, details are given in Table 8 above.

Finally the pharmacists were asked if there was anything they would like to add concerning the use of MCAs. All of the pharmacists expressed their personal views on MCAs. Seven pharmacists highlighted the problems regarding remuneration as being their prime concern. Two pharmacists felt that MCAs were not the answer to patients' medication problems. In contrast two pharmacists thought that filling MCAs was a useful service.

2.5.5 Discussion.

The pharmacies selected by the stratified randomisation method represented a good cross-section of the pharmacies in the area under investigation. Similarly the pharmacists taking part comprised both employees and independent contractors. Therefore this random sample, although small, could be considered to be a fair representation of community pharmacy across the country at the time the study was undertaken.

The pharmacists questioned identified doctors as being the healthcare professional most likely to request the issue of a MCA, followed by hospital staff. The subject of who requests the issue of a MCA to a patient has not been investigated in the literature and therefore it is difficult to say whether this finding is in line with procedures in other areas. Certainly in more recent times there is anecdotal evidence that hospital staff are most likely to make the request, and this is supported by the interviews in the main part of the study. It may be of course that the doctor was simply the conduit for the request, which had in fact been made initially by another healthcare professional or the patient.

Once the request had been received, the majority of the pharmacists would request the GP to provide 7-day prescriptions. This method of funding has been a matter of contention between pharmacists and GPs for some time. The results of a survey undertaken in Northern Ireland (McElnay and Thompson 1992) showed that 92% of the respondents felt that the NHS should pay for the provision of a compliance aid service to older people. When my preliminary study was undertaken the Disabilities Discrimination Act (1995) had not been fully implemented and therefore NHS funding for the provision of MCAs to any patients was not available. The issue of funding MCA provision has caused considerable debate; when a multi-national pharmacy chain introduced charges for the initial supply of a MCA, an article appeared in the medical press suggesting that this would mean an extra charge for prescriptions (MacDonald 2002). A response to the article accused pharmacists of 'profiteering' (Morrison 2002). This highlights the misunderstanding and suspicion that has arisen concerning the supply of MCAs.

Having decided to issue a MCA for a particular patient, the pharmacists were asked if they would try an alternative strategy first. Seventy percent stated that they would try to simplify the regime. Research studies have shown that non-compliance with

medication is often linked to polypharmacy (Cohen *et al.* 1998; Eagleton, Walker and Barber 1993; Col, Fanale and Kronholm 1991). Simplifying the regime would appear to be an action which should be taken prior to issuing a MCA. Although some interviewees stated that they would simplify the regime, further probing revealed that this was often in order to fit the medication into the MCA.

The pharmacists were asked about assessing the patients, 70% stated that they would assess the patient in some way, although only 50% would visit the patient to carry out this assessment. Research has looked at the ability of people to use MCAs (Griffiths *et al.* 2004; Nikolaus *et al.* 1996; Atkin *et al.* 1994), however all of these studies only investigated Dosett® boxes. Other studies have investigated patient preference (Walker 1990, 1991) and give an insight into which devices patients prefer. Research has been carried out into the ability of older people to manage different types of medication packaging (Beckman *et al.* 2005; Griffiths *et al.* 2004; Forbes, Rees and Ross 1990; Keram and Williams 1988). All of these studies investigated a number of different types of packaging including blister packs but not MCAs. Forbes *et al.* (1990) found that the study subjects experienced problems accessing their medication from blister packs, 28% of the study subjects aged 60 years or over reported that it was too hard to push the contents out. Twenty five percent in the same age group stated that they had difficulty holding on to the contents after opening. The other two studies reported fewer difficulties with blister packs, but Beckman *et al.* (2005) found that the ability to open blister packs lessened with declining cognitive function. Although these studies refer to blister packs, similar problems could be expected with the sealed disposable type of MCA and therefore it is particularly necessary for a pharmacist to check if the patient can use these devices successfully.

The pharmacists were asked if they would counsel the patients themselves on how to use the device. This is essential, as patients may be unfamiliar with MCAs. Eighty percent stated that they would counsel the patients with the two who would not being the pharmacists with the largest number of patients.

The remaining questions all related to the dispensing of medication into a MCA. Firstly the interviewees were asked about stability of medication in a MCA, 70% stated that they would check the stability of the drugs, however as the majority of pharmacies filled the MCAs weekly this was not considered a major problem. A study had been carried out investigating the stability of medication in MCAs (Walker 1992a), which concluded that, although the majority of solid oral dosage forms could be safely transferred to a compliance device for a seven day period, there were important exceptions to the rule. In addition the author stated that there was a lack of information on short term stability of medications in an easily accessible format. This issue of stability of medication in MCAs will be discussed further in Section 7.7.4.

Only two of the interviewees had a written protocol in place for the dispensing of medication in MCAs. In fact several of the respondents appeared surprised by the question. The Royal Pharmaceutical Society of Great Britain approved the introduction of standard operating procedures (SOPs) covering the dispensing process in February 1999. Guidance on developing and implementing these SOPs was published in December 2001 (RSPGB. Practice Division 2001) and dispensing in monitored dosage systems was listed under 'other issues' the pharmacist might wish to consider writing SOPs for. However at the time the preliminary study was undertaken a pharmacy was not required to have SOPs in place.

Accuracy checking during the dispensing of medication in MCAs was a cause for concern for all of the pharmacists interviewed. Two pharmacists preferred to fill the

MCA themselves rather than check the dispensing carried out by others; however they did not get their own dispensing checked. In two other pharmacies the dispensing was always double checked irrespective of whether the filling was carried out by a pharmacist or a technician. Seven of the ten pharmacists reported some concerns with the checking process and those pharmacists who always filled the devices themselves stated that they did this in order to remove the need to check. Accuracy in filling MCAs is extremely important and is discussed in more detail in Chapters 6 and 7.

The pharmacists were also asked if they provided a delivery service; five pharmacies employed a driver and in the remainder the delivery was undertaken by a member of staff or the pharmacist themselves. Patients may be disadvantaged by having their medication delivered by a driver because they have no opportunity to ask questions about their medication and receive no counselling or advice when new medication is delivered.

The pharmacists were asked to estimate the length of time taken to dispense a patient's medication in a MCA both on the first occasion and subsequently. This was intended to be a guide only and the pharmacists were not asked to time themselves, but just to use their judgement and give an estimate. The mode length of time for subsequent dispensing was 5 minutes. A research paper (McElnay and Thompson 1992) investigated the length of time taken to dispense into compliance packs. The six MCAs used in the investigation included a Dosett® and Medidos® both of which were used by some of the pharmacies in this study. McElnay and Thompson (*loc. cit*) found that the mean dispensing time into a Dosett® box was 1min 45 sec (range 1.01 – 3.25) and for the Medidos® the mean was 2min 52 sec (range 1.19 – 3.50). Another research article, published after this preliminary study was carried out, investigated the difference in the time taken to dispense into a MCA from either loose tablets or a patient pack (Green.

Johnson and Wells 2000). Green and colleagues concluded that it took longer to dispense into a MCA from a patient pack than using loose tablets. The figures given by the pharmacists in the preliminary study were only estimates and included the time to complete any paper work.

Returning medication in the MCA can indicate that a patient is not complying correctly with their medication regime. The pharmacists were asked to state what they would do if this situation occurred. The majority of the pharmacists would take no action on the first occasion; however three pharmacists said that they would talk to the patient to try to ascertain the reason. Subsequently, if this recurred, the pharmacists stated they would contact the GP. However as those pharmacists who used disposable MCAs observed, they may not be aware of the issue because the patient would not return the device to the pharmacy. The return of unused medication was investigated by Ryan-Woolley (2005). Ryan-Woolley found that in the pre-study period, the “wastage” in the intervention group was 18.1%. This figure declined after a MCA was issued to reach a level of 1% after 12 months. However it is not possible to state whether the decline in wastage levels were due to increased compliance or simply due to the research subjects disposing of any unused medication.

2.6 Part 3: Administered patient questionnaire

The third part of the study comprised administration of a structured questionnaire to the older people who were receiving their medication in a MCA provided by those pharmacists who participated in part 2 of the study in part two of the study.

2.6.1 Method.

The pharmacists assisted in recruiting the patients to the study by sending out letters and information leaflets (and in some cases visiting the patients themselves) to explain the study. Once a signed consent form had been obtained, the patient was contacted and a

time for the interview arranged. The patients were interviewed in their own homes and were informed that they could have a third party present if they wished. All the interviews took place in the daytime and lasted between twenty and thirty minutes.

The administered questionnaire

The structured questionnaire was based on one previously validated in an earlier study (Raynor *et al.* 2000). The questionnaire was piloted on 5 patients who were selected by the pharmacist who had piloted the pharmacist questionnaire. As a result of the pilot minor changes were made to the questionnaire.

The questionnaire was designed to answer the following questions: -

Did the patient know the names of, and indications for, their medicines?

Could the patient manage to use the MCA correctly?

Did the patient receive any assistance to use the aid?

How did the patient obtain repeat prescriptions from the GP and further supplies of medicines?

How did the patient feel they would be able to manage if they did not have the medicines in a MCA?

How did the patient feel the MCA compared with medicines in ordinary bottles and packs?

2.6.2 Results

Patient recruitment

A total of 169 patients were receiving their medicines in MCAs from the ten pharmacies who participated in part 2 of the study, from these, 61 (36%) signed consent forms were received by the research pharmacist. Reasons given for not giving consent included:

Not wanting a stranger to visit them at home.

Suspicion of the reason behind the study (was the MCA going to be taken away from them?)

The carer felt that patient was too old or too confused to answer questions

The patient was unable to read or understand the recruitment leaflet

Of the patients who consented, two people were admitted to hospital before they could be visited, two changed their minds and one forgot the appointment and was unable to arrange another.

Patient demographics

The age, sex, housing, and support arrangements for the patients are shown in Table 9.

Table 9: Patient demographic details (n=56)

Sex	Female	38
	Male	18
Age in years	Mean (range)	78.5 (46 – 93)
Type of Housing	Own home	43
	Sheltered	11
	Warden controlled	2
Living arrangements	Alone	40
	With partner	12
	With son/daughter	3
	With relative/friend	1
Support services	Home care	40
	District nurse	8
	Relative/friend who visits	4
	No help	9
MCA	Dosett®	20
	Nomad®	19
	Medidos®	6
	Venalink®	7
	Manrex Sun & Moon®	4

The patients were asked if they knew how long the MCA had been in use. Few could recall this information and despite making enquiries with the dispensing pharmacist the details for over 50% of patients were not available. For those patients where this information was available, the range of time was from 4 months to 8 years.

The patients were asked if they knew who had suggested that they had their medication dispensed in a MCA and the answers given by the patients are detailed in Table 10 below.

Table 10: Who suggested that patient had an MCA?

Who made the suggestion	Number of patients (n=56)	Percentage
Hospital staff	22	39%
GP / doctor	9	16%
Nurse	6	11%
Pharmacist	6	11%
Home care/warden	3	5.5%
Day centre	2	3%
Patient	1	2%
No information	7	12.5%

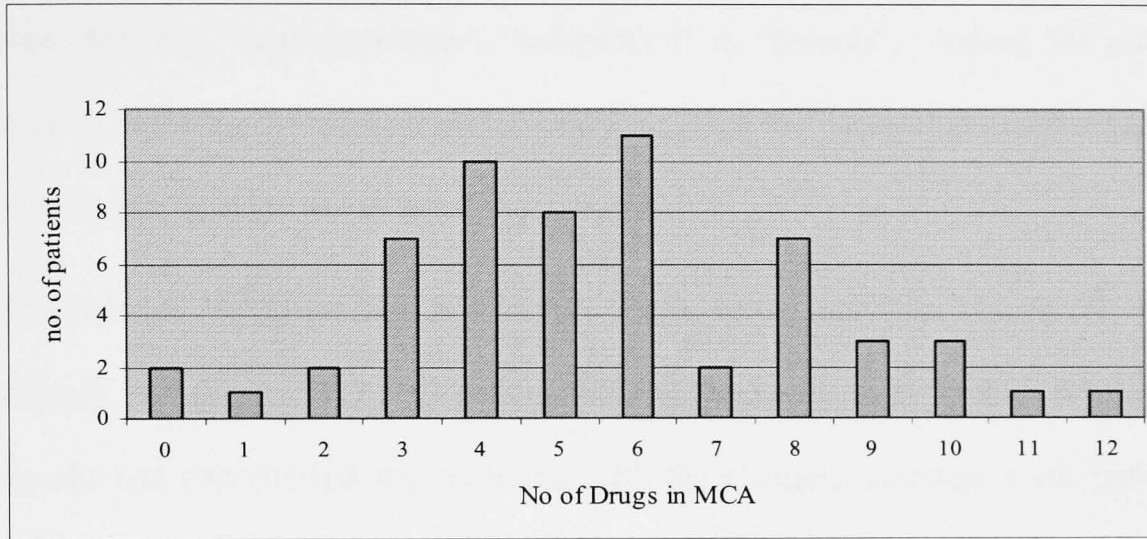
Patient Medication Details

Prior to the home visits, the pharmacists were asked to supply the patient medication details for those patients who agreed to take part in the research. The pharmacists either provided a computer printout or filled in a sheet provided by the research pharmacist.

The patients were asked by the research pharmacist for the names of all the medication they were taking and what they were taking the medication for. The answers were written on a chart within the patient questionnaire.

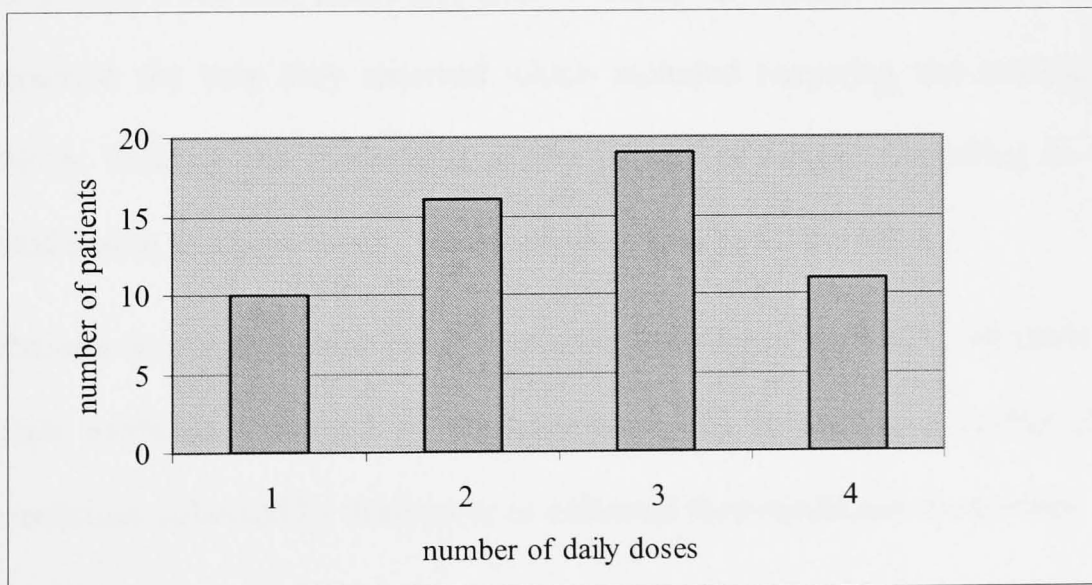
Figure 1 below provides details of the number of patients receiving different numbers of medication in their MCA.

Figure 1: Number of patients receiving different numbers of drugs in MCA



The mean number of drugs dispensed in the MCA was 5.75 (range 1 – 12) and the mean number of daily dosage times (i.e. the number of times during the day the patient had to remove drugs from the MCA and take them) was 2.5 (range 1 - 4).

Figure 2: Number of daily doses taken by patients.



There were 29 (52%) patients who had medication which was not in the MCA (usually liquid preparations or inhalers). Patients also had “prn” medications which were dispensed separately and two patients had regular medicines which they preferred not to have dispensed in the MCA. When questioned 38 (68%) patients did not know the

names of any medication in the MCA, 4 (7%) patients knew some of the names and 14 (25%) patients knew all of the names.

There were 36 (64%) patients who had some knowledge of why they were taking the medicine, e.g. “heart problems”, “indigestion” or “bowels”. Asking the patient what they were taking the medication for often triggered the name of the medication in those people who claimed not to know the names.

Twenty-nine (52%) patients had seen a doctor in the previous month (GP or hospital doctor). Of these, 7 (12.5%) patients had had changes made to their medication, and no-one had experienced any problems with the changes, although some patients were waiting to have the new medication dispensed in their MCA.

Help received with medicines

There were 42 (75%) patients who stated that they received no help to take their medicines, leaving 14 (25%) who stated that they did receive help. Patients received help from a relative, home care staff, a warden or a nurse. The patients were asked to describe the help they received which included removing the medication from the MCA, handing the medication to the patient or simply reminding or checking the medication had been taken. No carers were said to fill the MCA.

Patients were asked about the collection or delivery of the MCA. 48 (86%) patients had their medicine delivered by the pharmacy, the remaining 8 (14%) either had the medicines collected by third party or collected their medicines themselves.

Patient's abilities to use the MCA

When patients were asked if they had any problems using the MCA, 10 (18%) said that they did. These problems were usually that they found the MCA difficult to open or the

tablets difficult to remove. However, the problems were not sufficient to prevent any of the patients taking their medication.

Patients were then asked by the research pharmacist to demonstrate opening the MCA and removing a tablet. Only 4 (7%) patients were unable to demonstrate this satisfactorily. In these four cases this inability to use the MCA was due to either a sight problem, confusion or because the MCA was too stiff to open. Only one of these patients was not receiving help to use the MCA (the problems of this patient were referred back to the pharmacy and a different system was to be tried.)

Patients were asked to read the days of the week and times to ensure that they could use the MCA correctly. Five (9%) had difficulty reading the text, three of these patients had help to take their medicines but two patients did not. When asked how they managed if they found the text difficult to read, both patients replied that it did not matter because each day's dose was the same. The patients just started at one end of the MCA irrespective of what day of the week this was and worked across until all the doses were taken.

Patients were asked what they did about taking their medication if they had to go out during the day or if they went on holiday. Almost a third responded that they did not go out and therefore did not have a problem. The majority of those who did either go out during the day or go away on holiday, took the MCA with them. The remainder used other strategies as detailed below.

Adjusted time of dose or outing. These patients either timed their trips to fit in with their medication schedule or, more usually, altered the time they took their medication in order to fit in with their trip.

Takes medication out of MCA. The patient removed one or more doses from the MCA, usually placing the medication in another container but sometimes wrapping in a tissue and placing in the pocket. Two patients also took a bottle of water as well.

Misses dose. Two patients admitted that they would simply miss a dose out. As this happened infrequently they did not think it was a problem.

No problem. These patients usually had only one dose time in the MCA usually at breakfast time but occasionally at night. These patients had no problem with short trips out because they could take the medication before they went or when they came back. This group of patients did not go away for longer periods.

Patient compliance

The patients were asked if they used a strategy to remind themselves to take their medication. Approximately one third stated that they did not have a strategy and simply relied on the MCA. The majority of the interview subjects did have a personal system and these are described below.

Time Eleven (20%) patients relied on noticing the time either on the clock or by the radio or television.

Place Five (9%) kept the MCA in a particular place e.g. beside the kettle or near the cornflakes packet.

Own system Two (3%) patients had an elaborate system of their own device, which involved removing the medication from the MCA each day and placing in another receptacle.

Does forget One patient admitted that he/she forgot despite having the medication in the MCA.

Patients were asked if the pharmacy had given them a choice of which MCA to have. Only one patient said they had had a choice, the remainder had simply accepted the MCA sent by the pharmacy. Some patients did know that there were other types of MCA, but did not seem concerned by the lack of opportunity to choose. The research pharmacist noted that, although some of the pharmacists had a preferred MCA, patients from that pharmacy did not always have their medication in the preferred MCA. This appeared to be due mainly to problems regarding the number of different medications being taken (some devices are of larger capacity than others).

Patients who had medication that was not in the MCA were asked if this presented any problem. Of the 27 patients who had medication which was not in the MCA, 24 (83%) said that this presented no problem. One patient stated that there might possibly be a problem and 2 patients said that this was a problem.

Patients were asked how having their medication in an MCA compared with having their medication in ordinary bottles. The results are summarised in Table 11.

Table 11: Comparison of MCA with tablet bottles

How does MCA compare with tablet bottles	Number of patients (n=56)
Much better	52
A little better	2
No different	2
A little worse	0
Much worse	0

Patients were asked if there was anything else they would like to say about having their medication dispensed in an MCA. There were 9 (16%) patients who said they had no further comments. The remaining 47 (84%) had a wide variety of comments, ranging from enthusiasm with the system, to issues relating to the pharmacy. Twelve (25.5% of

those who commented) said that the best thing about having their medication in an MCA was that they could look at the MCA and tell if they had forgotten to take their medication. Eight patients (17% of those who commented) said that the MCA was much easier or much better to use.

2.6.3 Discussion

The low consent rate from patients using MCAs limits the generalisability of these findings. The Research Ethical approval obtained allowed only informed consent (rather than assent) and this will have eliminated those patients who were too confused to read and understand the patient leaflet. There was evidence, both in telephone calls and in writing, of relatives refusing to allow their elderly relatives to take part. A study in the USA investigated the opinions of family members about elderly relatives taking part in research (Williams 1992). The author stated that family members are frequently involved in the decisions of whether an elderly person should participate in research. In particular Williams noted that family members often advise elderly relatives not to sign any papers or agree to anything before getting their approval. The reasons why older people declined to take part in a research study was discussed by Petty and colleagues (Petty *et al.* 2001). The researchers identified ten broad categories of response when they followed up those who had declined to participate in a randomised controlled trial. Not all of these categories were applicable to the preliminary study but there was some commonality, for example, unable to read or understand the information sheet, feeling unwell, and mistrust of study objectives. The subjects questioned in the preliminary study may not be truly representative of those receiving their medication in MCAs, as those who were cognitively impaired were excluded and also those whose relatives sought to protect them were unable to take part. It is possible therefore that the subjects questioned were more self-reliant and mentally alert.

When asked who had suggested that the patient received their medication in a MCA, hospital staff were the most frequently suggested. This differs from the pharmacists who stated that most requests came from the GP. The patients' statement that it was hospital staff who instigated the request, is supported by an observation made by the research pharmacist. At the time of the study, the hospital NHS Trust issued Dosett® boxes to those patients who were deemed to need a MCA on discharge. The patients in the study exhibited their Dosett® box for the researcher to see, explaining that this was the device they had received on discharge from hospital.

The patients questioned in this preliminary study were prescribed between one and twelve medications that were dispensed in a MCA. This range of medications gives rise to a number of questions. Dispensing one medication in a MCA is neither cost-effective nor of benefit to the patient and on the other hand those receiving more than six medications might benefit from a medication review and simplification of the regime.

Over half the patients questioned could not name the medication they were taking. Research studies have linked knowledge of medication and medication compliance. A study of 24 older people who were living independently in the community found that the majority of the participants needed some form of education about the name, scheduling or function of their medication (Griffiths *et al.* 2004). In their study Griffiths and colleagues measured knowledge of medication by the simple approach of asking patients to identify all their current medications and describe function, dose and scheduling. This method mirrors that used by myself in this preliminary study.

A minority of those questioned stated that they found the MCA difficult to use, although only four were unable to demonstrate their ability to use the device satisfactorily. Similarly, a small minority had difficulty reading the printing on the MCA. It is interesting to note that the two interviewees with sight impairment who did not receive

help, did not see a problem. Instead they ignored the printed days of the week and started at one end of the device and worked through. Those interviewees were correct in pointing out that as each day's medication was the same it mattered little whether they took the medication marked for Monday on a Sunday. A problem could arise, however, if a third party tried to check the patient's medication compliance.

A majority of those questioned relied on personal strategies to aid their compliance with the medication regime in addition to the MCA. The use of both internal and external strategies to assist in remembering to undertake particular actions is well documented in the literature on memory and medicine taking (Branin 2001).

The patients were asked how they took their medication if they went out for the day or on holiday. Those who were not housebound described a number of strategies that they used to ensure that they took their medication as near to time as possible. A small minority did miss the dose out, perhaps feeling that having an opportunity to take part in social activities out weighed the need to take the medication. For others the MCA made going on holiday easier as they could be sure that they had all the required medication with them. For some, however, there were concerns about taking the MCA out of the house. These concerns centred on the fact that the MCA had a label on it which stated that it was the property of the pharmacy. Also there were uncertainties regarding obtaining extra medication to last the duration of the holiday. All these queries should have been addressed when the MCA was first issued either by a face-face counselling session or by an information leaflet.

The majority of the patients questioned in the preliminary study stated that they preferred to receive their medication in a MCA rather than in conventional packaging: the main reason for this appeared to be because they could tell if they had forgotten to take a dose. This statement that they could tell if they had missed a dose did lead to

another question 'what to do if they had missed a dose?' and many of those questioned were uncertain. This suggests that careful counselling of the patient should be undertaken when the device is first issued. In a survey of hospital in-patients about their information needs (Howard *et al.* 1999) almost 90% of those questioned stated that they regarded information on missed doses as important. A survey carried out in the USA (Lyons, Rumore and Merola 1996) discovered that less than 50% of those who responded had received any information on the consequences of missing a dose. Furthermore just over 50% did not know what action to take if they had missed a dose. Knowing what to do if the patient discovers two or three hours later that they have failed to take their medication is very specific to that patient. The action to take is determined by the particular medication being taken and therefore this information needs to be tailored to each individual patient. An Australian paper (Gilbert, Roughead and Sanson 2002) suggested that problems often arise because health professionals do not provide patients with sufficient information regarding missed doses.

The study subjects also had other questions concerning their medication, often producing a list when I first arrived. This quest for information could be indicative of a lack of opportunities to seek advice. The structured questionnaire allowed for little development of themes and ideas although some patients were eager to discuss specific problems outside the scope of the research study. The preliminary study therefore provided a snapshot of what was happening in the health authority area at one particular period of time. The study gave an indication of the prevalence of the use of MCAs and raised a number of issues concerning the appropriate use of these devices.

2.7 Conclusions.

This preliminary study provided a picture of the supply and use of MCAs in a particular area and at a particular time. The study highlighted several areas for concern:

The large numbers of MCAs issued despite the lack of evidence for the effectiveness of these devices.

The lack of assessment of the patients.

The failure to provide counselling and assistance to patients when a MCA is first issued.

The concerns expressed by the pharmacists regarding the lack of remuneration for supplying and filling MCAs.

2.8 How this preliminary study informed the subsequent research.

This preliminary study highlighted the increase in use of MCAs within Primary Care. This increased use was despite the fact that there was at that time (as now) little evidence to support the use of these devices to improve compliance with medication regimes.

In Chapter 3 a review of the available literature on MCAs and older people is described and the evidence for the use of these devices is discussed. The lack of evidence concerning the effectiveness of these devices raises the question, ‘why are these devices issued so frequently?’ The pharmacists interviewed were happy to dispense medication in these devices provided that surrogate funding could be obtained, however they appeared to give little thought to the suitability for a particular patient.

The structured questionnaire in the preliminary study gave little opportunity for the pharmacists to express their attitudes and beliefs concerning the use of these devices. The majority of the pharmacists simply responded to a request from another healthcare professional to issue a MCA. Interviewing other healthcare professionals to elicit their attitudes and beliefs about the use of MCAs would therefore seem to be an important next step.

The structured patient questionnaire similarly did not allow the patients to express their own opinions about the use of these devices. I was interested to discover what their feelings were, when a MCA was issued. This study provided information on the ability of those questioned to use the MCA, but did not explore their beliefs about taking their medication.

As a result of undertaking this preliminary study I identified four areas of interest which I wished to explore further. These areas of interest were:

Trigger for use. I was keen to explore what triggered the issue of the MCA in the first instance.

Use of MCA. How did the recipient of the MCA manage the device what did they and healthcare professionals see as the advantages and disadvantages of these devices?

Health beliefs. Did the health beliefs of both those using the devices and healthcare professionals affect the appropriate issue and use of the device?

Age. Were older people more likely to be issued these devices and was the issue of a MCA ageist?

A qualitative study using semi-structured interviews would give the opportunity to explore those issues which the participants saw as important. Such a study is described in Chapters 5, 6, and 7.

Chapter 3:

Review of Literature relating to the use of Multi-compartment Compliance Aids by older people

3.1 Introduction.

This chapter details the findings of a review of the literature concerning MCAs. Prior to undertaking the preliminary study, which is described in Chapter 2, a limited review of the literature relating to the use of MCAs was undertaken. This review suggested that a more structured search of the literature was needed in order to determine the evidence for the use of these devices. Section 3.2 explains the scope of the search and the search parameters. The search strategy is then explained and the methods of searching the data bases are described. The results of the literature search are detailed in Section 3.4. The following section details a critical analysis of the studies identified by the structured review. Section 3.6 contains the conclusions obtained as a result of undertaking this review. The final section contains a brief summary of the chapter.

3.2 Scope of the review

The review of the literature was designed to identify all the available published literature relevant to MCA use by older people. In order to ensure the breadth of the review, all eligible articles were included irrespective of research method or any methodological deficiencies. Inclusion criteria were set in line with the main focus of the study, i.e. the use of Multi-compartment Compliance Aids by older people living independently in the community.

3.2.1 Inclusion criteria.

All experimental studies which had as a main focus the use of MCAs by older people to aid compliance with a medication regimen.

All descriptive studies which described the use of MCAs to aid compliance, or the dispensing of drugs in MCAs.

Studies which looked at the use of MCAs by people aged 65 and over who were living independently in the community.

Systematic reviews of the literature referring to MCA use.

Papers published from 1982 onwards.

English language papers.

3.3 Search Strategy

The search parameters were designed in order to cover a wide range of the literature available. Searches were undertaken in the following databases:

- MEDLINE
- EMBASE
- CINHALL
- PsychINFO
- Pharmline
- International Pharmaceutical Abstracts (IPA)
- Cochrane Database of Systematic Reviews.

The search terms used were: patient compliance, reminder systems, and drug packaging, which are MeSH terms, and compliance aids which was a keyword search.

All the search terms were used in each database and the results recorded. Not all the search terms produced results in every database and it was necessary to try different combinations of search terms. Having identified a number of articles with the initial search, the titles were viewed and any with no connection to compliance with medication were rejected. Next the abstracts of the identified articles were obtained and those articles which did not have Multi-compartment Compliance Aids as the main focus of the research were rejected. The remaining references were recorded on a database. All the journal articles were obtained and read. A small number were discarded at this point because a more in depth review revealed that the article did not fit the inclusion criteria. Searches were also made of all the bibliographies of the journal articles obtained and searches were made of colleagues' personal reference collections. Details of the search strategy undertaken can be found in Appendix 2.

3.4 Results

A total of 36 references were identified by the above search methods. Details of the type of study or article are detailed in Table 12 below

Table 12: Numbers of different types of study identified.

Type of study	Number
Randomised Controlled trial	11
Non-randomised controlled trials	1
Cross-over trial	1
Longitudinal studies.	4
Cross-sectional studies	4
Systematic review	4
Descriptive studies	11

3.4.1 Randomised Controlled Trials

The aim of this literature review is to determine the evidence base for the use of MCAs. Randomised controlled trials (RCTs) are considered the gold standard of investigative studies and therefore would provide the highest level of evidence. Eleven RCTs were identified and are listed in Table 13.

Table 13: Details of randomised controlled trials.

Ascione et al 1984	ASCIONE F.J, L.A. SHIMP. 1984. The effectiveness of four education strategies in the elderly. <i>Drug Intelligence and Clinical Pharmacy</i> , 8 pp.926 –31
Becker et al 1986	BECKER L.A, K. GIANZ , E. SOBEL, J. MOSSEY, S.L. ZINN, K.A. KNOTT. 1986. A Randomized Trial of Special Packaging of Antihypertensive Medications. <i>The Journal of Family Practice</i> , 22, (4) pp.357-361.
Crome et al 1982	CROME P, B. CURL, M. BOSWELL, D. CORLESS, R.R. LEWIS, 1982. Assessment of a new calendar pack – the ‘C-Pak’. <i>Age and Ageing</i> , 11 pp.275 – 279
Huang et al TRACE study 2000	HUANG H-Y, M. MAGUIRE, E.R. MILLER, L. APPEL, 2000 Impact of Pill Organizers and Blister Packs on Adherence to Pill taking in Two Vitamin supplementation Trials. <i>American Journal of Epidemiology</i> , 152 (8) pp.780-787.
Huang et al VITAL study 2000	HUANG H-Y, M. MAGUIRE, E.R. MILLER, L. APPEL, 2000 Impact of Pill Organizers and Blister Packs on Adherence to Pill taking in Two Vitamin supplementation Trials. <i>American Journal of Epidemiology</i> , 152 (8) pp.780-787.
Lee et al 2006	LEE J.K, K.A. GRACE, A.J. TAYLOR, 2006. Effect of a Pharmacy Care program on Medication Adherence and Persistence, Blood Pressure and Low-Density Lipoprotein Cholesterol. <i>Journal of the American Medical Association</i> ,. 296 (21) pp.2563-2571.
Murray et al 1993	MURRAY M.D, J.A. BIRT, A.K. MANATUNGA, J.C. DARNEL, 1993. Medication compliance in elderly outpatients using twice-daily dosing and unit of use packaging. <i>Annals of Pharmacotherapy</i> , 27 (5) pp.616-621.
Park et al 1992	PARK DC, R.W. MORRELL, D. FRIESKE, D. KINCAID, 1992. Medication Adherence Behaviours in Older Adults. Effects of External Cognitive Supports. <i>Psychology and Aging</i> .

	7(2) pp.252-256.
Peterson et al 1984	PETERSON GM, MCLEAN S, MILLINGEN KS, 1984. A Randomised Trial of Strategies to Improve Patient Compliance with Anticonvulsant therapy. <i>Epilepsia</i> , 25(4) pp.412-417
Ryan-Woolley et al 2005	RYAN-WOOLLEY BM, J.A. REES, 2005. Initializing Concordance in Frail Elderly Patients via a Medicines Organizer. <i>The Annals of Pharmacotherapy</i> . 39 pp.834-839.
Simmons et al 2000	SIMMONS D, M. UPJOHN, G.D. GAMBLE, 2000. Can Medication Packaging Improve Glycemic Control and Blood Pressure in Type 2 Diabetes? <i>Diabetes Care</i> , 23 (2) pp.153-156.

3.4.2 Controlled trials without randomisation.

One article was identified that detailed a controlled trial without randomisation. A control group was present in this study, however allocation to either intervention or control group was not made by means of randomisation.

Ware et al 1991.	WARE, G.J. N.H.G.HOLFORD, J.G.DAVISON, R.G. HARRIS 1991, Unit dose calendar packaging and elderly patient compliance. <i>New Zealand Medical Journal</i> , 104, pp.495-497
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3.4.3 Cross-over trials

One study was identified as a cross-over trial. The patients in this trial acted as their own controls i.e. for half of the study duration the participants received either the intervention or acted as controls, and for the second half of the study, the groups swapped over intervention group becoming controls and vice versa.

Wong et al 1987	WONG, B.S.M. D.C.NORMAN, 1987, Evaluation of a Novel medication Aid, the Calendar Blister-Pak, and its Effect on Drug Compliance in a Geriatric Outpatient Clinic. <i>Journal of the American Geriatric Society</i> . 35, pp.21-26
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3.4.4 Longitudinal studies

Four longitudinal studies were identified; in these studies the participants were interviewed at intervals regarding the use of the MCA. None of these studies included a control group. Details of the longitudinal studies can be found in Table 14.

Table 14: Details of longitudinal studies

Bazire 1984	BAZIRE, S. 1984. An assessment of the 'Dosett®' compliance aid in psychiatric patients. <i>British Journal of Pharmaceutical Practice</i> pp.316-320.
Maguire 1986	MAGUIRE T. 1986. Compliance of elderly patients with drug dosage instructions. <i>The Pharmaceutical Journal</i> 1986 vol 237 557.
Walker et al 1990 (b)	WALKER R, L. BELLIS, F. JUMANI. 1990. A Community Pharmacy based Study to Assess Demand for Compliance Devices. <i>The Pharmaceutical Journal</i> vol 247 R25
Walker 1991	WALKER R. 1991. A Study of Factors which Influence the Desire to continue using a Compliance Device. <i>The Pharmaceutical Journal</i> vol. 247 R16

3.4.5. Cross-sectional studies.

The four studies which were cross-sectional in design looked at either the acceptability of particular MCAs or at the ability of the study subjects to either fill or use the MCA correctly. Details of the cross-sectional studies identified can be found in Table 15 below

Table 15: Details of cross-sectional studies

Atkin et al 1994	ATKIN PA, T.P. FINNEGAN, S.J. OGLE, G.M. SHENFIELD, 1994. The Functional Ability of Patients to manage Medication Packaging: A Survey of Geriatric Inpatients. <i>Age and Ageing</i> , 23 pp.113-116.
Park et al 1991	PARK DC, R.W. MORRELL, E.D. FRIESKE, A.B. BLACKBURN, 1991. Cognitive Factors and the use of Over-the-Counter Medication Organizers by Arthritis Patients. <i>Human Factors</i> , 33(1) pp.57-67
Walker et al 1990	WALKER R, A. MANDAL, T. DAYMOND, S. BANSAL, D. PENNINGTON, 1990. Assessment of Compliance Devices by Patients. <i>The Pharmaceutical Journal</i> R1
Wildin et al 1989	WILDIN J, S. SKELLERN, 1989. The role of compliance aids in patients with epilepsy. <i>The Pharmaceutical Journal</i> R12-13

3.4.6. Descriptive studies.

Eleven other journal articles were identified all of which were descriptive in nature, and the use of MCAs was the main focus of the article.

Table 16: Details of descriptive studies

Description of Devices	
Corlett 1996	CORLETT, A.J. 1996, Aids to compliance with medication, <i>British Medical Journal</i> , 313, pp.926-929
Hattaway 1998	HATTAWAY, V. 1998, Medication organisers, <i>New Zealand Pharmacy</i> , (March) pp.35-39
Rivers 1992	RIVERS, P. 1992, Compliance Aids – do they work? <i>Drugs and Aging</i> . 2(2) pp.103-111
Walker 1992(b)	WALKER, R. 1992, Which medication compliance device? <i>The Pharmaceutical Journal</i> , 248 pp.605-608
Risk factors associated with the use of MCAs	
Levings et al 1999	LEVINGS, B, S. SZEP, S. HELPS. 1999, Towards the safer use of dosettes. <i>Journal of Quality in Clinical Practice</i> . 19(1) pp.69-72.
Use of MCAs by district nurses	
Stewart et al 2001	STEWART, D, E. OGILVIE, E. KENNEDY, D. HANDSFORD, E. NEILL. 2001, Medication compliance devices in primary care: activities of community based nurses. <i>International Journal of Pharmacy Practice</i> . 9 pp.91-95.
McGraw and Drennan 2000	McGRAW, C. V. DRENNAN, 2000, The use of medication compliance devices by district nursing services. <i>British Journal of Community Nursing</i> , 5(7) pp.326-331

Prevalence of use of MCAs	
Nunney and Raynor 2001	NUNNEY, J. D. RAYNOR, How are multi-compartment compliance aids used in primary care? <i>The Pharmaceutical Journal</i> , 267 pp.784-789.
Green and McCloskey 2005	GREEN, C. S. McCLOSKEY, 2005, UK survey of the provision of multi-compartment compliance aids and medicine reminder charts on discharge from hospital. <i>International Journal of Pharmacy Practice</i> , 13 pp.85-89.
Time taken to dispense medication in MCAs	
McElnay and Thompson 1992	McELNAY, J. J. THOMPSON, Dispensing of medicines in compliance packs. <i>International Pharmacy Journal</i> , 6(1) pp.10-14.
Green et al 2000	GREEN, M. J. JOHNSON, R. WELLS, The impact of the patient pack initiative on the provision of monitored dosage systems, <i>The Pharmaceutical Journal</i> , 265 R71.

3.5 Description of studies and critical discussion.

In this section each trial is described in a standard format followed by a discussion relating to the 11 trials.

3.5.1 Randomised controlled trials

Study	Ascione et al 1984
Participants	158 elderly patients aged 60 – 89 years, living in their own home and taking one or more cardiovascular drug for at least one month.
Country	USA
Interventions	The participants were divided into seven groups as follows: No pre-test interview. – intervention oral instructions No pre-test interview. – oral instruction + reminder calendar Pre-test interview – oral instructions Pre-test interview – oral instructions + reminder calendar Pre-test interview – oral instructions + reminder package Pre-test interview – oral instructions + written instructions Pre-test interview – no intervention control
MCA	The medication reminder package was described as a ‘commercially available, seven-day compartment plastic package known as the Seven Day Pill Reminder.’ All the medication for each day was placed in one compartment.
Randomisation	Not disclosed. The study design was stated to be single-blind with physicians and interviewers unaware of which intervention the patient received.
Outcome measures	Improvement in drug knowledge and compliance behaviour. Compliance behaviour measured by self-report.
Conclusion	Oral instructions plus reminder package improved self-reported compliance compared with control. Fifty five percent of the patients in this intervention group who had admitted previous non-compliance became compliant after the intervention compared with ten percent of the control group (p<0.03)
Notes	The minimum length of time to follow-up was one week

Study	Becker et al 1986
Participants	180 patients aged between 20 and 80 who were already taking medication for previously diagnosed hypertension. All patients had demonstrated poor BP control on at least 1 visit in the previous 2 years
Country	USA
Intervention	All patients in the experimental group received their medication in a special packaging format consisting of 28 foil backed blisters marked with day of week and time of day. The control group received their medication in traditional pill vials. Medication was provided free of charge to both groups.
MCA	A commercially available system which comprised 28 foil-backed blisters. Each blister contained all the medication to be taken at one time. The foil backing was printed with the day of the week and the time.
Randomisation	Method not disclosed.
Outcome measures	Self-reported compliance. Patients were asked a non-threatening, non-judgemental question about their compliance behaviour. Pill counts. Patients were asked to bring in all remaining medication to each follow-up visit. Blood pressure control. Blood pressure was taken three times at each visit. The first measure was discarded and the average of the second and third was used as the blood pressure measurement for that visit. Blood pressure control was defined as a diastolic blood pressure of less than 90 mm Hg.
Conclusion	No significant improvement in blood pressure control or in the two other compliance measures were found in the intervention group.
Notes	Missing pre-enrolment and baseline data. Participants received free medication to ensure they stayed in the study. Participants in the intervention group considered the special packaging more difficult and less convenient to use.

Study	Crome et al 1982
Participants	78 elderly patients, age range 68 – 98 years, recruited from a hospital geriatric department.
Country	UK
Intervention	Patients in the intervention group received their medication in the ‘C-Pak’ (an individually prepared blister pack which allowed the presentation of a number of different drugs in each pack).
MCA	A disposable, calendar type pack. Each tablet is enclosed in an individual blister. The blisters are arranged on a card according to the day of the week and the time of day. Medication to be taken at the same dosage time is not all contained in one blister.
Randomisation	Method not disclosed
Outcome measures	Tablet count.
Conclusion	No difference between intervention and control group.
Notes	This study took place in a hospital setting with participants self-administering.

Study	Huang et al 2000 (TRACE study)
Participants	The 184 participants were recruited by means of advertisements and word of mouth. The age range was 44 – 72. Participants were only non-smokers, non-vegetarians and those not having taken anti-oxidant vitamin supplements in the previous 2 months. Approximately 50% had a history of disease and, a similar proportion, were taking medication. No further details were given.
Country	USA
Intervention	Participants were randomised to pill organizer or no pill organizer and one of four vitamin supplementation groups. Participants attended follow-up appointments one and two months after randomisation.
MCA	A refillable seven-day organiser with a single compartment for each day of the week.
Randomisation	Randomisation to use of an organizer was by means of computer generated random numbers. Randomisation of supplementation group was determined by a fixed randomisation scheme. The allocation was concealed by using opaque envelopes. Both participants and personnel were masked to the assignment of supplementation groups.
Outcome measures	Adherence to pill taking was assessed by pill count, serum vitamin levels and self-report.
Conclusion	The use of pill organizers did not enhance adherence when assessed by any of the three trial methods.
Notes	The pill organiser group received the organiser and two bottles containing vitamins or placebos. Instructions on the use of the organiser were provided.

Study	Huang et al 2000 (VITAL study)
Participants	297 retired teachers (age range 57-72) recruited via invitational mailings. Thirty percent had high blood pressure, 6% diabetes and 8% high cholesterol at baseline.
Country	USA
Intervention	Participants were randomised to receive one of two supplement groups either in a pill organiser or in a unit-dose blister pack.
MCA	<p>Pill organizer group received a seven-day refillable organiser with one compartment for each day of the week. The participants in this group filled the organiser with the vitamin pills provided.</p> <p>Blister-pack group received monthly blister-packs each with 31 blisters labelled with dates. Each blister contained the vitamins for that day.</p>
Randomisation	Method not disclosed.
Outcome measures	Adherence was assessed by pill counts, serum vitamin levels and self-reports.
Conclusion	Adherence was similar in the two groups when measured by serum vitamin levels. Adherence was improved in the blister pack group when measured by pill count and self report.
Notes	This study compared a pill organiser with a blister pack therefore no comparison with standard packaging.

Study	Lee et al 2006
Participants	200 elderly (65+) patients living independently in the community. Patients had to be taking 4 or more medicines for chronic conditions.
Country	USA
Interventions	The study consisted of three phases. In phase 1, patients were assessed for baseline adherence, BP and LDL-C. In phase 2, all patients received the intervention – education, regular follow-up by pharmacist and MCA. In phase 3, participants were randomised either to continue pharmacy care or to return to usual care.
MCA	Clear plastic blisters with a foil backing. Each blister contained all the medication for one dosage time (e.g. morning) and was numbered for the day of the month. Separate blister packs were provided for each dosage time.
Randomisation	Randomisation was undertaken using a computer-generated random number sequence. Allocation was concealed to both patients and study personnel.
Outcome measures	At the end of phase 2: change in number of pills taken vs. baseline. At the end of phase 3: between group comparison of medication persistence.
Conclusions	The pharmacy care programme increased medication adherence, medication persistence and lowered BP.
Notes	Interventions included education and follow-up by pharmacist as well as MCA.

Study	Murray et al 1993
Participants	36 patients aged 60 years or over and taking three or more prescribed medicines.
Country	USA
Intervention	Participants were randomised to one of three groups: Unit-of-use packaging with twice daily dosing Conventional packaging and twice daily dosing Conventional packaging and no change in dosing.
MCA	A unit-of-use package consisting of a two ounce plastic cup with a snap on lid containing all the medications to be taken at the time of dosing.
Randomisation	Not disclosed.
Outcome measures	Medication compliance assessed monthly for 6 months using tablet counts.
Conclusion	Unit-of-use packaging and twice daily dosing improved compliance with medication.
Notes	Intervention group receiving unit-of-use packaging also received a change in medication dosage to twice daily.

Study	Park et al 1992
Participants	61 elderly adults aged over 60 years taking a minimum of 2 prescribed medicines and living in the community. Participants were further divided into 2 sub-groups: young-old (aged 70 and younger) and old-old (aged 71 and older.)
Country	USA
Intervention	Participants were randomly assigned to receive: no intervention (control group), a medication organiser, a medication reminder chart or both organiser and chart.
MCA	The medication organiser consisted of 28 compartments. The compartments were labelled for four dosage times per day. Each set of four compartments was labelled with a day of the week. All medications for one dosage time contained in one compartment.
Randomisation	Method not disclosed.
Outcome measures	Medication compliance was assessed by means of an electronic bar-coding device, which was given to each participant.
Conclusion	The young-old subjects showed a high rate of adherence which was not improved by any of the interventions. The old-old group had a lower rate of adherence and those who received both organiser and chart had the best rate of adherence in this group.
Notes	Participants required to use a bar code reader and instructed to swipe the reader across the bar code for a particular drug at the time they were taking it. This reading provided the data on compliance. Participants received payment at the start of the study.

Study	Peterson et al 1984
Participants	53 consecutive attendees at an out patient clinic for people with epilepsy. Participants were aged from under 20 to over 60.
Country	Australia
Interventions	Patient counselling leaflet, Dosett® box, seizure diary and reminders for prescription and appointments.
MCA	Commercial Dosett® box. All medication for one dosage time contained in one compartment. Medication accessed by sliding down the plastic cover for the appropriate day of the week.
Randomisation	Coin toss method.
Outcome measures	Plasma anticonvulsant levels. Appointment keeping and prescription refill frequency.
Conclusion	The combination of strategies improved compliance with medication and clinical control of the participant's epilepsy.
Notes	Large number of interventions and therefore difficult to state which intervention improved compliance.

Study	Ryan-Woolley et al 2005
Participants	62 elderly residents of a sheltered housing association aged 60 years and over. Participants were divided into 2 matched groups.
Country	UK
Interventions	One member of each matched pair received a medication organiser and the other received medication in standard packaging. Questionnaires were administered pre- and post-study.
MCA	Nomad® tray. All medication for one dosage time contained in one compartment. Medication accessed by piercing the cellophane covering.
Randomisation	Method not disclosed.
Outcome measures	Both groups were asked to return any unused medication to the pharmacy at the end of each month. The percentage of medication returned was calculated.
Conclusions	The amount of returned medication in the intervention group was reduced over the period of the study.
Notes	Failure by control group to return unused medication meant there could be no comparison with the intervention group. The study was sponsored by Surgichem Ltd. (the manufacturers of Nomad® compliance aids).

Study	Simmons et al 2000
Participants	68 diabetic patients with poor glucose control. Age range 43 – 66.
Country	New Zealand
Interventions	The intervention group received a special kit which included a calendar blister pack and instructions on how to take the medication. The control group had medication in the usual containers.
MCA	A calendar blister pack, which was labelled for days of the week and times of day. All the medication for each dosage time was contained in one blister. The medication was accessed by pushing the tablets out of the blister.
Randomisation	By means of a random number sheet carried out by a third party.
Outcome measures	Participants answered a brief questionnaire, had their blood pressure and HbA _{1c} measured at the start of the study and after 4 and 8 months.
Conclusions	The intervention group showed a reduction in HbA _{1c} over an 8-month period compared with the control group.
Notes	All participants received a ‘medication box’. The intervention group had a calendar blister pack containing their medication inside their box. The control group received medication in standard packaging inside their box.

*Discussion of the randomised controlled trials identified.**Study subjects.*

This research is concerned with the use of MCAs by older people. All the studies included investigated MCA use in the older age group; however, in some studies the age range was wide. The aim of all the RCTs identified was to test how the intervention affected compliance with medication and if the study subjects were all good compliers, it would be impossible to detect any improvement. Only three of the studies identified enrolled subjects who were thought to have problems with medication compliance, (Simmons, Upjohn and Gamble 2000; Becker *et al.* 1986; Peterson, McLean and Millingen 1984). The TRACE study (Huang *et al.* 2000) recruited by means of advertisements and word of mouth; however the inclusion and exclusion criteria did not identify ability to take medication correctly. The VITAL study (Huang *et al.* 2000) recruited retired teachers. This provided an older age range; however it did not identify any problems with medication compliance. The remaining seven studies all recruited via geriatric hospitals, day centres or sheltered housing facilities, and this made recruitment easier for the researchers, but little is known about the ability of the subjects to manage their medication before the start of the study. The majority of studies were undertaken in the USA, with just two taking place in the UK and one each in Australia and New Zealand.

Sample size and power.

It is important when undertaking a research study to ensure that the size of the sample investigated is sufficiently large to ensure that the results obtained are reliable. Haynes, in his systematic review stated that:

“as a general guide, studies with a single intervention group and control group would need to include at least 60 participants per group if they are to have at least 80% power to detect absolute difference of 25% in the proportion of patients judged to have adequate adherence.” (Haynes et al. 2002 p.18.)

The number of participants taking part in these RCTs ranged from 31 – 297. Several of the studies divided the participants into more than 2 groups and only one study indicated that a power calculation had been carried out, (Simmons, Upjohn and Gamble 2000).

Randomisation

Randomly allocating a trial participant to intervention or control group provides a safeguard against the introduction of bias into the study. The method of randomisation should be clearly stated. Four studies gave details of the method of randomisation, (Lee, Grace and Allen 2006; Huang *et al.* 2000; Simmons, Upjohn and Gamble 2000; Peterson, McLean and Millingen 1984,). The method of randomisation was disclosed in the TRACE study carried out by Huang et al but not in the VITAL study. The studies by Huang, Simmons and Lee all described methods to conceal the allocation.

Subjects lost to follow up.

All studies will have participants who either drop out of the study at an early stage or who complete the full study but for whom no outcome data is obtainable. Researchers should give details of both numbers and characteristics of these subjects as large numbers of drop-outs or subjects lost to follow up can cause bias to a study. Nine of the RCTs under consideration had subjects who dropped out or who were lost to follow-up. All these studies stated reasons for the subjects' failure to complete the study. One study, (Lee, Grace and Allen 2006), provided a flow chart detailing the numbers who dropped out and reasons given at each stage of the study. The flow chart also provided information on how this affected the analysis. The remaining two studies did not lose any subjects during the course of the studies. For one study, (Park *et al.* 1992) the length of follow-up was short (two weeks) making it less likely that anyone would drop

out. In the other study (Ryan-Woolley and Rees 2005) all the study subjects lived in sheltered housing complexes and were therefore relatively easy to follow up.

Interventions.

The interventions for all the studies under consideration are briefly described in the tables above. The MCAs used comprised a mixture of refillable types similar to the Dosett® or to the devices which are on sale in community pharmacies and disposable devices similar to Venalink® or Nomad®. One study (Murray *et al.* 1993) used individual plastic pots for each individual dosage time. These appear unlike any commercial MCA in use and, as the participants had to be issued with one pot for each dosage time, would be difficult to transport and store. Another study (Crome *et al.* 1982) used individual blisters for each drug which were then stapled to cards according to the time of the dose. Participants using this type of MCA had to open a blister for each medication they were taking at any particular time. Four studies compared special medication packaging in the intervention group with standard packaging in the control group. The remaining 8 studies used multiple interventions. In two studies, the subjects in the intervention group received all the interventions and, in the other six studies, the intervention participants were further sub-divided to receive different interventions. This use of multiple interventions can make interpreting the impact of the results very difficult.

Outcome measure

All the studies used some measurement of medication compliance as an outcome measure. The majority of the studies used pill counts and self-report. Neither of these measures can be seen as reliable. Subjects may over or underestimate their compliance when reporting to the researcher; this may not be done deliberately or with any desire to

deceive. Pill counts again may not represent a true picture of medication compliance; subjects may remove medication from the container but not take the medication.

A systematic review of the literature investigating interventions made by community pharmacists to improve adherence to chronic medication (Van Wijk *et al.* 2005 p.326) discussed the various methods used to measure adherence and the authors stated that: “From the results of our review, it is impossible to recommend one of the different types of measurement of adherence.”

Researchers in Canada used pill count, self-report and pharmacy claims data to measure medication adherence in an elderly population (Grymonpre *et al.* 1998). They discovered that pill counts can underestimate adherence whereas adherence measured by self-report or from pharmacy data can often be over estimated. Another study which investigated adherence to anti-hypertensive medication (Choo *et al.* 1999) compared the adherence as reported by patient report, automated pharmacy records and pill counts with that obtained using a Medication Event Monitoring System (MEMS®). The MEMS® system comprises a special cap which fits onto a medication container and records on a micro-processor each time the cap is removed. The researchers concluded that adherence measured by pill count or pharmacy records was higher than that obtained by the MEMS® system.

Six studies used clinical outcome measures in addition to the compliance measures. The clinical measures included blood pressure control and serum levels of the medication being taken. In studies which investigated people with diabetes, HbA_{1c} levels have been used. HbA_{1c} levels give a reading of mean blood glucose levels over the previous 8 weeks and therefore provide a good indication of diabetic control.

Including clinical outcome measures has been considered to be more rigorous than relying on compliance measures alone.

Follow-up period.

The length of time which elapsed before the subjects of the study were followed up varied greatly between the different studies. The shortest time to follow-up was one week (Ascione and Shimp 1984; Crome *et al.* 1982), followed by 2 weeks (Park *et al.* 1992). In the remainder of the studies, the follow-up time ranged from 1 to 14 months. A very short follow-up period could be considered a confounding factor because the subjects' behaviour may still be influenced by the original interviews or instructions when they were initiated into the trial. Haynes, in the Cochrane Systematic Review (Haynes *et al.* 2005) stated that studies of patients with long-term conditions should be followed-up for at least 6 months following positive initial findings.

Analysis of results.

All the studies described how the results of the trial were analysed; with nine studies giving clear details in a separate section of the paper. The remaining three studies, (Murray *et al.* 1993; Becker *et al.* 1986; Crome *et al.* 1982), referred to the statistical analysis briefly at the end of the method.

It is important for researchers to give clear details of the type of analysis and statistical methods used in order that the reliability of the results can be ascertained. All of the studies under investigation compared the results of the different groups by means of hypothesis testing. The researchers gave details of the statistical tests employed and therefore it is possible to determine if the tests used were the correct ones for the type of data in question, the shape of the distributions and the groups involved. All the studies collected data on compliance with medication and these were either collected by pill count or by self-report. Pill counts, which are undertaken by the researcher and then

expressed usually as a percentage, are metric continuous data. Self-reports of compliance are more difficult to deal with as these are usually expressed as an opinion, for example, “very good”, “good” “moderate” “poor”. Data of this type is usually considered as ordinal categorical data. Four studies (Huang *et al.* 2000; Simmons, Upjohn and Gamble 2000; Becker *et al.* 1986; Peterson, McLean and Millingen 1984;) use clinical measures (BP, Serum / plasma levels and HbA_{1c}), as outcome measures - this type of data is metric (continuous) data.

Three studies (Ryan-Woolley and Rees, 2005; Ascione and Shimp, 1984; Peterson *et al.*, 1984) stated that paired t-tests were carried out; however only the Ryan-Woolley study used matched pairs in the study design. For those studies, which combined clinical outcomes with measurement of compliance, different statistical tests may be needed to deal with the different types of data. All the studies with multiple outcome measures described using more than one statistical test.

Four studies, Lee, Grace and Allen 2006; TRACE & VITAL (Huang *et al.* 2000) and Park *et al.* 1992, used a form of multi-variable regression analysis. This type of analysis allows the researcher to look for causal relationships between one variable and one or more other variables. Therefore investigating a casual relationship between changes in medication compliance and the medication packaging and / or other interventions would appear to be very useful for these studies. Some researchers also wished to explore the relationships of medication compliance with other variables e.g. age.

Finally in this section on statistical analysis, it is important to investigate how the researchers dealt with the patients who either dropped out or were lost to follow-up. How this data (or lack of data) is handled can make a considerable difference to the reliability of the study results. Two studies, (Lee, Grace and Allen 2006; Simmons,

Upjohn and Gamble 2000), stated that they used 'intention-to-treat' analysis, which is regarded at the best method for dealing with missing data in RCTs. Two studies, (Ryan-Woolley and Rees 2005; Park *et al.* 1992), did not record any patients lost to follow up, although Park did state that there was some missing data due to equipment failure. The remaining studies all lost some subjects during the course of the study and, in these studies the analysis was completed on those subjects who completed the study. This may give rise to bias because trial completers are not the same as all subjects.

Conclusions drawn by the studies.

Three studies concluded that there was no significant difference in outcomes between the intervention and control group. Eight studies reported significant differences in outcomes between intervention and control although, in six studies, the interventions were complex and it is difficult to decide which part of the overall intervention caused the improvement.

The main difficulties with all of these studies lie with the subjects investigated and the outcome measures used. The numbers of subjects in almost all cases are insufficient to power the study, especially when the improvement in outcome measures being investigated is small. A trial may also be confounded by using subjects whose level of compliance prior to the study had not been determined, thereby making it impossible to prove that the MCA had improved compliance. All of the studies used outcome measures of pill count and self-report. These are open to question because they do not give a definitive value for compliance, rather they give, either the subjects' perception of their actions or what they chose to say. Pill counts only give a value of pills removed from the container not an indication of whether they were actually swallowed. Some of these trials did try to improve on the outcome measures by including various clinical measurements and this would appear at first glance to be a more rigorous approach.

However, it must not be forgotten that there are patients who comply perfectly with their medication and yet fail to see an improvement in their condition. This may be due to individual pharmacodynamics or pharmacogenetics.

The quality of the RCTs investigated.

The discussion in this chapter has indicated that the RCTs investigated have, in the main, been of poor quality and inconclusive in their findings. This conclusion has been supported by the findings of the systematic reviews detailed in this chapter. My analysis of the RCTs has discovered that the poor quality of these RCTs is due to a number of factors namely:

- Insufficient numbers of participants to power the trial
- Little or no information on the baseline compliance of the subjects of the trial.
- Outcome measures which are difficult to measure and do not provide an unbiased measurement of medication compliance
- Short length of follow-up time
- Little information on subjects lost to follow up and incorrect methods of dealing with the data from these individuals
- In some trials very little details given about the statistical analysis undertaken and making it difficult to assess if the correct statistical methods have been employed.

3.5.2 Controlled Trial without randomisation.

Study	Ware et al 1991
Participants	84 elderly patients (mean age 78 yrs.) admitted to one of two hospital wards and then discharged into the community.
Country	New Zealand
Interventions	The intervention group received medication in a calendar blister pack and the control group in conventional bottles and packs.
MCA	A foil backed plastic blister pack with 28 compartments. All medication for one dosage time was contained in one blister. Medication was accessed by pushing through the foil back.
Outcome measures	Home visits were carried out at 10 days, one month and three months post discharge. Compliance was checked by oral interviews and/or tablet counts.
Conclusions	A significant improvement in patient compliance in the intervention group compared with the control group.
Notes	Unequal numbers of participants in intervention and control group. Large number of participants lost to follow-up.

3.5.3 Cross-over trial

Study	Wong et al 1987
Participants	22 elderly patients attending a geriatric clinic. Age range 66 – 90 years.
Country	USA
Interventions	11 patients received their medication in a calendar blister pack and 11 patients received medication in standard bottles. At the end of 3 months the intervention group and control group were crossed over. Each patient therefore acted as his/her own control.
MCA	A calendar blister pack with 31 large blisters. All the medication for one dosage time was contained in the blister. Separate cards were issued for each dosage time.
Outcome measures	Compliance was measured by means of pill count and a 'non-compliance index' calculated.
Conclusion	The use of the calendar blister pack significantly improved compliance as measured by the 'non-compliance index'.
Notes	Larger number of male participants than is usual in trials in this age group.

Discussion of non-randomised controlled trials

There were only two trials identified and each used different methodology. Both trials employed control groups but the subjects were not randomly assigned to either group.

The subjects in both studies were patients at geriatric hospitals.

The Ware study investigated subjects who started as in-patients on two hospital wards in the same hospital. For a three month period, the patients who consented to take part in the study on one ward were in the intervention group and those from the second ward were controls. At the end of the three month period, the role of the wards was reversed.

The study subjects self-medicated on the wards and continued after discharge. Demographic details of the study subjects were given and the two groups were similar.

The study subjects in the Wong trial were outpatients at a USA Veterans facility. Each subject received the intervention for 3 months and acted as a control for three months. Half the group received the intervention first and then had it removed; whilst the other group received normal packaging first and then received the intervention. This type of study design could be open to bias because the study subjects who received the intervention first may not revert to pre-intervention behaviour when the intervention is removed. Therefore it is difficult to determine the effect of the intervention.

The numbers recruited by both studies were insufficient to detect a significant improvement in medication compliance.

The Ware study lost a total of 29 subjects to follow-up, 14 in the intervention group and 15 controls. Five subjects were lost to follow-up in the Wong study reducing the number in this study still further. Neither trial indicated how they accounted for the missing data caused by subjects withdrawing or being lost to follow-up.

The interventions in both studies were a calendar blister pack very similar to the sealed MCAs available in this country. The control groups received their medication in ordinary packaging.

Pill counts were undertaken in both studies to assess adherence and in addition the Ware study included data from oral interviews.

The intervention groups in both studies were followed up for 3 months however because of the study design in the Wong study the subjects participated in the study for a total of 6 months.

No details of any statistical analysis were given in the Ware study and it appeared from the report that none was undertaken. Wong et al did give details of the statistical tests used.

Conclusion of studies.

Both these studies concluded that compliance with medication was improved in the intervention group. However, the results can not be considered reliable due to the lack of randomisation, the small numbers involved and the lack of statistical information.

3.5.4 Longitudinal Studies

Four studies were identified which did not use a control group. However the study subjects did receive an intervention and the result of this intervention was recorded over a period of time.

Study	Bazire 1984
Participants	12 non-compliant psychiatric outpatients. Age range 39 – 87.
Country	UK
Interventions	Dosett® box.
Outcome measures	Compliance measured by recording how many tablets remained in the Dosett® box at the end of each week over a four week period.
Conclusion	9 patients demonstrated obvious improvement in compliance. 1 patient required a prolonged period of training in the use of MCA. 2 patients were described as failures.
Notes	Useful list of disadvantages which were identified with the Dosett® box.

Study	Walker 1991
Participants	125 outpatients aged over 55 and taking at least one solid oral dosage form.
Country	UK
Interventions	Participants were given a MCA to take home and use. Participants chose their own device from a selection on offer.
MCA	Dispensatab, Dosett®, Medidos®, Mediwheel, Medsystem, Pill Mill and Redidos. All devices held one week's supply of medication.
Outcome measures	Participant satisfaction with the device.
Conclusions	80 participants stated that the MCA had helped them to keep to the treatment programme.
Notes	No information on which devices were chosen by the participants.

Study	Maguire 1986
Participants	54 geriatric patients, living independently in sheltered housing.
Country	Northern Ireland.
Interventions	Three compliance devices were tested. A Dosett® box, a tear-off capsule device and a memory card or counselling.
Outcome measures	Pill count.
Conclusions	Compliance aids of the type tested are only of limited value in improving compliance and should only be used as an adjunct to counselling.
Notes	

Study	Walker et al 1990
Participants	Subjects recruited via community pharmacies after requesting the purchase one of a number of compliance devices advertised in the pharmacy. 22 subjects completed the interview.
Country	UK
Interventions	Participants used the chosen device in their own home, filling the device with their medication.
MCA	Dispensatab, Dosett®, Medidos®, Mediwheel, Medsystem, Pill Mill, Redidos and Daily Pill Minder.
Outcome measures	Structured questionnaire administered 4 – 8 weeks after the initial purchase. Participants were asked for the opinion of the device they had purchased.
Conclusions	Participants who were interviewed found the compliance device useful.
Notes.	The participants received the compliance device free of charge in return for agreeing to be interviewed.

Discussion of longitudinal studies.

These four studies are of limited value. There are no control groups and the sample size in three studies, (Walker, Bellis and Jumani 1990(b); Maguire 1986; Bazire 1984), is too small to show evidence of effect. The fourth study (Walker 1991) recruited larger numbers; however 36 subjects dropped out of the study before completing the second follow-up interview.

Follow-up period.

A follow-up period of at least six months is considered to be needed in order to provide evidence for the effect of the intervention. In these studies the follow-up periods varied from one month, (Walker, Bellis and Jumani 1990(b); Bazire 1984), to six months for the other two studies.

Interventions.

The intervention in the Maguire study was complex with subjects receiving one of three compliance devices or counselling. The study period of 24 weeks was divided into five experimental periods. Baseline compliance was monitored during the first period and then subjects were given one of three compliance devices or were counselled. Pill counts were taken at the end of each experimental period and subjects who were still non-compliant were changed to a different device.

Interventions in the other three studies consisted of a compliance device. In Bazire's study, all subjects received a Dosett® box; in both studies by Walker, the study subjects selected their device from the different types on offer.

The use of complex interventions can make interpreting the results difficult as it is not always apparent which intervention or combination of interventions has caused the effect.

Outcome measures

The outcome measure in both of Walker's studies was patient satisfaction with the device. The subjects in the 1990 study were interviewed once, four to eight weeks after receiving the device. Those subjects in the 1991 study were interviewed after 6 weeks and 6 months using a structured verbal questionnaire; however, no details of the questions asked are provided.

The other two studies employed pill counts as the outcome measure.

Although patient satisfaction is of importance when considering the use of these devices, it is a difficult outcome measure to assess. Pill counts can also be considered as less than reliable as it is impossible to determine if the participant has taken the medication or simply disposed of it.

Statistics

The only study to include details of statistical analysis was Walker's 1991 study while the other three studies simply gave brief numerical details.

Conclusions

Two of the studies investigated the role of the MCA in improving compliance with medication and the subjects investigated were either known to be non-compliant (Bazire 1984), or had their compliance assessed at baseline (Maguire 1986). The two studies by Walker investigated volunteers, and their ability to take their medication as instructed was not considered prior to the start of the study.

None of these studies could be used to provide evidence of the effectiveness of MCAs in improving compliance with medication; however, the Bazire study in particular is frequently cited as evidence of the efficacy of a MCA.

3.5.5 Cross-sectional studies.

Four studies were cross-sectional studies, that is, each study investigated a group of subjects assembled at one moment in time to investigate a particular intervention. No control groups were used and the subjects were not followed-up at a later date. Although MCAs were the focus of each study, none of the studies investigated compliance with medication. However, the findings of each of these studies may provide information to inform the use of MCAs.

Two studies, (Walker 1990; Wildin and Skellern 1989), investigated the subjects' preferred MCA. In both studies, the subjects were outpatients – (52 subjects were enrolled in the study by Wildin and 222 in the study undertaken by Walker). The intervention in both studies comprised showing each participant a number of different MCAs and then asking a series of questions about the devices.

Wildin et al 1990. In this study the participants were shown a Dosett® and a Medidos® and then asked which they preferred. Questions were also asked about knowledge of medicines and their medication regime. Subjects were asked if they would use a compliance aid if given one and whether they would be prepared to buy one.

Walker et al 1990. This study evaluated seven different MCAs. The participants were asked to remove a tablet from each of four different devices, the devices had been assembled in groups of four and subjects were randomly assigned to test a particular group of four. Subjects were scored for their ability to remove the tablet on a scale of 1-5. Subjects were also asked for their preference.

The other two studies (Atkin *et al.* 1994; Park *et al.* 1991) investigated the patient's ability to correctly fill a MCA and the ability of the patient to remove medication from the packaging including a MCA.

Park et al 1991. Park and her colleagues assessed the ability of arthritis patients to correctly fill medicine organisers, which could be bought over the counter. Three different types of organiser were assessed, with each subject filling one type of organiser. The investigation took place in the office of the local rheumatologists where details of current medication and understanding of their medication regime were noted. Next the subjects were asked to fill the organiser with their medication. Finally they completed a questionnaire about health and a test to measure verbal intelligence. Analysis was carried out to determine the subjects' knowledge of their medication and their ability to load the organiser correctly. Statistical tests were undertaken to look for relationships between knowledge of medication and errors in loading; also relationships between age and errors in loading. This study provides information on how accurately

participants load the organisers under test and two of the organisers investigated appeared to be similar to ones that can be purchased over-the-counter in the UK. However, the test was carried out in very artificial circumstances and this is a confounding factor. Nevertheless this type of information would be useful when deciding whether or not to suggest an older person fills their own MCA.

Atkin et al 1994. The fourth study in this group investigates the ability of patients to manage medication packaging. The study participants were 120 elderly patients of a teaching hospital acute geriatric service. The study subjects were assessed for their ability to undertake six different tasks relating to medication packaging - one of these tasks was to open and remove a tablet from a Dosett® box. This study provides clear details of the methods used and the results obtained. The statistical tests used are detailed and the relationship between Mini-mental state score and functional ability was assessed. The study concluded that the manufactured drug packaging currently available significantly impeded the access by older people to their medications. This was particularly true of the Dosett® box.

Discussion

Although these studies did not attempt to evaluate the effectiveness of MCAs they provide an important view of the problems which may occur when such devices are issued to older people. The inability of older people to remove the medication from MCAs will be discussed later in this thesis. This is obviously an important consideration and yet the study by Atkin remains one of only two studies identified which investigated this issue. The second study, (Nikolaus *et al.* 1996) investigated elderly patients' problems with medication both in-hospital and post-discharge and does include testing the ability of the patients to open and remove tablets from a number of different packaging formats. Included in the different types of packaging was a

Dosett® box. This assessment took place while the patients were in hospital and the study then investigated the patients post-discharge to identify risk factors which might be associated with poor medication compliance. The use of the MCA was not the main focus of this study and therefore it was not included in the review. The authors however state that their findings on the ability of the patients to open a Dosett® are not consistent with the findings of Atkin et al. A higher proportion of patients in the Nicklaus study were able to open the Dosett®. Further investigation of this study revealed the fact that the term ‘dosett’ was used generically, that is different types of MCA were tested. The authors state that they selected the MCAs most likely to be suitable for their patients.

3.5.6 Descriptive studies

Finally, the remaining studies were descriptive in nature and did not involve study subjects. The studies were included in the review because MCAs were the main focus of the work and, although not investigating improvement in compliance, this group includes work on important factors relating to the use of MCAs.

Four studies, (Hattaway 1998; Corlett 1996; Rivers 1992; Walker 1992b), are simply descriptive, describing the different types of devices available. These studies make no attempt to assess the usefulness of each device and, as can be seen from the reference details, were written some time ago. The study by Hattaway describes those devices available in New Zealand and therefore is of little value for those working in the UK. Similar studies have been carried out in the USA and include descriptions of electronic devices. The studies by Rivers and Corlett describe not only MCAs but also devices for assisting patients to use eye drops, inhalers and insulin syringes.

Two studies investigated the use of MCAs by district nurses, (Stewart *et al.* 2001; McGraw and Drennan 2000). The study by McGraw and Drennan investigated a

number of issues regarding the use of MCAs in primary care in England. In particular, they investigated the filling of MCAs by district nurses which is deemed 'unsafe practice which carries risk for both practitioner and patient' (United Kingdom Central Council for Nursing 1992). The study by Stewart et al took place in Scotland also referred to the UKCC advice on nurse filling of medication compliance devices. This study investigated the activities of nurses providing community-based services in Scotland. Both these studies concluded that significant numbers of community based nurses were filling MCAs. However the studies were undertaken shortly after the UKCC advice on the filling of MCAs by nurses and perhaps there had not been time for a change in practice to occur.

One study, (Levings, Szep and Helps 1999), looked at the safety of MCAs. This study was undertaken in Australia and used data obtained from the Australian Incident Monitoring System (AIMS) which is operated by the Australian Patient Safety Foundation. Similar studies undertaken in the UK have not been identified, despite anecdotal evidence that many errors do occur. This is an important area for investigation, as it is as vital to know if the use of MCAs can cause harm, as much as it is to know whether MCAs improve medication compliance. In other words, we need to investigate both risk and benefit.

One paper, (Green and McCloskey 2005), gave details of a survey carried out to investigate the prevalence of use of MCAs in secondary care. This studied used a postal questionnaire to determine how many acute hospitals provided MCAs and medicine reminder charts to patients on discharge. The questionnaire also requested information on the type of MCAs used and any form of patient assessment was used. The response rate to the questionnaire was over 73% and therefore this survey does provide a picture of the provision of MCAs within acute hospitals. The conclusion drawn was that,

although a majority of acute hospitals provided these devices, only a minority reported having an assessment process which would allow them to target the MCAs appropriately. This survey, which was published in 2005, provides a clear view of the situation in acute hospitals at that time. This appears to be the only published survey of this type and therefore provides useful information on the use of MCAs in acute hospitals.

The other paper which described the use of multi-compartment compliance aids in primary care and the prevalence of this use (Nunney and Raynor 2001) refers to the preliminary study described in Chapter 2.

Two studies, (Green, Johnson and Wells 2000; McElnay and Thompson 1992) investigated the length of time taken to dispense medication in a MCA. The study by McElnay and colleagues investigated the length of time taken to dispense the medication regime for five fictitious patients into each of six different MCAs. Only two MCAs of the six investigated are in regular use today (Medidos® and Dosett®). The mean dispensing time into the Dosett® was 1 min 45 sec. and into the Medidos® 3 min 59 sec. In the second study, Green and colleagues investigated the difference in time taken to fill one type of MCA – a Nomad® – with either loose tablets or tablets which had first to be removed from a patient blister pack. The majority of oral solid dose medications obtained by pharmacies will now be in patient packs and therefore this is of relevance to pharmacists who issue MCAs. The task in the study by Green consisted of dispensing 28 days supply of medication into four Nomad® trays. Ten sample prescriptions were dispensed twice by each of ten dispensers. The study concluded that there was a significant difference ($P < 0.05$) between the times taken to dispense from loose medication and that taken to dispense from patient packs; with the time taken to dispense from patient packs being the longer.

These two studies appear to be the only ones which have looked at the time taken to dispense into MCAs. Both studies are small however they indicate that dispensing time is significantly longer than conventional dispensing. This information would be very useful for community pharmacists who may wish to charge for providing medication in MCAs.

Discussion

Although these studies provide no data on the ability or otherwise of MCAs to improve compliance, they do indicate areas where more research is needed. For example more up-to-date descriptions of the latest type of MCA available would be useful for healthcare professionals who wish to provide such devices. Information on the safety of these devices is very important and would provide information to healthcare professionals who need to balance risks and benefits. Further information on the prevalence of the use of these devices would assist any health economics evaluation of the use of these devices.

3.6 Systematic Reviews

Systematic reviews are pieces of research which aim to answer a clear question by identifying and reviewing the literature in that particular field of enquiry. Systematic reviews must be transparent, replicable and systematic.

A review by Haynes for the Cochrane Collaboration (Haynes *et al.* 2005) investigated strategies to improve medication compliance. It was first published in 1996 and has been revised in 2002 and again in 2005. The interventions investigated by the studies were diverse, in fact the authors stated: “No taxonomy of simple labels would do justice to the often complex interventions tested” (Haynes *et al* 2005 p.6.). They then list 15

different common themes or groupings one of which is “special reminder pill packaging”.

Only one trial is included in the special reminder pill packaging section, which is the trial by Becker et al, (1986), already described above. Also included in the review was the trial by Peterson et al, (1984), which again has been detailed above. Three studies identified in the current review and discussed above were excluded from the Haynes review, (Simmons et al 2000; Murray et al 1993; Wong and Norman, 1987). The studies were all excluded for deficiencies in study design (as the Haynes review only considered RCTs) and its overall conclusion was that current interventions to improve medication compliance in long-term chronic conditions are complex and not very effective. This review asks a clearly stated question and follows the procedures laid down by the Cochrane Collaboration for undertaking reviews.

A second Cochrane review has been published recently, (Heneghan, Glasziou and Perera 2006), which investigates the role of reminder packaging in improving medication adherence in long-term conditions. The focus of this review was on RCTs which sought to improve medication compliance by the use of ‘reminder packaging aids’. The reviewers included participants of any age provided they were self-administering their medication. The participants had to be taking their medication for one month or more. The methodology of all identified trials was assessed according to Cochrane Systematic Review guidelines. Eight trials were finally included in the review of which three studies (Simmons, Upjohn and Gamble 2000; Becker *et al.* 1986), and the TRACE study (Huang *et al.* 2000) are included in my literature review. Of the five remaining trials identified four did not meet the age requirements and the fifth (Winland-Brown and Valiante 2000) investigated the use of a voice activated device and a pill box which was not clearly described in the text. However close scrutiny of

the picture in the journal article showed evidence of an electronic timing device incorporated in the pill box and for that reason this study was not included in my review. The reviewers concluded that only one study, (Simmons, Upjohn and Gamble 2000), was of sufficiently high standard. This is interesting because this trial was excluded by the Haynes review, the reason given being “follow-up too short or on less than 80% of participants”. The reviewers drew the final conclusion that, although reminder packaging may provide a simple method for improving patient adherence with medication, it may not provide the best answer and errors may occur.

The third systematic review was commissioned by the World Health Organisation (WHO) and looked at trials which investigated fixed-dose combination pills and unit-of-use packaging, (Connor, Rafter and Rodgers 2004). The review aimed to identify all RCTs where participants were adults taking more than one oral self-administered medicine. The intervention had to consist of the use of combination pills or unit-of-use packaging compared with usual pill containers. Outcome measures had to include one of either adherence measure, pharmacological goal of medication or cost of therapy. Fifteen trials were identified that met the inclusion criteria of which three trials related to combination pills and the remainder to unit-of-use packaging. Three trials, using unit-of-use packaging investigated patients with HIV, leprosy and malaria which are not conditions normally found in the over 65s in the UK. Two further studies were undertaken prior to 1982 which was the start date for this review. Seven of the remaining eight studies were included in the review described in this chapter, (Huang *et al.* 2000; Simmons, Upjohn and Gamble 2000; Murray *et al.* 1993; Ware *et al.* 1991; Wong and Norman 1987; Becker *et al.* 1986; Crome *et al.* 1982). The eighth study (Binstock and Franklin 1988) investigated four compliance strategies on the blood pressure control of 112 patients. However the details of the age of the participants were

incomplete. The authors simply stated that almost one-half were aged between 50 and 65, and there is no information given as to whether the remaining subjects were older or younger or a mixture of both. Therefore this was not included in my literature review..

The systematic review undertaken for the WHO was well designed with a clear question posed. The researchers searched six databases and provided details of the search terms used. There was no evidence of hand searching of journals although web sites relating to conferences and research institutions were searched.

The reviewers discussed various limitations in the identified studies. For example, as has been mentioned previously, the sample sizes were too small to detect small increases in adherence. The length of follow-up was too short in some cases and the number of participants lost to follow-up and intention-to treat analysis was only carried out in one unit-of-use packaging trial (Simmons, Upjohn and Gamble 2000). Once again the trial undertaken by Simmons and his colleagues was identified as methodologically rigorous. The review concluded with the comment that the lack of reliable evidence about effective strategies for improving adherence is extraordinary given the amount of time and money spent on assessing clinical effectiveness and the number of individuals taking multiple medicines.

Finally, a review undertaken by McGraw (2004), followed similar methodology to previous reviews although only two databases were searched, (Medline and International Pharmaceutical Abstracts). The review considered RCTs which compared the effect of MCAs to standard packaging in community-dwelling adults. The participants had to be taking one or more prescription medicines for an on-going condition and have problems with adherence. The researchers investigated a large number of search terms and gave a detailed description of their search strategy.

Thirteen studies were initially identified and eleven eventually excluded for not meeting the criteria. The two studies which were included were Becker et al (1986) and Simmons et al (2000). The reviewers stated that the study by Simmons was designed and conducted to a high standard. The study by Becker et al was considered to be of a lesser standard. The review concluded that further research needs to be carried out to assess the effectiveness of MCAs. This review is limited by only searching two electronic databases which may allow some studies to be missed. However the methodology used is robust and transparent and the researchers assessed the validity of the studies thoroughly.

3.7 Conclusion

This review of the literature was carried out between January and April 2003. Subsequent updates were undertaken in April 2006 and April 2007. The findings of this review have been inconclusive, with the majority of the RCTs being of poor quality. Four of the studies were carried out more than twenty years ago and a further three were undertaken in the early 1990s. This may explain some of the methodological problems encountered with the studies. The remaining five studies were published in the last seven years. However even the later studies are not without problems. One of the main difficulties with this type of investigation is the type of participant chosen. I have previously stated that in order for a RCT of a device to improve medication compliance to be conclusive, the participants must be known to be non-compliant, otherwise it is impossible to determine if the intervention has worked. Studies are still carried out with groups of older people on multiple medications but these facts by themselves do not indicate non-compliance. A further difficulty with this type of study is the measurement of compliance; pill counts and self-reports are open to abuse as the participants will be aware of the nature of the study. Clinical outcome measures may give greater accuracy

although it must always be remembered that patients can be compliant with medication and still fail to respond, due to differences in pharmacodynamics and pharmacogenetics. However, arguably the biggest problem with this type of research is the fact that the researcher is trying to measure changes in behaviour and these may occur for a variety of reasons. For example, simply taking part in the study may improve compliance even if the participant is in the control group (the Hawthorne Effect) (Mayo 1946).

How could RCT designs be improved?

I suggest that by employing the following methods the quality of a RCT investigating this question would be improved:

- Only select participants who have known problems managing their medication.
- The number of participants must be sufficient to detect a significant difference in compliance
- Care must be taken to ensure that in all respects, except the issue of a MCA, control and intervention groups are treated identically.
- Outcome measures should include where possible a clinical measure, for example blood pressure measurement.
- Follow up should be for at least 6 months.
- Details of subjects lost to follow up must be meticulously recorded. In particular details of subjects who drop out of the study due to inability or reluctance to use the MCA must be documented.

Finally, I conclude that the current evidence does not support the use of these devices to improve compliance with medication by older people living in their own homes. This

conclusion is supported by the work of other review authors. Studies need to be undertaken which are methodologically sound and well constructed.

Statistical tests used must be suitable for the study design

3.8 Summary.

In this chapter I have described my review of the literature on the use of MCAs. I have provided details of the databases searched and the search terms used. As a result of this structured literature review I identified 37 journal articles which investigated the use of MCAs, of which 11 were RCTs. I also identified 4 relevant systematic reviews. The critical analysis of these studies reveals many deficiencies in the research methods used and highlights the difficulties of undertaking research in the field of medication compliance. Finally, I conclude that at the present time there is still no reliable evidence to support the use of MCAs to improve the medication compliance of older people. That is not to say that these devices may provide some support to older people who have complex medication regimes and further research may reveal that these devices do improve compliance.

The review of the literature also raised further questions regarding the use of MCAs by older people, in particular the reasons which healthcare professionals have for recommending the use of these devices. The main study which is described in the following chapters will attempt to answer these questions and to provide guidance on further research which needs to be undertaken.

Chapter 4:

Research methodology and underpinning theory

4.1 Introduction to the chapter.

In this chapter, I discuss the reasons for the choice of a qualitative approach for this part of the study. The choice of Grounded Theory as described by Strauss and Corbin (1998) is discussed and justified. The chapter commences with a discussion of the conflicting views held by various groups of healthcare professionals, about the relative merits of qualitative research methods and quantitative research methods (section 4.2.). The following section gives a brief description of the historical background to qualitative research and the various theoretical concepts which underpin it. In section 4.4, I discuss the rationale for choosing qualitative methods for this part of the study. Grounded Theory is then defined, along with a description of its development and the split which occurred between the two original authors. I defend my reasons for choosing the Grounded Theory approach in section 4.6. and then discuss its limitations.

4.2 Qualitative or Quantitative methodology.

A general definition of quantitative and qualitative research can define quantitative as being numeric, and qualitative as mainly descriptive (Gerrett and Stevenson 1995). Temple (1997) describes quantitative research as positivist, that is, based on the results from external stimuli which can be both observed and measured and this has been discussed in Section 2.3.1. Qualitative research has been defined as social constructionist, which can be interpreted as identifying reality in terms of social or cultural practices. I have previously stated that positivism can be defined as a view of the research process in which the researcher is independent of the reality they are describing. The researcher's gender, race, age, ethnicity or class are not relevant factors

in the research. Social constructionism on the other hand states that no researcher can stand outside of their social world (Temple 1997); they have an influence on the research as a whole from the selection of topics, through data collection and analysis, to interpretation of the findings. Quantitative research, therefore, is related to interpreting the results of a research study by the use of numerical and statistical strategies. These can be interpreted as hard facts. Qualitative research, on the other hand is the interpretation of results using the social and cultural practices of those being studied.

Historically, research undertaken in the fields of medicine and pharmacy has been quantitative in nature. These research studies have been designed to determine the efficacy of a particular drug or treatment and, by means of statistical interventions, have tried as far as possible to make the results applicable to the wider population. This need to provide solid evidence about the intervention being investigated runs deep within the minds of those working within these particular fields. Randomised controlled trials are seen as the “gold standard” of experimentation and, indeed, it is by the clinical trials method that all new drugs are investigated.

This opinion is supported by the first article in a series on qualitative research published in the British Medical Journal (Pope and Mays 1995). The authors discussed how the rigid demarcation between quantitative and qualitative research does not encourage movement between the two opposing camps. Another article in the British Medical Journal describes the difference between the two paradigms (Greenhalgh and Taylor 1997). Quantitative research is described as starting with an idea, progressing to data generation and by deduction ending in a conclusion. Qualitative research, on the other hand, begins with an interest in exploring a particular area, proceeds through data collection and by inductive reasoning develops ideas and hypotheses.

4.2.1 The quantitative versus qualitative debate.

Within the medical and pharmaceutical professions, there has been considerable debate concerning the reliability and generalisability of qualitative research. Some professionals see qualitative research as unreliable and unable to produce reproducible “facts”; whereas quantitative research is seen as having the ability to produce hypotheses which can be tested and reproduced by other researchers. In an editorial, Black (1994) argues that quantitative research has “acquired a bogus value”. He continues that if something can be measured or counted it is seen as “scientific”, whereas this type of credibility is not given to the unmeasurable.

Malterud (2001) argues that qualitative methods could improve our understanding of medicine. He states that qualitative research is still regarded with scepticism by the medical community, who point to the subjective nature of the research and the absence of facts. This difference of opinion is typified by the reaction in the British Medical Journal to two articles which appeared in the same issue in 2000. In the article which looked at assessing quality in qualitative research (Mays and Pope 2000), the authors discuss whether it is possible to assess both qualitative and quantitative research according to the same criteria and continue by detailing how qualitative research may be assessed. The second study (Lilford *et al.* 2000), put the case for randomised controlled trials to be allowed to track developments in a particular research area and not be forced to wait for new treatments to stabilise. The authors called these proposed trials “tracker trials” and the paper discusses in some detail how these trials might be carried out and the statistical methods employed. Some time after this issue was published, the journal published a strongly worded letter (Isbister 2000) praising the paper on “tracker trials” and stating that the paper on qualitative research lacked “clearly discernible logic”. The author of the letter went on to say that the terminology used in the qualitative paper was

jargon and the terms used “unscientific”. The letter writer continues by saying that he believes that all research should “be concerned to develop theory.” A spirited correspondence followed with all of the respondents supporting the qualitative research article and remonstrating with the original letter writer for his lack of education on the subject of qualitative methodology. This illustrates the depth of feeling which does exist within medical fields regarding qualitative research. I supported the views of those respondents who stated that the paper gave a clear description of qualitative methods.

4.2.2 The pharmacy perspective.

Pharmacy research was for many years implanted in the “scientific” tradition and it is only in the last twenty years that “pharmacy practice” research has come to the fore as a respected discipline. The International Journal of Pharmacy Practice, for example, was first published in 1991. An article published in the Pharmaceutical Journal on the subject of qualitative research states that pharmacy practice research was defined in 1991 as a “new and rapidly expanding area of research.” (Kairuz, Crump and O'Brien 2007). The late arrival, therefore, of qualitative research into the field of pharmacy research has resulted in difficulties in the understanding of the paradigm. For sociologists, psychologists and those in educational research, this method has been understood since the early part of the twentieth century and over that period the underpinning knowledge and theory have been rigorously explored. The first in a series of articles published in the International Journal of Pharmacy Practice aimed to draw attention to the failure of pharmacy practice researchers to engage with sociological theories when undertaking their research (Bissell, Traulsen and Haugbolle 2001). The authors state that this failure to incorporate sociological theories into research studies hinders the development of pharmacy practice research. However, in my opinion it may

be the lack of understanding of these sociological approaches that leads pharmacists to be hesitant of undertaking qualitative research.

4.3 Qualitative research: the historical background.

Qualitative research has its roots within sociology and is often said to have started out in the “Chicago school” in the 1920s and ‘30s. Other sociologists point to the work of Max Weber in the 19th century as the start of qualitative research. In their three part work “The Landscape of Qualitative Research”, Denzin and Lincoln (1998) consider five stages in the development of qualitative research. The traditional phase from 1900 to 1950, the modernist or golden age from 1950 to 1970, the blurred genes phase from 1970 to 1986, the crisis of representation from 1986 to 1990 and the post-modern or present moments from 1990 to present. The different phases saw the development of theories and practices in qualitative research. Each phase had its protagonists and leading figures in the world of sociology have come to be linked with certain phases. As time has passed, the work of these prominent figures has fallen out of favour to be replaced by others and then sometimes to be revived at a later period. There are many theoretical approaches to the study of sociology and therefore many theories e.g. functionalism, Marxism, symbolic interactionism, post-structuralism, post-modernism and feminism. These different theories provide methods to interpret our actions and behaviours and help us to see how these are influenced by the wider world around us.

The practice of sociology within the medical field has emerged relatively recently, as compared with other disciplines; although it would seem obvious that how people behave when they are ill can be influenced by their own beliefs, by their relationships with healthcare professionals and by the wider social world. Understanding these influences is important for the functioning of an efficient national system of healthcare provision.

In the next three sections, I intend to discuss briefly three of the major theoretical approaches which have been prominent in the twentieth century and continue to influence sociology today.

4.3.1 Functionalist sociology and the role of Talcott Parsons.

Talcott Parsons is often seen as one of the founding fathers of sociology (Bissell, Traulsen and Haugbolle 2002b). His influence on sociology from the 1930s to his death in 1979 was considerable. However, his theories were called into question in the latter part of the twentieth century. Talcott Parsons' work falls within the functionalist theory of sociology. Functionalism is concerned with describing society as a series of interacting and self-regulating elements. Each element has a part to play in maintaining the whole therefore ensuring order in the system. Parsons was interested in producing "grand theory" or "grand narrative" bringing together the theories of some of the major thinkers in sociology such as Max Weber and Emile Durkheim. Parsons believed that ill health should be seen as a social phenomenon rather than something appertaining to individuals. Therefore too many sick people resulted in a failure in the effective performance of social roles and, consequently, the correct functioning of the social order. Parsons formulated the "sick role" (Parsons 1951) in which individuals had rights and responsibilities both in their relationship with their doctors and with the wider world. Parsons described four components of the sick role:

Ill people are exempt from their normal social responsibilities such as work or domestic labour. This exemption requires some form of legitimisation from doctors or those in medical authority.

Ill people are not held responsible for their condition and cannot be expected to recover by an act of will.

Ill people must want to try to get well – if not they can be accused of malingering.

Ill people are obliged to seek and co-operate with medical practitioners to help make themselves well again.

Parsons' ideas can be used to understand the issue of compliance with medication, in other words, as Parsons states, it is the duty of the sick person to co-operate with doctors and sick people must want to make themselves well again. Therefore patients, who deliberately fail to take their medication as directed can be seen as deviant. From Parsons' perspective, the doctor-patient relationship is both harmonious and consensual, despite being unequal in terms of power. Parsons' theories and grand narratives became unpopular in the 1960s and 1970s for a number of reasons. Firstly, his sick role model does not appear to allow for chronic illness. Many people with chronic diseases have to continue in employment and, therefore, do not fit into the sick role pattern. Secondly, Parsons' sick role theory states that the patient cannot be held responsible for their illness. This conflicts with, for example, the case of smoking related illnesses. Thirdly, Parsons describes a paternalistic doctor- patient relationship; patients today are more likely to question their diagnosis and treatment than they were half a century ago.

In particular, with reference to this research, Parsons' theories conflict with the idea of concordance. The concordance has, in the past ten years, superseded the term compliance, when referring to medicines management issues. The report produced by the Royal Pharmaceutical Society (1997) describes concordance as a negotiation between the prescriber and patient as a therapeutic alliance. This is completely at odds with Parsons' view of the relationship, in which, he refers to the "institutionalised superiority of the professionals' role" (Parsons 1951). My research is aimed at discovering if the attitudes and beliefs of the older people and healthcare professionals

affects the appropriate use of MCAs by older people living in the community. In later chapters of this thesis, I will discuss the attitudes and beliefs of these two groups, observed when undertaking research interviews. Some of these attitudes and beliefs can be understood by referring to the work of Parsons.

4.3.2 Symbolic interactionism.

Symbolic interactionism came into prominence in the 1960s and 1970s and arose from work carried out in the sociology department of Chicago University. Symbolic interactionism is of interest to many healthcare professionals because it has been in part responsible for a number of research techniques commonly used in qualitative healthcare studies. The proponents of interactionism do not refer to it as a theory but rather as a loose collection of ideas which guide research in sociology. The term symbolic interactionism was first used by Herbert Blumer in 1937; Blumer based much of his work on the thoughts of George Herbert Mead (1934), whose pupil he was. (Blumer 1969). Mead thought that human beings could move beyond their biological control and be responsible for their own behaviour as they interact with the world around them. Annandale (1998) describes this as self development by means of role-taking and by seeing ourselves as others see us.

Symbolic interactionism has found a place in the fields of medicine and health, with one of the most influential proponents being Erving Goffman, who studied the behaviour of staff and patients in mental hospitals (Goffman 1961). Goffman argued that rather than helping the patients, the environment of the mental hospital actually contributed to the patients' behaviour. Therefore it was necessary to see the behaviour sympathetically from the patients' point of view in order to understand it. Goffman was also interested in the rituals and ceremonies which occur during the normal interactions of everyday life. This work has been taken forward by researchers who have looked at these

interactions in the field of medicine and health, in particular the work of Strong (2001) who investigated paediatric outpatient clinics. Glaser and Straus, in the 1960s, investigated death and dying and produced the term “awareness contexts” to conceptualise

what each interacting person knows of the patient's defined status (as a dying person), along with his recognition of the others' awareness of his own definition. (Glaser and Strauss 1965 p.10)

They recognised bargaining as central to organisational life as the patient endeavours to obtain what he wants and at the same time the staff attempt to strike bargains with the patients. This negotiation has been at the heart of the interactionist theory.

Within pharmacy research, the interactionist paradigm has a great deal of relevance to patient compliance, for example, as interactionism would lead us to question whether it is right for patients to blindly follow the doctor's orders. In a study of patients diagnosed with epilepsy (Conrad 1985), the author proposes that the two dominant theories on medication non-compliance (problems with the doctor-patient relationship and patients' health beliefs), are joined by a third less developed perspective. This third perspective, which Conrad states is rarely mentioned in studies of compliance, is a patient-centred one. Patients are seen as active rather than passive agents in their treatment. Conrad examined the social meanings of medications from his patients' perspectives and concluded that varying their medication was due to four distinct reasons: testing, control of dependence, destigmatisation and practical practice.

Another area of pharmacy practice, which may benefit from interactionist consideration, is the area of lay health beliefs. The interactionist would give full backing to the patient's own health beliefs because these are forged from the patients' own experience of his social world. Health professionals may say that these lay beliefs are the product

of ignorance or a lack of understanding and it falls to interactionist writings to help the healthcare professional see through this argument.

In my research, I intend to investigate the beliefs and attitudes of older people and healthcare professionals about the use of MCAs and therefore investigating these beliefs with reference to interactionist theory would give me a greater understanding of the data obtained.

In their paper on interactionist sociology and its relationship to pharmacy practice research, Bissell and colleagues (Bissell, Traulsen and Haugbolle 2002a) state that few pharmacy practice researchers engage with the original theories on which qualitative research is based. They say that this is particularly true of those researchers who use grounded theory as a method of data analysis and who make little reference to the theoretical issues which underpin this method. They further state that little work has been done to investigate the experience of medicine taking and how it impacts on the patients' sense of self. One question they pose is "is the use of medicine stigmatising?" and I feel that this question can also be asked about using a MCA. Therefore I see a role for interactionist theories in my study on the appropriate use of MCAs.

Symbolic interactionism has more recently been criticised. The most common criticism is that it fails to take note of the issue of power and the way that power can shape meaning.

4.3.3 Michel Foucault and the Post-modernists.

Annandale (1998) states that there is constant debate between the conflicting approaches in sociology and this is seen as a productive feature of sociological theorising. However, more recently considerable changes have taken place resulting in great debate. The work of Michel Foucault has produced much discussion within the

field of social theory; he has produced an innovatory analysis of power and the individual subject. Foucault was interested in how knowledge of the human subject is gained and then used, particularly in terms of creating power differentials. Foucault's work does share some similarities with that of Parsons as they were both interested in the role of illness in modern society and viewed it as deviant behaviour. Parsons thought this deviance could be legitimised by entering the "sick role", but Foucault saw the role of medicine as that of disciplining the population. Foucault is often associated with two recent, major theoretical movements in sociology – post-modernism and post-structuralism, although various authors dispute to which one he belongs or if he belongs to either. Foucaultian principles of research use discourse to explore the concepts of knowledge, power and surveillance. These methods have been used in health research to explore the discourses around HRT treatment (Harding 1997). However as Bissell and his co-authors point out little work has been carried out within the area of pharmacy practice using Foucaultian principles (Ryan, Bissell and Traulsen 2004). The post-modern perspective has come to the fore in the later part of the twentieth century and this theoretical framework is more difficult than many of the others to define.

To post-modernists there are no "real things". An editorial in the *British Medical Journal* entitled "Medicine, postmodernism, and the end of certainty" (Hodkin 1996) discusses "the death of the House of Belief". The writer goes on to say that medicine alone remains immune to these uncertainties, which he attributes to the medical professions' continuing support for the belief that there is "one truth out there" which can be known, understood and controlled by any rational and competent human being. The reaction to this uncertainty, the editorial continues, is Evidence Based Medicine, which promises certainty.

4.4 Why choose Qualitative research methods?

When embarking on a research project, it is important to decide which type of methodology would be most appropriate for the topic under investigation. No method can necessarily be seen as better than another, just better suited to the topic under consideration. Qualitative research is considered more appropriate for answering the “how” and “why” questions and for assessing how people interpret events and make sense of the world around them. Pope and Mays (1995) state that qualitative methods should be used in health and health services research because these methods allow the researcher to access areas such as lay and professional health beliefs, which are not easily studied by quantitative methods.

Another article which aims to give an overview of qualitative research (Kairuz, Crump and O'Brien 2007) states that issues can be explored from the participants' perspective and study the nature and structure of people's attitudes, feelings, ideas and thoughts.

A number of different methods are available to qualitative researchers for example, Phenomenology, Ethnomethodology and Grounded theory.

The preliminary study in this thesis, (see Chapter 2) suggested that patients who were using a MCA had attitudes and beliefs about the devices, their medicines and their healthcare professionals, which could be explored in greater depth by qualitative methods. The reasons why healthcare professionals promote the use of these devices was not explored in the preliminary study and, by using qualitative methodology, I hoped to discover if the attitudes and beliefs of the healthcare professionals led to the appropriate use of these devices.

It is also important, when considering a qualitative approach, to decide which conceptual framework is best suited to the area under investigation. In the previous

section, I have tried to give a historical and methodological perspective to qualitative research. I have indicated that a method based on the symbolic interactionist conceptual framework would seem appropriate for the area I wish to study. Glaser, in his 1978 book, argues that grounded theory allows the researcher 'to discover what is going on.' A paper that investigates 'method slurring' (Baker, Wuest and Stern 1992) states that a researcher's purpose in using grounded theory is to explain a given social situation. The authors of this paper continue by describing how identifying core categories and sub-categories allows the researcher to understand the underlying principle of what is happening in the given situation. I intended in my research to interview older people about their use of Multi-compartment Compliance Aids and to listen to their narratives concerning managing their medication and how this fitted into their daily lives. I also intended to interview healthcare professionals to understand why they recommended the use of these devices and listen to their descriptions of the medicines management abilities of their older patients.

This research which asks, "why, how and when?" appeared to me to be eminently suitable for investigation using a grounded theory approach.

4.5 What is Grounded Theory?

Grounded Theory is a method of qualitative analysis developed in the 1960s (Glaser and Strauss 1967). Glaser and Strauss stated that rather than starting with a theory about the world and then testing it; the data should be collected first and the theory developed from the analysis of this data. The theory is then firmly grounded in the data which has been collected. Charmaz in her chapter on grounded theory states that the power of grounded theory lies in its tools for understanding empirical worlds. (Charmaz 2000 p.510)

Glaser's background was in positivistic methodology whereas Strauss worked in the symbolic interactionist tradition. They collaborated, in a seemingly unlikely alliance, to produce a method of identifying theory which was grounded in data. Glaser and Strauss sought to link the rigour of quantitative research with the rich insight of symbolic interactionism. They stated that by generating the theory as the data was collected, a theory was developed which was best suited to its purpose; as opposed to making a priori assumptions and then attempting to get the data to fit them. Glaser and Strauss go on to say that theory that is generated in this way, from the data, cannot usually be refuted by more data, or replaced by another theory. In the first book on grounded theory which they co-authored "The Discovery of Grounded Theory" (1967), they describe what they mean by grounded theory, its place in sociological research and its differences from other ways of generating theory. They then describe the methods which can be used to generate and develop grounded theory, starting with comparative analysis continuing through the flexible use of data and concluding with a final section on the implications of grounded theory.

In her study of patients with Alzheimer's disease, Orona (1990) describes how she started the study with an interest in how carers of people with Alzheimer's disease made the decision to move the patient into nursing care. As the research progressed and she coded the data, she realised that the carers were explaining how, by the time the decision was taken, the person the carers knew was 'gone'. This loss of identity became the focus of the study. She goes on to say that, "the beauty and strength of the grounded theory approach is that it is *not* linear. Instead, the approach allows for the emergence of concepts out of the data." (Orona 1990 p 1249.)

Another paper, Charmaz (1990), also discusses this property of grounded theory which can lead the researcher to follow "interests, leads or hunches" that they find in the data.

Grounded theory allows the researcher to follow the directions suggested by the data; therefore if the data reveals a new area of enquiry this can be pursued.

Glaser and Strauss eventually went their separate ways. Glaser remained constant to the original grounded theory methodology whereas Strauss in conjunction with Corbin (Strauss and Corbin 1990) further developed the analytical techniques and provided guidance for novice researchers.

The main difference between the two methods lies within the method of coding the data. Glaser's (1978) coding method divides the process into two phases – substantive and theoretical, with the substantive coding further sub-divided into open and selective. Strauss and Corbin's coding begins with open coding which is followed by axial coding and finishes with selective coding. Although Glaser and Strauss and Corbin use similar terminology, their definition of the terminology is different. Glaser (1992 p.38) defines coding as: "conceptualising data by constant comparison of incident with incident, and incident with concept." On the other hand Strauss and Corbin (1990 p.61) define coding as: "the process of breaking down, examining, comparing, conceptualising and categorising data".

In 1992 Glaser wrote another book "*Basics of Grounded Theory Analysis: Emergence vs. Forcing.*" This book opened with the description of correspondence which had taken place between himself and Strauss. These letters are described by Melia (1996) who discusses the content of the letters and the questions they raise. Melia describes how Glaser accuses Strauss of writing about a different method which he (Strauss) then called "grounded theory." Glaser names this other theory "full conceptual description." Stern (1994) describes how, in her opinion, two methods have sprung from the original work on grounded theory, and she characterises these as Straussian and Glaserian

models. This difference of opinion about what now constitutes “grounded theory” is taken up by (Kelle 2005). Kelle sees this difference of opinion as arising from an attempt by both authors to “explicate, clarify and reconceptualise” some of the basic tenets of their original approach. Kelle goes on to say that Glaser accuses Strauss and Corbin of “forcing” categories on the data by means of “coding paradigms”, and he describes Glaser as remaining true to the original methods which has researchers approaching the research field without any prior questions or problems.

4.5.1 How is Grounded Theory research carried out?

Grounded Theory has become a very popular method of undertaking research within the healthcare field. This may be because the Grounded Theory method is seen by some researchers to be inherently positivist in nature and therefore healthcare professionals who find the concept of qualitative research difficult may find it easier to take the grounded theory approach, which they see, rightly or wrongly, as leaning towards the quantitative side.

The researcher must approach the research without strong or specific hypotheses to be tested and then deal with a large amount of data which must be constantly reviewed and compared. I have discussed in the previous section (3.5) the split that occurred between Glaser and Strauss and how two methods of Grounded Theory can now be identified. The method, developed by Strauss and Corbin (1990), has been described as a method suitable for the novice researcher (Heath and Cowley 2004) and, as a novice researcher after investigating both methods, I decided to follow that of Strauss and Corbin. Therefore my description of how to undertake Grounded Theory research is according to the later work of Strauss and Corbin (1998). Strauss and Corbin (1998) state that

“A researcher does not enter the field of research with a pre-conceived theory in mind. Rather, the researcher begins with an area of study and allows the theory to emerge from the data.” P.12

In my main study I determined my area of study by reviewing the work I had undertaken in the preliminary study. As I have stated in section 2.8 the preliminary study gave rise to a number of unanswered questions and I translated these into areas of interest which I wished to explore that is I wished to discover what triggered the issue of a MCA, the views of the older people and healthcare professionals on the use of MCAs, the health beliefs of both groups and was age a factor in the use of these devices. I feel that this method of interrogating the data is completely in accordance with Strauss and Corbin’s methodology as stated above.

Data Collection.

The most common method of data collection used is in-depth interviews. These are semi-structured interviews which follow a basic topic guide to aid the researcher as the interview progresses. Interviews are usually audio-recorded if permission is given by the participant. In addition the interviewer usually writes field notes as soon as possible after the interview has been concluded. These field notes consist of the interviewer’s thoughts and perceptions on what the respondent had said, details of body language and any other incidents which may have occurred during the interview. Other methods of data collection can be used in grounded theory research, for example, observations and field work notes.

Sampling.

Sampling, that is, the selection of participants for interview, can be carried out purposively or theoretically. Purposive sampling can be defined as “the identification and selection of particular individuals who share characteristics relevant to the study” (Smith 2002). However when using Grounded Theory, theoretical sampling is

considered to be the method of choice. Theoretical sampling is defined by Strauss and Corbin as:

“ sampling on the basis of emerging concepts, with the aim being to explore the dimensional range or varied conditions along which the properties of concepts vary.” (1998 p. 73).

The sampling, within a grounded theory approach, changes as the study progresses: so in the first instance when the research is just starting, the sampling is described as open sampling. Strauss and Corbin suggest that one way in which open sampling can be carried out is to proceed very systematically down a list going from one person to another on the list and recruiting, for example, every third person who comes through the door, or everyone on the list who agrees to participate. This, they suggest, is a practical method most used by novice researchers. As the research progresses and the coding of the data moves from open coding to axial coding, then sampling will still proceed on the basis of theoretical concepts but the focus will change. Axial coding aims to relate categories to sub-categories and further develop categories in terms of their properties and dimensions. Sampling therefore becomes relational and variational in order to find incidents which demonstrate the dimension and variation of a concept and its relationship amongst other concepts.

The third type of sampling is known as discriminate sampling when the researcher samples specifically to obtain the maximum opportunity for comparative analysis.

Sampling continues until theoretical saturation occurs, that is when no new data emerges regarding a category, the category is well developed in terms of its properties and dimensions and the relationships between the properties and the categories are well established and validated. Strauss and Corbin (1998) state that theoretical saturation is of great importance and unless all the categories become saturated, the data collected will be unevenly developed.

Coding and systematic comparison of the data.

Analysis of the data must commence as soon as the first data are collected. In the first instance the data is subjected to open coding. Strauss and Corbin recommend that, at the beginning of a research study, the data is subjected to micro-analysis, which is described as detailed line-by-line analysis. This level of analysis is necessary in order to generate initial categories; however it can be seen as time consuming. Alternatively Strauss and Corbin state that open coding can also be carried out by reviewing whole sentences or paragraphs and asking the question ‘what is the major idea in this sentence or paragraph?’ A concept can then be named and a more detailed analysis undertaken.

Open coding.

Open coding is defined by Strauss and Corbin as “The analytical process through which concepts are identified and their properties and dimensions discovered in data.” (Strauss and Corbin 1998 p. 101) The open coding process breaks down the text into discreet sections which can be examined and compared for similarities and differences.

Axial coding

Axial coding is the second stage of Strauss and Corbin’s three stage coding method. Having “opened up” the data using open coding it is now necessary to reassemble the data by making links between a category and a sub-category, this is accomplished by axial coding. In the second edition of their book, the authors introduced a coding paradigm to assist with axial coding. The basic components of this paradigm are:

Conditions – a conceptual way of answering the questions why, where, how and when.

Actions/ interactions – which are strategic responses made by individuals or groups to issues, problems, happenings or events which arise under those conditions.

Consequences – which are outcomes of actions / interactions. (Strauss and Corbin 1998)

Selective coding.

Selective coding is the final stage in this three stage approach and is defined by Strauss and Corbin as: “the process of integrating and refining the theory. (Strauss and Corbin 1998 p.143)

In this final stage, there is a detailed development of categories, a selection of core categories and finally integration of the categories.

Comparison.

Once sufficient data has been obtained to form a comparison, e.g. two interviews, the data should be analysed and the comparisons begun. This procedure is described in detail by Boeije (2002). Boeije explains that constant comparison is an important element in developing a theory that is grounded in the data but that researchers often fail to explain how this comparison took place. In their original book Glaser and Strauss (1967) described this constant comparison method as occurring in four stages:

1. *comparing incidents applicable to each category*
2. *integrating categories and their properties.*
3. *delimiting the theory*
4. *writing the theory. (Glaser and Strauss 1967p.105)*

After the two authors went their separate ways, Strauss and Corbin retained “theoretical comparisons” which they state are different from “constant comparisons”. Theoretical comparisons allow the researcher to think about properties and dimensions and to enable theoretical sampling to take place.

Figure 3 below illustrates my interpretation of the procedure for carrying out grounded theory analysis.

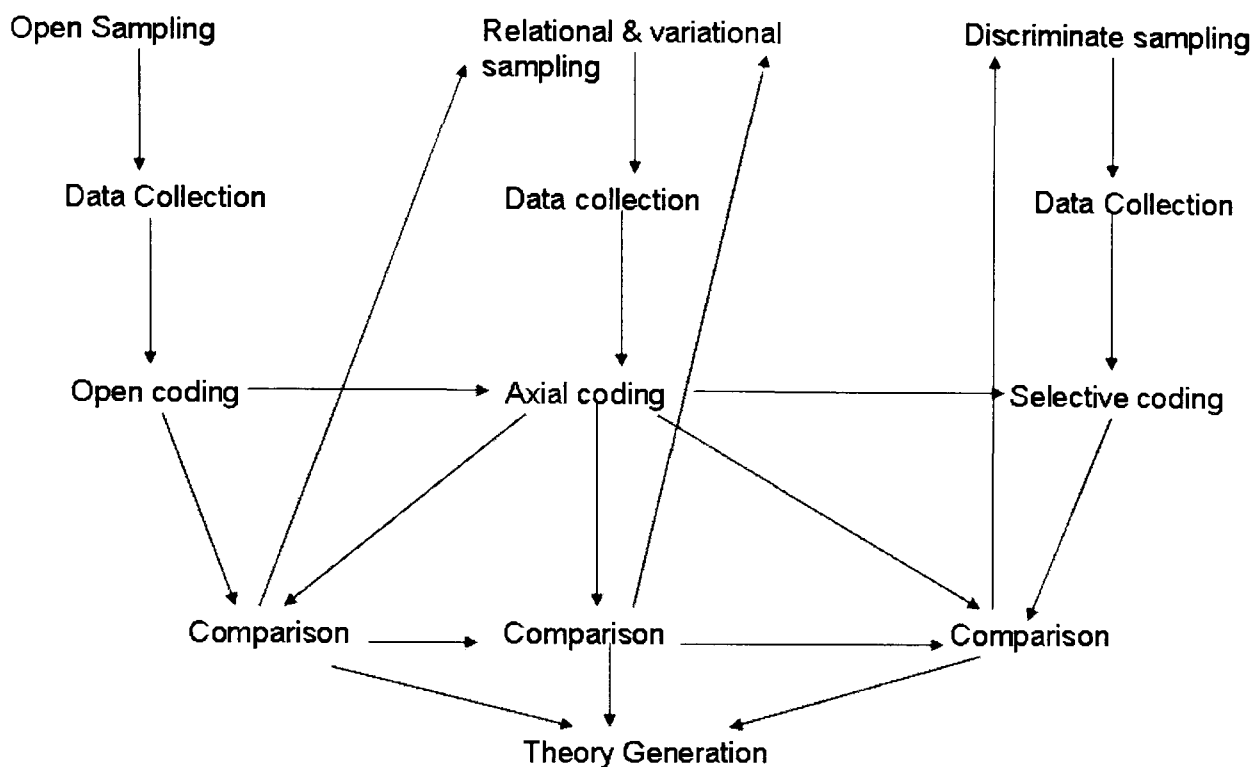


Figure 3: Steps in Grounded Theory Analysis

Memos and diagrams

Strauss and Corbin state that, as the coding progresses, the researcher should write memos which can take several forms, e.g. code notes, theoretical notes and operational notes. These memos are said to be important because they provide a record of how the analysis progressed and help the researcher to reflect on the analysis.

Diagrams are visual memos which allow the researcher to explore relationships between, for example, categories and subcategories. Diagrams can change as the type of coding changes and become more complex as the selective coding stage is reached.

The place of the Literature review.

In their original work, Glaser and Strauss (1967) stated that a literature review should not be undertaken prior to the start of the research. In other words the researcher should commence the research with an open mind. Glaser retained this belief but Strauss in his work with Corbin (1990, 1998) states that the researcher will enter the field with a degree of prior understanding about the topic under consideration. Strauss and Corbin

state that there is no need to review all the literature in the field prior to starting a study and to do so would run the risk of constraining the researcher. Other researchers have written about the place of a literature review when undertaking a grounded theory study. (Heath 2006; Hickey 1997). Heath describes how she decided to begin with a literature review, however she limited the reading to abstracts. This limitation prevented her from becoming too familiar with the literature. Hickey, in his study of district nurses, followed the method advocated by Strauss and Corbin. He goes on to describe, how as the themes emerge from the data, literature can be used to develop these themes.

I have already described in Chapter 3 my structured review of the literature on Multi-compartment Compliance Aids. The information I obtained from this review simply confirmed the information I had obtained in my previous research. This literature review informed part of the original topic guide for the older peoples' interviews but the review of the general literature on compliance and other related areas was only reviewed as themes emerged from the interviews.

4.6 What are the limitations of the Grounded Theory approach?

Among researchers in the field of healthcare, there exist two opposing sets of opinions about the role and use of the grounded theory method. There are those who dismiss the method as being of little use and those who embrace the method and use it frequently. A review of published grounded theory research (Becker 1993) discovered that many of the studies reviewed were not grounded theory studies but simply descriptive. Becker goes on to say that this may be due to using the wrong type of sampling; in grounded theory the sampling should be theoretical as opposed to selective. In addition, Becker also highlights the problems regarding the lack of understanding that researchers may have concerning the underpinning theory which supports the grounded theory methodology. In another paper (Wilson and Hutchinson 1996), the authors identify

methodological mistakes which have occurred in studies which purport to be following grounded theory method. The authors go on to state that in their opinion these mistakes may cause authentic Grounded Theory approaches to be viewed as less credible.

The reported high prevalence of poor studies which state that the grounded theory method was used may be the reason why some researchers are unimpressed with this method. This thought is supported by Charmaz (1990), who reasons that criticisms of Grounded Theory may suggest an incomplete understanding of the method. She goes on to say that: “Weaknesses in **using** the method may have become equated with weaknesses inherent in the method.” (p.1164)

Another problem with the grounded theory method is that the researcher needs to be clear which grounded theory approach they are undertaking. As a number of authors have pointed out, after Glaser and Strauss split they each developed their own vision of grounded theory. Therefore if a researcher uses the Glaser approach and the work is reviewed by someone from the Straussian school, the work may be judged as poor.

Researchers using the grounded theory method must also be clear from the beginning which approach they are taking and avoid the possibility of mixing interpretations.

In an article discussing qualitative research on chronic illness (Conrad 1990), the author discusses the type of data used in grounded theory analysis and describes the procedure for data collection and open coding. The author expresses the opinion that, as the data is broken down by open coding and then reassembled by axial coding; it loses its relationship with the original narrative. Thus the data becomes simply coded extracts removed from the original context. Conrad contrasts the grounded theory method with that of narrative data analysis which he says “stresses the importance of the story the respondent has to tell.” Conrad continues that despite misgivings, he is a user of

grounded theory methodology; however he states “how much of the narrative life world do we sacrifice to create a meaningful sociological world?” This appears to me to be a valid point, by breaking the data down in this way and then grouping together in categories and sub-categories there is the risk that some context is lost.

4.7 Summary

In this chapter, I have discussed the differences between qualitative and quantitative research and highlighted the differing opinions within the fields of medicine and pharmacy regarding these two research paradigms. In section 4.3, I have given a brief historical and philosophical background to the different theoretical approaches which are found in qualitative research. Within this section, I have also attempted to link these theoretical approaches to various aspects of pharmacy practice research and to this current research in particular. I have defended my decision to choose qualitative methods and grounded theory in section 4.4. Section 4.5 defines grounded theory, discusses its discovery and the subsequent schism between the original authors. I have given a detailed description of the method of undertaking grounded theory analysis according to the work of Strauss and Corbin (1998) in section 4.6. Finally in section 4.7 I discuss the limitations of using grounded theory as a method of qualitative analysis.

Chapter 5:

Methods and Analysis of the older persons' and healthcare professionals' interviews

5.1 Introduction.

In this chapter I will discuss the method used for both the older persons' and healthcare professionals' interviews. Firstly I describe the setting for this study. In Section 5.3 the procedure for obtaining ethical consent and how this affected the recruitment process is discussed. There follows a detailed description of the methods used, and a defence of the choice of semi-structured interviews. This is cross-referenced to the grounded theory methodology described in Chapter 4. In section 5.5 I provide a detailed description of the analysis methods employed and relate this to the grounded theory approach of Strauss and Corbin (1998).

5.2 Setting for the study.

The study was carried out in a large industrial city located in the North of England. When the study was undertaken, the city was divided into five Primary Care Trusts (PCTs). These were arranged so that each PCT covered inner-city and outer suburban areas. Prior to the commencement of this study, I had considerable contact with the pharmacists working in all five PCTs, both through previous research work and my role as a tutor for the Centre for Pharmacy Postgraduate Education (CPPE). I contacted the Heads of Medicines Management in all five PCTs at the start of the study and all were supportive. The Head of Medicines Management in two PCTs indicated that they would be willing to assist with recruitment if needed. The decision was therefore made undertake the study in these two PCTs.

Contact was also made with the pharmacy department at the secondary care trust in the same northern city. Senior staff working in the department also indicated that they would be willing to assist with recruitment if needed.

The Local Medical Committee and the Local Pharmaceutical Committee were informed of the research and their support obtained.

5.3 Research ethics approval and consent.

During the time span of this research, there have been a number of changes within the field of research ethics. When I originally registered to undertake a PhD in May 2002, each individual Research Ethics Committee arranged its own system of research ethics approval. I was able to obtain research ethics approval from both committees of the city where the research took place, by sending application forms to one committee, were the application was considered for “chairman’s actions”. When approval had been given I was able to receive reciprocal agreement from the other committee. Research Ethics approval was obtained in June and August 2003. A change had been made to the rules governing research in April of that year and it became necessary to obtain research governance approval in addition to research ethics approval. This was obtained from the Research and Development Unit which covers NHS research in a number of towns and cities in the area. Approval was obtained with the proviso that I obtained an honorary NHS contract with all local Primary Care Trusts. An honorary contract was applied for and obtained.

Undertaking research with older people can give rise to some ethical problems. Older people may not be sufficiently competent to give informed consent and the Mental Capacity Act (2005) includes safeguards for the conduct of research involving such people who may be unable to give consent. Normally approval by a Research Ethics

Committee would be subject to the participant giving informed consent. Participants must be able to read and understand the information leaflet and sign the consent form. For the purposes of this study, I wished to be able to undertake an interview with the older person and this would require a certain level of understanding; therefore informed consent was suitable for my purposes. Many older people who receive their medication in MCAs have reduced cognitive function and undertaking research with this group would require the identification of a consultee (someone who has a role in caring for the person who lacks capacity but is not paid or acting in a professional capacity). Approval for this type of research is usually more difficult to obtain.

When the study was first commenced, I was advised that, because I was not interviewing patients within the secondary care trust, only members of staff, it would be sufficient to gain the consent of the staff member and permission from their line manager. When I was ready to commence the interviews in 2005 this policy had changed and it was necessary to obtain Research Ethics approval from the secondary care trust's Research and Development department. This was obtained in December 2005.

5.4 Research methods.

The reasons for undertaking a qualitative research study in this case have been fully discussed in Chapter 4. The next decision relates to the precise method of data collection for this study. The preliminary study, which is described in Chapter 2, used a very structured questionnaire consisting of mostly closed questions along with the use of observation to assess the older person's ability to accomplish various tasks. It was clear that frequently, in this earlier study, the older people wished to discuss their concerns in greater detail but this was not acceptable within the framework of that study. For this main study, I needed the older people to be able to express their own

views about a variety of subjects, for example, MCAs, their medicines, and the health professionals with whom they came into contact.

Within qualitative research, several different methods of data collection can be used to obtain data from members of the general population and from healthcare professionals. These include, direct observation, interviewing, video recording and collection of written evidence provided by the people concerned e.g. letters, self-filled questionnaires.

It is important to choose the method of data collection which is best suited to the data source and to the type of data which you wish to collect. Many would argue that direct observation is the most suitable means of obtaining data, whereas, in this study it was felt that talking directly to both older people and the healthcare professionals would provide the type of data required.

5.4.1 The choice of in-depth semi-structured interviews

Within qualitative methods, in-depth semi structured or loosely structured interviews are the form most frequently used. In this type of interview, the interviewer uses a pre-prepared 'topic guide' of open-ended questions. I judged that this type of interview would allow the older people to discuss their experiences of using a MCA and to elaborate on their attitudes and beliefs about medicines. The same type of interview was used for the healthcare professionals and again I wished to explore the interviewees' attitudes to the use of MCAs and also their beliefs about the ability of older people to manage their medication. Using in-depth semi-structured interviews allowed me to explore the interviewees' attitudes and beliefs to a greater extent than if the interviews had been structured, or if I had chosen focus group methodology.

Because of the short time available for each interview, it is necessary for the researcher to be able to rapidly build up a positive relationship with the interviewee (DiCiccio-Bloom and Crabtree 2006). When interviewing the older people, I introduced myself as 'a research pharmacist' from the university. Research has been carried to investigate whether the professional role of the interviewer can influence the outcome of qualitative interviews (Richards and Emsli 2000). In their study, Richards (a G.P.) and Emsli (a sociologist) undertook in-depth interviews with 60 middle-aged men and women of varied occupational social class. The interactions that took place during the interviews were noted by both researchers. While some interactions were common to both sets of interviews, some appeared to be associated with being a doctor or a sociologist (who actually introduced herself as a researcher.) The researchers concluded that the professional identity of the doctor is so well known that it overshadowed the personal characteristics of this researcher. By introducing myself as a pharmacist, I may have introduced a level of response from the interviewees which may not have occurred with a different interviewer.

The interviews with the healthcare professionals were undertaken in the same way as the older people, using a slightly different topic guide. The interviewees were all informed before they agreed to take part that the interviews would last approximately 30 minutes. My previous experience showed that it can be difficult to recruit healthcare professionals as the time they have available for such work is very limited. Setting a time limit was an attempt to maximise recruitment by addressing the problem of time commitment. I also insisted that we had a quiet place to conduct the interview in order to be able to record it and not to have interruptions such as telephone calls or staff queries. Piloting the topic guide with a community pharmacist, a junior hospital doctor and a nurse showed that 30 minutes was sufficient time.

Undertaking all the interviews myself, I was concerned that I might influence how the interviewees behaved. I have interviewed pharmacists before but never other healthcare professionals. Research has been carried out looking at the effect of the interviewer interviewing fellow professionals. As part of two qualitative studies employing semi-structured interviews with GPs, the interviewees were asked their opinions on being interviewed by a GP researcher (Chew-Graham, May and Perry 2002). The study concluded that the professional identity of the researcher can influence the type of data obtained and must be stated both in the results and the discussion. Six pharmacists were interviewed for the study and of these four were known to me, mostly through my previous role as a CPPE tutor. None of the other healthcare professionals were known to me.

5.4.2 Topic guides.

When undertaking in-depth semi-structured interviews, the interviewer usually prepares an interview guide which consists of the topic headings that the interviewer intends to discuss with the interviewee. This interview guide (more commonly called a Topic Guide) acts as a pointer to the interviewer showing him or her the way forward. Using the topic headings, the interviewer can guide the interviewee in the chosen direction. The topic guide can also include prompts and probes which may be used if the interviewer wishes to encourage the interviewee to elaborate further. Care must be taken both in the ordering of the questions or topics and to avoid the use of closed or leading questions. The novice researcher may ask leading questions or fail to note whether cues are picked up or ignored (Britten 1995). Barbour and her colleagues in a description of a training workshop on semi-structured interviewing (Barbour, Featherstone and Members of WoReN 2000) suggested that asking questions in

qualitative research can be a difficult art to master for the new researcher in particular getting the correct balance between being both precise and also flexible.

As a novice researcher, I was fortunate in being able to attend a number of training sessions on qualitative interviewing and address these problem areas.

The general questions which I produced for the older peoples' interview guide were informed by the results of the preliminary study which I describe in chapter 2. The interview schedule for the healthcare professionals was also informed by this study, but in addition, I was able to draw on the responses from the older people's interviews. The topic guides produced are included in Appendix 3. In accordance with grounded theory methods as the interviews were undertaken, when new themes emerged, I reviewed the topic guide and made alterations to the topics in order to address these issue. For example, the first two interviews with older people introduced the themes of independence and control, which had not been in the original topic guide. I therefore added these topics to the guide. I was able to pilot the healthcare professional's interview schedule with a community pharmacist, a nurse and a junior hospital doctor. These interviews were recorded and transcribed but were not included in the findings. These three interviews highlighted a number of problems with my original schedule and I made significant alterations prior to commencing the main interviews.

5.4.3 Recruitment of Older People.

The approval from the local Research Ethics Committee stipulated that I could not approach older people directly to recruit them to the study. I therefore asked for help from healthcare professionals who regularly came into contact with older people using MCAs. The sampling of the older people was purposive – see Section 5.4.4 for a further discussion of sampling.

A letter was written to all the community pharmacists in two selected Primary Care Trusts enclosing details of the study and explaining about the help needed. Community pharmacists who were willing to assist with recruitment were asked to return a reply slip to me and I then arranged to visit the pharmacy and explain the recruitment protocol further. Participant information leaflets and consent forms were left with the pharmacist for distribution to prospective participants. Details of the relevant paper work used during the recruitment of the older people can be found in Appendix 3. The pharmacists were asked to forward details of older people who were willing to take part in the study to me and I would then contact the participant directly and arrange an interview. I received support from the Head of Medicines Management at both PCTs who were eager to see this research progress further. As a result of this support, I was able to arrange that a pharmacist working with the Intermediate Care Team would assist in recruitment by identifying suitable participants during visits to older people to review their medication. This face to face recruitment was much more successful than the more distant recruitment offered by the community pharmacist; who usually included the information leaflet and consent form in the bag with the dispensed medicines. Those community pharmacists who followed up the leaflets with a telephone call were more successful at recruiting participants. In addition a pharmacy technician who had been recruited by another PCT to undertake medication reviews with older people also assisted in recruitment. She regularly attended events organised by the local Elderly Action Group and I was able to accompany her during 'Ask about Medicines Week' and hand out leaflets about the study.

In order to be included in the study participants had to fulfil the following criteria:

be over 65 years of age,

take four or more regular solid dose oral medications which were contained in a MCA and

live independently in the community.

The exclusion criteria were:

Being unable to read or understand the patient information leaflet

Being unable to undertake the interview in English.

When recruitment started, it became obvious that not all older people using multi-compartment compliance aids were having the devices filled by the community pharmacists. Some older people had bought a device and were filling it themselves and some were having a device filled by an informal carer usually a relative. I therefore decided to include all these participants in the study in order to provide a balanced picture of MCA use by the older population.

Ensuring confidentiality.

The participant information leaflet gave clear information concerning confidentiality. I was careful to explain to the prospective participants, when I contacted them to discuss the research, that they would not be identified in any part of the research. I have used code numbers to identify the participants in this thesis and none of the written documentation contains any means of identification. The tape recordings have been kept in a locked filing cabinet throughout the study and have only been accessed by myself and the authorised transcriber. I was careful when interviewing the participants not to use their name. All tapes and transcripts will be destroyed at the end of this study.

5.4.4 Recruitment of the healthcare professionals.

In Chapter 3, I described the sampling strategies which can be used in grounded theory research. The two main types of sampling are purposive and theoretical and when recruiting the older people I used purposive sampling. However, when recruiting the healthcare professionals, the sampling became theoretical because I used the emerging themes for the older people's interviews to provide details of the healthcare professionals I needed to recruit. This change in the type of sampling used as the research progresses is in accordance with the procedures described in Strauss and Corbin's 1998 edition.

Pharmacists, doctors and nurses were identified by the older people recruited as being responsible for the institution of their MCA. These healthcare professionals were working in secondary, that is within a hospital, or in primary care, providing care to older people in their own homes. In addition three older people had received their MCA from the pharmacist working with one of the Intermediate Care teams in the area.

Intermediate Care

The term Intermediate Care first came into use in the mid-1990s and at first the term covered a wide range of services and there appears to have been no official definition. However the National Service Framework for Older People (Department of Health 2001) introduced a detailed definition of 'intermediate care' in Standard Three which states that:

older people will have access to a new range of intermediate care services at home or in designated care settings, to promote their independence by providing enhanced services from the NHS and councils to prevent unnecessary hospital admission and effective rehabilitation services to enable early discharge from hospital and to prevent premature or unnecessary admission to long term residential care (p 41.)

The provision of intermediate care has varied throughout the country with some areas focusing on intermediate care wards either within a secondary care hospital or in a separate establishment. However in the area where the main study was undertaken the main focus of intermediate care was provision of support in the older person's own home.

At the time of the study there were a number of dedicated intermediate care teams which were separate from the primary care provision. The function of intermediate care is to provide a link between secondary care and the patient's own home. Intermediate care can consist of a number of different services brought together under one umbrella organisation.

Therefore I decided to recruit from all three professions and, as far as possible, from secondary and primary care and from those working within intermediate care. Letters were distributed to all general practitioners in the two PCTS which were supporting this research. I had previously contacted the community pharmacists and I recruited from those who had already expressed a willingness to assist with the research. Letters were sent to the Intermediate Care services and to the district nurses based in each PCT. The hospital pharmacy in the secondary care trust was contacted and through this contact I was able to recruit hospital pharmacists, doctors and nurses.

Details of the interviewees can be found in Section 7.2.

Ensuring confidentiality.

Confidentiality was ensured in the same way as described above. The healthcare professionals are only identified by a code number in this thesis and I have been careful to avoid any statements which might identify them. As before, the tapes were kept in a

locked filing cabinet. The transcribing was undertaken by myself or a university transcriber and all transcripts were also kept in the locked filing cabinet.

5.4.5 Undertaking the interviews.

All the older people's interviews took place in the participants' own homes. Most of the participants were alone. Although on three occasions a relative was present in the house at the time of the interview, the relative was asked to remain silent while the interview took place. Interviews took between 20 and 45 minutes and were recorded; all the participants were asked to give permission for this and no-one declined. Participants were informed that the tape recorder could be switched off at any time during the interview if they so wished. In addition to the recorded interview, participants were asked to give some brief details about themselves, date of birth, living arrangements (i.e. own home, sheltered housing), any help they received (warden, home care) and details about the multi-compartment compliance aid they were using.

The richness of the interviews varied greatly between participants, with some participants being very vocal and giving great details of their medicines and how they managed, whilst other participants simply gave one word answers and were very reluctant to elaborate, making the interview very difficult. The transcribed interviews ranged from 1000 to 4200 words.

The healthcare professionals' interviews were undertaken in their place of work. Each participant was asked to arrange a time and venue convenient for themselves, when we would be able to have approximately thirty minutes of uninterrupted time. I also requested a quiet and private venue where it would be possible to record the interview. All participants were asked to give permission for the interview to be recorded, and as before, I stated that the tape recorder could be switched off at any time. No participant

refused to be recorded and no participant asked for the recorder to be switched off. Interviews were recorded early in the morning, before the start of the day's work or during a lunch break. One community pharmacist arranged to undertake the interview on a day when a second pharmacist was present. Thirty minutes may seem a relatively short time to undertake a qualitative interview, however the topic guide was short and I knew that the healthcare professionals would be reluctant to give me a longer time. All the interviews lasted between 30 and 45 minutes and the word count varied between 1300 and 5500.

5.4.6 Theoretical saturation.

In grounded theory methodology, recruitment usually continues until 'theoretical saturation takes place' (Strauss and Corbin 1998), that is until no new themes are discovered in the data. Strauss and Corbin, however, state in their 1998 edition that sometimes this is not possible and that constraints of time, energy and availability of participants may impose limits on the data collected. Within this study, the older person's interviews reached theoretical saturation with no new themes emerging from the later interviews. The recruitment of the healthcare professionals was limited by the availability of participants and time constraints. However analysis of the interviews indicates that theoretical saturation was reached.

5.5 Analysis of interviews.

The analysis of the interviews began as soon as possible after the first interview was undertaken. I decided to undertake the analysis manually rather than use a computer programme. Computer aided qualitative data analysis (CAQDAS) has become popular in recent years and various software packages are available for the researcher to use. e.g. NVivo® and NUD*IST®. Although using a computer programme can assist the researcher in indexing and retrieving text, I preferred to analyse my data by hand using

index cards. In a paper on 'common pitfalls in grounded theory analysis' (Becker 1993), the author suggests that the use of computer programmes to aid analysis in grounded theory studies can result in the lack of creativity required in this method of analysis. Although computer programmes are useful for handling and sorting data in the grounded theory type of qualitative analysis, the analyst needs to identify the conceptual links themselves.

5.5.1 Tape transcription and review.

Immediately after each interview I wrote short field notes giving details of the interview and my initial thoughts. As soon as possible after this I listened to the tape, firstly to check that the recording was clearly audible and secondly to make initial identification of themes. The tapes were then transcribed either by myself or by an experienced transcriber working for the university. When transcription of each tape was completed the transcript was checked very carefully against the original tape and any errors corrected.

It is suggested that returning the transcribed interview to the study subject for verification increases the validity of the data. In this study I decided not to do this. The older people I interviewed were willing to take part in a single interview but many expressed concern that they might be contacted again either by myself or by other university researchers. I reassured them that this would not be the case and that their names would remain confidential for the duration of the study and then destroyed. To have returned the transcripts for comment would have broken this assurance. Other researchers have found that returning the transcripts is not always successful (Dearnley 2005). Having decided not to return the transcripts to the older people it was then not possible to return the transcripts to the healthcare professionals as this would have introduced bias.

5.5.2 Open coding

The transcripts were printed out on A4 paper in tabular form with a column on the left and right hand side and the text in the central column. The lines were numbered and line-by-line coding commenced. The first two interview transcripts were analysed using the microanalysis method, which is a detailed line-by-line analysis. This microanalysis allows initial categories to develop and emerging themes to be identified. Later interviews were also analysed line by line or paragraph by paragraph. Details of the themes were noted on the side of the transcript and sections of the transcript were highlighted. This type of initial analysis is described by Strauss and Corbin (1998) as open coding. In this method, the data are broken down into smaller sections and the ideas and thoughts held within those sections assigned a meaning or theme. These themes are then compared across the data and the data re-examined for re-occurring themes. Figure 4. illustrates how the data was broken down into smaller sections indicated by the different coloured marker pens. The individual rows were numbered for easy reference and notes were written in the margins. These notes and suggested themes were then transferred to index cards and to memos.

JN	39	Yes	
OP	40-43	So that one there is co-amilofruse - water tablet (laughs) you'll know that one and this is a new one they've put me on this is for pains in me leg that is gabapentin. 300mg take one in the morning and one night. Those are me morning medication.	→ diagnosis ↓ knowledge of medicine
JN	44	Can you think back to before you used to have a box?	
OP	45	It isn't long since	
JN	44	How long do you think it is?	
OP	47	Since I used to take the medicine on me own ? about 3 or 4 month	time
JN	48	Right do you know who actually suggested that you had a box	
OP	49-88	Now I got to know last time my doctor - anyway it was me own doctor because I only---. Now then they switched me I used to take me own I knew all my medication I knew what it was for and everything they started delivering these dosette boxes and they started sending them wrong and I went a full week without anything in place of warfarin it was when I had just come out of hospital and they had stopped me warfarin and the chemist knew and the doctor knew cause I rung the doctor myself to tell them and they knew that they had put me on this clopidogril anyway I was getting neither clopidogril or the other one I am going to be in a right hole here I go t on about it and then next time what happened one time when he come I'd got me warfarin to take at night a tablet and a clopidogril to take in the morning Well if I hadn't have known I could have been in serious trouble there I would have had to have gone in hospital because there would have been too much for me for me blood, well you'll understand that. You see because they were both for the same thing. Anyway as I say I've been having quite a bit of trouble and I said look stop it I said I'm sick and fed up stop it and I'll go back on to how I was before so anyway they sent me me loose medications fair enough then she talked me into it again she said 'are you going to go back onto your dosette box again the doctor would like you to go back on it I said I'll go back on it on condition you don't make anymore mistakes I said it's my life that your messing about with I said and if you make anymore mistakes that's it I'm ringing the doctor and I'm going to complain to the doctor about it all because it isn't fair is it and that was another they stopped me that raloxifen I wrote that on I said to them what's the matter I only take one a day but that's for osteoporosis and I must take that one a day for brittle bones I said why haven't you put that on? Anyway they finished up they got in touch with the doctor and the doctor has given them all that (shows a list) they've stuck all them on (shows labels stuck on medidos) so those are actually what I take now. This is Losec MUPS I've had quite a do about that I've had these gastric ulcers oh I've three I must have had them about 25 years I've had some very bad dos you know vomiting the blood up when they used to bleed and anyway as you will know ulcers gradually - they don't really heal but mine have - they do what they call skin over mine have skinned over and they are not causing me any problems now but I	<p>independence - avoid of MCA - errors warfarin → healthcare professionals knowledge. importance of med change. own knowledge - awareness of error. OP's perception of drug use problems back to original packaging GP's worries - threat?? - organisation ulcer throat - patient's explanation of conditions</p>

Figure 4: Details of open coding on a page of interview transcript.

5.5.3 Memo writing

Strauss and Corbin (1998 p217) state that memos are: “written records of analysis which may vary in type and form.”

Writing memos is considered to be an important part of the analysis procedure, however the way memos are used can vary between researchers. In her study of people with Alzheimer’s disease (Orona 1990), Orona describes in detail how her use of memos developed as the research progressed. Firstly she used memos to record whatever thoughts came into her head as she read the interviews. Secondly she used memos when she felt the analysis had become blocked in order to try and clarify her thoughts. Thirdly she used memos to begin to conceptualize the data.

My memos were written in a separate book, the interviews were identified by code number and the line numbers were used to identify each memo, a memo consisted of a précis of the original transcript and then my interpretation of that section.

An example of a memo is shown in Figure 5 below.

Figure 5: Example of a memo.

USE OF MCA

Interview F/75/18

June 2-10 - Saw box in advertisement in magazine (why did she notice this advert. - was it because she was having a problem) Holds 3 weeks supply - & she worked out own system (v. important in control, also 3 wks supply also important) Warfarin kept separate (WARFARIN - special important must be kept separate) but remains with other tablets Take Warfarin at 6 PM (IMPORTANT take 6 PM) Important not to run short & have to ~~dash~~ dash to pharmacy for EMERGENCY SUPPLY (interesting way of emphasised the words Emergency Supply. Always ready in case she goes away f. to weekend or for longer (this is important if son turns up & says 'I'm taking you to my home f. the weekend' she doesn't have to worry about tablets) - In effect tablets are organised & forgotten about - Of feels in control.

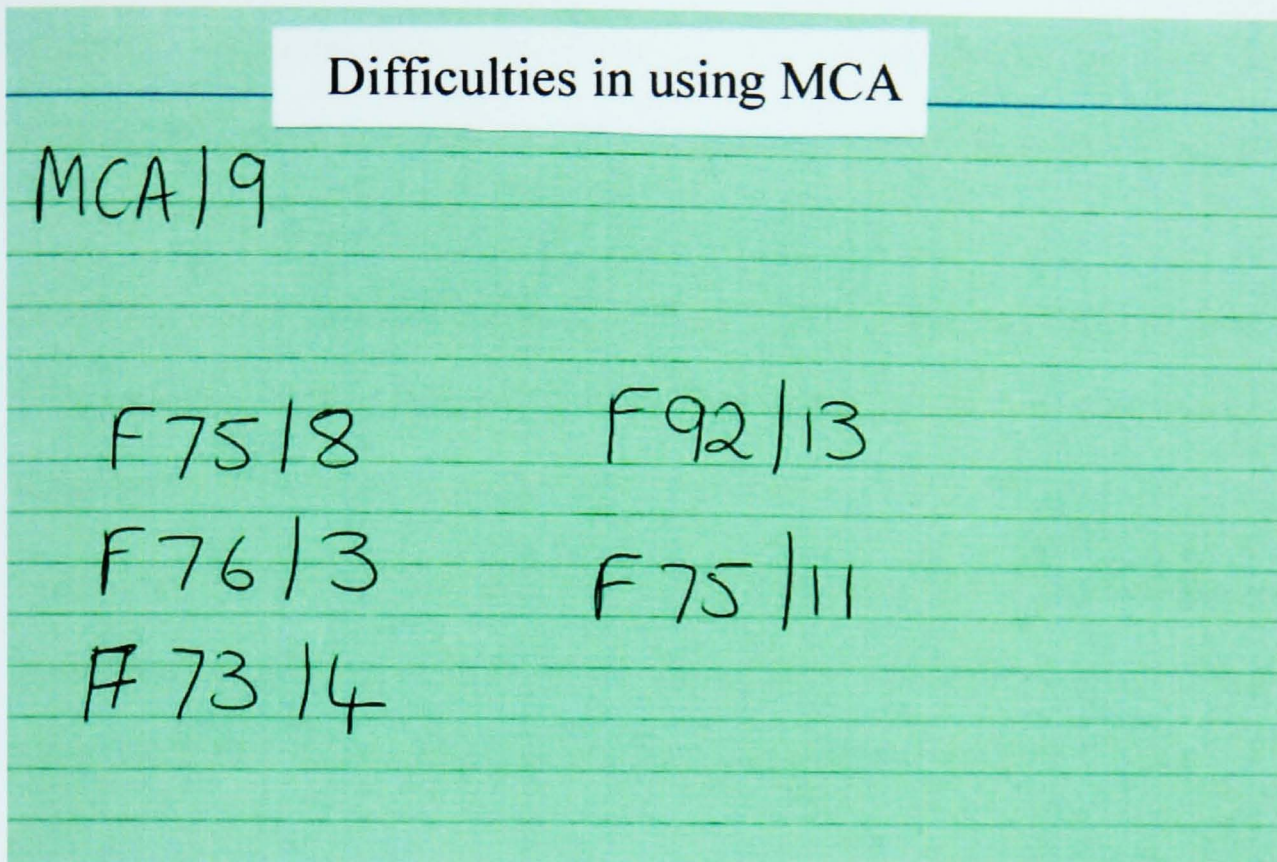
Writing the memos allowed me to express my thoughts concerning a particular section of the data. Later in the analysis I used the memos to compare themes across the data sets.

5.5.4 Axial coding

Axial coding has been described in chapter 4 section 4.5.1. Having carried out open coding on transcripts the process moved to the axial coding stage. Details of themes had been entered on index cards and by using the index cards I was able to re-assemble the data making links between categories and sub-categories. The index cards were colour coded to link in with the four 'areas of interest' which I identified as a result of undertaking the preliminary study (see section 2.8).

Figure 6 below shows an example of an index card

Figure 6: Index card from MCA area of interest.



The index cards gave details of the theme and theme reference number; the other codes refer to the particular interview.

The four areas of interest which I referred to above are:

Trigger What triggered the first supply of the medication in a multi-compartment compliance aid.

MCA How the older person managed using the MCA and how they felt about it.

Health Beliefs What health beliefs and attitudes to medicines use the older person might have.

Age. If the older people thought that their age might affect how they were treated.

Each of these areas of interest was assigned a colour and the transcripts were highlighted with coloured pens to indicate which area of interest a particular line or paragraph fell into.

Themes were entered on to index cards which were colour-coded in line with the areas of interest. Using the index cards the themes with similar ideas or meanings were grouped within the area of interest into sub-categories and the sub-categories grouped into larger categories.

To aid the analysis of these themes and categories, a database was designed using a computer spread sheet to show which themes had been identified by each participant, a separate work book was used for each area of interest.

After sorting of the themes using the index cards and I began to develop categories and sub-categories, tables were then produced linking the interviewees own words with the themes and categories. An example of such a table can be seen in figure 7.

Figure 7: Part of a table of “Trigger themes” from healthcare professionals’ interviews.

Category	Theme	Healthcare professional details
Question: Do you supply / request the supply of medicines to older people living in the community? Followed by can you tell me a little more about this.		
Decision is ours	Pharmacy suggests	“you know usually the last two or three have probably been identified by ourselves” <i>Community pharmacist 5/11</i>
	Risk management	“she (patient) made a mistake yesterday and that is I’m thinking at what point do I say the risks are too great sort of thing.” <i>Community matron 16.201</i>
Decision of non professionals	Relatives request supply of device or purchase themselves	“we have a lot of people purchasing them over the counter. It tends to be ‘Oh I’ll get one of those for mother’ sometimes they buy two or three” <i>Community pharmacist 5/6</i> “sometimes the relatives would identify it, sometimes relatives buy a box from the chemist and they fill them up each week.” <i>ICT nurse 2/188</i> “the members of the family ask us sometimes” <i>GP 10/171</i>
	Patients seek help themselves	“patients may be aware that they are not quite in control of what they are taking and want help to sort it out” <i>Community pharmacist 5/18</i>
	Patients buy their own MCA and fill it themselves (self fillers)	“yes well some people just buy a Dosett® box and fill it themselves on a Sunday afternoon and put them out for themselves.” <i>Community matron 16/253</i>
Decision of other professionals (but not us)	Hospital discharge	“ you know the hospital put them on venalink and often will fax a copy of the discharge so we know what they are on” <i>Community pharmacist 5/80</i> “we get a discharge note that says please put in a venalink” <i>Community pharmacist 4/6</i>

5.5.5 Selective coding

The final stage in the grounded theory approach as described by Strauss and Corbin (1998) is selective coding. When the researcher reaches this stage of the analysis process he or she is ready to develop categories and to deduce a number of core categories which will underpin the theory.

I used the database to assist with this final stage of coding and was able to identify core categories in my data. Figure 8 below shows the portion of the Excel® spreadsheet which refers to the table shown in Figure 7 above. Therefore the core category became 'decision making,' which contained four sub-categories and ten themes.

Figure 8: Portion of spreadsheet showing Trigger for use categories.

Decision making	Decision is ours	Pharmacy suggests
		Risk management
	Decision of non-professionals	Relatives request
		patients seek help
		patients buy own MCA
	Decision of another HCP	hospital discharge
		another HCP
		myth of homecare
		ICT request

Trustworthiness.

In order to ensure that the researcher's analysis of the data can be considered trustworthy it is advisable to ask friends or colleagues to work with portions of the data in order to audit the analysis. I asked my supervisors to review the themes which I developed from the analysis and a colleague reviewed a sample of the transcripts and the themes which I derived from those transcripts.

5.5.6 Refining the theory

Finally Strauss and Corbin (1998) write about 'Refining the Theory'. This consists of reviewing the data for consistency and logical development and to identify a core concept. In a paper which compared the different approaches to grounded theory of Glaser and Strauss (Heath and Cowley 2004 p.149), the authors stated:

*"it is wise to remember that the aim is not to discover **the** theory, but **a** theory that aids understanding and action in the areas under investigation."*

In later chapters I will discuss the findings of both sets of interviews and in the final chapter of this thesis I will draw together these findings and present a theory based on the data obtained. The important question when undertaking a grounded theory study is 'how useful is the theory generated?' (Baker, Wuest and Stern 1992). I intend to discuss the implications of my theory for practice and for research.

5.6 Summary.

In this chapter I have described the setting where the research was undertaken. Details of the Research Ethics approval obtained are provided and I also discussed the process for obtaining approval for projects involving older people. I discussed the various methods of data collection used in qualitative research and justified my choice of semi-structured interviews. The difficulties which occur when recruiting both older people and healthcare professionals for this type of research are discussed alongside my

methods for overcoming these difficulties. The procedure used when undertaking the interviews is described and the difficulties I encountered explained. In the final section of the chapter I gave a detailed explanation of how the analysis was undertaken including examples of the various analytical processes.

Chapter Six:

Interviews with Older People – Findings and Discussion

6.1 Introduction

This chapter details the findings of the analysis of the older people's interviews and follows with a discussion of these findings. The chapter commences with a description of the demographic details of the interviewees and goes on to describe how these interviewees were categorised according to who filled the MCA they were using. I continue by explaining that the interviews were designed to explore four areas of interest namely:

What triggered the initial supply of the MCA (section 6.3)

The advantages and disadvantages of using a MCA (section 6.4)

The health beliefs of the older people. (section 6.5)

Themes related to age and ageism are identified in section 6.6

In section 6.7, I discuss the findings and relate these findings to those found in other research studies. Finally the chapter concludes with a summary.

6.2 Demographic Details

Fifteen older people were recruited to the study by the methods described in Chapter 5 Section 5.4.3. At the beginning of the interview, the participants were asked for some personal details including their age, their living arrangements and their MCA use.

The demographic details of the interviewees can be seen in Table 17.

Table 17: Demographic Details of the older people interviewed for the study

ID no.	Age	Gender	Living arrangements	Accommodation	Support Services
OP1	74	Male	Alone	Own home	None
OP2	86	Female	Alone	Sheltered	Warden
OP3	76	Female	Alone	Housing assn.	No
OP4	73	Female	Alone	Sheltered	Warden Home care
OP5	89	Female	Alone	Sheltered	Home care
OP6	72	Female	Alone	Own	No
OP7	79	Male	With wife	Own	ICT
OP8	75	Female	Alone	Own	No
OP9	88	Female	Alone	Own	No
OP10	79	Female	With daughter	Own	No
OP11	79	Female	Alone	Own	No
OP12	91	Female	Alone	Sheltered	House manager
OP13	92	Female	Alone	Sheltered	Warden
OP14	85	Female	Alone	Own	No
OP15	88	Female	Alone	Sheltered	Warden

Table 18 gives details of the MCA and medicine usage of the older people and as a result of these findings the older people were divided into three groups categorised by who filled their MCA.

Table 18: Details of MCA and medicine use by the older people recruited to the study

ID No.	Type of MCA	Length of use	Nos. medicines	Who fills	Who requested
OP1	Nomad	18mths	7	Pharmacy	patient
OP2	Medidos	3-4 mths	7	Pharmacy	GP
OP3	Dosett	5mths	8	Self	relative
OP4	Venalink	12 months	13	Pharmacy	relative
OP5	Dosett type	unknown	8	Carer	relative
OP6	Type unknown	7 years	5	Self	patient
OP7	Type unknown	1 yr	8	Carer	IC pharmacist
OP8	Type unknown	2 weeks /2 yrs	5	Self	IC pharmacist/self
OP9	Nomad	unknown	4	Pharmacy	unknown
OP10	Dosett type	2 weeks	12	Carer	ICT pharmacist
OP11	Venalink	1 yr	11	Pharmacy	Hospital / GP
OP12	Venalink	1 yr	6	Pharmacy	hospital
OP13	Venalink	2 yrs	8	Pharmacy	unknown
OP14	Venalink	2-3 mths	5	Pharmacy	GP/daughter
OP15	Type unknown	2 mths	4	Carer	Relative

Not all the interviewees had their MCA filled by the pharmacy, as described in Section 5.4.3. I also recruited older people who were filling a MCA themselves and those whose MCA was filled by an informal carer. These three distinct groups were named “Pharmacy filled”, “Carer filled” and “Self filled”. Further details are given below.

Pharmacy filled

The subjects in this group received their MCA directly from the pharmacy: - the MCA usually contained 7 days supply of medication and was either delivered by the pharmacy or collected from the pharmacy by a carer or the older person themselves. In this group, the pharmacy was usually responsible for ordering and obtaining the older person’s prescription from the GP surgery.

Carer filled

The interviewees in this group had their medication put into a MCA by a relative or informal carer. The carer had often purchased the MCA themselves, although not in every case, and the medication was dispensed by the pharmacy in ordinary packaging. The process for obtaining repeat prescriptions from the GP surgery was either organised by the carer or by the pharmacy

Self-filled.

The participants in this group had purchased a MCA and then filled the device themselves using the medication dispensed by the pharmacy in ordinary packaging. These subjects were usually responsible for organising the repeat prescriptions although some might use a pharmacy operated repeat prescription service.

I wished to investigate if there was any difference in the attitudes and beliefs held by the interviewees in each group

6.3 What were the triggers for use?

This section looks at what triggered the use of a MCA in the first place. Initially the interviewees were asked to think back to the time before they received the MCA and discuss how they managed their medication.

6.3.1 How did the older people manage before?

All the interviewees were asked if they could think back to a time before they used a MCA. The participants were divided in their answers, some admitted to a degree of problems with medicine taking:-

“I was taking them at dinnertime and again at teatime and I wasn’t supposed to take them like that.” OP11

“it’s a hard job to remember them all.” OP3

However, other participants did not admit to any previous problems.

“I don’t forget, I do forget (other) things but I don’t forget my tablets.” OP14

“I used to take me own I knew all my medication I knew what it was for and everything.” OP2

Almost half of the interviewees stated that they had had no problems managing their medication prior to receiving an MCA. Such self-reported compliance can be open to question; however, my previous work with this age group suggested that they make the utmost effort to be honest in their answers (Raynor *et al.* 2000)

6.3.2 Did the older people have any system for reminding themselves to take their medicines?

Previous studies have shown that people who take a number of different medicines often devise their own routine or method of reminding themselves to take their own medication (Branin 2001). I wanted to discover if these older people had previously used such a system as this might impact on the way they used their MCA.

This prompt resulted in a number of descriptions of places to keep medicines, and containers to keep the medicines in. Sometimes the containers were produced for me to see.

"I used to have them all on the side, I used to sit there and have them all in the drawer." OP4

"I used to have a smaller little box, just for every day and get them ready like that." OP3

6.3.3 Who suggested that they used an MCA?

The participants were asked "Who first suggested that you had your medicines in this type of box?" Two participants stated that their GP had initiated the supply.

"...my doctor said you see, the doctor said he was going to do this" OP14

"I said who's put me on this Dosett box and why (participant to pharmacist) – she said it's your doctor." OP2

A third of the older people stated that a relative had initiated the supply of the MCA.

"...it was my daughter that arranged it for her Mam." OP4

"I think it was when my daughter went with me to the doctors." OP14

However, not all of the participants were clear about the reasons and stated that they did not know why they had been given the MCA and that it had arrived unannounced and with no apparent warning.

"...well as far as I was concerned there was nothing said about me changing to a Dosett box." OP2

"They (the chemist) didn't tell me it (MCA) just came." OP9

6.3.4 What circumstance may have led to receiving a MCA?

Discharge from hospital after an emergency admission frequently was given as a reason.

"I went into hospital a week before Christmas and I must have had a brainstorm or something." OP10

"I fell I got tripped in the garden and hurt my knee, I was in hospital three weeks." OP2

These interviewees described being taken into hospital after an accident or a sudden severe illness, and admitted that they were often confused in the hospital setting, finding

it difficult to understand what was going on. None of the interviewees talked about any medicines assessment they may have had in the hospital setting and so it is difficult to know if any was carried out.

“...they (hospital staff) gave me some to bring out with a thing similar to that (indicates MCA) and I thought when I’ve finished I will have to go to the doctor’s but I haven’t at all.” OP12

“It was the hospital in the first place that gave me a little leather sort of a box in there and they kept on with that.” OP11

Hospital discharge also led to confusion with medication, even in those people who had managed well previously.

“They changed all my medication while I was in hospital and so I wasn’t really au fait with what I was taking.” OP10

“Coming out (of hospital) with a list of medicines you are to take and you had to study which hour and what time of day and I was getting confused.” OP1

The participants, who were filling their box themselves, had usually made their own decision to obtain and fill the MCA. The trigger in this case was the recommendation of a friend or relative or seeing an advertisement in a magazine. The fact that the self-fillers were open to such suggestions may indicate that they had already identified some problem with their medicines management although nobody stated this.

“I enquired at the chemist and they had one there so I purchased it from there.” OP6

“I saw this box for tablets advertised in a magazine and sent for it, I found it would hold three weeks supply of medication and I worked out a system.” OP8

A number of the self-fillers referred to their need to be organised.

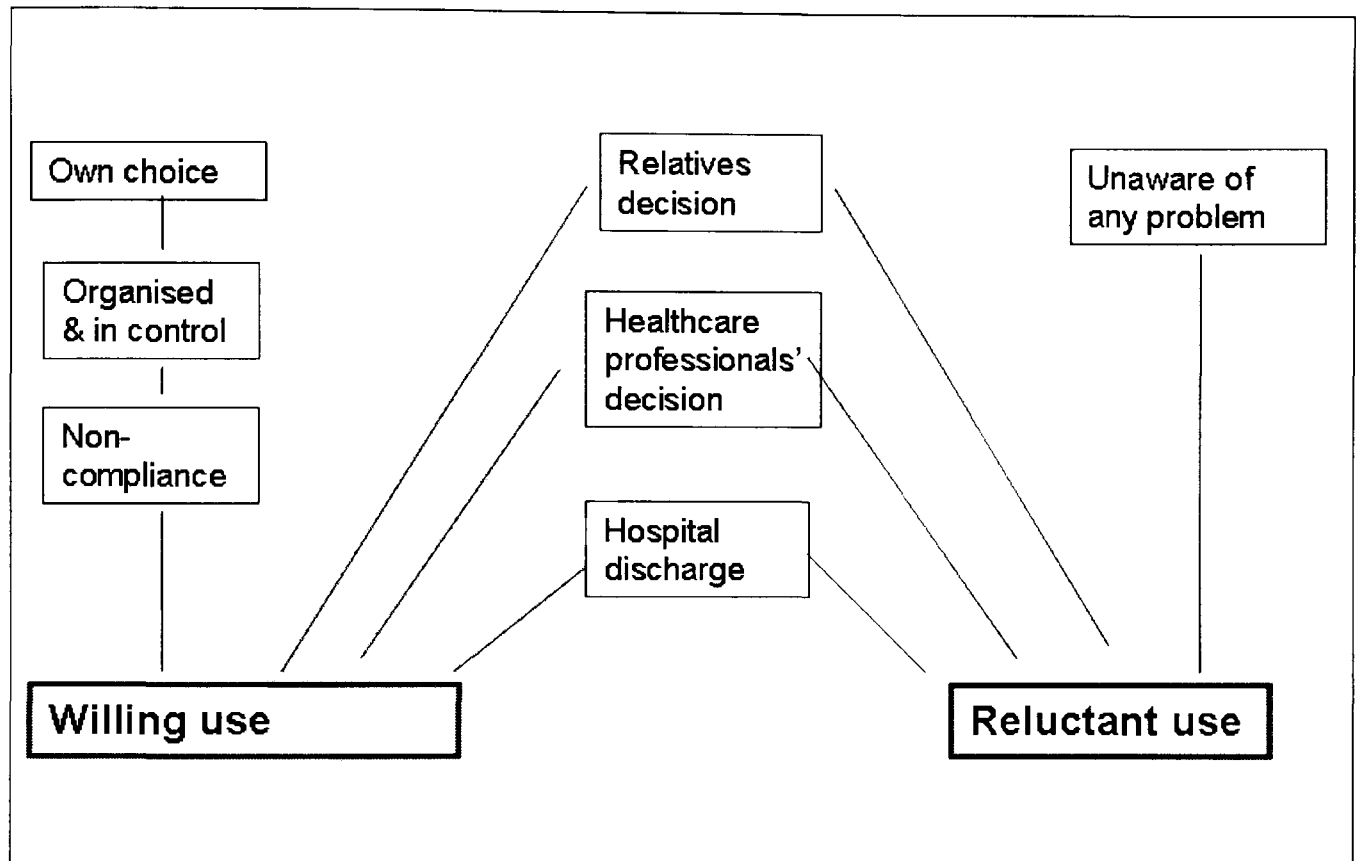
“I suppose in a way I’m that kind of person, orderly. Routine that’s how I’ve always been.” OP8

“I try to keep them separate, this is for morning that’s for afternoon and that’s for night yer know which, then I know what I’m doing.” OP3

6.3.5 Overview of themes and categories emerging from ‘Trigger for use’.

The themes which emerged from this analysis were grouped into categories. Two categories were identified: **Willing to use** and **Reluctant to use**. Figure 7 below shows the relationship between the themes and the categories.

Figure 9: Categories and sub-categories emerging from ‘trigger for use’



6.4 Older people’s opinions about their MCA

Previous studies have looked at user preference when issuing a MCA. In one study 222 people aged over 55 were given the opportunity to try a number of different MCAs and to rank the devices in order of preference (Walker *et al.* 1990(a)). However this study took place over 15 years ago and the MCAs in the study do not reflect the devices available today. Patients are rarely given the opportunity to choose which device they wish to use and there is evidence that patients are not checked for their ability to use the

device they are given. (see Section 7.4.2.) Therefore, I wanted to discover how these older people were managing their MCAs.

The first general question was “How do you manage your box?”

6.4.1 It’s easy to use

A majority of participants stated that it was easy to use, or that it was simple to use or very handy.

“I found it a lot easier to use because it had the date and the time like when to take them.” OP11

“I find it easy really because I can keep them on hand you see.” OP14

6.4.2 Always available

Another aspect, which was popular with the participants, was the fact that their medicines were always available. This was especially important to those people who regularly went away on holiday or to stay with relatives.

“... and at holiday times, I tell them a fortnight beforehand and they give me three lots of those (MCA) that’s for three weeks.” OP1

Another important factor which was another aspect of ‘medicines always available’ was the fact that they were less likely to run out of their medication.

“I would mentally stock up and make sure that I had tablets to refill without dashing to the chemist for an emergency supply.” OP8.

This lady was a self-filler and liked the fact that because she filled the device herself she could assess if she needed to obtain further supplies.

For other participants, the fact that the device was filled and delivered weekly by the pharmacy and the ordering of repeat prescriptions was handled by the pharmacy meant that they always had sufficient stocks of medication.

6.4.3 Acts as a reminder

None of the participants stated that the MCA helped them comply with their medication regime or prevented them from forgetting to take their medication. However, approximately one third of the interviewees remarked that the MCA did either act as a reminder, or by placing the MCA in a special place it contributed to reminding them.

“it’s the matter of the order they are in these boxes, I can look and see. It’s a bit awkward this week because I’ve got double lots in the box and that and I’ve almost three weeks, but I can tell what I’ve taken and what I haven’t.” OP5

“I keep them (MCA) here (interviewee pointed to place on the hearth) if it’s facing that way it’s the morning.” OP1

6.4.4 Still uses own reminder system

Two of the participants removed medication from the MCA and placed it in another receptacle in order to facilitate remembering to take their medication.

“Yes I’ve got them (medicines) in a saucer on there (points to sideboard) but I won’t take any more until the lady comes to make me my lunch.” OP13

“I get them ready at night, I always get them ready at night because I have a little pill box and I always put it on the table where I have my breakfast.” OP14

In particular warfarin was a drug which was frequently placed in a separate container.

“It’s (warfarin) separate, it’s only to be taken at 6pm, it’s separate is warfarin.” OP8

6.4.5 Unhappy with using MCA “it’s difficult to use”.

Not all participants thought that the device was useful or helpful, and those interviewees who were unhappy with their MCA were usually very quick to tell me about this.

“I’ve had a little trouble and all with this Dosett box lately.” OP2

“I didn’t like it when they started with these, I said I wanted my other box back but they won’t give it me back.” OP13

This lady had used a Dosett type box for some time and the community pharmacy had changed over to a sealed Venalink type system which she found very difficult to use.

Previous research by myself (see Chapter 2) and by others (Atkin *et al.* 1994) has shown that older people can have difficulty removing the medication from a multi-compartment compliance aid. Therefore, I asked the older people to describe to me how they removed their medication from the MCA. A number of participants highlighted difficulties that they experienced in using the devices. These ranged from having to make sure that all the different medications had been removed from the compartment, to serious problems piercing the foil to access the medication from a sealed unit.

“it’s very hard to open, I find it difficult and there is nothing wrong with my fingers.” OP8

“yes you cut at the back, you cut through them like that and you put your hand in to get the tablets out, but I think I’m getting used to it now but I still don’t like it” OP13

A number of the participants had devised their own methods of coping with the problems they encountered using their compliance aid. The methods employed indicated a level of improvisation and responsibility.

“ Oh I can tell you what I use (to remove the medication) eyebrow pluckers! Well I can’t get my fingers in and I have an old pair.” OP14

6.4.6 Identifying medicines: a question of trust.

The fact that it can be difficult to identify medicines when dispensed in a MCA was a problem for some of the interviewees and there did need to be a level of trust between the older person and the dispensing pharmacist. For one interviewee, this trust had seriously broken down.

“if you make any more mistakes that’s it I’m ringing the doctor and I’m going to complain to the doctor about it all.” OP2

This interviewee was reporting a conversation she had had with the pharmacist - in her opinion there had been a number of dispensing errors.

The ability to identify the medication in the MCA was important to approximately half of the participants. Although the MCAs filled by the pharmacies did have labels affixed

to some part of the device, it was not easy for the older person to read the label and associate the information with a particular tablet or capsule in the MCA. The participants recognised the medication by means of colour or shape and if the medication in the MCA looked different from what they had received before they became unsettled and unsure.

*“I tell you what bothers me, I mean I take, this is what I take today, that is supposed to be Nitrazepam 5mg where does it say that it is 5mg Nitrazepam?”
OP2*

The Nitrazepam tablets which this participant had previously received were marked with a ‘5’ and an ‘N’, the tablets in the MCA had no markings.

“ I couldn’t name them but I can tell what they are you know what I mean, I can tell by the colour and the shape.” OP5

“I don’t know what this blue and pink thing is, I don’t know what that one is. You see these are tablets I’ve never had before.” OP10

6.4.7 Six o’clock warfarin.

Warfarin tablets caused concern among those participants who were prescribed this medication. Those participants who had been started on warfarin in hospital were given their medication during the 6pm ward drug round and this need to take warfarin at precisely 6pm then continued into home life. Some participants removed the warfarin from the MCA so as they could remind themselves to take the dose at 6pm.

“I take warfarin, I take that at about 6pm in the evening so it is not in my box but I still have to remember to take it.” OP10

6.4.8 Problems caused by change in device.

A minority of interviewees had experienced a change in the type of MCA issued. The change was either because they were discharged from hospital with one type of device and then had a different device issued by the community pharmacy or because the pharmacy changed the device it was providing. Most of those affected by the change

appeared to take it in their stride, although there was little evidence of counselling regarding the change.

“This is only the second week I’ve had this (sealed type MCA). I don’t know why they changed it. They just came differently a couple of weeks ago.” OP12

However, one lady was very upset about the change and found the new device very difficult to manage.

“I didn’t like it when they (pharmacy) started with these, I said I want my other box back but they won’t give it me back.” OP13

6.4.9 What are the benefits of a MCA?

Finally in this part of the interview, I asked the participants if they could describe to me the benefits of using the MCA. The fact that the MCA removed the need to think about their medicines had been suggested in my previous research and again this was discussed.

“I was surprised and very pleased about it because it stopped me thinking, you know sort of going to get my tablets you know because you can forget when you get to a certain state.” OP14

“the doctor said he was going to do this (arrange an MCA) and I thought goodness me I am getting looked after.” OP14

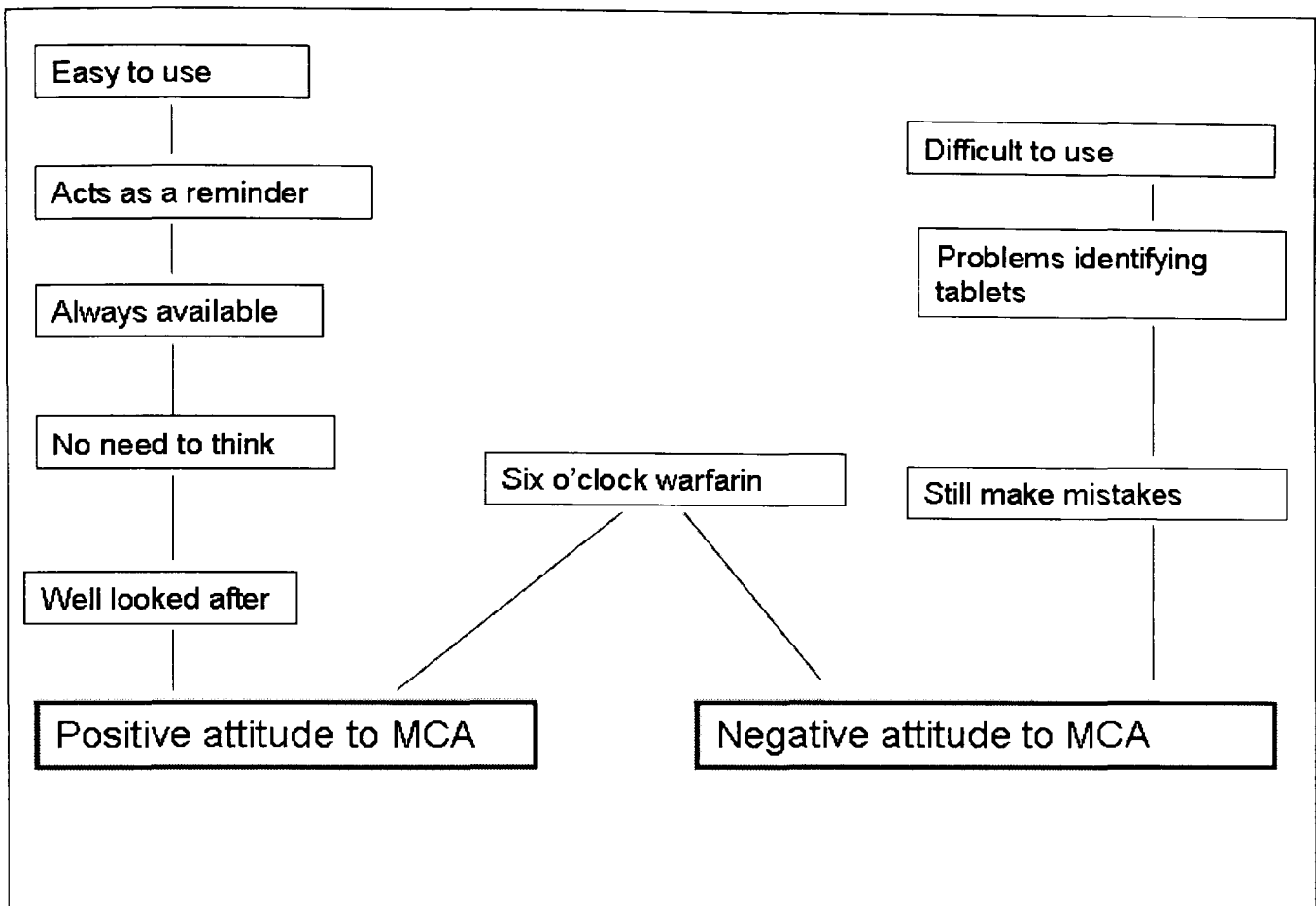
Some participants admitted that although the MCA was useful they still had some problems and had on some occasions not taken the medication correctly.

“sometimes I forget, but I can tell I get right woozy, after about 4 or 5 hours and it dawns on me I must have forgotten to take my tablets.” OP1

6.4.10 Overview of themes and categories emerging from ‘Use of MCA’

The themes which emerged from analysis of the older peoples interviews and which were related to the use of MCAs were sorted into sub-categories and categories as detailed in figure 10. below

Figure 10: Categories and sub-categories emerging from “use of MCA”



6.5 Health Beliefs of the older people.

Research has shown that compliance with medication can be linked to the health beliefs of the patients taking the medication (Horne and Weinman 1999). The main aim of this study is to determine whether the attitudes and beliefs of older people with regard to medication use have an influence on the appropriate use of a Multi-compartment Compliance Aid. The participants were asked if they had any personal beliefs about taking medicines.

6.5.1 Medicines are important.

A majority of the participants felt that medicines were important and that they understood the need to keep taking the medicines.

“I would be frightened if I didn’t take them, I don’t want to die just now for the want of taking them” OP4

“Important they keep you fit. I feel that I am taking them for my own good.”
OP9

6.5.2 Medicines are harmful and should only be taken when necessary.

Conversely a minority of the participants viewed medicines as harmful and were concerned particularly about side effects.

“Then they stopped me taking some because G (daughter) found out that some of them which I was taking created some problem and so she or the pharmacist rang the doctor.” OP10

“Since November they put me on these new tablets and I told the doctor about it, I said I’ve never ever sat in a chair and gone to sleep, I said I could come in here now and sit down and the next thing I could be asleep.” OP11

These participants also were worried about taking unnecessary medication and felt that healthcare professionals should discuss any new medication with them and prove that it was necessary.

“I don’t want to be taking unnecessary medication if it isn’t necessary because they just seem to write a prescription out anytime and they just assume you know what you are taking.” OP10

Two participants stated that they felt that they were taking too many medicines.

“I don’t think I need all these tablets.” OP11

“...but I’ve got all this other rubbish here, there’s so many.” OP10

Changes to medication were also a worry and the arrival of an unrecognised tablet or capsule in a MCA could cause problems.

“Yes well I’ve suddenly seen this red and blue one and I don’t know why that’s cropped up.” OP10

This was a particular problem for those older people who had their MCAs delivered by the pharmacy. There was often little contact between the older person and the pharmacist and the medicines were delivered by a driver; therefore changes to medication were often not discussed and interviewees were left worried and bewildered.

6.5.3 Knowledgeable about medicines.

Some participants were very knowledgeable about their medication and were able to name their medication and to state what they were taking the medication for.

“These are me (sic) morning (ones) what I take in the morning at breakfast. That one is clopidogril in place of warfarin, that one is for blood pressure, that is Losec MUPS now then that is for brittle bones, raloxifene.” OP2

“ ...when I take four in the morning that’s it, then I take one at dinnertime and one at night. Is that aspirin? Then that’s thyroxine, one of these is for my stomach and this one is digoxin.” OP15

The interviewees were identifying the individual medicines in the MCA and therefore it was important to them that they could identify the medication. Interviewees were also relying on their memories as it was not always easy to read the labels attached to the MCA. This point was emphasised by some participants who said that taking tablets was a routine or a way of life. This was particularly true of those who had taken regular medication for a number of years.

“It doesn’t bother me taking them you know, it has got to be a way of life more or less.” OP9

“I’ve always taken them, they’ve sort of grown. They’ve been added to as I’ve gone along you know, different things that I need them for.” OP5

6.5.4 The relationship with healthcare professionals.

The relationship that the participants had with various healthcare professionals was also important when it came to taking their medication. Those participants who trusted their doctor or other healthcare professional were more likely to follow the treatment as prescribed, often without any further discussion.

“The experts have provided them, the consultants and they know better than me, I just take anything (they suggest).” OP8

“There is no point in the doctor trying to help me if I don’t take the tablets.” OP14

Following the doctor's orders however does rely on the older person having a good relationship with their doctor, and some participants explained that this relationship can sometimes be difficult to create.

"You get used to your doctor you see and the doctor I had before he was marvellous when my husband died, he really was. 'You can come and see me anytime M' he said if you are worried about anything. I thought how lovely it was and then all of a sudden he's going back to Newcastle where he came from and I've got to get used to a new doctor, which took a long time." OP14

However, if the relationship with the healthcare professional has broken down, and there is no trust, then the participant may become suspicious of any treatment provided.

"I'm talking about my doctors because I'm just about sick of them, when I go I'm really poorly sometimes and they put me on gabapentin and say it's my nerves." OPI

There had been a real breakdown in communication between this participant and his GPs, which was due to a misunderstanding of the use of the word 'nerves'. The participant was in considerable pain and had consulted his GP he had been prescribed gabapentin but had thought that the reference to nerves meant that the problem was all in his mind and that he was imagining the pain. However despite this he was taking the gabapentin but was reluctant to consult the doctors again.

6.5.5 Independence and being in control.

I had realised after undertaking and analysing the first two interviews that "independence" was a word or topic which was important to the participants and therefore I added a question about independence to the topic guide. For all the participants, maintaining their independence was of prime importance and a number of participants thought that using the MCA was contributing to maintaining independence.

"Independence, I have always strived for (it) since I lost my husband 15 years ago." OP8

"I've always been independent, always." OP11

Alongside independence was the importance of being in control and making your own decisions.

"I have choices, I want to make my own decisions." OP8

"I like basically to be in control of what I'm taking." OP10

However it was possible that some of the interviewees regarded receiving the MCA as a way of losing their independence.

The underlying threat as seen by many of the participants was having to give up their own home and move into residential care and therefore they strived to remain as fit as possible and to be seen to be managing, so as to remove any suggestions of residential care.

"I mean how can I ensure that I am staying here (in own home)?" OP8

"so they said 'would you like to go into a (residential) home.' I said not likely I don't want no home." OP13

The ability to adapt to changing circumstances was apparent in a number of participants and they were prepared to accept the limitations that advancing years and illness had imposed and were able to make the best of their situation.

"I'm quite happy as I am you know and I can get out for a walk and I can meet my friends and go to church." OP14

I'm not that person sitting in the house and watching that telly don't get me wrong only today because your coming. I'm always out, trying to be out as much as possible." OP3

However for some (and not always the oldest participants I interviewed), getting out was not an option, these participants were housebound and did feel isolated. The biggest worry was having a serious fall or collapsing and being unable to call for help

"I'm worried about having a bad do when I'm on my own and I've locked the door you know what I mean and I can't tell anyone." OP1

"I wear this 'charmer' and you just press it and get the paramedic men. How the devil they are going to get me down on that chair I don't know because I won't go down on my own." OP13

This lady was in a first floor flat which was provided with a stair lift.

Although I did not ask any particular questions in this area, death and bereavement did feature in the participant's interviews, only one participant was living with a spouse and for some the death of a spouse had left them struggling to manage with their health problems and medication when previously this had been taken care of for them.

"Then Dad (her husband) died whilst we were on holiday about 7 years ago, while we were in the Isle of Wight. It was the last day we were there but there is nothing you can do about it so you just have to accept these things". OP10

"N (husband) took over and started doing the tablets but then when he got to the back end and started being poorly then he got really mixed up, so consequently when he died last year I had to start again and it's a hard job to remember them all." OP3

Some of the participants felt that they had been near death themselves and, as a result, were careful to take their medication.

"...there was a nurse at the side of me and she said 'you have been very poorly, all you were saying was 'let me die, let me die' and she said the doctor said Oh no we don't let anybody die. And that was some years ago and that's why I take these little blue heart tablets although I don't have any trouble with my heart." OP13

"they found a clot around me (sic) heart so they gave me this drug and I had a heart attack when they were doing it, it were really awful, I thought I were going to die." OP3

Finally, in this part of the interview, I asked those participants who were filling their own devices if they were aware that some pharmacies filled MCAs for patients. I made it clear that I was not offering this service to them but hypothetically asked if they would accept the service if offered. All four of the self-fillers made it clear that although they were aware of the service they did not feel that they needed it yet.

"yes but I don't think I'm in that category as yet thank goodness. I've got my independence and I'm capable of doing it so therefore everything I can do on my own I'm pleased to be able to do." OP/6

"I don't need it yet but there are a lot who do." OP8

It was clear that the self-fillers, although using a MCA, saw the devices provided by the pharmacy in a different category and those people who required this service to be in a different state of health to themselves. I tried to discover what sort of person would

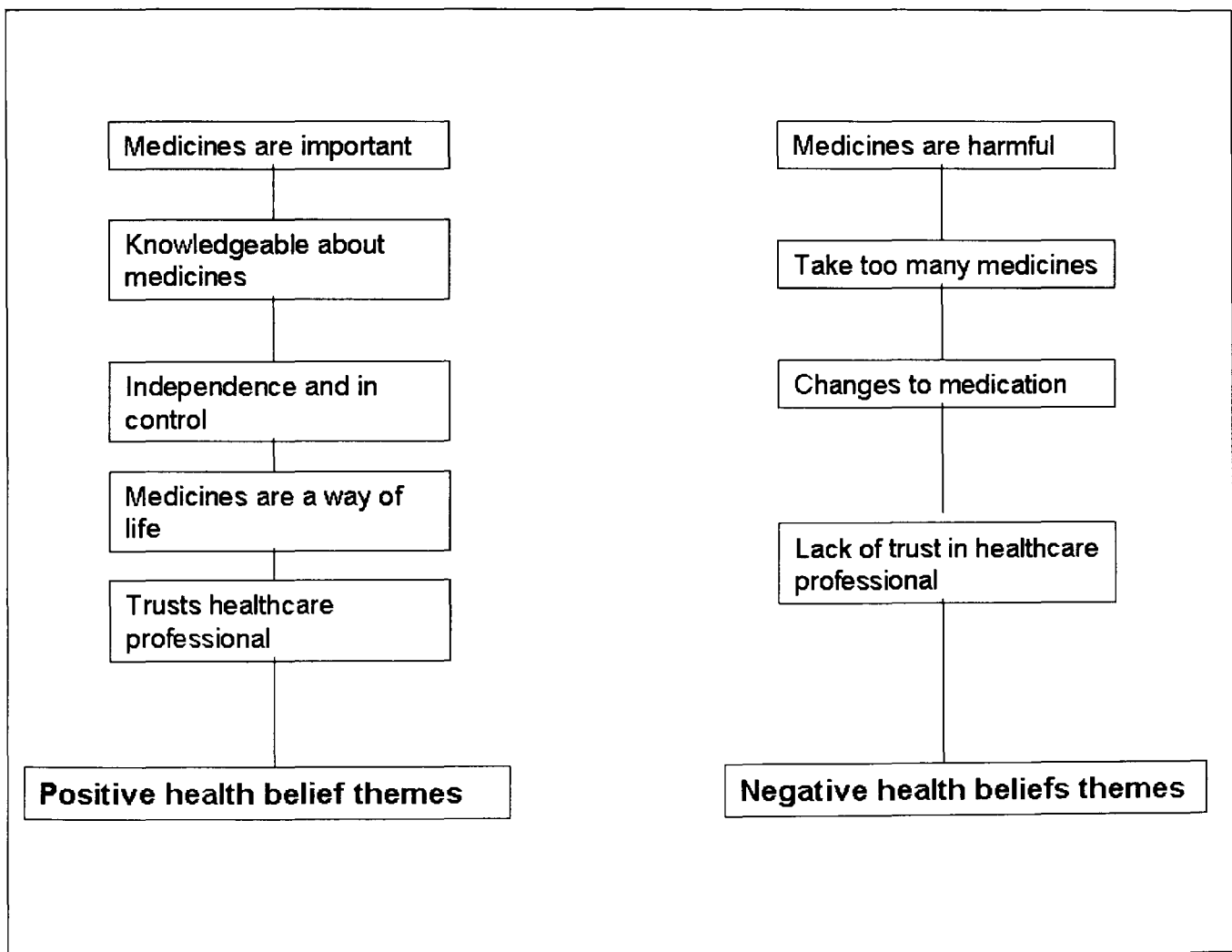
require the service and it became clear that they thought it was people with cognitive problems.

“well I would assume dementia or somebody living on their own and they might forget.” OP/8

6.5.6 Overview of the themes and categories emerging from health beliefs

The themes which emerged from the health beliefs area of interest were grouped into categories and subcategories and details are given in Figure 11 below.

Figure 11: Categories and sub-categories emerging from health beliefs.



6.6 Themes related to Age and Ageism

Multi-compartment compliance Aids are often recommended for use by older people. This may be because there is a perception that people in the older age groups are less likely to take their medication as directed or that older people are more forgetful. I wished to discover if the older people I interviewed thought that they had been given an MCA because of their age and if so, what their feelings were about this. The first interviewee raised the question of ageism without prompting, he was very vocal on the subject and said that he felt that many people, not just healthcare professionals, treated him like a child.

6.6.1 Lack of respect: treated like a child

“They treat you like a kid you know like an old age pensioner which I am but I don’t like to be told that. I want to manage on my own, I think they talk down to you when you get to a certain age that’s the feeling I get. I don’t want them here.” OP1

One other participant was very concerned about the way she was treated in hospital and had complained to the staff.

“I just tell them straight I said ‘look lets face it I’m 75 and I’m not a kid at 2 year old that you are talking to.’” OP11

Some participants felt they were treated with a lack of respect by the healthcare professionals and they attributed this lack of respect to their age.

“I wasn’t asked if she (member of staff) could be in on my private conversations, she wasn’t a professional and their attitude wasn’t professional either. If I had been 50 would I have been treated like that?” OP8

This comment refers to an incident which happened when the interviewee was in hospital, she felt that she had not been treated with respect and had in fact been seen as confused and incapable.

6.6.2 Lack of communication and consultation

Another concern, for some participants, was that they felt marginalised, that decisions about their care and their medication in particular were taken by healthcare professionals without discussion; sometimes a relative was involved in the decision making which gave rise to feelings of resentment.

“...both the pharmacist and G (daughter) know more about what I’m taking from the doctor than I do myself now. Now that is something that I wouldn’t say irritates me but I think, I should be knowing that.” OP10

6.6.3 Fear of losing mental faculties.

Another concern for the participants was the thought that they might be losing their mental faculties. The interviewee who did not want to use the MCA and had already sent it back on one occasion, found out from the pharmacist that it is the GP who has requested that her medicines are dispensed in this way and this worries her.

“I was a bit upset I thought Oh God do they think I am going bonkers or something, you know.” OP2

This worry that mental confusion was waiting around the corner was expressed by other participants.

“In fact I go and help at the luncheon club down at church because I think how long will I be on this side and not the other.” OP6

“And I’m all there, I know what’s going off. That’s it isn’t it because some people have dementia and all sorts.” OP15

6.6.4 Proud of their age

Not all the participants saw their age as a problem, a number were proud of their age and especially the fact that they were told that they did not look their age.

“I find that people say ‘you are not as old as that M are you?’ you know I go ‘well yes’ and I give them the date that I’m born and you can’t get away from that can you?” OP14

“No I’m proud to brag about it (age). I mean there is a lady at (flat number) who is coy about her age, now I can’t imagine people being like that who don’t want people to know.” OP12

This group had maintained a quality of life and although they may have had to adapt to their changing circumstances they still enjoyed life.

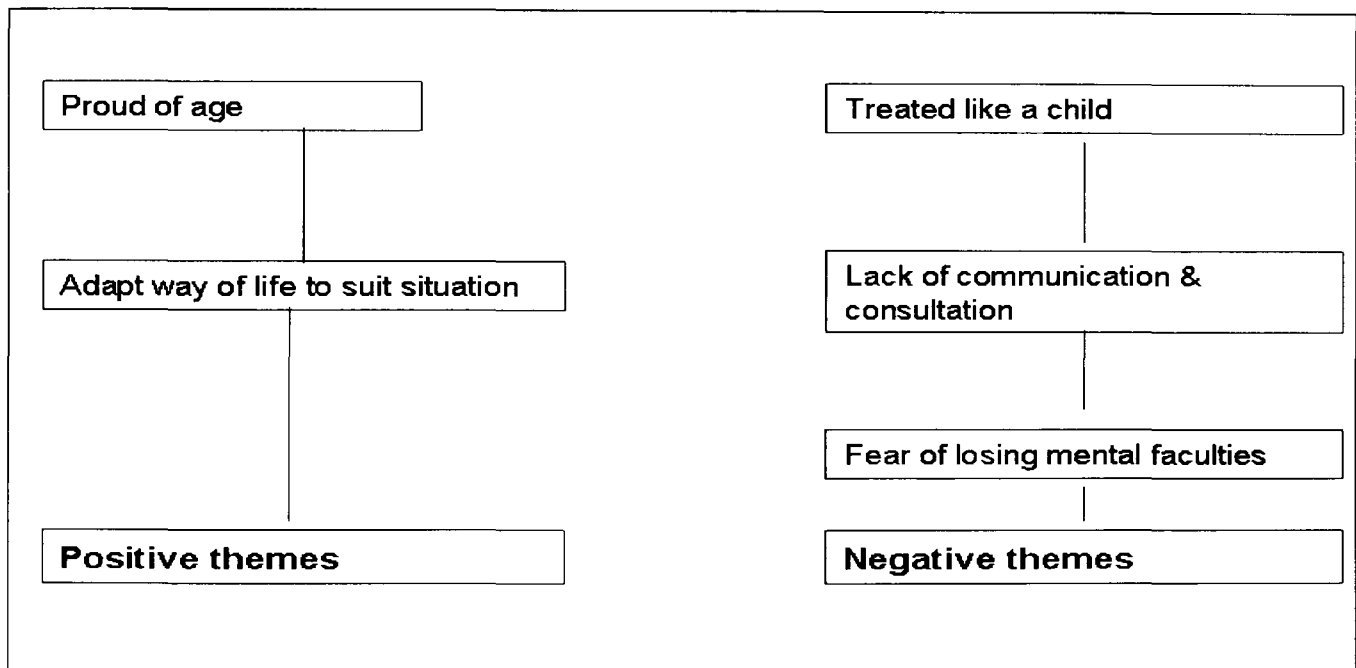
“ I’m quite happy as I am you know and I can get out for a walk and I can meet friends and I go to church. I do everything really and I do try to keep it up but I am tired in the morning and I can’t get used to that but I forget about it.” OP14

“as long as I am able to look after myself and cook and clean that’s all I’m happy.” OP9

6.6.5 Overview of the themes and categories emerging from age and ageism

The themes which emerged from this area of analysis were grouped into categories and subcategories. Details of the categories and subcategories are given in figure 12 below.

Figure 12: Themes which emerged from the Age and Ageism analysis



6.7 The older people’s interviews: Discussion

6.7.1 Trigger for use

The themes which emerged from the interviews in this area of interest could be divided into those which led to the older people willingly using the device and those which led to reluctant use. Some themes could be defined as falling into both categories.

A majority of the interviews produced themes which came within the willing use category. Interviewees were willing to accept and use a MCA if the use had been suggested by a family member.

The three interviewees who acknowledged problems in taking their medication prior to receiving the MCA, were also happy with the device. These interviewees accepted that they had problems managing their medication and were grateful for the assistance the MCA gave. However, one interviewee did state that he still forgot, occasionally, to take his medication.

The themes which were grouped in the decision of a healthcare professional sub-category led to both willing and reluctant use of the MCA. For two of the interviewees, the decision was made by their GP. The decision was welcomed by one interviewee, possibly because the decision was supported by a family member, but not by the other. The interviewee who was reluctant to use the MCA had, in fact, returned the device on a previous occasion and was considering returning the current device. This lady was suspicious of the motives of both the GP and the pharmacist and felt that she had managed her medication perfectly well prior to her accident and hospitalisation.

Approximately half of the interviewees stated that the issuing of the MCA had been a decision made by a healthcare professional and, for the majority of these older people, this was connected to a hospital stay. This mirrors the findings of the preliminary study where 39% of the patients interviewed had, had their MCA instigated by hospital staff. The hospital admission, for those interviewees in the main study, appears to have been an unplanned one, resulting from a fall, an unexpected collapse or worsening of a known medical condition. One interviewee, OP15, indicated that the fall she had was

caused by the medication she was taking, although it was unclear whether it was a case of overdosing or being prescribed a medicine she did not require.

Research studies have looked at the incidence of drug related factors in admission of older people to hospital. Polypharmacy, (defined as taking five or more regular medicines), and taking drugs with a narrow therapeutic index were concluded to be risk factors amongst sheltered housing residents (Johnson *et al.* 2006). The older people therefore often arrived in hospital confused, anxious and disorientated and may appear to the hospital staff to be unable to manage their medication on discharge, leading to the issue of a MCA. A paper published recently (Young and Inouye 2007) suggested that older patients may be diagnosed as demented when in fact they are suffering from delirium. The problems of waking up in a hospital bed and trying to make sense of what had happened were discussed by two of the interviewees. While some interviewees were happy to receive a MCA on discharge others were not and the inclusion of unfamiliar drugs within the MCA could lead to further distress. The most common complaint was that 'nobody told me'. This lack of communication on hospital discharge can lead to inappropriate medication compliance. A study of 103 elderly patients, discharged from a general hospital, looked at the impact of counselling by a clinical pharmacist prior to discharge (Sweeney, Dixon and Sutcliffe 1989). The patients in the counselled group showed a reduction in medication errors compared with the control group. Studies have looked at the provision of particular strategies to improve medication compliance after discharge, however these have not always been conclusive. Four different educational strategies were investigated in 42 patients aged 65 or over who were being discharged from hospital (Esposito 1995). The interventions included educational material, a medication schedule and 30 minutes verbal instruction and the four groups each received different combinations of the interventions. The

groups which received the medication schedule (similar to a reminder chart) had the highest compliance rates.

The older people in this study, who received the MCA as a result of a hospital stay, were divided in their willingness to use the device. If the decision was made by the healthcare professional without reference to the older person then this was likely to lead to a degree of dissatisfaction. However, if the older person believed that they had made or contributed to the choice themselves, they were much more willing to use the device.

It could therefore be conjectured that making one's own decision or agreeing with the decision might be an indicator in how happy a person is with their MCA. The interviewees who were self-fillers all discussed taking control or responsibility oneself. Liking to be organised and working out one's own system were also themes which came out of these interviews. These themes did not emerge from those older people receiving a MCA via the pharmacy or having one filled by a carer.

The question of choice in healthcare is one which has been given a great deal of publicity in recent years. The Department of Health has set mechanisms in place to allow patients to make choices about their healthcare.(Department of Health 2007a).

For some interviewees, the reason they had received a MCA was a mystery. As far as they were concerned, they had been managing their medication well and could identify no problems. There may be an element of self denial in this and, while the older person thinks they had been managing well, others (such as relatives, healthcare professionals) may have detected problems. A quarter of the interviewees stated that they had a particular method of reminding themselves to take their medication and these strategies used as an aid to remembering can be very important (see Section 7.7.4.).

The consequences of issuing a MCA to older people who are already using their own reminder methods can be counter-productive. Older people may try to continue using their own method by removing the medication from the MCA and using their home made reminder system. This can cause confusion both for the older person and for healthcare professionals who may wish to monitor medication compliance.

6.7.2 Use of the MCA.

The themes for MCA use were divided into seven sub-categories which were then grouped into two categories. The categories were 'Positive attitude towards MCA use' and 'Negative attitude towards MCA. Firstly I will discuss the positive attitudes.

A majority of the patients cited ease of use, simplicity or 'handiness' as advantages and this sub-category was found right across the three groups. Only two participants (both 'pharmacy filled') did not see these advantages. Provided that the user could manage to use the device successfully, removing the necessity to open separate boxes and bottles was an important consideration to these interviewees.

Another reason given for having a positive attitude to the MCA was that there was 'no need to think about medicines'. The medicines were in the MCA which was filled by a carer or the pharmacy and the older person simply took what was in a particular compartment without any thought, more medicine arrived as required and for some people this situation was ideal. People, who are happy to take their medication in this way, have been described as 'Passive Users'(Dowell and Hudson 1997). This view of patients as passive recipients of medication was also discussed by Stimson (1974). Stimson thought that this view of "ideal" patients as passive recipients of care was the view of the majority of healthcare professionals at this time and he sought to question this perception. For those older people in this study who could be defined as "passive

users”, the fact that the pharmacy organised the repeat prescriptions and often delivered was also seen as a positive point.

The self-fillers took control of their medication, they were willing to spend up to thirty minutes on one day each week filling the device in order to make taking the daily doses easier. Therefore, despite some misgivings about the particular device, the self-fillers could see a benefit.

Only three participants, one from each group, stated that the MCA reminded them to take their medication. Some interviewees stated that they kept the MCA in a special place, others were reminded by events during the day and others removed the medicines from the MCA and put them elsewhere. Remembering to take one’s medication as directed is often considered to be a prospective task. That is, the patient has to remember to undertake a task in the future (Einstein and McDaniel 1990). However researchers have argued that medication adherence is a much more complex task than this, involving working memory, long-term memory and social factors (Park and Kidder 1996). Research has been undertaken, to investigate the ability of young and older people to perform various memory tasks (Maylor 1996). Despite the opinions to the contrary, older adults have demonstrated a superior ability in many of these memory experiments. Research into memory and adherence among older people has suggested that older people are more likely to use memory strategies to aid memory (Branin 2001). These memory strategies can be internal e.g. relating medicine taking to one’s own routine, or external e.g. using a MCA or writing notes. Research has shown that older adults use more internal strategies than external when adhering to their medication regimen.(Branin 2001; Gould, McDonald-Miszczak and King 1997).

Those interviewees, who trusted their healthcare professionals, were most likely to have a positive attitude to using the MCA. Interviewees described excellent service from community pharmacists both in terms of delivery and in managing changes to the medication regime. Having a good relationship with the GP was also likely to lead to positive MCA use.

Negative attitudes were also identified in over half the interviewees and these are discussed below.

Some interviewees found the MCA difficult to use despite thinking that the device was 'handy' or that the medicines were always available. A study by Atkin et al (1994 p.115) found that 24% of the study group could not open a Dosett® box, in fact the researchers go on to say

“it is likely therefore that patients most in need of such containers are the least likely to be able to manage them. Perhaps the true value of such devices is to aid carers in the management of patient medication.”

Another study found that 16.8% of the study group could not open a 'Dosett' (Nikolaus et al. 1996). The researchers in this last study examined the difference between their findings and those of Atkin et al and stated that this was likely to be due to the fact that they had tested different 'dosetts' and chosen the most appropriate for the needs of their patients. This suggests that careful selection of a MCA and trial with the older person may result in easier use. I have been unable to discover any recent research studies which have looked at the ability of older people to remove medication from the sealed disposable type of MCA e.g. Venalink® or Nomad® and yet my own personal experience from previous research and the comments made by interviewees in this study suggest that older people can experience considerable difficulty in removing medicines from these devices. In Section 7.7.4. I discuss the healthcare professionals' opinion about this.

A number of interviewees had had the type of MCA changed. This may happen after hospital discharge when the hospital provides one design and the community pharmacy provides a different one. On other occasions the community pharmacy changed the type of MCA they supplied. For some older people this was a problem and often the change was made with little consultation or communication leaving the older person upset and confused. Neither the hospital nor the community pharmacies appeared to base their decision regarding which MCA to issue, on the ability of an older person to use the device. Green and McCloskey (2005) surveyed 217 hospitals about their use of MCAs. The 168 respondents used a range of different MCAs and the researchers stated that the reasons for choosing to use a particular MCA were unclear. However the study showed that choice was unlikely to be made based on patient assessment. Those participants who were self-fillers or who had the device filled by a carer were less likely to experience this problem, although having purchased a device which then proved unsatisfactory might make the purchaser reluctant to discard it.

The problem of identifying medicines in the MCA was noted by 50% of the participants including two whose MCA was carer filled. Older people, who had been in control of their medication previously, still felt the need to check that the correct medication had been supplied and the arrival of an unfamiliar medicine in the MCA caused concern. The possible confusion caused by the change in appearance or packaging of dispensed medication was investigated among patients attending community pharmacies in Merseyside (Goulbourne and Rubinstein 1989). Three quarters of the patients interviewed had experienced unexplained visual changes to their dispensed medication and 69% expressed a wish that the appearance of their medication should remain the same on each prescription. This highlights a problem caused by the lack of communication between the older person and the community pharmacist. Those older

people who received pharmacy filled MCAs usually had their medication delivered by the pharmacy. The delivery services were provided by a driver. The older people therefore missed out on the counselling and advice which those people attending a pharmacy to have their prescriptions dispensed would receive.

6.7.3 What were the health beliefs and attitudes of the older people?

The older people interviewed held very definite attitudes and beliefs about many aspects of their lives. Their health and medication use was not necessarily the most important consideration, although these issues did form part of the wider picture.

From the very first interview, the importance of maintaining their independence emerged as a theme. This was not a theme which I had originally considered and therefore the topic guide was modified to include a question on independence. However it was seldom necessary to ask this question as interviewees were keen to tell me of their desire to remain independent or in control. Independence and control are considered to be attributes of autonomy (Jacelon 2004). In her study of older adults admitted to hospital in USA, Jacelon investigates the concept of autonomy. She defines autonomy as “the freedom and ability of older adults to act on their own behalf.”(p.30). Although Jacelon’s study investigated hospital in-patients there appears to be a great deal of relevance to the older people in my study.

As would be expected, all the ‘self-fillers’ gave strong indications about their independence and the importance of making their own decisions and being in control. When asked the hypothetical question about having a MCA filled by the pharmacy, two stated that they did not need that service yet, indicating that they felt that MCAs were filled by the pharmacy for people who were confused or unable to manage their medication. As one interviewee stated

“I’ve got my independence and I’m capable of doing it so therefore everything I can do on my own I’m pleased that I’m able to do so and until the time comes (when) I may have to revert to the chemist doing it and I will accept it if I’m unable to do it on my own.” OP6

The interviewees, who had the MCA filled by a carer, were less likely to discuss independence; three of the four people in this group relied heavily on family support and might not manage without it.

A majority of those using a pharmacy filled MCA also discussed the importance of maintaining their independence and especially remaining in their own home. So it may be that these participants accepted the MCA as a means to maintaining their independence.

Irrespective of whether the MCA was filled by the pharmacy, a carer or themselves, the majority of the interviews produced themes which fell into the ‘medicines are important’ sub-category. This finding agrees with other research that has shown that, rather than being non-compliant with their medication, many older people are concerned about their health and realise that taking their medication as instructed is important (Britten 1994). A number of the interviewees were very knowledgeable about their medication and implied that they would discuss this knowledge with the healthcare professional if the need arose.

Some of the participants regarded their health problems as serious and therefore viewed medicines used to treat these illnesses as important. This finding supports the Health Belief Model (HBM) (Becker and Maiman 1975). The Health Belief Model, as described by Becker and Maiman, proposes that the likelihood of a person adhering to a medication regime is determined by five variables:

The perceived susceptibility to the disease process.

The perceived severity of the disease.

The perceived benefits of the action weighed against.

The perceived cost of taking action.

The degrees to which internal or external cues to action are present to activate the other variables.

In this study, those participants who viewed their medical condition as serious were meticulous about taking their medication, usually this was medication to treat a cardiovascular problem and warfarin was singled out as being extremely important and not to be missed. On the other hand, the same participants often missed doses of other medication, for example analgesics, which they viewed as less important, although they realised that without the analgesics the pain would return.

The relationship the interviewee had with healthcare professionals could have a positive effect on their beliefs about their illness and their medication or it could cause the opposite effect. Some participants trusted their doctors and were happy to 'follow doctors' orders' seeing the doctor as the expert. This was particularly true of hospital consultants whose views the interviewees rated highly. Research has confirmed this trust that many older people have in their doctors. A study of 170 French adults aged 18 – 93 rated their likelihood of taking a medication intended to relieve physical suffering in 27 scenarios (Herve, Mullet and Sorum 2004). In younger adults, high trust in the physician was not sufficient a reason to accept a new medicine whereas in very elderly adults high trust led to high acceptance.

This issue of trust in the healthcare professionals was found across all three groups.

Not all the themes which emerged from the interviews could be considered to fall into the positive category. A third of the interviewees viewed medicines as harmful and to be avoided if at all possible. There was a feeling among this group that too many

medicines were prescribed and the interviewees wanted to be convinced that any new medicine was necessary. This attitude has been discussed in other research studies (Britten 1994; Donovan and Blake 1992) In the study by Britten one respondent used the word “carcinogenic” to describe medicines while others saw medication as unnatural and harmful. Donovan and Blake found that patients stopped taking medication because of fears of side effects or publicity about withdrawn drugs. In a qualitative study which investigated patients decisions regarding their antihypertensive drugs (Benson and Britten 2002) similar findings were discussed. Patients’ reservations about taking their antihypertensive medication were related to opinions that drugs were unnatural or unsafe and best avoided. There appeared to be a lack of information and counselling given to the older person about any new medication and this often left them confused and unsure. A study of patients with chronic conditions who were prescribed new medication found that about one third did not take the new medication as prescribed (Barber *et al.* 2004). The researchers found that many of the patients expressed a need for further information.

Some interviewees stated that their medications were changed when they were discharged from hospital. These interviewees felt that they weren’t fully consulted about these changes, although on some occasions their relatives were informed and this led to resentment. Various studies have looked at the problems which occur with medication management after hospital discharge and various strategies have been tested. Special counselling by a pharmacist, pharmaceutical care plans and reminder cards were found to improve compliance with medication after discharge (Al-Rashed *et al.* 2002; Smith *et al.* 1997).

Other negative beliefs that the interviewees discussed fell into the sub-category of the consequences of old age. All the participants apart from two lived alone and four found

it almost impossible to get out of the house even with help, while others had to rely on assistance from relatives or friends. Consequently some participants found themselves isolated and worried about a worsening of their condition and being unable to call for help. A few interviewees discussed problems which had occurred as a result of the death of a partner and how in some cases their illness had worsened. The fear of death also made some interviewees very determined to keep taking their medication in case non-compliance with their medication might lead to very serious consequences.

6.7.4 Have I got this because of my age?

Age can be represented by our chronological age (Bytheway 1997), however this is not always a useful discriminator. Old age at this present time appears to start when a person receives their state pension, at the time of writing this thesis that is 60 years for women and 65 years for men in the UK. However many women work until they are at least 65 and men beyond their 65 years pension date. For this research study, I set the minimum age for interview as 65 years, although in reality the youngest I interviewed was 72 and the oldest 92. When looked at in terms of health and quality of life there was no relation between these factors and chronological age, the interviewee who appeared to be in the poorest health was 73 and one of the fittest and mentally most alert interviewees was 91.

I have previously stated in section 6.3 that research studies have not identified a link between medication non-compliance and age. Researchers in the USA who investigated compliance with anti-hypertensive medication by elderly Medicaid enrollees (Monane *et al.* 1996) found that old age was associated with better compliance. The study investigated 4068 elderly patients aged over 65 and found that those patients aged 85 or over were most likely to be compliant followed by the 75 – 84 age group with the patients in the 65 – 74 age group least compliant. The researchers hypothesised that

those patients who were in the older cohort might represent a 'survivor cohort' who had attained their age by taking their medication as directed. A study in the UK compared compliance with two different medication regimens in young and old adults (Lorenz and Branthwaite 1993). The results of the study suggested that age alone was not a reason for poor compliance. Based on the different research studies, old age cannot be seen as a reliable predictor of non-compliance and I was therefore interested to discover if the MCAs had been issued to the participants solely because of their age.

The first interviewee, OP1, left me in no doubt about his thoughts on ageism and several other interviewees also introduced the subject of age. Ageism has been described as a set of social relations that discriminate against older people and stereotype them in an oversimplified and generalised way (Minichiello, Browne and Kendig 2000). Research into ageism has usually centred on identifying ageist practices, rationing of services according to age or discriminatory treatment. Fewer studies have looked at ageism from the older person's perspective. Minichiello (*loc.cit.*) interviewed older people in order to discover their views on ageism and his respondents spoke freely of the negative experiences of "being seen as old" and "being treated as old".

Some participants interviewed in my study stated that they felt they were treated like children and in particular were "talked down to," with healthcare professionals assuming that they couldn't understand. This type of behaviour results from stereotyping older people and has been observed by other researchers (Koch and Webb 1996). Lack of respect was another theme which emerged, with some interviewees thinking that healthcare professionals did not show them respect or treat them respectfully. The interviewees related this type of treatment to their age. This is supported by the research undertaken by Koch (1996) who undertook interviews with patients on a Care of the Elderly ward in a large UK hospital. The interviewees in the

Koch study felt that they were treated like objects and that little thought was given to treating them as individuals.

Positive views on age were held by less than half of the interviewees in my study, adapting their way of life to suit their situation was mentioned by about a quarter of the participants and about an equal number expressed pride in having achieved the age they had. These older people accepted their stage in life adapted to changes in circumstances and in some cases looked forward to the coming years.

Leading on from this, there was resentment that relatives or carers seemed better informed about their condition than they were. The four participants who had their MCA filled by an informal carer, in each case a relative, had differing views on this arrangement. The interviewee OP7 who had the MCA filled by his wife was very accepting of the situation and had probably been looked after by his wife all their married life. One interviewee OP5 was very accepting of her daughter's help and the interview revealed that the daughter who filled the MCA was acknowledged to be the 'bossy one' in the family who arranged everything. This was all described with good humour. The third interviewee (OP 10) was grateful for the arrangement at first but as she regained her strength and independence was showing signs of resentment. The fourth interviewee (OP15) was happy to receive help from her family.

Studies have looked at the role of informal carers in managing medicines for older people (Francis *et al.* 2002; Boyle and Chambers 2000). These studies identified a paternalistic attitude among some of the carers interviewed which may also be the problem for the two participants of this study detailed above.

Regarding the issue of MCAs, two negative themes emerged in this section. Some interviewees felt that people, (not necessarily themselves), might be insulted if given a

MCA, i.e. it implied that they couldn't cope and were being treated like child. Another worry mentioned by people, who had received a MCA, was that the healthcare professional thought that they (the older person) were losing their mental faculties.

6.8 Summary of chapter.

In summary, this chapter has found that:

The **Trigger for use** most frequently identified by the participants was admission and subsequent discharge from hospital.

Use of MCAs was linked to positive themes in many of the participants but there were difficulties for some people in using the device. Making medicine management easier was the most frequent positive theme and very few participants stated that using the MCA helped them to remember to take their medication.

The Health Beliefs of the older people were an important indicator of the participants' compliance with their medication.

Age and ageism. Some participants identified themes linked to ageism while others did not. There was some suggestion that MCAs might be issued to people because of their age.

Chapter 7: Interviews with healthcare professionals: Findings and Discussion

7.1 Introduction.

This chapter details the findings of the analysis of the healthcare professional interviews and follows with a discussion of these findings. The chapter commences with the demographic details of the healthcare professionals recruited to the study. The triggers which can lead to the issue of a MCA to an older person and the characteristics of the recipients are discussed in section 7.3. The following section details the advantages and disadvantages of the MCAs as perceived by the healthcare professionals. The health beliefs and attitudes of the healthcare professionals are explored in section 7.5 and the attitudes of the interviewees towards age and ageism are discussed in section 7.6. A discussion of the findings is contained in section 7.7. and Section 7.8 summarises the chapter.

7.2 Demographic Details.

Seventeen healthcare professionals were recruited by the methods described in Chapter 5. At the beginning of each interview, the participants were asked brief details about themselves including their job title and the number of years since they registered with their professional body.

Table 19 shows details of the healthcare professionals who consented to take part in the study.

Table 19: Healthcare professionals' demographic details

ID no.	gender	Profession	Sector	Years since registration
HCP1	Female	Pharmacist	Intermediate Care	9
HCP4	Male	Pharmacist	Primary Care	5
HCP5	Female	Pharmacist	Primary Care	19
HCP6	Male	Pharmacist	Secondary Care	27
HCP7	Female	Pharmacist	Secondary Care	1
HCP11	Female	Pharmacist	Secondary Care	29
HCP9	Male	Doctor	Primary Care	13
HCP10	Male	Doctor	Primary Care	19
HCP13	Female	Doctor	Secondary Care	23
HCP15	Female	Doctor	Secondary Care	3
HCP8	Female	Nurse	Secondary Care	30
HCP14	Female	Nurse	Secondary Care	2
HCP12	Female	Nurse	Intermediate Care	23
HCP2	Female	Nurse	Intermediate Care	6
HCP3	Female	Nurse	Intermediate Care	7
HCP16	Female	Nurse	Primary Care	20
HCP17	Female	Nurse	Primary Care	2

7.3 What triggers the issue of a MCA?

The research study was first briefly described to each healthcare professional and I explained that 15 older people, aged over 65, who were taking four or more regular solid dose oral medicines contained in a MCA, had been interviewed. I followed this explanation with a simple closed question:

“Do you recommend the use of multi-compartment compliance aids for older people in your care?”

This question did have to be modified slightly for the community pharmacists as they are more likely to respond to a request than initiate the use themselves. At this point only one person said that they did not recommend the use of these devices and then went on to explain why not:

“To be honest I don’t actually recommend the use of compliance aids ‘cause I think that people who are going to forget to take their medications you know just using ordinary boxes, medicine boxes, I don’t think the Dosett boxes help remind them to be honest that’s my opinion really.” HCP14

This young Staff Nurse did have some very definite ideas about the use of MCAs but although this answer might seem like the end of the interview almost before it had begun, she did go on to develop her own theories further. The other participants did recommend the use or in the case of the community pharmacists did dispense in MCAs.

This question was then followed up by: “Can you tell me a little more about this?”

This probe led to further clarification concerning who would request the issue or use of an MCA and what the characteristics were of the older person.

7.3.1 Who would request use?

This question brought forth a good deal of discussion about who would request the use of an MCA for a patient. Two interviewees suggested that they might request the supply themselves. Surprisingly from my perspective one of these was a community pharmacist.

“You know usually the last two or three have probably been identified by ourselves.” HCP5

Interviewee HCP16 also indicated that she would make the decision herself if she felt concerned about a particular patient.

The majority of the healthcare professionals interviewed stated that the request was made by other healthcare professionals rather than themselves. Hospital discharge was seen as a driver for MCA issue, by those working within the primary care.

“you know the hospital put them on Venalink and often will fax a copy of the discharge so we know what they are on” HCP5

“we get a discharge note that says ‘please put in a Venalink’.” HCP4

“The myth of home care”

The most frequently stated reason given by the healthcare professionals was “the myth of home care”, the phrase used by one of the hospital pharmacists interviewed. It is used here as an “in vivo code”, as described by Glaser and Strauss (1967) where the name assigned to the theme or code is one used by an interviewee themselves.

“They (the patients) are going home and they are going to have home care and there is still this myth that perpetuates that home care can’t assist medication unless it is in a compliance aid.” HCP11

This idea that home care staff were unable to prompt a patient to take medication unless the medication was dispensed in a MCA was discussed by a number of participants.

“ we only request it, compliance aids, if we know that they’re going to have home care prompt medication, in which case it’s a legal requirement because home care aren’t able to get them (medicines) out of separate boxes.” HCP12

“sometimes it’s somebody else that is going to prompt them and also home care will only prompt people even though we keep hearing that they have this fantastic new scheme where they are training all the healthcare assistants so that they will be able to prompt people not from dosetts but they won’t at the moment.” HCP13.

“mainly if they were having home care, then they would need it, if they weren’t able to do their own medicines then if home care were going to prompt or give medication they have to be in a compliance aid.” HCP2

Some healthcare professionals stated that the Intermediate Care Team also preferred that patients who were being discharged into their care had the medication in a MCA.

“if they (nursing staff) have arranged for ICT to supervise the tablets.” HCP7

“Intermediate Care team like them so that they can supervise the patient taking them (medicines).” HCP6

Relatives request the supply of a MCA

Relatives were also cited as requesting a MCA or the healthcare professional felt that the relative would purchase a device themselves.

“sometimes the relatives would identify it, sometimes relatives buy a box from the chemist and they fill them up each week.” HCP2

“the members of the family ask us sometimes.” HCP10

Self-fillers

Finally, the healthcare professionals identified those patients who bought and filled their own MCAs as described in Section 6.2 and categorised as “self-fillers”.

“yes well some people just buy a Dosett box and fill it themselves on a Sunday afternoon and put them out for themselves.” HCP16

7.3.2 What were the characteristics of the older people?

The interviewees were asked if they could describe the type of older person who would be likely to receive their medication in a MCA.

Memory problems

A number of the interviewees stated that memory problems were a reason for initiating a MCA.

“they’ve (patients) got a problem with memory, a Venalink or Dosett box is better for them because it prompts them to take just the tablets that day.” HCP8

“most commonly it would be patients who are a little cognitively impaired and who are struggling to manage their medication when it is presented to them as separate boxes or bottles.” HCP13

“Elderly patients, some of them with say with difficulty remembering to take their medicines at specific times of the day or take their medication in the appropriate kind of prescribed way.” HCP10

Expert patient.

The healthcare professionals also identified different levels of expertise with medication amongst the older people. A number of interviewees stated that many of the older people they saw could be considered “expert patients” in regard to their medicine management skills.

“I would say most people we see like to be meticulous about the tablets and they take it very seriously because they want to maintain their health.” HCP12

“you know some of these people come in and they are 99 and they are on polypharmacy and they still remember every iota that they are taking all the doses all the times.” HCP15

Less knowledgeable patient

However some older people were identified as being “inexpert” with little knowledge of what they were taking or why and who seemed happy to simply follow instructions.

“they (the patients) just like them in a box because they weren’t interested, they trusted their doctor they just took what they were told, when they were told and they liked the aids.” HCP2

“you ask people who are still on tablets what tablets they are taking , some people say ‘I’ve no idea’.” HCP3

Physical disabilities

Aside from memory problems, the interviewees saw physical disabilities as a reason for initiating a MCA; arthritic hands and visual impairment were given as reasons for initiating use.

“Sometimes people with physical arthritis, arthritic hands things like that.” HCP12

Polypharmacy

Problems due to having a large number of different medicines were also mentioned as a reason for using a MCA.

“I can see the advantages particularly with the polypharmacy patients, these are not young people and they are on all sorts of tablets.” HCP15

“patients who are taking a lot of medication.” HCP16

7.3.3 Assessment of the older people.

The issue of assessing older people, before initiating a MCA, was brought up by many of the healthcare professionals. The healthcare professionals, who were most likely to initiate use, were those who discussed their assessment in some detail.

“the pharmacy needs assessment is very much about what is the patient’s usual routine, who orders the medicines, where do you keep them and things like that.” HCP1

“ when a nurse initially assesses a patient one of the nurse’s roles is to look at the medication and we have an assessment tool which we use and we identify lots of things about whether the patient knows what medication they are taking, why they are taking it, when they are taking it do they have any difficulty opening boxes do they use any compliance aids.” HCP12

Healthcare professionals, who were not so closely involved in the original setting up, were often likely to criticise their colleagues, suggesting that the older person had not been properly assessed.

“and sometimes they (patients) are sent home with these Venalink and they have no idea, they’ve never seen them before and sometimes their tablets have been changed whilst in hospital and they don’t know exactly which ones.” HCP3

Two healthcare professionals raised the point that knowing when and where to assess the patient could be very important. One of these healthcare professionals was a community pharmacist who recently had a short stay in hospital and her comments were based on personal experience.

“I presume they use a proper assessment tool in the hospital ----they send a lot of them (older people) out on Venalink or what ever but I mean I’ve just been this last week, I’ve been in for a tooth operation and I had a general anaesthetic, I was very disorientated for a couple of days and it does make me think do they (older people) appear a lot worse in the hospital situation, they’re not in their own homes.---- may be they are alright at home but deemed to be worse (in hospital) I don’t know.” HCP5

The other healthcare professional to highlight this possible problem was a consultant in Care of the Elderly.

“Ideally in my view, and it is only my idea, ideally you wouldn’t ever do this (assessment) from a situation in which the patient’s in a sort of unstable condition, so if someone’s not been well and been in hospital you wouldn’t choose that as the right time to assess whether they can from now on in perpetuity manage their own medication or not.” HCP13

7.3.4 Try other strategies first.

Finally in this section on ‘Triggers’, I asked if the healthcare professionals would try something else before resorting to a MCA. A number of alternatives were mentioned,

the most popular being medication charts and reviewing the medication to try and reduce the number of medicines.

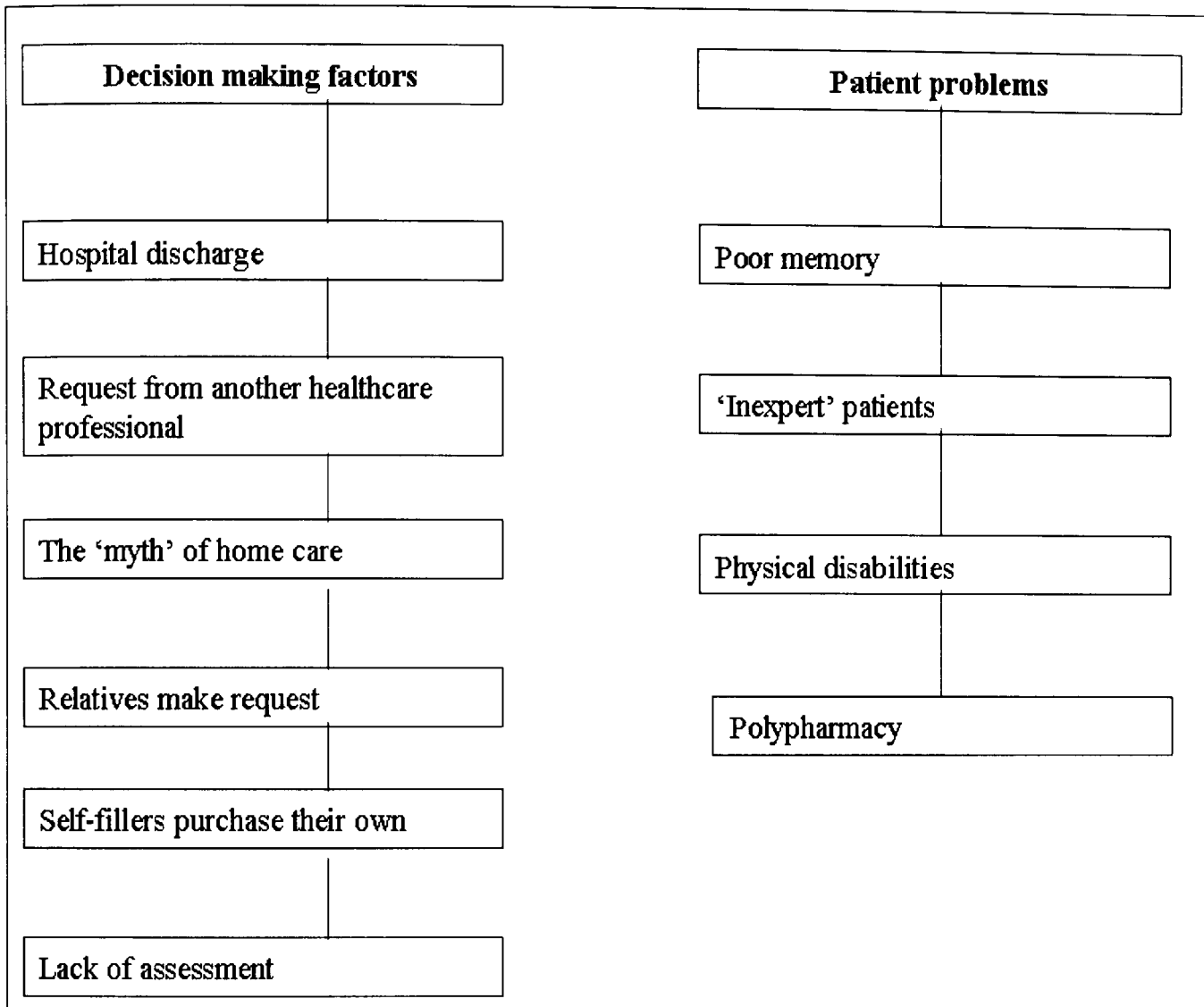
“the first thing we go for is a medication card which is a list of all the tablets, their name, the brand name, what they look like, what they are for briefly like for your heart or for blood that sort of thing. Then there is four rows and we put how many they should take of each tablet at the four times of the day.” HCP11

“ we do ask GPs for a medication review or we try to condense them (medicines) down to once or twice a day.” HCP12

7.3.5. Overview of themes emerging from Trigger for use.

The themes emerging from the trigger for use analysis were arranged into sub-categories and finally the sub-categories were placed within two main categories. The two categories which were identified were decision making factors and patient problems. All the themes which emerged from the initial analysis of the interviews could be placed within one of these categories. Figure 13 depicts the sub-categories and categories identified.

Figure 13: Sub-categories and categories emerging from Trigger for use.



7.4 Advantages and disadvantages of Multi-compartment Compliance aids

All the healthcare professionals were asked “what advantages do you see in the use of multi-compartment compliance aids by older people living in their own homes?”

7.4.1 Advantages

The majority of the interviewees were able to discuss advantages of MCAs, both for the older people themselves, or for the healthcare professional.

Ease of use and convenience.

A majority of the interviewees cited ease of use and convenience as the main advantage of these devices.

“I can’t get away from the fact that you ask a patient to open six different bottles of medicine and read the labels and get it right and follow a chart it is obviously much easier to open one little slot in a compliance aid.” HCP1

“for the patient, I think, sometimes it can be simple because it is all just in compartments so they don’t have to worry about the timings and the quantities and all that stuff and sometimes it’s easier for them.” HCP16

Memory aid

A number of healthcare professionals stated that the MCA acted as a memory aid and that this was a main advantage.

“they’ve (patient) got a problem with memory then a Venalink® or Dosett® box or Nomad® is better for them because it prompts them to take just the tablets that day.” HCP8

“the fact that they are set out for them (patients) it is a prompt to remind them to take the tablets.” HCP17

Independence.

Another advantage which was discussed by some of the healthcare professionals was independence. Independence had been a main theme which emerged from the older people’s interviews and it was interesting that the healthcare professionals also brought this out.

“Yes if it helps the patient to stay independent at home but you have to make sure the patient can use it (MCA) ...yes certainly there are certain patients who it (MCA) helps their independence.” HCP11

“I think they do enable people to stay in their own homes whereas they might be admitted to a semi-residential home or something like that.” HCP14

To benefit others

Other advantages, which were discussed, were clearly not for the patient’s benefit but rather for the benefit of a healthcare professional or a carer.

“I think the advantages tend to be that people can see what doses they have taken so it’s good for carers and such like to be able to see what people (patients) are taking or they believe they are taking.” HCP4

“it can be an advantage also for you as a professional to monitor because if you are going in every day you can check whether the stuff has gone out of (MCA).” HCP16

Continuous supply

The fact that those older people who had their MCA filled by the community pharmacy usually had the device delivered as well was seen as an advantage by two of the healthcare professionals. In addition to delivery, the community pharmacy would often arrange the repeat prescription thus ensuring that the older person did not run out of medication.

“they (MCAs) get delivered to the house.” HCP17

Although most healthcare professionals quickly named a number of advantages some interviewees struggled to answer and it became obvious that this was something that they had never given any serious consideration.

7.4.2 What are the disadvantages?

I followed up the question about advantages with one about disadvantages although some participants were eager to discuss the disadvantages right from the start.

“I don’t see that much advantage in MDS. It tends to cause more problems than it cures.” HCP4

“It’s really that I am not aware of what the overwhelming advantages are, if there are no advantages then we have to way this up against any disadvantages there might be.”HCP10

The number of disadvantages discussed far outweighed the advantages that had been cited and interestingly what had been seen as an advantage to some participants was then given as a disadvantage sometimes by the same participants.

No use for those with cognitive impairment.

Memory prompting and use in those with some cognitive dysfunction was cited as an advantage, however more participants gave these two themes as disadvantages.

“They don’t as you know always work as well as they should because a lot of times the patient, depending on the level of functioning really, the cognitive functioning, they (patient) may take them (medicines) all at once or they may tip them up and empty them on the floor.” HCP9

“In terms of practicalities obviously if you don’t know what day it is and you don’t know what time it is having a box which says Monday breakfast doesn’t necessarily help.” HCP13

Not a memory prompt

Despite a minority of participants having stated an advantage of using a MCA was that it would be a memory aid, the majority of the healthcare professionals interviewed stated that MCAs did not act as a memory aid.

“if they (patients) forget to take the tablets, if they forget to look at the boxes (original packs) in my opinion they’re not going to remember to look at the Dosett box either ‘cos it’s not like it actually tells you to take your tablets, you still have to remember to look at it.” HCP7

“and the other thing is that even if you’ve got the thing (MCA) you still have to remember to take it (medicine) haven’t you?” HCP16

Having established that the MCA does not really remind or prompt the patient to take their medication, the healthcare professionals then went on to discuss other disadvantages.

Unable to use the MCA

The physical problems which older people might have in accessing the medication from the MCA were discussed by a number of participants.

“I see a lot of people coming out of hospital with Venalink and they can’t actually get into them and I see a lot of people struggling to use the aids they have been given which always really frustrates me because if they have come out of hospital they have been in a controlled environment and someone should have asked if they could actually use it.” HCP1

“well I certainly have come across patients who are unable to get tablets out of the compliance aid. I’ve come across patients who can’t read the instructions so they’ve taken them out in a haphazard fashion, so they don’t take out Monday, Tuesday, Wednesday, they take them out randomly.” HCP6

This issue of older people being unable to use the MCA was discussed in some detail by most of the healthcare professionals and amongst some there was the feeling that those healthcare professionals who had issued the MCA had failed in their duty of care to the patient because they had not checked that the patient could use the device.

Change of device.

The interviews with the older people had shown that if the MCA had been issued by the hospital on discharge there was a likelihood that when the community pharmacy took over the supply the device would change. The older person, who has been instructed how to use one device may then be issued with a completely different device and possibly no further instructions.

“do we completely confuse them (patients) by giving them a weeks (supply) in a Venalink and then changing it when they get home, which I think is a bit of an issue.” HCP7

“I can certainly see that (changing MCA post discharge) will be a problem and it’s difficult to know how we should manage that really.” HCP6

A problem, which could be associated with changing a MCA, was identified by one of the more recently qualified interviewees.

“we have actually had a few problems with them we had a patient who...you know how they (MCAs) usually go down on the days of the week and they usually go across don’t they with the times we’ve had patients take them (medicines) Monday, Tuesday Wednesday all down in one.” HCP14

Here, the interviewee is describing a problem caused by the different styles of various brands of MCA. The patient may be used to the days of the week running horizontally across the device with the times of day running vertically down, if the device is changed to another brand, the style may be different. To give an example, in a Dosett® box the

days run horizontally and the times vertically; however, in a Venalink® the days run vertically and the times horizontally. A patient having the device changed without further instruction could use the device incorrectly.

The community pharmacists were divided on whether this was a problem. One had obviously never considered the matter and the other, although aware of the problem, thought that with the use of sealed devices becoming the norm then the differences were negligible.

“It (changing MCA post discharge) hasn’t been a problem, no it hasn’t been a problem, I mean it hasn’t happened that many times but it seems fine. I mean I’ve never looked into it, I’m sure we could go to some lengths to get a specific thing if (required).” HCP5

Yes I know it’s a common thing that people will just think of MDS as being just one type of device and yes. Less of a problem now because I think we all tend to use quite similar sealed devices whereas before some people had the plastic Medidos boxes and things like that, but now for clinical governance not many people use them so people are quite used to a push out blister type of device.” HCP4

Prefers own system.

Another disadvantage which was mentioned by the healthcare professionals is connected to the expert patient theme which emerged from the ‘trigger’ area of interest. These expert patients often wished to follow their own routines and systems which they may have developed over a period of time and trying to persuade them to use an MCA can be difficult.

“you do occasionally get patients who can’t adjust to them (MCA) and they would prefer to use their own system worked out beforehand, which has usually been working adequately .” HCP12

Older person’s choice

Another issue which fits into the ‘expert patient’ theme is the removal of choice from the older person, which a number of healthcare professionals saw as a disadvantage.

“And so they (patients) find it hard when we put them (medicines) in an MDS to maintain that level of choice about what they want to take. We have people perhaps who don’t want to take their pain killers now and then or they don’t want to take their sleeping tablets one night out of seven, or maybe they don’t want to take their Frusemide tablet one morning and it limits people’s ability to decide what they want to take and what they don’t want to take.” HCP4

Identifying medication in the MCA

The difficulty of identifying tablets when they are in a MCA was also discussed by the healthcare professionals and is connected with the older person’s choice. If the older person does not want to take a particular medication, then it is vital that they can identify that medication from the three or more others contained in the same compartment. Some older people also feel the need to check as far as possible that the correct medicines have been dispensed and again this relies on being able to identify the medicines in the MCA. Identifying medicines, however, can be fraught with difficulty, because all the tablets may be white and look very similar or the colour of the generic medicines dispensed may change from month to month.

“yes it’s a problem (identifying medicines) and it’s also a problem for things like soluble tablets. I know some places still put soluble aspirin in compliance aids and it’s mixed in with other tablets so they have to fish out the soluble one and that can be a problem, or some of the chewable ones, they have to fish out their calcichew.” HCP11.

“it’s very difficult when things change brands or something like that and even for me to tell is that really the correct one because they might have changed and I’m not aware of it. So I can see patients would be very nervous about taking something that’s a different colour or shape.” HCP6

“Actually there was a lady yesterday who was trying to dissolve her prednisolone ‘cause she thought it was her aspirin, because it was in a Dosett® box that’s a another problem because they both looked identical.” HCP16

The problem caused by being unable to identify individual medicines within a MCA can therefore lead to older people not taking their medication or to a loss of trust in the pharmacist providing the medicines.

Stability of medicines in a MCA.

The question of the stability of medicines in a MCA was discussed, not only by the pharmacists, but also by other professionals. The fact that not all medication can be dispensed in a MCA, usually for reasons of stability, was clearly seen to present a problem for the older person.

“for one thing you can’t put all medication in it, some medication has to be kept in the dark or airtight and all that sort of stuff.” HCP16

“if you are giving someone a compliance aid and you believe they need it, then what is to be gained by then giving somebody also a separate box of Vicorel and a box of Lansoprazole capsule separately. Where’s the logic in it?” HCP4

Both community pharmacists interviewed had serious concerns about the information available on stability of drugs when dispensed in a MCA. Notably this was not mentioned in this way by other healthcare professionals although there was awareness that some drugs could not be dispensed in MCAs. The community pharmacist concerns were about finding out the relevant information and this represented a serious ethical dilemma for the pharmacist; without the information should they dispense a drug in a MCA.

“The lack of evidence behind medication being in there, limited stability medications, there’s lots of formulations that we have no evidence if when they remove packaging are stable and we find ourselves putting things in that we know are not stable when they go in MDS and as a professional that’s very hard for us.” HCP4

“apart from literally ringing every single manufacturer (about stability) and ask what they suggest and often they say ‘well this is what we say’. It’s not that they have done any research you see, you don’t always get a proper answer.” HCP5

Inflexible dispensing.

Leading on from this theme of drugs which cannot be dispensed in a MCA, there is also the problem that MCAs provide a very inflexible form of dispensing. Provided the drug which the older person is taking is to be taken every day and between one and four times each day with no other special instructions, then everything will be fine.

However, there are a number of drugs which are taken, particularly by older people, with very specific instructions. For example a drug used to treat osteoporosis (alendronate) is usually taken once weekly and must be taken on an empty stomach at least 30 minutes before breakfast (and any other oral medications). The tablet must be swallowed whole with a full glass of water and the patient must stand or sit upright for at least 30 minutes. In order to comply with these instructions, the older person must either have the alendronate packed separately or be able to identify it from the compartment which may contain other drugs. This particular problem was discussed by a number of the healthcare professionals.

“so for example, things like alendronate once a week doesn't fit into a compliance aid very well when you've got other things that you've got to pick up four times daily. So you can't put everything in so then you start losing the benefits of having it.” HCP6

Another problem caused by the inflexibility of the MCA was drugs which have doses of more than four times daily, most notably these would be drugs used to treat Parkinson's disease.

“because you know the way the compartments (in MCA) are there are only four compartments for example if someone has Parkinson's Disease you know and they are trying to take the Sinemet more frequently you can't do that sort of thing.” HCP16

Drugs which are taken when required were also seen to be a problem. Are these drugs to be put into the MCA to encourage older person to take the dose regularly or simply to miss out the doses which they feel they don't want or don't need?

“other medication is PRN medication that's a problem because either they (patient) have either got to have it (paracetamol) four times daily or not have it so a lot of people end up taking paracetamol four times daily whereas they would have normally just taken it a couple of times a day.” HCP16

Practicalities of supply

Another group of disadvantages highlighted by the healthcare professionals were linked to the category of 'practicalities of supply' (of the MCA). A number of healthcare

professionals mentioned that the MCAs were costly and difficult to provide and fill, surprisingly it was not only the pharmacists who highlighted this problem.

“it’s a dispensing practice and it can be very time consuming for us from a dispensing point of view if you’ve got one or two Dosett® boxes to do every day because we are very busy up there with general prescriptions so we pass it on to the chemist who will look after their dispensing from then on.” HCP9

“if they (community pharmacists) are asked to fill all these Dosett® boxes it takes them loads longer so clearly they are going to recoup that cost from somewhere.” HCP13

The problems regarding the supply and filling of MCAs led to difficulties in finding a community pharmacist to fill one for an older person.

This problem was particularly highlighted by those working in secondary care, who would like to discharge a patient with a MCA, but needed to find a community pharmacy to continue the service.

“In fact I’ve got a patient on the ward who wasn’t on a compliance aid before they came in, has now gone to the Intermediate Care Team who have requested that they have a compliance aid filled so that they can help supervise medicines for the patient and I have to find a chemist who will fill that for them. It’s ok for me to do it for a week but I’ve got to find somebody else and I asked the patient which community pharmacy they used and they weren’t sure so I am now having to ring round community pharmacists to find out if a) whether they know this patient or b) whether they would be willing to fill the compliance aid. So that’s a lot of work.” HCP6

“not every chemist that are local to the patients will do Dosett boxes, nomads or Venalink.” HCP8

Having identified a community pharmacy to provide this service for the older person, it may be necessary to arrange delivery if the older person cannot get to the pharmacy.

Not all community pharmacies provide this service so this may cause problems.

“we do prescription collections from surgeries but we don’t as a rule do deliveries.” HCP5

The community matron noted that, although the pharmacy may deliver, it is unlikely to be the pharmacist who does the delivery and therefore the older person may not be able

to get assistance or advice if required. One of the community pharmacists interviewed had trained the delivery driver to provide advice to the patients.

“we have a driver who I’ve trained up and he’s got a SOP to be able to offer advice to people on how to use them (MCA)”. HCP4

One of the General Practitioners noted that the older people may not get sufficient instruction in the use of the MCA.

“I sometimes think that they (patients) may not be given sufficient guidance from there (pharmacy) -----can be possibly that they are not receiving sufficient training or guidance or follow-up even in using the Dosett box or compliance aid.” HCP9

However other healthcare professionals felt that they themselves did provide the older person with adequate instructions.

“We usually do it (demonstrate how to use) if we are involved. If we’re visiting the patient and we’ve requested (MCA) we feel it’s our responsibility to follow it through and part of our ongoing assessment to make sure they can use it.” HCP12

“Show them how to use it (MCA) Oh yes. If it’s not them then it’s the carer or somebody else in the family.” HCP5

Problems caused by medication changes.

The healthcare professionals also noted that problems can occur when the older person has their medication changed. MCAs are usually delivered weekly, and so if a dose change occurs or a new drug is prescribed mid-week then either the new drug has to be dispensed separately or the MCA has to be returned to the pharmacy for re-dispensing.

“the pharmacist has probably taken the medicines for the week on the Friday, the antibiotics are prescribed on a Saturday so they have to decide whether to put them in (MCA) or quite often people keep them separately and take them separately.” HCP16

“the big thing that we always get involved in is that if they have a blister pack (MCA) and suddenly we need them on a new tablet we then have to get the blister packs back to the pharmacy to be filled up again with the new tablet in them.” HCP17

Changes in dose of an existing drug can cause almost bigger problems as this can mean considerable delay in the change of dose being actioned.

“from my perspective when I’ve worked in the anti-coagulant clinic, trying to then co-ordinate a changing dose for somebody with a compliance aid is very difficult and you do worry whether you actually get it done in time.”

HCP6

“having to get a phone call on a Wednesday, like this person’s dose has been changed and you’ve delivered one (MCA) on Tuesday, as I say it is becoming more and more of a problem that we try and sort out.” HCP4

The wrong medicine or the wrong box.

Dispensing errors were something that concerned the older people whom I interviewed and the healthcare professionals also had deep concerns which were based on serious occurrences.

“and the other big issue I’m very much aware of is mistakes so clearly if a pharmacist is dispensing a whole bottle full of pink pills and a blue one gets in there it is apparent immediately whereas if you are putting a lot of coloured tablets in a lot of different slots it seems to me that the possibility of error is high.” HCP13

“and we’ve had patients who have actually had the pharmacist dispense the wrong Dosett box to the wrong patient and they took the medication and didn’t realise because cause they didn’t think to check the box and they were actually taking someone else’s medication.” HCP14

“there is the other possibility for error which I have encountered on two separate occasions which have had extremely serious consequences have been when people have had the wrong Dosett box delivered to their house by the chemist and have taken someone else’s medication.” HCP13

Finally, in the disadvantage section, two healthcare professionals pointed out that having an accident with the MCA could cause serious problems.

“The only trouble is if they drop the damm thing because I mean she (patient) once brought it in, she said I’ve dropped it and there were tablets -----some actually managed to skip into others so she brought it back in. I mean she had the sense to bring it in.” HCP5

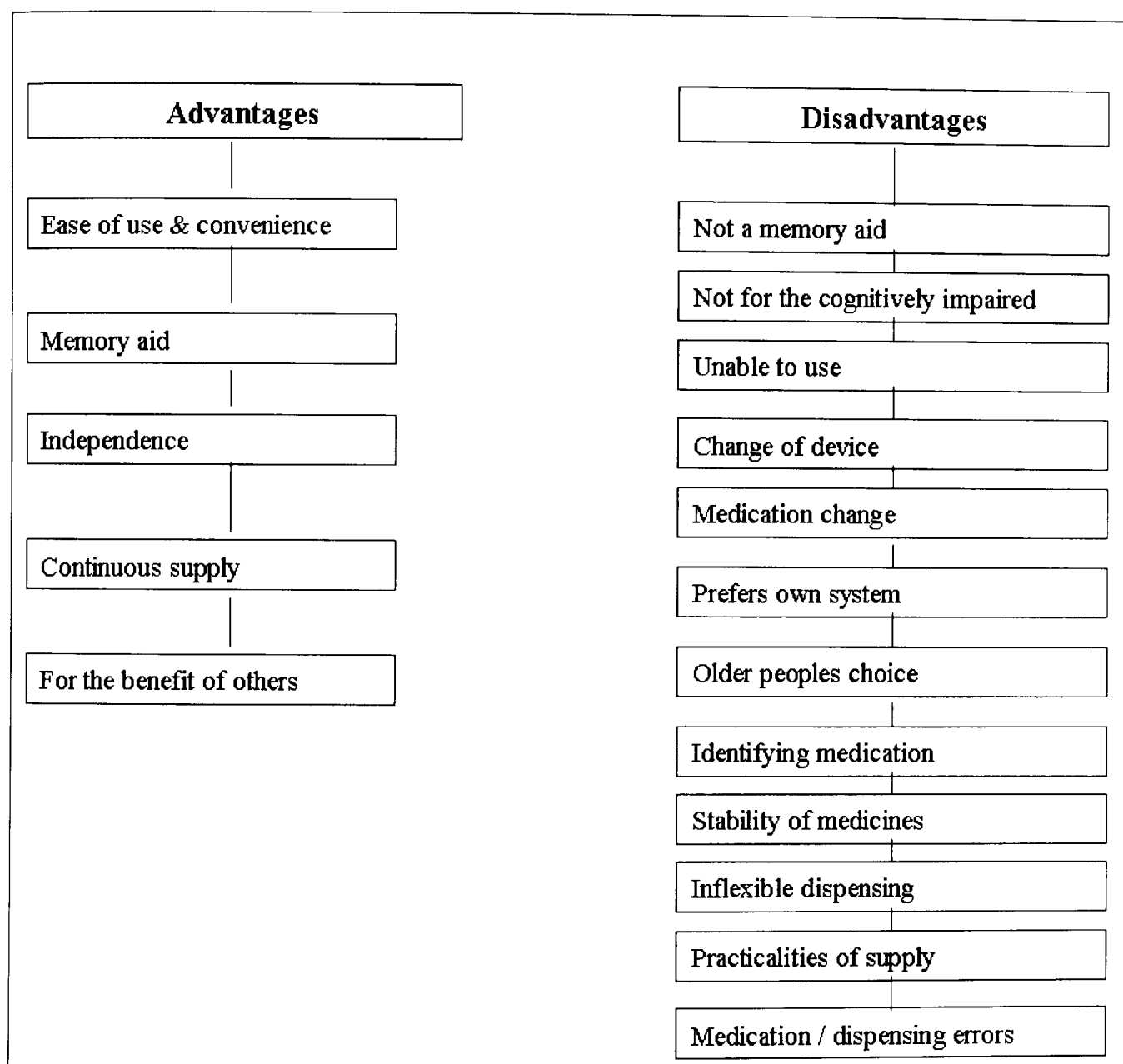
“in fact if they (patients) lost the blinking thing well then you would be absolutely in a bit of trouble then wouldn’t you, cause you would have no medications at all.” HCP15

7.4.3 Overview of the themes emerging from Use of MCA

The themes identified concerning the use of multi-compartment compliance aids were grouped into sub-categories and categories. The two categories were advantages and

disadvantages and the subcategories which were linked to these categories are detailed in Figure 14 below.

Figure 14: Categories and sub-categories emerging from “Use of MCA” area of interest.



7.5 Beliefs and attitudes concerning MCA use.

I was interested in finding out how the health beliefs and the attitudes of healthcare professionals and older people might influence the use of MCAs. The interviews with

the older people had identified a number of themes and these themes were used to inform the topic guide for the healthcare professionals.

7.5.1 Independence

Independence was seen by a number of the older people as extremely important to them and something which must be maintained at all costs. I tried to discover what impact the provision of a MCA might have on the older person and then asked the healthcare professionals if they had experience of these attitudes in older people. Some healthcare professionals thought that the MCA helped an older person maintain their independence.

“so I think they (MCAs) do help to maintain some independence .” HCP8

However, other healthcare professionals were of the opinion that older people might regard the issue of a MCA as loss of independence.

“and in a way the Dosett® boxes do maintain their (the patient’s) independence because it allows them to remain at home but on the other hand some independence has been taken away from them because they are not in control of their own medication anymore, someone else is putting it in front of them.” HCP17

“it (MCA) does kind of take the responsibility away from some of the patients, who may be functioning perfectly adequately mentally, in that their medicine is drawn up, their tablets are drawn up and prepared by somebody else and delivered to them so they may over a period of time become a little less familiar with why and what they are taking.” HCP9

The healthcare professionals also noticed that many older people like to remain in control as much as possible.

“those who are independent, yes, I can see that they would, they like to be in control of their lives as much as they can.” HCP6

Healthcare professionals were also aware that older people very often had their own routines which often seemed complicated or peculiar to the healthcare professional but very reasonable to the older person.

“some of them are very good and they have good systems and it’s worth talking to them about how their system works because you get a feel for whether they have confidence in their system and know what they’re doing. You do get a general impression of how compliant they are with their prescribed regimen.” HCP6

“I do try and make quite strenuous efforts to understand because people have these really weird methods of working it out which often does to them make sense and it’s scary looking in on it.” HCP16

Despite at times finding the older person’s routine less than satisfactory, many of the healthcare professionals realised that older people often preferred their own systems and would simply revert back to their old ways.

“we do occasionally meet people that can’t adjust to them (MCA) and would prefer packets and bottles and it’s usually because they have their own little system worked out beforehand which is usually working adequately probably, our team have stuck our nose in a bit too far and assumed that a compliance aid would be beneficial to them but it’s not always. It usually is but not always.” HCP12

“ yes people have reverted back to complementary resources and in fact we have found drivers go in and say “Mrs so and so’s popped them all out into a little eggcup again that’s sat by the side of the table”. It really is frustrating for us to go to the effort of filling them and then to find that out but that’s one of the things that goes on.” HCP4

I wanted to discover if healthcare professionals had particular attitudes and beliefs concerning older people and their medication. I decided that to ask directly what these attitudes or beliefs were might not result in a useful answer. Therefore, I decided to ask the healthcare professionals if they saw evidence of intentional non-compliance among their older patients, i.e. older people making a decision not to take their medication as opposed to simply forgetting to take their medication or being unable to access it. I wanted to discover if the healthcare professionals had any particular views on this topic and also any strategies to deal with it.

7.5.2 Intentional non-compliance.

Only one healthcare professional said that they saw little evidence of intentional non-compliance

“my personal experience of when I have been working with patients is that the majority of non-compliance I see is unintentional, they (patients) are confused, they have dementia, they are forgetful, they are blind and they can't see but that might be the picture they are giving to me, do you see what I mean?” HCP1

All of the other interviewees stated that they were aware of older people in their care who had decided not to take their medication. This might be on a permanent basis or just occasionally.

Side effects.

The reasons for intentional non-compliance which the healthcare professionals saw were varied but the main cause appeared to be side effects.

“they come in and they're on a multitude of tablets or they might say this tablet makes me go too often or it makes me wet myself or it's given me diarrhoea -----they've a lot of tablets to take and especially if they have been put on something new they say it's given me an upset stomach I'm not taking that.” HCP8

“yes there's been quite a few, I'd say quite a few, several instances of people saying 'well nobody ever tells me what these tablets are for, therefore I'm not taking them' or they've perceived that they are not doing any good or they've perceived they're doing harm.” HCP7

Poor knowledge about medication.

Another reason, quoted by the healthcare professionals, was poor knowledge of the medication.

“there was a lady, and she has never admitted it before, she said “I only take my anti-depressant when I feel a bit low” and obviously she hadn't understood the method of its working. So in that situation it is a matter of education really.” HCP16

Lack of communication.

Approximately fifty percent of the healthcare professionals felt that there was a lack of communication with the older person and that this was often the cause of the problem.

“I think we don't do enough in the hospital of talking to patients about the change that we've made to their medicines, to get them on board, for them to become concordant with that, when we change something we ought to be saying to them 'is this OK?' but equally I think some things get changed around by GPs without communication either so it (works both ways).” HCP6

Taking too many medicines.

One third of the healthcare professionals also stated that this intentional non-compliance was often due to the health beliefs of the patient. Many older people are taking large numbers of medicines and this can become a burden, some of the healthcare professionals felt that in these circumstances the older people might decide to stop taking one or more of the medicines.

“Yes usually when they have a lot of tablets just that there are too many and they are quite selective and they will stop taking some or all of them for a couple of days.” HCP11

“nobody wants to be on more tablets and we are told that frequently, but we might not really be aware of how deep seated the belief is amongst everybody, almost everybody, there’s very few people want to be on tablets.” HCP9

The healthcare professionals’ attitude to intentional non-compliance.

I then asked the healthcare professionals how they felt when they became aware that older people were deciding for themselves not to take their medication. For some healthcare professionals, this was not a problem, they respected the older person’s decision, although, they might feel it necessary to convey this information to the prescriber.

“I respect their decision, you know, if it’s someone who I’ve got no concerns about the mental health, I respect their decision and we do usually tell the GP about it if they stop like a particular drug we will report it back to the GP, but we don’t try we explain the advantages of taking the drug and if they don’t if they choose not to take it that’s up to them.” HCP12

For other healthcare professionals, there was an undercurrent of censure, although they went to great lengths to say that they respected the older person’s decision.

“you do get some patients that are not honest and you can see them “I’ll take them in a few minutes” and then they’ll put them in their handbag. You see a collection in their handbag of ones they don’t want to take and others are more honest and say “I don’t want to take that.”HCP2

The healthcare professionals also felt that they saw the consequences of the older people's intentional non-compliance and, although, they said they would not be judgemental there was a feeling that this was a problem.

“what's brought them into hospital is because they've not been taking their water tablets so their heart failure has got worse or whatever and especially someone who's been bouncing back for the same reason you think you're fighting a losing battle.” HCP8

What are the solutions?

When asked about solutions to this problem, there were many different suggestions. A number of solutions focused on counselling about their medication, what it was for, why they (older people) needed to take it.

“Generally it's just been because they don't know what they're taking but I will sit down and go through what they are taking, why I think they are taking it, if it's not obvious, it's not always clear from the notes, in several cases they've turned round and said that's fine now I know why I am taking it, I'm quite happy to take it, but they've been on it for years and nobody has ever said anything or they didn't feel like it had been reviewed.” HCP7

“I think the big thing is communication. You've got to communicate with the patients, try and be honest, see if you can work with them and get the best plan that is going to work.” HCP2

Try to reduce side effects.

Alongside counselling and communication, the healthcare professionals did talk about some practical solutions. For example, if side effects were the cause of the intentional non-compliance than perhaps it would be possible to change to a different medication.

“if the side effects are that bad we might be able to think of something similar that they could take you know a similar medication that they could take instead.” HCP14

Simplify the regime.

Simplifying the medication regimen was also mentioned as a possible solution.

“I am quite keen on trying to look at reducing the burden of medication on people at medication reviews which we do fairly frequently in the practice.” HCP10

Encourage or coerce.

However some healthcare professionals saw their role as encouraging or coercing the older person to take their medication.

“I’ve got my agenda when I go to visit a patient which is ‘I must get them to take all these pills.’ Full stop.” HCP1

“we usually just try to persuade them, you know try to explain why they need to take their medication and usually with a little bit of gentle persuasion we encourage them to take them, but I mean sometimes it is really difficult.” HCP14

Negotiation

Negotiation was also seen as a method of overcoming the problem.

“I mean myself I like to address the problem in an open way and I’d like the patient to be honest so we can work with the patient, the doctor the nurses and try to find a compromise.” HCP2

“Some times it’s a matter of negotiating like some people don’t like taking their water tablets when they are going to the day centre so you have to assess the risks of that sort of thing, is it going to matter for one day or are they really in quite bad heart failure and it is going to tip the balance.” HCP16

7.5.3 What other health professionals think and do.

The healthcare professionals frequently suggested that it was the attitudes and behaviour of other healthcare professionals which could be called into question. For example, one of the community pharmacists felt that many of the older people who received a MCA were started in hospital and that the hospital staff saw the issue of the MCA as a ‘quick fix’ which would speed up discharge.

“I think lots of elderly people are started (on a MCA) in hospital because they’re elderly and because there isn’t time or the staff to explain to them how to take their regimen and they believe – there’s this perception with doctors and nurses this is the easiest way out.” HCP4

A hospital pharmacist also stated that ‘other people’ see MCAs as the best thing that can be used to help a patient with medication.

“a lot of people do see compliance aids as the overall thing that will help patients and they don’t realise that there are other things that can be used first and the difficulties that can be encountered.” HCP11

This idea was endorsed by the pharmacist working with the Intermediate Care team.

“I would say then that they (healthcare professionals) generally think that a compliance aid is going to solve all problems and I think a lot of people think oh I’ll put a compliance aid in and I’ve done my bit.” HCP1

7.5.4 What are the older person’s beliefs concerning their health and treatment?

Healthcare professionals also expressed their own opinions about the older people’s beliefs concerning their health, their treatment and how this might affect their life.

Loss of independence.

The healthcare professionals acknowledged that for some older people the worry of losing their independence and having to go into nursing or residential care loomed large.

“Right yes, it is a horrendous thing when you think about it that old people live in this kind of fear that somebody is going to come along and put them in a home.” HCP13

Some of the healthcare professionals suggested that by agreeing to use a MCA the older person could be trying to retain their independence.

“They want to keep their independence and they want to get back home as soon as possible, back to their own home, back to their own routine to do what they want to do and not be bound by hospital rules and things.” HCP8

However other healthcare professionals felt that older people felt disempowered when given a MCA. The healthcare professionals said that they could understand this attitude.

“certainly some people feel very resentful when somebody tells them, switches their medication to a Dosett box they feel very disempowered and some people feel that they actually managed their medication better before.” HCP13

“I would be wary of someone else filling a compliance aid for me because you’ve lost your independence, somebody’s taken this over, this part of your life over filling this compliance aid for you and you’ve got no control over what it is and you can’t tell whether they’ve done it right or not so you are having to trust somebody else and that is quite difficult I suspect.” HCP6

Having trust in the healthcare professionals.

The healthcare professionals also stated that it was often very important to older people to be able to trust their healthcare professionals. This was seen as a generational attribute, in that older people belong to a generation who admire doctors and nurses,

perceiving them as trustworthy. Visiting the same community pharmacy and trusting the staff may also come into this category. This attitude was seen by the healthcare professional as sometimes helping and sometimes hindering the older person's medicines management skills.

For example, being admitted to hospital and having your medicine changed by an unfamiliar doctor with little or no explanation, was likely to lead to non-compliance.

“yes if that patient's been on that tablet for years and suddenly the doctor in there (hospital), not their own GP, because they have more trust with their own GP, the doctor on the ward has stopped it and it might be the first thing that they said ‘Oh the doctor stopped that tablet, I don't know why though.’” HCP3

The healthcare professionals were also aware that older people needed to trust their pharmacist, and this could give rise to problems when the older person's usual pharmacy would not dispense in a MCA after discharge from hospital.

“in other cases it becomes difficult when the chemist that the patient usually uses has said that they haven't time to do it or won't do it, then we have to start looking for another chemist because it is a sort of trust issue in a lot of cases the patients are used to one pharmacy, they don't want to go somewhere else.”HCP7

7.5.5 Six o'clock warfarin.

Finally I asked the healthcare professionals if they had any concerns or issues about the dispensing of warfarin in a MCA. This question was not in my original topic guide but this theme had emerged from the older people's interviews. A number of older people had stated that they never forgot to take their warfarin and that they took it every day at exactly 6 pm. In order to carry this out the older people had in some cases gone to extreme lengths, for example, returning early from a day out or purchasing a separate container to put the warfarin in. The older people explained that “warfarin's different” and “it (warfarin) has to be taken at 6 pm.” I was therefore interested to ask the healthcare professionals if they encountered this behaviour and if they could give reasons for the older people's actions.

The answers given by the interviewees revealed that among healthcare professionals there were some misconceptions about the timing of warfarin doses.

“it is interesting the six o’clock thing because we have at the moment a patient who is on warfarin and she had just started medicines, she had never had medicines before and she kind of had it in her head that she could remember to take medicines in the morning but there was no way she could remember at teatime, so we switched it to the morning and the amount of people who have said ‘oh you can’t give warfarin in the morning’. Why can’t you give warfarin in the morning? As long as the people who are testing know you are taking it in the morning and when it’s a steady state I can’t understand.” HCP1

Some healthcare professionals noted that older people could get very stressed if they did not receive their warfarin dose exactly at 6pm.

“you know like if they do the INR during the day, it’s not always back in time for the doctor who’s on the ward to write it up and then of course you have to get the on call doctor to write it up and he’s busy and he can’t get here and I can see the fright in their eyes as they lay on their beds waiting for their warfarin because I know (laughs) perhaps I shouldn’t laugh but you think ‘what do you think is going to happen if you don’t get your warfarin at 6 o’clock?’” HCP8

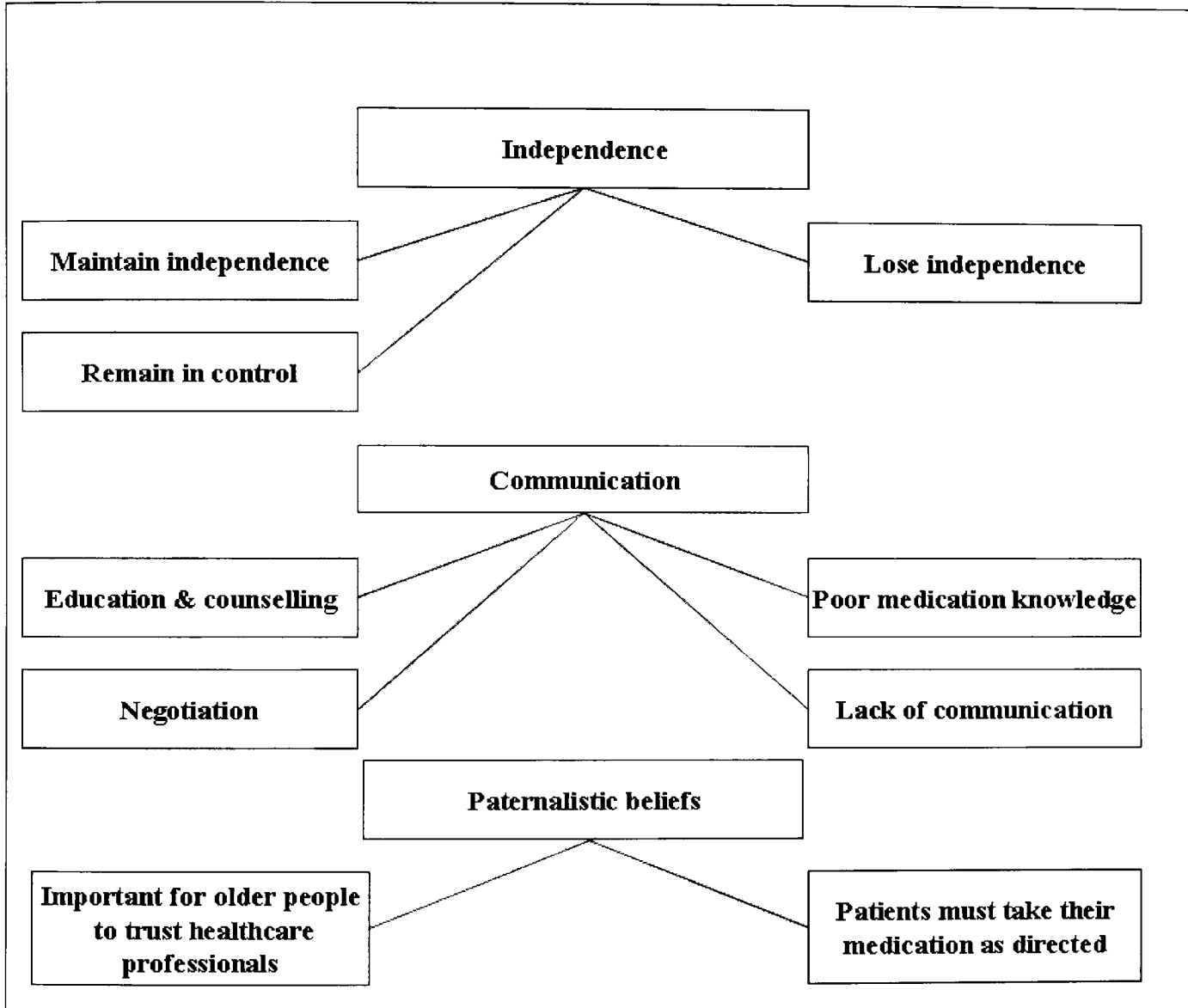
One community pharmacist felt the problem had become more serious and prevalent with the increase in the number of patients who were prescribed warfarin. This pharmacist also thought that the involvement of more pharmacists in anti-coagulant clinics gave rise to much more explicit counselling about how to take warfarin and this was the reason for the 6 pm dose.

“Like warfarin is a major issue. -----it’s become more acute because of the new guidelines, the guidelines on AF and because suddenly more people have been diagnosed with AF, everyone and his dog tends to go on warfarin, so before you had a couple of patients, who were elderly who were on warfarin and it was all well and good, now every second person is on warfarin, so it’s become more of a problem. Pharmacists are getting more involved in anti-coagulant clinics and pharmacists are far more aware that people should be taking the warfarin dose at the same time every day and there are certain times of the day that are easier for people to take it and it might interact with some medication. So you find them (pharmacists) being very religious on the fact like telling these people you must take warfarin at 6 o’clock, it must be the same time every day.” HCP4

7.5.6 Overview of the themes emerging from health beliefs and attitudes

The themes for health beliefs and attitudes were grouped into sub-categories and categories and details of which are given in Figure 15 below.

Figure 15: Categories and sub-categories emerging from Health Belief area of interest



7.6 Age and Ageism

Themes which were concerned with age and ageism had emerged from the older people's interviews, in fact some participants had very definite views on the subject. I therefore put this point to the healthcare professionals.

“ Some of the older people I interviewed felt they were treated differently because of their age, have you seen any examples of this attitude in your area of practice?”

There was a spread of opinions about this particular theme, most participants said they could understand what the older people were talking about but that they hadn't seen any evidence of this in their area of practice. However, some healthcare professionals stated that they could imagine that sometimes their actions could be construed as ageist.

“yes situations where they've for years and years had their own routine and then their memory problems have deteriorated and then we have gone in and treated them like a child.” HCP3

“I haven't been told that directly but I can see where they (patients) are coming from actually and I know the aids and that they probably do, they look very childlike really the aids themselves.” HCP9

7.6.1 Providing a MCA could be seen as patronising

Healthcare professionals themselves stated that giving an older person a MCA could be seen as being patronising.

“it is a bit patronising isn't it especially for people who are borderline you are saying you can't manage we are doing it this way because we know you can't do it.” HCP16

Some of the healthcare professionals thought that older people were started on a MCA simply because of their age and an assumption that if you were older then you would be unable to manage your medication.

“So yes I think lots of people are started (on MCA) because of their age because people have this misconception that they won't be able to retain the information of how to take the medication especially if they are on multiple medications.” HCP4

“I don't know if it's (they are) too old to understand, I think on the wards sometimes they don't take the time and possibly they haven't got the time but they still should take the time and they don't take the time to explain exactly what the patient's got.” HCP11

7.6.2 Blame others.

The healthcare professionals often laid the blame at the door of other healthcare professionals and then went on to state that in their particular field they were well trained to avoid this type of behaviour.

“I mean the problem is outside of elderly medicine there is a different opinion held elsewhere. -----it’s the ageist argument it keeps coming up all the time.” HCP15

“but our team we’re highly skilled in assessing older people and we know how to, you know how to use the right approach, we’ve done it for so long assessing them, so I can’t think of anyone I have worked with in recent years who would treat an old person like a child.” HCP12

7.6.3 It does happen but it is not intentional.

Some healthcare professionals admitted that this type of behaviour might happen on occasions but that it was never intentional.

“I suspect this does happen and I suspect some of us do it unconsciously without realising it. The NSF did have a section on this for elderly people. It talks about having policies which are discriminatory in making elderly people special whereas in fact they should be treated the same as everybody else. I don’t know whether I’ve come across specific examples but I’m sure it does happen.” HCP6

7.6.4 Misunderstandings.

Other interviewees suggested that the older people might be misinterpreting the healthcare professionals’ motives. Therefore, although the healthcare professional did not explain matters relating to their medication, this was not because of age.

“I think perhaps not necessarily an age thing more of a medical condition that we sort of say “well they’re not going to understand, there’s no point.” HCP7

“I don’t mean to sound ageist by saying this but some of them are confused and things and a lot of them don’t realise that they are. So I think just to keep them safe we do need to keep an eye on how they are going with their medications and that probably does sound ageist but I don’t mean it to sound that way. If you know what I mean.” HCP14

7.6.5 Older person in denial.

The healthcare professionals also pointed out that I was asking this question because of statements made by the older people themselves; the healthcare professionals thought that older people were often in denial about their condition.

“but a lot of them are in denial about how forgetful they are so you will get a picture from the patient which is ‘don’t treat me like I’m stupid’ and you speak to the family, relatives and they say ‘she hasn’t a clue she is really forgetful.’” HCP1

“but obviously they are probably in a bit of denial not knowing, thinking that my memory is fine something like that so it’s probably a part of them understanding that their memory isn’t as good as it was five years ago.” HCP3

7.6.6 The healthy aged.

The converse of this was that many of the healthcare professionals had examples of older people who retained all their faculties well into their eighties or nineties.

“you do get the very healthy active eighty five, ninety year olds coming in and they feel almost victimised that they are in the same ward as some of these other patients that may be very demented or have devastating strokes or whatever and just this spectrum of severity is so wide that they are almost completely out of place and they almost feel as if you are not appreciating that they have all their marbles.” HCP15

7.6.7 The relatives’ involvement.

Healthcare professionals also pointed out that relatives can be involved in the supply of MCAs and that it is often relatives who indicate that their elderly relative is not managing their medicines. This can sometimes give rise to conflict between the older person and their relatives and the healthcare professional can find themselves caught between the two.

“I had a patient in (place name) recently who was just discharged -----nothing wrong with her mentally, fantastic memory, plans her own life-----so she came out with a Dosett box and she was really cross about it and the ward and her niece had set it up between them without consulting her and she was really, really cross about it and she made no bones about it.” HCP12

Some healthcare professionals felt that involving the relatives of the older person with their medication could be beneficial.

“I will always first of all try family to fill the box and I have trained quite a few different families – relatives to fill boxes. --- ----- I always say to them I’d much rather you (relative) did it because it enables someone younger and compos mentis to be championing their (the patient’s) medicines.” HCP1

However, this could also cause problems if the family member goes away.

“if you are relying on a relative to fill it (MCA) up that could cause problems if they are away.” HCP17

7.6.8 It’s an ethical dilemma.

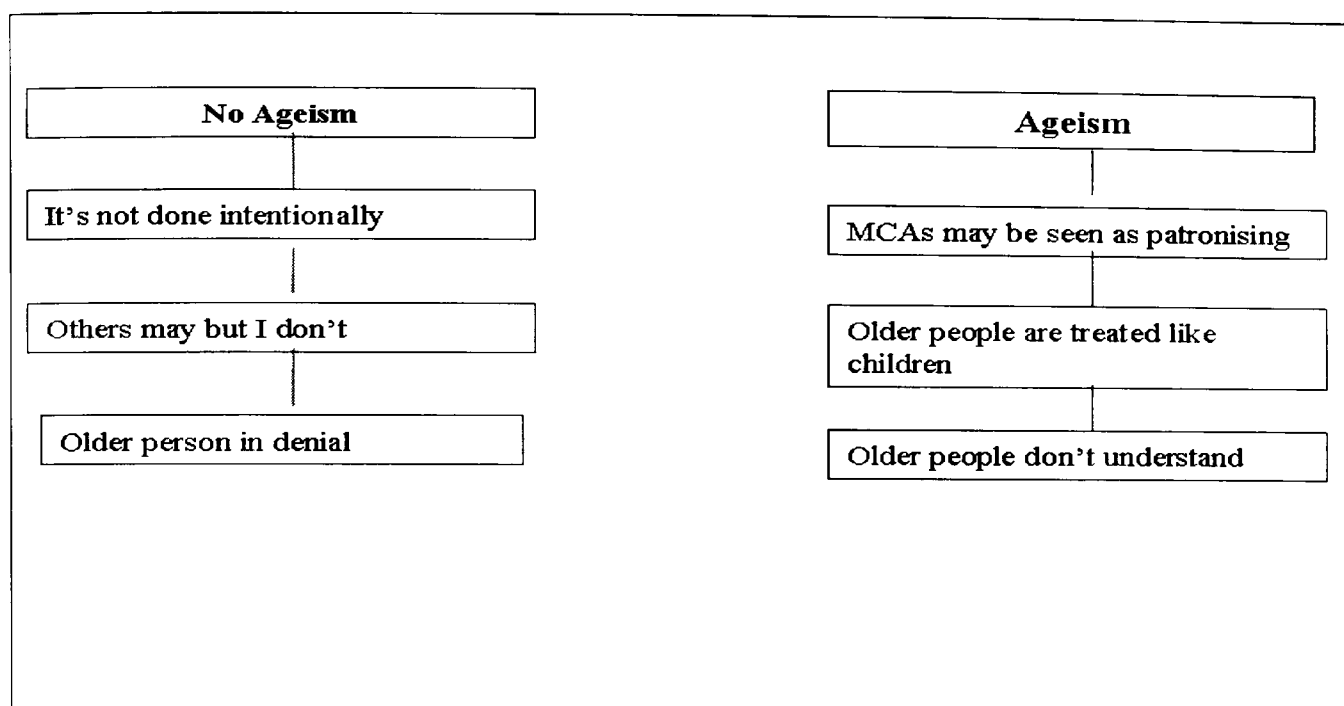
Finally, one healthcare professional highlighted what might be considered to be an ethical dilemma. Does the healthcare professional follow their own professional opinion or does he or she follow the older person’s own wishes?

“You certainly see that where this very difficult judgement has to be made sometimes by the healthcare professionals. The patient may want to go home alone and you do that and they come bouncing back a week or so later and you try and do it again and this time you say ‘well we can give you more support’ and they don’t want more support. Then it’s a difficult fine line as to how much you cajole or persuade them to have support which they probably need but against their free will and it’s a very difficult fine line I suspect sometimes.” HCP6

7.6.9 Overview of the themes emerging from age and ageism

The figure, below, gives details of the classification of the themes relating to ‘Age and Ageism’ identified during the analysis of the healthcare professional interviews. The themes were grouped into sub-categories and then into categories, which are detailed below.

Figure 16: Categories and sub-categories emerging from Age and Ageism area of interest.



7.7 Discussion about the Healthcare Professional interviews

7.7.1 What triggers the decision to provide an older person with an MCA?

With the exception of interviewee HCP14, all the other professionals stated that they did at some time recommend the use of MCAs for older people living in the community or, in the case of the pharmacists, dispensed medicines in these devices. One other healthcare professional stated that he had considerable reservations and this was HCP10 (a GP), who had very strong views about the use of MCAs, coupled with the pharmacists' requests for 7-day prescriptions. This had led him to believe that the community pharmacists were profiting from the dispensing of MCAs and promoting the use of the devices. This practice of requesting the GP to provide 7-day prescriptions for those patients who had their medicines dispensed in a MCA was discussed in the chapter detailing the preliminary study (Section 2.4.3).

Those interviewees who stated that they did recommend the use of MCAs then discussed their reasons. The majority of themes in this area were concerned with either the characteristics of older people or with problems concerning the medication.

“Problems with memory” was the theme most frequently discussed by the healthcare professionals in this section of the study. Almost half of the interviewees stated that problems with memory would be an indication that an older person might require help managing their medication. There is a general perception that the older a person gets the more forgetful they become. However, as discussed in Chapter 6 section 6.3, research into memory has not shown a link between age and failing memory (Lorenc and Branthwaite 1993; Park *et al.* 1992). The relationship between memory and medication adherence will be discussed in greater detail in section 7.7.4.

A minority of healthcare professionals described older people as being either expert or inexpert with regard to medicine management. Both opposing characteristics were given as reasons for an older person to receive a MCA. Expert older people were described by the interviewees as those who knew their medication, the names, the doses and what they were taking it for. These ‘experts’ wanted to stay in control and to retain some degree of choice in their medicine taking. The older people who were self-fillers came into this category; they wanted to retain control of their medication and chose to use a MCA to make things easier for themselves. The term ‘expert patient’ has been used by the Department of Health in the ‘Expert Patient Programme’ (2001). The aim of the Department of Health programme is to enhance the self-management skills of patients living with long-term conditions. The interviewees, in this study, were not using the term ‘expert patient’ in exactly the same way as defined in the report. They were identifying older people who were knowledgeable about their medication and their illnesses and wished to remain informed and in control of their treatment. The

healthcare professionals also suggested that the expert older person might welcome a MCA if they had identified a diminishment of their medicines management skills. The MCA could be seen as a way of maintaining independence and retaining some control of the medication. The theme of 'expert patient' was identified by nurses and one pharmacist.

Those older people who were classed as 'inexpert' were seen to be uninterested in their medication in addition to showing little knowledge or understanding of their medicine regimen. These people were happy to accept a MCA and in some respects welcomed the fact that using a MCA required little thought on their part. These characteristics were only discussed by nurses. I have previously discussed in Section 6.7.2 research which described some patients as 'passive users' (Dowell and Hudson 1997)

Some healthcare professionals identified older people who had a degree of physical disability as suitable candidates for a MCA. Having problems with your hands, resulting in a lack of dexterity, was an example given. The healthcare professionals suggested that it might be easier to remove the medication from a MCA rather than several blister packs. Visual impairment was also given as a reason for suggesting a MCA. The Disabilities Discrimination Act (1995) requires service providers to make reasonable adjustments to their service so that people with disabilities are able to use it. Not only does the pharmacist have to ensure that people with disabilities are able to access the premises but also make full use of the services provided. Pharmacists have therefore to make sure that people with disabilities are able to take their medication and if they are not able then provide suitable support. The support required has been interpreted as providing a compliance aid however, having considered the comments of the older people interviewed, it is easy to see that a MCA is not suitable for everyone and in fact could make the medication less rather than more accessible. The

introduction of the new contract for community pharmacy in 2005 required community pharmacists to assess patients and determine if they fell within the remit of the Act. For patients who are assessed as requiring assistance under the terms of the Act pharmacists are able to provide two levels of service:

Level 1 includes making adjustments to labelling and packaging and providing reminder charts.

Level 2 is providing a MCA.

The introduction of this support within the Pharmacy Contract does mean that community pharmacists are paid for providing the service. However this is not a separate payment but a small amount added to the payment for each item. There remains no payment for those people who may be seen as needing a MCA but are not considered “disabled” under the terms of the Act.

Polypharmacy was the medicine problem mentioned by a number of interviewees as a reason for issuing a MCA. The healthcare professionals defined polypharmacy as having a large number of medicines to take by mouth each day along with a complicated dosage regime. Polypharmacy has been defined as the concomitant use of five or more drugs (Viktil *et al.* 2006). This study, which took place in Norway, studied patients admitted to six internal medicine and two rheumatology departments in five hospitals. Comparisons were made between those patients taking five or more medicines with those taking less than five medicines. The drug-related problems experienced by each group were compared. The study found that the number of drug-related problems increased approximately linearly with increase in the number of medicines taken. Another study which investigated medication use in a community-based sample of elderly men and women (Cohen *et al.* 1998) concluded that non-

compliance was significantly increased if the number of drugs taken exceeded two daily. This suggests that the healthcare professionals I interviewed were right to consider polypharmacy as a trigger for non-compliance.

Several of the healthcare professionals stated that they didn't make the decision to issue a MCA themselves. The decision was either taken by someone else or was implemented because another healthcare professional or professional group demanded this action. Throughout the interviews with the healthcare professionals, this 'pass the buck' attitude was prevalent. Approximately one third of the interviewees stated that if the older person was having help from home care then a MCA was essential. This attitude was described by one of the hospital pharmacists as 'the myth of home care'. A third of interviewees stated that if home care staff were involved with the patient's medication it must be in a MCA. One or two interviewees stated that this was a legal requirement. However, in other parts of the UK, home care staff are trained to prompt or administer medicines from ordinary packaging (Asghar, Gray and Woolfrey 2001; Taylor, Harris and Sandford 1999). Some interviewees also stated that the Intermediate Care Team required that patients discharged to their care must have a MCA. However, when I queried this with the ICT nurses, this was denied.

Hospital discharge was given as the most common reason for issuing a MCA, the community pharmacists stated that this was the main way they received requests. The secondary care staff also stated that older people were often considered for a MCA on discharge, this was linked to concerns that if the older person failed to take their medication correctly they would 'bounce back' into hospital. Research in the USA supports this point of view, finding that 22% of medicine related re-admissions were due to patient non-compliance.(Bero, Lipton and Bird 1991). Studies have looked at interventions to improve patients' medication management post discharge. A self-

medication programme was found to result in higher levels of compliance post discharge (Lowe *et al.* 1995). Counselling by a clinical pharmacist prior to discharge led to reduction in medication errors post discharge (Sweeney, Dixon and Sutcliffe 1989) and discharge plans followed by domiciliary visits by community pharmacists produced no significant difference (Nazareth *et al.* 2001). It would appear that simply issuing a MCA on discharge would not necessarily lead to reduced re-admission rates.

The assessment of the older people prior to issuing a MCA was discussed by a majority of the interviewees. The hospital pharmacists and healthcare professionals from the ICT stated that they would assess the older person prior to issuing a MCA. The healthcare professionals working in Intermediate Care employed assessment procedures which looked at medicines management alongside nursing and daily living requirements. In particular, the nurses working in Intermediate Care explained that their assessment procedures would take place over a period of days or even weeks and would involve observing the older person and providing assistance if needed. The Single Assessment Process (SAP) was introduced in Standard 2 of the National Service Framework for Older People (Department of Health 2001). This Standard aims to ensure that the NHS and Social Care treat older people as individuals and enable them to make choices about their own care. The assessment undertaken on hospital discharge and when entering Intermediate Care would fall into SAP and this was why those working in Intermediate Care felt that this type of assessment would identify any problems. The hospital pharmacists also stated that they would assess the older person and would be prepared to refuse to supply a MCA if, in their opinion, it was not the best option for the older person. Examples of medication packaging, including a MCA, could be brought to the ward for the older person to try. However, the issue of whether the ward setting was the most appropriate place and time to undertake this assessment

was discussed by a number of the healthcare professionals. Older people, who have been admitted to hospital in an emergency situation, are often confused and disorientated and hospital wards are noisy and busy, this was discussed in Section 6.7.1. Studies have shown that older people find it difficult to remember what advice was given to them on discharge and assessing their ability to manage their medication at this time may not be the best solution. A study in Germany looked at elderly patients who had managed their medication themselves prior to an emergency hospital admission (Nikolaus *et al.* 1996). The patients were assessed for their ability to perform activities of daily living and for their cognition and affect. In addition, the patients were tested for manual dexterity and cognitive capacity. Finally, the patients were assessed for their ability to open and remove tablets from four types of pharmaceutical packaging including a Dossett® box and were also tested for visual acuity. Patients were visited after three days and three months post-discharge. The researchers made some simple recommendations as a result of the research, which included assessing the patient's ability to use the medication container prior to discharge, and supervising and training the patient about their medication within the first few days after discharge.

A minority of the healthcare professionals stated that they would try other solutions first, the most popular being the medication chart. Various studies have assessed charts (Raynor 1997; Grymonpre, Sabiston and Johns 1991) and found them to be useful in aiding compliance.

7.7.2 The advantages and disadvantages of MCAs

All the healthcare professionals were asked what advantages and disadvantages they saw in the use of these devices.

More than half the healthcare professionals, spread across all three professions, stated that ease of use and convenience was a big advantage. The fact that the older person could access all the medication for one dosage time by opening one section of the MCA meant that medication errors were less likely and could save the older person time. The fact that 'patients like them' was also given as an advantage. While it may be true that removing the medication from a MCA may be easier and take less time than removing five or six different tablets or capsules from their individual blister packs, this does not seem to be a sufficient reason for issuing an older person with a MCA.

Continuous supply was also seen as an advantage, the fact that the pharmacy filled devices were usually delivered to the older person's door without the need for a repeat prescription to be collected from the surgery, meant that running out of medication was unlikely to happen. The healthcare professionals saw this as an advantage.

The issue of independence had been discussed by the older people in their interviews and it was obvious that, to some interviewees, this was an important issue. I asked the healthcare professionals if they thought independence was important to the older people in their care and many agreed that it was. A minority of the healthcare professionals thought that providing a MCA would maintain the older person's independence allowing the older person to remain in their own home.

The issue of independence will be discussed further in Section 7.7.5.

Approximately one third of the healthcare professionals saw advantages either to themselves or to other healthcare professionals in the use of MCAs. The suggestion was made that the healthcare professional could use the device to monitor what the older person was taking, although observing that a day's supply of medication had disappeared from the MCA does not confirm that the medication has been taken. A

number of healthcare professionals were aware that older people might dispose of their medication in an attempt to deceive them.

A significant minority of the health professionals stated that using a MCA was an advantage to those older people who had memory problems. An equal number of the healthcare professionals stated that one of the disadvantages was that the MCA did not remind the older person to take their medication. The MCA was not considered a suitable device for use by those older people who have any degree of cognitive dysfunction.

Looking in more detail at the issue of memory, MCAs are often recommended by healthcare professionals and others for use by older people because there is an assumption that, as we age, our memory deteriorates. Memory is a very complex function and consists of:

Retrospective memory, which is a memory for past events, for example remembering events in earlier times or the plot of a film or book.

Prospective memory which is memory for things to be undertaken in the future, for example going to a meeting or putting a meal in the oven.

Compliance with medication has been cited as a prospective memory task (Einstein and McDaniel 1990). However, work by Park and colleagues (Park et al 1996), has suggested that a number of factors, prospective memory, working memory, long term memory and social factors, are involved.

In order to take medication correctly a person must remember the instructions that have previously been given by using retrospective memory. They then use prospective memory to take the medication at the correct time (Einstein and McDaniel 1990). Park and Kidder (Park and Kidder 1996) stated that retrospective memory is of importance in

complying with a medication regime and that this can be a difficult task because of the complexity of the information associated with each medication.

The affect of ageing on the memory function has been the subject of many research studies. There appears to be a clear link between age and deficits in retrospective memory; (Gould, McDonald-Miszczak and King 1997) however, research into prospective memory has suggested that older adults do better on these tasks than younger adults (Park *et al.* 1999). The better performance of the older adults in prospective memory studies appears to be due to the use of memory aids or strategies (Branin 2001). The memory aids or strategies in use can be either internal or external. Internal strategies involve mental activities which are aimed to improve the quality of the encoding of the material to be remembered or to improve the retrieval of already encoded material. Older people are often encouraged to 'use it or lose it' meaning that they should undertake mental activities such as crosswords or quizzes in order to increase or maintain mental capacity. External strategies involve using physical changes to the environment, for example, writing and leaving notes in view. These strategies could include using a MCA or a medicine chart or placing the medication by the kettle or on the bedside table. Research studies have been carried out to determine which type of strategies older people used when taking their medication. A study of 190 older adults living independently in the community in the USA looked at the strategies they employed to remember to take their medication (Branin 2001). The participants in this study used more internal memory strategies than external strategies, with relating taking medication to their daily routine being the most frequently used strategy. Another study of 51 older adults, which looked at the use of memory strategies for taking medication, (Gould, McDonald-Miszczak and King 1997), also found that the older adults used more internal than external strategies.

In chapter 6, I looked at the reminder systems that the older people had indicated to me that they used, external strategies such as placing the MCA or original packaging in a special place, and removing the tablets from the MCA and placing elsewhere were frequently mentioned. The internal strategies of linking the taking of the medication to the daily routine were also commonly used and a number of the older people mentioned that taking their medication had become a 'way of life'.

During the interviews with the healthcare professionals a number of interviewees discussed the reminder systems which the older people had put in place. Some interviewees stated that they found it difficult to accept these memory strategies especially when the older person had been given a MCA and had then reverted back to their old reminder system. The research studies discussed above indicate that older adults will decide to use whatever system suits them best and, whether, their system relies on internal or external cues will depend on how that particular person uses their memory.

Clearly a MCA will help someone who has a complex medication regimen which they find hard to cope with as the MCA will remove the need to retrospectively remember which drugs to take and how many of each. When it comes to remembering to take all the medication at the correct time, the MCA can be seen as an external cue but the older person will have to remember what it is they have to remember and the MCA may not help at all.

Healthcare professionals also stated that a MCA would be no use for those older people with a more severe cognitive impairment than mild memory loss. Using a MCA correctly does depend on the user having an understanding of days of the week and times of day. A study comparing the abilities of cognitively intact older people with a

group with Alzheimer's disease found that the patients with Alzheimer's disease were 50% less likely to process the instructions on a drug label correctly than the cognitively intact group (Park *et al.* 1994). Healthcare professionals have reported instances of older people taking all the medication in a MCA on one day and older people with a degree of cognitive impairment would be most likely to be unable to use a MCA correctly.

Almost 50% of the healthcare professionals stated that not all older people can use a MCA and individual brands were highlighted as being more difficult to use. There was a degree of anger among some of the healthcare professionals who stated that they had found older people with a device which they could not use. Blame was laid at the door of other healthcare professionals for failing to check that the older people could manage the device they were given. A number of studies have looked at the ability of older people to use various types of medicine container (Nikolaus *et al.* 1996; Atkin *et al.* 1994). Another factor which added to the difficulty of using the device was the fact that, if the secondary care trust discharged the older person with one type of device, then this might change when the community pharmacy took over. The healthcare professionals who worked in Intermediate Care were the ones who complained most bitterly about the people they visited who had a device which they couldn't use. They were also the most likely to check over a period of time that the older person could manage.

Healthcare professionals from both Secondary and Intermediate Care spoke of the problems they had in finding a community pharmacy which would fill a MCA for an older person. The hospital pharmacists stated that often they had to ask a different pharmacy than the one that the older person usually used, which could cause problems with accessibility or delivery as well as asking the older person to use an unfamiliar

pharmacy. A number of the non-pharmacists interviewed observed that it was time consuming and costly to dispense medication in a MCA. It was interesting to note that interviewee HCP9 (a GP from a dispensing practice) sent the prescriptions for the patients who required a MCA to the local pharmacy for dispensing because he said it took too long to fill a MCA.

Research studies have looked at the time taken to dispense medication in a MCA. A time and motion study carried out in community pharmacies in Northern Ireland found that the Dosett® was the quickest to fill with a mean filling time of 1 min 45 sec., while the Medidos® took 2 min 52 sec. (McElnay and Thompson 1992). This was for a one week supply of three medicines which had already been dispensed into labelled tablet bottles for each patient prior to filling the MCA. Clearly it would take longer to dispense into a MCA from the blister packs which are the main type of packaging used for medication today. Another study (Green, Johnson and Wells 2000) looked at dispensing into MCAs, in this case a Nomad® tray, from manufacturers' blister packs and compared the time taken with the time taken to dispense from loose tablets. The results showed that for certain tablets the time taken to dispense into the Nomad® tray from patient packs was twice that from loose tablets.

Healthcare professionals also discussed the choice of MCA, most community pharmacies only supply one type of MCA and other healthcare professionals noted that the type offered might not be suitable either for the older person or for the medication regimen they were on. Community pharmacists who were willing to obtain different devices in order to meet a particular need were rated very highly by other healthcare professionals.

Dispensing errors were mentioned by a number of healthcare professionals. The hospital consultant felt that it was less likely that a dispensing error would be noticed when the medication was all put together in a MCA. Similarly, a number of other staff in the Secondary Care Trust stated that they were aware of patients who had been hospitalised due to errors in the dispensing of MCAs. Although it did seem as if this might be a frequent occurrence, it appears more likely to be a case of a number of different healthcare professionals reporting the same problems. The healthcare professionals also thought that the older people might be less likely to notice an error than when the medicines were dispensed in original packs. A study in Australia identified and analysed Dosett®-related incidents reported to the Australian Incident Monitoring (AIMS) Study (Levings, Szep and Helps 1999). The study identified 52 Dosett® related incidents reported to AIMS from the first 12,000 incidents. The incidents fell into three categories: problems with filling (26 problems), problems with use (16 problems) and problems which were neither related to filling or use (12 problems). Fifty percent of the errors identified were therefore due to filling errors, the majority of the errors being made by nurses. The paper points out that most filling of Dosett®s is done by nurses in Australia. The UKCC issued guidance for nurses (United Kingdom Central Council for Nursing 1992) and instructed nurses in the UK not to fill MCAs for patients. Only 3 of the 26 errors, in the Australian study, were made by pharmacists. Around a third of the errors involved the incorrect use of a correctly filled Dosett® with patients responsible for the majority of the errors. The errors were mostly due to poor communication, haste and distraction, or patient confusion and dementia. The researchers concluded that errors made during filling can cause serious problems for patients. They advised that strict protocols for filling MCAs should be designed and

adhered to. They also recommended that patients and carers should be educated about potential errors in filling and using MCAs.

Just one non-pharmacist stated that not all medicines can be put in a MCA. Interviewee HCP16 was well informed about problems of stability and stated that some drugs could not be put in to the MCA because they had to be in the dark or airtight. The two community pharmacists were both concerned about the problems of stability and felt that on some occasions it could be considered an ethical dilemma trying to decide whether it was possible to include certain drugs in a MCA. Studies have looked at the stability of drugs in MCAs (Church and Smith 2006;Walker 1992a) In both these studies the researchers obtained information on a number of different medicinal products from the manufacturers and presented the advice in table form.

In the study by Church and Smith, the pharmaceutical companies gave permission for the information to be published provided the following disclaimer was printed

“it is important to note that the individual manufacturers do not endorse this practice of transferring medicines from the original packs to compliance aids as it may be outside the terms of their product licence. For the majority of manufacturers any information they provide is based on anecdotal evidence or in-house studies as no formal studies would have been carried out.”

Therefore although information on stability is available the various manufacturers are careful to remove themselves from giving any responsibility. The pharmacist therefore still has to make his or her own decision.

As well as the problem of stability, there were other reasons why individual medicines were not put into the older person’s MCA. PRN medicines (that is, those taken by the patient when required) were mentioned by a number of healthcare professionals as presenting a dilemma. Usually these are analgesics and the older person may only wish

to take them when the pain is severe. Should these drugs be packaged separately or put in the MCA encouraging the older person to take them regularly? Taking the analgesics regularly may improve the effect in some circumstances. However, if the older person has decided that they do not wish to take their pain relief regularly, they may try to miss out the dose or move the tablet from the MCA and errors may result.

Other medicines with non-standard doses and specific instructions were also identified as potential problems, for example, medicines taken only weekly or at more frequent times during the day.

Finally, medicines which may require frequent dose changes were also seen as causing problems. Warfarin was a particular problem as the older person may have their dose changed just after a new MCA has been delivered. When any dose change is communicated to the community pharmacy, either the change is not implemented until the following week or the MCA has to be collected and a new dose dispensed. However, there may not be a new prescription at this point only a faxed message from the clinic. Once again the pharmacist is presented with a dilemma. One of the community pharmacists stated that this had become more of a problem in recent years now that the guidance on the treatment of AF includes use of anti-coagulants (National Institute for Health and Clinical Excellence 2006). The National Patient Safety Agency has recently issued a patient safety alert entitled "Actions that can make anticoagulant therapy safer." (National Patient Safety Agency 2007) Step nine of this statement advises that a risk assessment should be carried out on the use of Monitored Dosage Systems for anticoagulants for individual patients. The statement goes on to say that the general use of MDS for anticoagulants should be minimised as dosage changes are more difficult to enact when using these systems.

7.7.3 What are the beliefs and attitudes about the use of MCAs

I wished to discover if healthcare professionals believed that giving an older person a MCA would lead to better health and quality of life. I also wanted to discover if healthcare professionals had specific beliefs and attitudes towards older people and whether these drove the decision to issue a MCA.

A minority of the healthcare professionals believed that the MCA would help maintain the older person's independence but one GP thought that issuing a MCA might reduce an older person's independence. However more healthcare professionals stated that older people wished to remain in control and to continue to follow their own routines. These observations agree with the findings of a research study undertaken in Australia (Thompson and Stewart 2001). In the Australian study 94% of respondents reported a method for remembering to take their medication. These methods included taking with a meal, take immediately on rising, keep where likely to be seen and use of a chart or calendar. This use of external reminders or cues agrees with the work done on medication adherence and memory discussed in section 7.7.4. (Branin 2001; Gould, McDonald-Miszczak and King 1997) Not all the healthcare professionals were happy with their older patients using their own routines and strategies for reminding themselves. Comments were made about the more unusual and bizarre systems. Other healthcare professionals were happy to let the older people use their own systems, feeling that trying to introduce another system might be counterproductive.

The interviewees were asked if they were aware of older people who intentionally chose not to take their medication. I used this area of questioning to try to determine the healthcare professionals' beliefs and attitudes concerning older people and their medication.

Non-compliance has been described as being divided into intentional and non-intentional as discussed in Section 1.4.2. A study of people aged over 60 in the USA found that 73% of the non-adherence identified was intentional. The authors went on to conclude that “traditional efforts aimed at reducing the incidence of forgetting to take medicines would not seem to be helpful in cases of intentional non-adherence” (Cooper, Love and Raffoul 1982). If this is the case, providing an older person with a MCA would seem to be of little value. Another paper hypothesised that intentional and non-intentional non-compliance were two separate behaviours which have different factors associated with them (Wroe 2002)

To look at this issue further, I asked the healthcare professionals if they were aware of older people who made a decision not to take their medication. This was followed up with prompts to try to elicit their feelings and to find out what action they would take. All of the healthcare professionals with the exception of HCP1 stated that they were aware of intentional non-compliance in some older people. Side effects of medicines and the older people’s own beliefs about medicine taking were the reasons most interviewees gave for intentional non-compliance. When asked how they felt about older people deliberately deciding not to take their medication there were a number of different points of view. One nurse felt that she would respect the older person’s decision whereas others thought that the older people were not honest about their medicine taking behaviour. The use of the word ‘honest’ implied that the healthcare professional did view intentional non-compliance as a form of deviant behaviour. This is discussed by Donovan and Blake who pose the question “Patient Non-compliance: Deviance or Reasoned Decision making?”(Donovan and Blake 1992). Donovan and Blake suggest that patients perceive medicine taking in a different way from healthcare professionals and in particular do not ‘follow doctor’s orders’. Patients weigh up the

costs and benefits of taking the medication, by taking into consideration their own circumstances. Thus, whilst the behaviour may be seen as 'deviant' by the doctor (or other healthcare professional), from the patient's point of view it is perfectly reasonable. The findings from my study appear to agree with this hypothesis, the healthcare professionals stating that they understood that the older people had their own reasons for not taking their medication but this behaviour was seen as deviant or not honest.

I tried to discover if there was a feeling of resentment on the part of the healthcare professionals when they saw older people whose worsened condition could be attributed to non-compliance with their medication. The healthcare professionals were reluctant to admit to any resentment although interviewee HCP8 said that the reason for re-admission would be discussed and that staff would be more saddened than resentful.

Older people's own beliefs about medicine taking were seen as a reason for non-compliance by about half of the interviewees. The healthcare professionals noted that sometimes the older people's beliefs were incorrect. For example, not taking medication regularly for fear of addiction or 'getting to used to it'.

Communication was the best solution for the majority of the healthcare professionals. They felt that the older person had not received sufficient information about their medication and therefore did not understand why compliance was important. This opinion is supported by a study which investigated acutely hospitalised older patients (Shabbir, Han and Naglie 1999). The researchers found that approximately half of the patients investigated had not received any medical education prior to discharge despite changes to their medication regimes. The solution, according to the healthcare professionals interviewed in my study, was obvious; talk to the older person about their medication. Explain what each medicine was for, why it was important to take it and, if

necessary, inform them about possible side effects. Research supports the use of such interventions (Rich *et al.* 1996) A telephone call from a suitably trained pharmacist to provide information about newly prescribed medication was also found to improve compliance (Clifford *et al.* 2006). Some of the healthcare professionals in the main study stated that they would consider other courses of action. For example if side effects were causing the problem the pharmacists would discuss with the prescriber a change of drug and other healthcare professionals would also consider this. Reporting non-compliance back to the prescriber was seen as a 'duty' by a number of the nurses, whereas the prescribers stated that they would discuss the issue but would be happy for the older person to make the decision.

Did the number of years post registration affect the healthcare professionals' attitudes and beliefs?

I tried as far as possible to recruit both recently registered and more experienced healthcare professionals within my purposive sample. I aimed to compare the interviews across the different professions and across the level of experience. The length of time on the register for the healthcare professionals ranged from one year to thirty years. The young staff nurse who stated that she did not recommend the use of MCAs for patients in her care (Section 7.3) had been on the register for one year. The junior hospital doctor (3 years post registration) stated that patient problems (poor memory, physical disabilities, home circumstances) were most likely to trigger the issue of a MCA. Only one other interview produced more themes around patient problems and that was given by a nurse (23 years post registration). The junior hospital pharmacist had the best knowledge of intentional non-compliance among the recently registered group and was also aware of the meaning of the term concordance.

Communicating with the older people about their medication was only discussed by the junior hospital pharmacist and the junior hospital doctor.

A study which measured the attitudes to concordance in newly qualified medical, nursing and pharmacy graduates (Raynor *et al.* 2001) concluded that newly qualified doctors, nurses and pharmacists hold favourable attitudes to concordance but a significant minority, mainly pharmacists, held negative views. The differences in the understanding of concordance may reflect the different training in medicines management undertaken by the different professions. The pharmacy undergraduate will have studied compliance and concordance but this may not be so for the other groups.

7.7.4 Did the healthcare professionals think ageism existed?

The older people whom I interviewed had introduced this theme in the first interviews. I included a question about age and age discrimination in the topic guide for the healthcare professionals, by using the statements made by the older people to introduce the topic. The majority of the interviewees stated that, although this type of behaviour might occur elsewhere, they did not act in this way.

The National Service Framework (NSF) for older people (Department of Health 2001) Standard One states that “NHS services will be provided, regardless of age, on the basis of clinical need alone. Social care services will not use age in their eligibility criteria or policies, to restrict access to available services.” Standard Two-Patient-centred care: states that “older people should be treated as individuals and enabled to make choices about their own care”. The King’s Fund commissioned research to look at age discrimination (Roberts, Robinson and Seymour 2002) This report concluded that the objectives of the NSF to eradicate ageist practices from the NHS would not be met unless more help was given to local managers to implement the policy.

The healthcare professionals thought there was a danger in appearing to patronise the older person and a minority of the interviewees said that they might on occasion treat the older person like a child, albeit with the best of intentions. A study in Belgium explored a number of issues concerned with the inappropriate use of medicines for elderly patients admitted for acute care (Spinewine *et al.* 2005). A number of categories were identified as underlying inappropriate use of medicines including 'Paternalistic decision making'. The researchers stated that ageism could be viewed as a form of paternalism and they concluded that this may contribute to the inappropriate use of medicines in elderly patients. Another qualitative study investigated the diagnosis and management of heart failure in primary care using focus group interviews with GPs (Fuat, Hungin and Murphy 2003). Ageism was highlighted in all the focus groups with GPs stating that they would be more likely to 'aggressively treat' a younger patient rather than an older one.

Some interviewees stated that this was not 'an age thing' but sometimes older people might be treated in a certain way because they couldn't understand or couldn't manage because of a physical disability. One interviewee said she thought she shouted at all the older people automatically because so many were deaf but realised that this might be offensive to someone whose hearing was perfect. These statements highlight a stereotypical way of thinking about older people. Age stereotypes have been defined as knowledge structures which people use to process information concerning age (Hummert 1999). Age stereotypes can influence both our perceptions of and behaviour towards others. The healthcare professionals exhibited stereotypical opinions regarding older people, in particular concerning memory and ability to understand.

The healthcare professionals interviewed held the belief that older people were more forgetful despite the fact that this has not been conclusively proved by research. This

negative stereotype of the forgetful older person is common in our society and there is evidence to suggest that older adults respond to these attitudes by behaving as the stereotype (Hess 2006).

Communication or lack of communication was again linked to problems in this area with some interviewees stating that often misunderstandings can happen when the right explanations are not given.

Are Multi-compartment Compliance Aids ageist?

This point was raised in the older people's interviews when one or two interviewees questioned why they had received a MCA; 'is it to do with my age?' they had asked. Those interviewees who were self-filling when asked about a pharmacy filled MCA replied that they didn't need that help yet, implying that MCAs were for people less able to manage than themselves.

The healthcare professionals thought that MCAs might look rather child-like and insulting.

MCAs are rarely given to groups other than the elderly. People suffering with HIV/Aids sometimes use them because the regimens are very complex, and occasionally MCAs are given to people with learning difficulties who are taking a number of medications. It could be said, therefore, that the use of MCAs is ageist as they are primarily issued to older people. However this would depend on the indications for their use. Provided that the recipient is happy to use the device and is capable of using it then this should not be a problem. The difficulty arises when the MCA is issued without consultation or assessment and the reasons for the issue are unclear.

7.8 Summary

In summary this chapter has looked at the findings from the interviews with healthcare professionals and identified the following issues.

The **Trigger for use** of multi-compartment compliance aids was most frequently hospital discharge.

Use of MCAs. The main advantage identified by the healthcare professionals was ease of use and convenience. However the interviewees identified more disadvantages than advantages. There was some difference of opinion among the professions about the use of MCAs. In particular there was a tendency to lay the blame for problems at another professional's door.

Health Beliefs. The healthcare professionals discussed not only their own attitudes and beliefs about older people managing their medication but also the beliefs of other professionals and older people. There were differences between the professional groups in their attitude to intentional non-compliance, with some interviewees taking a more paternalistic point of view.

Age / ageism. The majority of the healthcare professionals stated that ageism might occur but not in their particular area of practice. Some interviewees did state that the issuing of an MCA could be seen as insulting to some people. There was understanding of the older person's point of view but there was also a feeling that older people should follow the 'doctor's orders'.

Chapter Eight: Further discussion of the findings and implications for practice and further research

8.1 Introduction.

This chapter draws together the findings from all the parts of the study previously described, commencing with a review of the aim of the programme of work.

Chapters six and seven contained the findings obtained from the interviews both with older people and healthcare professionals and a discussion of these findings supported by references from the literature was presented. In this chapter I compare and contrast the findings from both sets of interviews and the comparisons are then used to explore the level of agreement between the two parts of the main study and the preliminary study. Also included are explanations for the findings, using the underpinning theoretical approaches which were described in chapter 4. Finally, I put forward the implications of this research for policy, practice and for further research.

8.2 What was the aim of the study?

The aim of the study was to discover how the attitudes and beliefs of older people and healthcare professionals affect the use of multi-compartment compliance aids (MCAs) by older people living in the community. Firstly, to consider the older people, their beliefs would concern:

The seriousness of their illness.

The likelihood that the illness was treatable

The safety and efficacy of the medication.

These are all aspects of the Health Belief Model (Becker and Maiman 1975). The beliefs of the older people are usually based on evidence. However that evidence may not always be reliable when viewed by a healthcare professional, but seem genuine to a lay person. This is supported by research undertaken with 100 patients with Type 2 diabetes and 104 healthcare professionals (Clark and Hampson 2003). The study revealed several differences in beliefs and attitudes between patients and healthcare professionals with the patients believing that type 2 diabetes was a less serious condition compared to the healthcare professionals. The patients, therefore, were less likely to see the value of maintaining tight blood sugar control than the healthcare professionals.

Attitudes, on the other hand, are often based on the person's own feelings or opinions and may have little to do with evidence; the attitude of a patient to their doctor may rely on any number of factors which have little to do with medical expertise. Older people may not only have beliefs about medication but also attitudes concerning how they take their medication. Some people will take their medication exactly as instructed whilst others will maintain a much more relaxed attitude not worrying too much if they miss a dose or take an extra dose. It may be easier to change a person's attitude to medicine taking but harder to change a deeply held belief.

The healthcare professionals, because of their medical training, hold evidence-based beliefs about the treatments they prescribe for patients. However, at times these beliefs may be challenged by new research or government guidelines. Attitudes on the other hand can influence the behaviour of healthcare professionals both in the way they relate to older people and their medication problems. A study of the prescribing behaviour of doctors in the USA (Epstein, Read and Winickoff 1984), investigated the relationship between physician beliefs and attitudes when prescribing anti-inflammatory drugs. The

physicians were asked both “belief” and “attitude” questions concerning commonly prescribed anti-inflammatory drugs. The researchers concluded that, while there was no relationship between physician’s beliefs and prescribing behaviour, there was a relationship between certain attitudes and the physician’s behaviour. The researchers concluded that attitudes are based on more complicated patterns of information including personal biases, and may be more difficult to alter.

In order to ascertain if these attitudes and beliefs, held by both groups, affected the use of MCAs by older people living in the community I considered four areas of interest. The four areas of interest, ‘Trigger for use’, ‘Use of MCA’, ‘Health beliefs’ and ‘Age and ageism’ were investigated from both the older person’s and the healthcare professional’s point of view. The intention by doing this was that I would be able to compare the data obtained from the two groups and use the two sets of data to corroborate one another.

8.3 Comparison of the findings from the older peoples’ and healthcare professionals’ interviews.

In order to understand how the attitudes and beliefs of both groups might influence the use of MCAs, it was necessary to find out from the older people what lead to the issue of the MCA. I also needed to explore this from the ‘other side’ and so the healthcare professionals were asked to describe the characteristics of an older person for whom they would request the issue of a MCA.

8.3.1 What triggered the supply of the MCA and what are the characteristics of older people receiving a MCA?

Hospital admission and discharge were highlighted as triggers for MCA use in both the preliminary study and the main studies. In the preliminary study the patients cited hospital discharge as the occurrence most likely to lead to the issue of a MCA. This

supports the findings from the older peoples' interviews in the main study. A majority of older people interviewed in the main study stated that they had managed their medication perfectly satisfactorily until either they had gone into hospital or had experienced a worsening of their illness. The healthcare professionals in the main study characterised the older people who would be issued with a MCA on hospital discharge as forgetful, having a large number of different medicines and as at risk of "bouncing back" into hospital. These were the main influences for issuing a MCA, supported by the professionals' beliefs that the device would improve compliance and that patients should take their medication as directed.

There was a belief among many of the older people that hospital admission or failure to cope at home would lead to residential care. A research study in Australia (Quine and Morrel 2007) interviewed older people about the hopes and fears that they held for their future. The fear of nursing home admission was ranked third in the list of fears by the respondents, with loss of independence in general ranked second. In another study undertaken in Australia, interviewees stated that they would rather die than have a hip fracture treated and have to be admitted to nursing home care.(Salkeld *et al.* 2000).

This belief was supported by the Care of the Elderly consultant who stated

"...it is quite a horrific thought really you know people don't want to come into hospital because they perceive that they will never be allowed to come back home again." HCP 13

The need to remain in their own home and look after themselves was uppermost in many of the older peoples' thoughts. Therefore, this would lead to acceptance of any medication or device on discharge, with only the most determined and independent questioning any decision. Thus MCAs and medication changes were accepted, and only once they were established back home did they begin to question their medication regimen or the use of the MCA. This finding is directly consistent with the symbolic

interactionist theory, which I described in Chapter 4 and which will be discussed later in this chapter.

Research studies have investigated discharge from hospital and the problems that can occur with medication, as discussed in Section 6.7.1. The most widely held opinion of the healthcare professionals was that older people who ‘bounced back’ repeatedly did so because of non-compliance with medication. This was then a main driver in the issue of a MCA when discharging the patient.

However, is there evidence that repeated re-admissions to hospital in the older age group are due to non-compliance? Several research studies have looked at drug related admissions to hospital. Some studies have looked at adverse drug reactions (Mannesse *et al.* 1997; Pirmohamed *et al.* 2004) and other studies have looked at a range of drug related incidents (Bhalla, Duggan and Dhillon 2003; Mc Donnell and Jacobs 2002; Chan, Nicklason and Vial 2001). The studies which looked at admissions resulting from adverse drug reactions considered only those admissions which could be directly linked to a serious adverse reaction to the patients’ prescribed drug therapy and excluded overdosing, under-dosing and non-compliance. The studies which looked at drug related incidents also considered non-compliance and omission of indicated treatment.

A study undertaken in Tasmania (Chan, Nicklason and Vial 2001) considered 240 patients aged 75 and over who had unplanned admission to hospital over an 8-week period, of these 240 admissions 4% were considered to be caused by non-compliance. A similar study in Cambridge (Bhalla, Duggan and Dhillon 2003) considered acute adult admissions over a 9-week period. These admissions were reviewed by a clinical pharmacist and a review panel made the final decision on which admissions were drug-

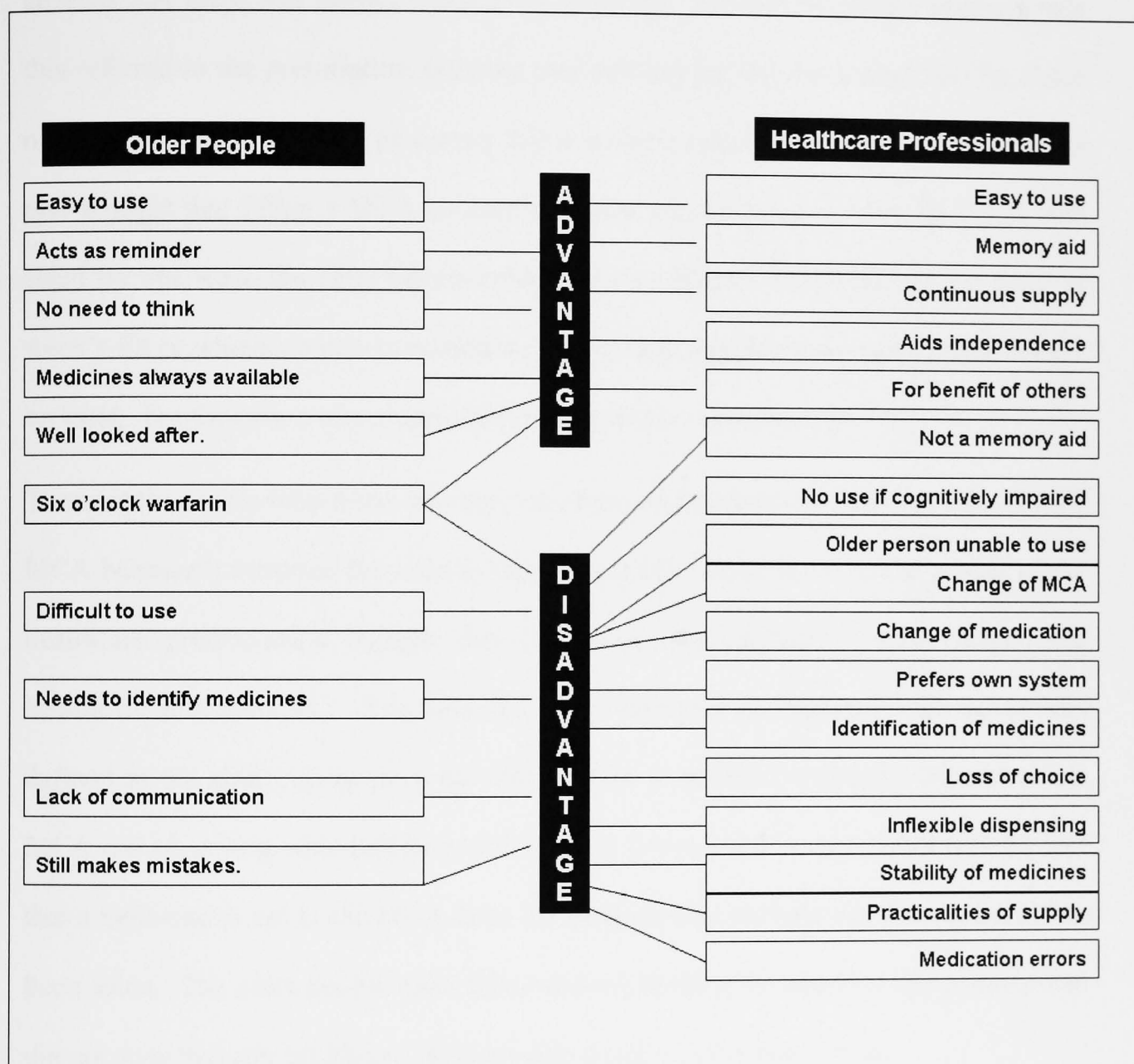
related. 840 admissions were screened and 85 (10%) patients were identified as having a drug-related admission. Eighteen percent of these admissions were considered to relate to drug therapy failure, the most implicated category of which was non- or poor compliance. A third study, carried out in the USA (McDonnell and Jacobs 2002), comprised a retrospective chart review of 158 adverse drug reactions linked to hospital admission. The researchers linked a third of these admissions to non-compliance with medication. In all the studies, the main cause of drug-related hospital admission was an adverse drug reaction; however each study concluded that compliance issues were also a cause of a significant number of hospital admissions.

Further investigation reveals that non-compliance in each study was defined differently. Chan (op.cit.) included both patient non-compliance with prescribed medication and non-compliance due to failure on the part of the physician to prescribe. McDonnell (op.cit.) included problems with OTC medication in their patient compliance issues. Bhalla (op.cit.) included non-compliance in the therapeutic failure category, which also contained changes to medication, e.g. dose reduction and dose discontinuation. Therefore, although non-compliance appears to play a significant part in hospital admissions in these studies, the cause may not lie completely with the patient.

8.3.2 Perceived advantages and disadvantages of MCAs

Both the older people and the healthcare professionals had very clear views on the advantages and disadvantages to the older person of using a MCA. Figure 17 below compares the advantages and disadvantages as seen by the two groups.

Figure 17: Comparison of themes relating to advantages and disadvantages of MCA use.



A majority of the older people took a practical attitude to the use of the MCA seeing ease of use as the most important advantage. Ease of use was also cited as an advantage by users in the preliminary study. The healthcare professionals also stated ease of use as an advantage and also suggested that the MCA was a memory aid. The older people used the term 'reminder' rather than saying that the MCA aided their memory and there is a subtle distinction here, with 'reminder' being suggestive of a gentle prompt about

something which has just slipped the memory whereas a memory aid suggests something which helps the failing memory. Both groups noted that having a MCA ensured that there was always medication available. For the healthcare professionals this referred to the prescription ordering and delivery by the pharmacist and for those older people supplied by the pharmacy this was also an advantage. The self-filler group also thought that filling a MCA ensured a regular supply because when the MCA was filled for one week the older person could calculate if there was sufficient for the next week's fill or whether a new prescription was needed. Medication was therefore always on hand. For the carers who filled MCAs this was also an advantage.

Those older people who fitted into the "uninterested in medicines" category liked their MCA because it removed the need to think about their medicines. About a third of the healthcare professionals thought that giving an older person a MCA helped the healthcare professional. The help that the healthcare professional referred to was defined as the ability to monitor the older person's medicine usage, by looking at the MCA and observing what had been removed. It is important to remember that the fact that a medicine is not in the MCA does not conclusively indicate that the medicine has been taken. The older people interviewed did not seem to be aware of this practice and did not state that any healthcare professionals asked to view their MCA.

It is easy to see from Figure 17, that numerically the perceived disadvantages of MCAs outweighed the perceived advantages. The older people did not identify as many disadvantages as the healthcare professionals. In fact, for the healthcare professional, disadvantages cited outweighed advantages by almost two to one.

The difficulty of removing the medication from the MCA was discussed both by older people and healthcare professionals and is also a finding from the preliminary study.

The older people discussed problems experienced by themselves and also indicated how others might have problems using the devices. Some healthcare professionals held very strong views about the difficulty of using a MCA; these views usually concerned the lack of assessment carried out by colleagues in another sector.

Despite some healthcare professionals stating that MCAs did act as a memory aid, the majority thought that MCAs did not act as in this way and that this was a disadvantage. The healthcare professionals also stated that MCAs are not suitable for those older people with cognitive impairment; these statements were all anecdotal, that is based on clinical experience, as little research appears to have been carried out in this area. Research with cognitively impaired older people presents problems because Research Ethics approval usually requires the study subjects to be able to give informed consent. Therefore subjects who cannot provide this consent will not be included in the study. A study of older people discharged from hospital into the community investigated the relationship between cognitive impairment and medication adherence (Conn, Taylor and Miller 1994) This study is rare in seeking to investigate the abilities of the cognitively impaired, however the authors do state that the participants had only moderate impairment. It appears that both groups managed their medication well although twice as many of the cognitively impaired group received help from a third party than did the cognitively intact. In another study (Botello and Dudrak II 1992), adherence to long term medication was not associated with impaired cognitive abilities although, as the authors indicate, the study was limited by the small number of participants. In contrast several of the self-filler group stated that a characteristic of someone who received a MCA filled by the pharmacy might be confusion or dementia. Similarly one of the pharmacy-filled group wondered if she might have been issued with a MCA because someone thought she was confused.

The pharmacists were the only professional group to discuss the problems which might occur post-discharge if the community pharmacy provides a different MCA to the one issued by the hospital. Presumably other healthcare professionals are unaware that this might happen. Approximately a quarter of the older people interviewed had experienced a change in the MCA. The reasons for this were either a change on hospital discharge or a change of device by the community pharmacy. This change was met with very different opinions; some older people coped very well whilst others were unhappy with the change. This change of device for whatever reason appears to be an important issue and should only be undertaken with clear counselling by a suitable professional. One of the youngest healthcare professionals interviewed observed that not all MCAs are set up in the same way and the days and dosage times can be in different positions. Careful instruction is required to make sure that errors do not occur. The underlying issue here is that the older person should be assessed and if a MCA is deemed to be necessary then the most suitable one for that older person should be chosen and continued. Further assessments would then be necessary at intervals to check that the MCA is still suitable.

We have seen that the inability to identify the medication in the MCA was highlighted as a disadvantage both by older people and the healthcare professionals. The older people felt the need to be able to identify the tablets in the MCA for a number of reasons. These included to check the right medicine had been dispensed and to correctly identify a medicine they didn't want to take. Healthcare professionals also acknowledged this problem particularly relating to generic medicines which might have a different colour, shape or markings. This means that the older person may become unsure about the medication in the MCA and may be more likely to become confused by the changes, effective counselling led to a decrease in confusion and a lessening of

fears. We have seen that the older people who receive a MCA are sometimes less likely to receive any face-to-face counselling about their medication.

So the removal of the medication from the original packaging removes a point of reference and means that the older person cannot check if the correct drug has been dispensed. Those older people categorised as “expert patients” are most likely to be the ones who notice changes to the medication or who adjust doses of medication according to symptoms or health beliefs. This behaviour is unlikely to change because a MCA has been issued and therefore more problems may occur.

The older people categorised as “uninterested in medicines” are not likely to be concerned about identifying medicines and therefore not be aware of changes to their medication or dispensing errors.

Only three healthcare professionals observed that not all medication can be put into a MCA - two of these were pharmacists and one was a nurse. The pharmacists were concerned about stability and while the nurse was aware of this, she also mentioned ‘when required’ medicines, which also can cause a problem. Research carried out with community nurses in Scotland (Stewart *et al.* 2001) discovered that 51% of those interviewed stated that they did not know of any drugs which should not be dispensed in a MCA. The majority of the older people interviewed in the main study had other medication which was not in the MCA; and, in contrast to the healthcare professionals, none said that this was a particular disadvantage, although having to remember to take weekly medication was remarked upon. Approximately half of the interviewees in the preliminary study had medication which was not in their MCA and the majority stated that this presented no problem. This particular aspect of MCA use does not appear to have been studied.

The healthcare professionals discussed another aspect of the use of MCAs, which was 'practicalities of supply'. The themes in this section all related to problems which the healthcare professional might experience when arranging or dispensing in a MCA. Although these problems might constitute disadvantages for the older person these were not themes discussed by the older people.

The fact that not all community pharmacies will dispense in MCAs was discussed by a third of the healthcare professionals. This might mean that the older person would get their prescription dispensed by a different pharmacy to the one they had used regularly before. This raises the prospect of older people obtaining dispensed medication from two different sources resulting in incorrect patient medication records (PMRs) and the possibility of some medication being dispensed twice and some medication not being dispensed at all.

Although the older people were worried when different medicines appeared in the MCA, no mention was made of the problems which could occur if a new medicine was prescribed or a dose changed which required alteration to the drugs in an already filled MCA. Just one older person mentioned the changes to dosage which might occur with her warfarin. However she explained that the pharmacy would receive instructions from the hospital and would then arrange to make any changes to the medication in the MCA. The interviewee was full of praise for the system. This is in complete contrast to statements made by a number of healthcare professionals regarding the problems they now face because of the increased use of warfarin by older people. Both community and hospital pharmacists discussed the need to change the dose of the warfarin and explained that if a new MCA had just been delivered there could be a delay in the new dose being implemented. The junior nurse working in primary care pointed out that

dose changes and new medication often meant that she had to visit the pharmacy to obtain a new MCA for the patient.

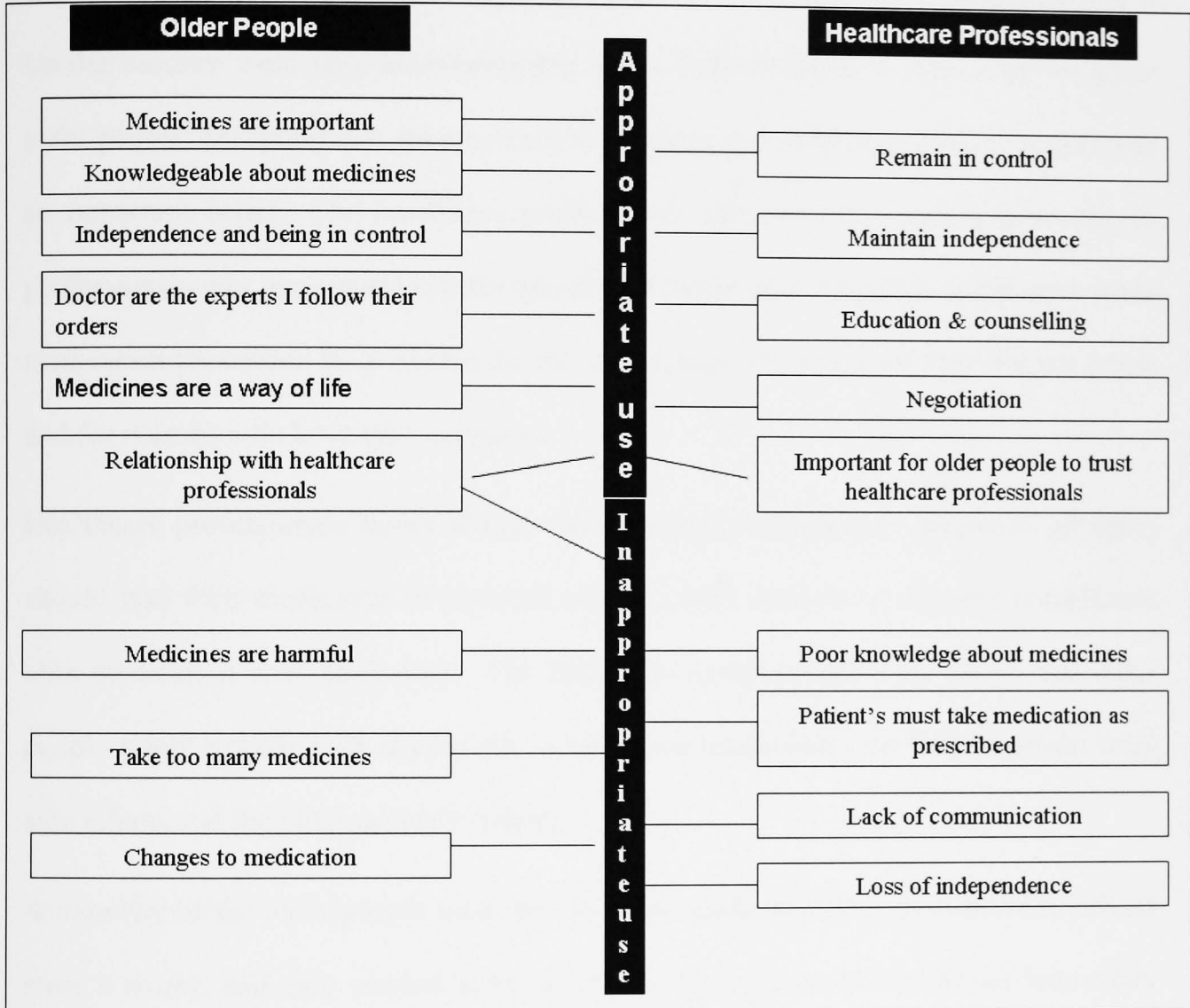
Errors were discussed by both older people and healthcare professionals. The older people were worried that the pharmacist might make a mistake when dispensing the medication and this was the reason why the self-fillers were happy to fill the MCA themselves. The self-fillers stated that they liked to be in control and that they had no problems filling the device, and the healthcare professionals were happy to suggest that older people did this for themselves. However there could be a danger that the older person could make a mistake. The ability of a group of arthritis patients to correctly load their medications into three types of over-the counter medication organisers was investigated in the USA (Park *et al.* 1991). This small study showed that patients do make errors filling these devices and that these errors are related to the number of medications the participants are taking. The healthcare professionals in my study who suggested that older people could be provided with a device to fill themselves did not express any concerns about accuracy and did not state that they would check the older person's ability to carry out this task. Among the healthcare professionals there was some enthusiasm for devices being filled by an informal carer and again there is the concern about accuracy. The Intermediate Care pharmacist stated that she had 'trained' some family members to fill a MCA and the Primary Care nurse discussed a 'responsible' family member filling the device. One of the older people interviewed whose MCA was filled by a family member described how this family member refused to allow anyone else to fill the MCA despite this causing problems when she went away. The relative who filled the MCA was said not to trust anyone else to fill the MCA correctly.

8.3.3 The health beliefs of the older people and the healthcare professionals.

The main focus of this study was to determine whether beliefs and attitudes of both sets of interviewees affected the use of MCAs. The topic guides for both sets of interviewees was designed to ascertain what health beliefs the interviewees might hold. In Section 6.7.3, I discussed the health beliefs and attitudes held by the older people and in Section 7.7.5, I explored the health beliefs and attitudes of the healthcare professionals.

Figure 18 below illustrates the health beliefs of the older people and the healthcare professionals and shows how these health beliefs affect the use of a MCA.

Figure 18: Comparisons of the themes relating to beliefs and attitudes regarding use of MCAs and medication.



The comparison of the beliefs and attitudes of the older people and the healthcare professionals shows both similarities and differences.

Both older people and healthcare professionals identified independence as being important. For the older people independence meant being in control and therefore this belief was unlikely to lead to use of an MCA with the exception of those who were self-fillers. The healthcare professionals saw independence as both a hindrance and an encouragement for use. This means the healthcare professionals must identify the older

person's opinions about their independence. Providing a MCA to someone who sees this as indicating a loss of their independence could result in failure to use the device and a breakdown in the healthcare professional / patient relationship.

A large majority of the older people thought that medicines were important and a similar number were very knowledgeable about their medication. However for some older people, accepting that doctors were the experts and following doctors' orders was an important belief. The healthcare professionals identified that trust in a healthcare professional was important for older people and noted that difficulties could arise when medication prescribed by a trusted doctor was changed by someone they did not know and for reasons which weren't explained.

Healthcare professionals believed that older people (and probably people of all ages) should take their medication as directed and therefore methods to improve compliance with medication were important. The healthcare professionals were aware that older people might intentionally decide not to take their medication; the reasons given were side effects and the older people's beliefs.

A minority of the older people took the view that medicines were harmful, side effects were a worry, and they needed to be certain that any prescribed medicine was really necessary. One of the older people interviewed was of the opinion that doctors were too keen to write prescriptions at the "drop of a hat".

The healthcare professionals were asked specifically if they recognised intentional non-compliance among their patients. The majority stated that they did and their views on the causes agree with the views of the older people. Side effects were seen as an important cause of intentional non-compliance as were poor understanding among older people of how their medicine worked and the best way to take it. However the

healthcare professionals thought that a good deal of intentional non-compliance was due to the patient's own beliefs about medicines, i.e. that they were taking too many, they are fed up with taking the tablets, or they think their illness has improved and they don't need to take the medicine any more. The healthcare professionals attitude to this varied, some respected the older peoples' decisions, but some took a different approach as discussed in Section 7.7.5.

The healthcare professionals had many solutions to the problem of non-compliance including issuing a MCA. However if the non-compliance is intentional it is unlikely that the MCA will have any effect. Many healthcare professionals discussed communication as a good means of improving the older person's compliance and many studies have been carried out looking at such ideas (Opdycke *et al.* 1992, Lowe *et al.* 2000a). Both these studies found that education programmes improved medication compliance and knowledge. This idea of communication is supported by the older people who often expressed a wish that they were better informed about their medication.

Both the interviews with the older people and the healthcare professionals produced themes which were categorised as "6pm warfarin" and this category gives an insight into the health beliefs of both groups. Five older people had been prescribed warfarin, four were still taking it at the time of interview and one had had the prescription changed after a fall led to bleeding and hospitalisation. This particular interviewee was very articulate about her medication and knew that the bleeding in her knee joint was due to her warfarin treatment. She was adamant that she had taken her medication correctly prior to the accident although the unannounced arrival of the Dosett® box immediately after discharge may indicate that there was a level of non-compliance. The problems arose because the first MCA contained neither warfarin nor clopidogrol

leaving her for a week without treatment and the next MCA contained both. It is hardly surprising that this lady was reluctant to use her MCA.

The other participants also reported excellent compliance with their warfarin and stated that “*warfarin was special*” and they never forgot to take it. Research studies have investigated the influence of compliance on anti-coagulation control with warfarin (Kimmel *et al.* 2007, Engova, Duggan and MacCallum 2002). Kimmel *et al.* monitored patients from anticoagulation clinics in the USA for a mean of 32 weeks. Compliance with the medication was measured using a Medication Event Monitoring System (MEMS). The MEMS device records the removal of the bottle top and thus gives an indication of compliance. The results showed that poor compliance with warfarin medication does lead to poor anticoagulant control and that even small variations in compliance can lead to clinically significant changes in anticoagulation. The older people in this study indicated that they did take their warfarin exactly as directed and rarely if ever forgot a dose. The older people interviewed shared a belief that warfarin was important to maintaining their health and showed some understanding of the side effects.

In a preliminary study undertaken by Engova (2002), a survey of patients attending a hospital based anticoagulant clinic identified compliance from total plasma levels of warfarin. Subjects were also questioned about their levels of compliance, health beliefs and knowledge of medication. Sixty percent of the patients recruited had INRs within the standard therapeutic range on two or all three occasions; 93% knew the indication for warfarin and all the patients knew their current dose. Three quarters of the patients took their warfarin in the evening and the researchers explored the reasons for this, noting that 92% of the patients whose warfarin was started in hospital took their dose in

the evening. Engova and colleagues concluded that lack of compliance was not the main cause of instability in warfarin controlled anticoagulation.

The two studies quoted above have reached different conclusions with one study identifying non-compliance among the patients taking warfarin and the second study reporting a degree of compliance. The two studies investigated a similar number of patients attending anti-coagulant clinics, the mean age of the patients in the Kimmel study was 58.5 yrs and in the Engova study was 67 years, there were more men in the Kimmel study. The Engova study findings are very similar to those in this study with interviewees reporting high compliance in conjunction with a 6pm dose.

The senior secondary care nurse interviewed also supported the view that older people were meticulous in taking their warfarin at 6pm and she remarked on the fact that some older people became quite distressed if the dose was not given on time. The pharmacists interviewed were aware of the 6pm dose regimen and the reasons for it and reported some level of resistance among other staff if the dose was changed to the morning. For some older people, changing the warfarin dose time to breakfast time would be better especially if all other medication is taken at this time. Provided the medication is always taken at the same time and the anticoagulant clinic knows when the dose has been taken there is no clinical problem.

A bigger problem may be caused by the time lag which may occur between the INR test being carried out and any change of dose being actioned. One of the community pharmacists spoke at length about the difficulties encountered because of the large number of older people taking warfarin (the number of has increased in recent years due to the guidelines on the treatment of AF). A time lag may occur if the dose change was implemented on the days following the issue of a new MCA. If another box is not

sent out then the patient may wait a week for the new dose to be included. This may have implications for subsequent INR results as research (Kimmel *et al.* 2007) has shown that even small numbers of missed tablets can affect the anticoagulant range. A patient safety alert in relation to anticoagulant therapy has recently been published (National Patient Safety Agency 2007). This safety alert suggests that the use of MCAs for anti-coagulants should be minimised.

The majority of the older people interviewed stated that they did take their medication as directed; however there was some indication of intentional non-compliance. Some interviewees were also worried about taking too many medicines and they were also concerned about side effects. These feelings are supported by various qualitative research studies which have looked at patient's beliefs about medicines. Horne (2004) discussed two factors which appeared to influence patients when making decisions about medicine taking. These two factors were the extent to which the medication was needed and the risks involved in taking it. The older people interviewed have also discussed these issues.

The healthcare professionals also had very strong attitudes towards other healthcare professionals often pointing a finger of blame at someone else. So the community pharmacist states that it is the hospital staff that drive the issue of MCAs in order to discharge older people more quickly. The secondary care staff state that, if the older person is receiving home care, then a MCA must be issued. The staff in Intermediate Care seemed the happiest to make their own decisions based on assessing the patient. Finally one General Practitioner accused the community pharmacists of initiating MCA use in order to gain more dispensing fees. This comment highlights the lack of understanding among other healthcare professionals regarding the funding of dispensing. The community pharmacists' concern over the lack of funding for MCAs,

was discussed in Section 2.5.5. This culture of blame and accusation does not encourage co-operative working among the different professions. There is a great deal of misinformation circulating concerning the use of MCAs within all sectors of healthcare and this attitude does not assist the appropriate use of these devices. Research has been undertaken into inter-professional team-working (Molyneux 2001; Snelgrove and Hughes 2000) however this has concentrated on those healthcare professionals working in multi-disciplinary teams. The healthcare professionals interviewed in my study were not referring to other healthcare professionals on the same team but someone working in another place and often in another sector of the NHS. Frequently the complaints could have been resolved if communication between the different professions and sectors had been better. One interviewee who received a complaint from a healthcare professional in another sector concerning older people discharged with a MCA they could not use, took steps to ensure that a more rigorous assessment was undertaken in future.

The healthcare professionals expressed strong beliefs about compliance with medication. This was despite apparently accepting that older people should make their own decisions about their medication and that these decisions be respected. There was an underlying belief that medication should be taken as prescribed. During the course of the interviews the pharmacists did discuss the issue of concordance, but for the other healthcare professionals this was an unfamiliar expression, a minority were able to define what concordance meant and others did explain that they would talk to the older person about their medication. Healthcare professionals' attitudes to concordance are discussed later in this chapter.

Changing a person's beliefs or behaviour can be complex and this process plays an important part in health promotion. This suggests we should look to the strategies used

in such activities as smoking cessation. We know that, in order to give up smoking, a patient has to have reached a certain point on the transtheoretical model of behaviour change as described by Prochaska and DiClemente (1982). Only then can the various smoking cessation methods be discussed and the most appropriate method decided on. In the same way, it is of little value to issue a MCA to a person who has decided not to take their medication unless this process has been preceded by counselling or an education programme. Research into non-compliance with post-transplant medication has looked at exploring the use of behaviour change for improving compliance with medication (Robbins 1999). The cycle of change consists of five stages: precontemplation, contemplation, preparation, action and maintenance. Patients who are in the first stage are not ready to take action even if the action is lifesaving or life enhancing. Patients in the contemplation stage are more aware of the benefits but are easily discouraged by side effects or inconvenience. Those patients in the preparation phase are poised for action; they see the benefits and are keen to continue with treatment. Those patients in the action phase have begun to take the medication but only for a short period of time. However they see the advantage and believe they have the ability to continue. Finally, those patients in the maintenance phase have adjusted their life to include taking their medication and feel they are able to continue. Older people who intentionally do not take their medication as directed will therefore need more support than simply issuing a MCA. Although some studies investigate the use of educational strategies, there appears to be little work done on changing the behaviour of older people in this context.

8.3.4 Age and Ageism

A third of the older people interviewed in this study complained of some form of ageist treatment. Being treated like a child or being 'talked down to' were two commonly

occurring themes. Other interviewees related occasions when healthcare professionals assumed that they could not understand the instructions or the diagnosis which was being given. This assumption of a lack of understanding was then made worse by giving the information to a relative or carer. The older people felt ignored and belittled. The provision of a MCA was not seen as ageist although three interviewees thought that other people might be insulted by being given this type of help. There was also the thought, expressed by the self-fillers and by one of the pharmacy-filled group, that receiving a pharmacy-filled MCA indicated a decline in mental faculties. The majority of the interviewees were anxious to point out that they still had their mental faculties, describing completing crosswords, describing their hobbies and just simply remarking that they were 'all there'. Clearly losing ones mental faculties is a fear that many older people will have, we are reminded frequently in the press of the increasing incidence of Alzheimer's disease and other forms of dementia and that the incidence of dementia in the over 80s is 1 in 5. Receiving a MCA may suggest to some older people that they are thought to be losing their faculties and this may cause distress.

The healthcare professionals were all well aware of the requirements of the NSF for older people (Department of Health 2001) regarding ageism. Approximately a third of the interviewees agreed with views expressed by the older people concerning treating older people like children and being patronising. The majority of interviewees stated that they knew this occurred but it was others not themselves. A minority of the healthcare professionals admitted that their own behaviour might occasionally be regarded as patronising, although they stated that this was not intentional.

In contrast to the older people, who expressed a fear that healthcare professionals might consider that they were cognitively impaired, the healthcare professionals felt that many older people are in denial about their cognitive state. The healthcare professionals

supported this idea by stating that the families of older people would often report instances of mental confusion.

It is important to consider whether the issuing of a MCA is done mainly on age grounds, i.e. the person is over 65 and has a complex medication regime and there is a suspicion of non-compliance. It is well known that other groups of patients are at risk of non-compliance and have very complex medication regimes; however these patients are commonly in the under 65 age range. These groups include post-transplant patients and patients with end stage renal disease. The report “A question of choice – compliance in medicine taking.” produced for the Medicines Partnership (Carter, Taylor and Levenson 2004), looked at compliance in different groups of people including those mentioned above. The report consisted of a literature review supported by the views of individual patients and patients groups. The post-transplant patients exhibited high levels of non-compliance despite knowing that failure to take the medication as directed can lead to transplant failure and possible death. The strategies used to improve compliance in these patients and which were described by the report included oral and written information, videotapes, computer-based decision aids and the internet with no mention of MCAs. The post-transplant patients resemble older people in all criteria (i.e. possible life threatening effect of non-compliance, complex medication regime, side effects of drugs) with the exception of age, as very few transplant patients are over 65years. The question could therefore be asked: “Are older people missing out on more rigorous strategies to assist them with taking their medication?”

8.4 Exploration of key findings.

The aim of the thesis is to determine how the attitudes and beliefs of older people and healthcare professionals affect the use of multi-compartment compliance aids by older people living in the community. The key findings are described below and summarised in figures 19. and 20.

The thesis begins with a preliminary study which provided background information for the main study. This preliminary study raised a number of questions concerning the use of MCAs by older people living independently in the community. Part one of the preliminary study indicated that the number of MCAs in use in primary care was much higher than had been initially thought. A prior literature review had indicated that the evidence for the use of MCAs was sparse and this raised the question “why were so many MCAs in use when there was no solid evidence that the use improved compliance with medication?”

The literature review as described in Chapter 3 was undertaken in order to obtain a more definitive view on the efficacy of MCAs. The studies reviewed were divided in their opinion on the value of MCAs and suggested that more rigorous studies needed to be undertaken.

The main study investigated the use of MCAs by older people and sought to discover their attitudes and beliefs concerning not only the use of a MCA but also medicines management and their health. Healthcare professionals were interviewed to discover their attitudes to MCA use and their beliefs about older people and their medication.

Reviewing the data obtained from all sections of the thesis leads, in the first instance, to enquire what triggered the issue of the MCA. The interviews with patients in the

preliminary study and the older peoples' interviews in the main study indicated that hospitalisation and subsequent discharge was the most frequent trigger. However a majority of all interviewees were uncertain about the reason for the issue. Data from both the preliminary study and the main study indicated that many older people found their MCA both convenient and easy to use. However there was little indication that the users thought that using the MCA improved their compliance with medication. Delivery of the MCA and organisation of repeat prescriptions by the pharmacy were seen as advantages, however there was evidence in both the preliminary and the main study that this may disadvantage the recipient because contact with the healthcare professional is lost. The MCA user also becomes distanced from their medication receiving just an anonymous collection of multicoloured tablets and capsules with no means of identification.

Those people who made this decision to use and fill a MCA themselves, i.e. the self-fillers, saw themselves as independent and in control. They were responsible for their own medication supplies and retained contact with healthcare professionals. However using a MCA removed the need to think about their medication for the majority of the week.

The problems encountered by the older people using the MCA were initially discovered during the preliminary study and were similar in the main study. Interviewees found it difficult to remove medication from the MCA and often resorted to their own methods to resolve the problem. The healthcare professionals were well aware of these difficulties but never-the-less there was little indication of an assessment of the patient prior to issue. The review of the literature on MCAs revealed very few studies on the ability of patients to use these devices; studies were mainly concerned with discovering whether using a MCA improved a person's medication compliance.

One of the key findings of the main study was the importance of independence and remaining in control for the older people interviewed. The importance of independence and control to the older people was also recognised by the healthcare professionals. The importance of independence and control to some of the older people can indicate their personal beliefs concerning their health. These beliefs have been interpreted using various social control models. Wallston (1982) discusses the degree to which individuals believe they are responsible for their health. Those individuals who believe they are directly responsible are described as exhibiting “internal” control. While those who believe that other people are responsible are said to exhibit “external” control. Therefore those older people who state that they are independent and in control may be unhappy receiving their medication in a MCA which removes an element of personal control. For those older people who were happy to “follow doctors orders”, that is they exhibited “external” locus of control, then accepting a MCA would be in keeping with their beliefs.

The majority of the older people interviewed gave details of their lives and how this had affected their current state of health and quality of life. I realised, as I listened to their stories that taking their medication as directed was, for many of them, not high on their list of priorities. Conrad, writing on the experience of illness (Conrad 1987), states people who are sick spend only part of their time in a patient role and that this role may not be the most important thing in their lives. Therefore the older person may welcome the issue of a MCA because it allows them to take less time managing their medicines and enables them to get on with their everyday lives. In a similar vein Charmaz(1987) states that people with chronic illnesses do not want to be seen as patients first and people second, they wish to be seen as individuals living a life outside of their illness. This agrees with the symbolic interactionist theory as described by Mead (1934) who

describes the role of self as looking back at oneself from the other's perspective. The older people whom I interviewed did not wish to be seen as patients who used a MCA but as individuals who were trying to accommodate their illness within the context of their everyday lives.

Another key finding which emerged from the study is the belief of the healthcare professionals that medication should be taken exactly as prescribed. Despite some of the healthcare professionals stating that they would respect the older person's decisions not to take a particular medicine, the underlying feeling is always that the doctor prescribes and the patient responds by taking what is prescribed; if this were not the case MCAs would not be issued. This type of belief is much more in line with the functionalist approach as described by Talcott Parsons (1951). There was little indication that the healthcare professionals would discuss medication management with the older people and identify any problems and listen to the older person's point of view. Considering that the healthcare professionals were, in the main, aware of the limitations of these devices their actions seem open to question. However the healthcare professionals' actions in supplying a MCA routinely to patients who fit a certain criteria can be interpreted as "being seen to do something" or, as one pharmacist interviewee put it, "to tick a box". These actions therefore can also be interpreted by interactionist theory, with the healthcare professional needing to be seen by other healthcare professionals as addressing a problem. In addition to this need, healthcare professionals are also under pressure from NHS management to follow treatment guidelines and once again the healthcare professional needs to be seen to be adhering to these guidelines despite the fact that this may not be in the best interest of the patient. This aspect was discussed by the doctors interviewed, in particular the Care of the Elderly consultant and the pharmacist working with the Intermediate Care Team.

The question which I have to ask is ‘is compliance really necessary?’ Although the earliest reference to compliance with medication is often stated to have been made by Hippocrates the literature starts in earnest in the 1950s with the introduction of new and powerful drugs, for example antibiotics. A study in the *Lancet* in 1957 (Dixon, Stradling and Wootton 1957) investigated compliance with the anti-tuberculosis treatment P.A.S. The study tested the urine of outpatients with tuberculosis who were being treated with P.A.S. (a combination of isoniazid and p-aminosalicylic acid). The results showed that only 50% of the patients tested had been taking the medication despite professing to the contrary. The authors concluded that the non-compliance was due to the unpleasant side effects of the drug. However their attitude to the patients is interesting, the article starts with a quotation from Hilaire Belloc’s *Cautionary Tales*:

*“Matilda told such Dreadful Lies,
It made one Gasp and Stretch one’s eyes”*

Further on in the article, patients are described as ‘untrustworthy’ and the article goes on to describe how ‘many tablets can be found scattered in flowerbeds surrounding some of our hospitals’. The authors draw the conclusion that this drug is unsuitable for outpatient use, in other words, the patients must be supervised strictly while taking this treatment. It is easy to understand the worries and frustrations of these authors, effective treatments for tuberculosis was relatively new and they were already aware that resistance to treatment might develop. Studies into non-compliance with medication continued to increase and by the year 2007 the number of studies identified by a MEDLINE search using the Mesh term Patient Compliance was 11913. This interest in compliance with medication indicates the importance placed on the subject by the healthcare profession, however not everyone see compliance in the same light. James Trostle (a medical anthropologist) argues that compliance with medication is

itself the problem,(Trostle 1988) Trostle goes on to state that many articles have been written about the causes of non-compliance and the methods used to address the problem, but few have asked why this subject came to be so important. In the introduction to his article, he states that rather than being concerned with improving medical treatment it is, albeit covertly, about power and control. Another article, written ten years later, also discusses non-compliance and professional power (Playle and Keeley 1998). Playle and Keeley discuss the history of research into non-compliance with medication and again pose the question “why has the issue of non-compliance in healthcare become such a major focus of interest and research?” The article concludes that this increase in interest in non-compliance while appearing to research strategies and interventions to improve compliance actually seeks to justify and reinforce professional authority and power. The article goes on to say that healthcare professionals should re-think the professional – patient role and consider patients as active participants rather than passive recipients in their own healthcare.

This theory leads on to the introduction of concordance as discussed in the report by the Royal Pharmaceutical Society (1997). This report described concordance as a negotiation between prescriber and patient. During the healthcare professionals’ interviews the pharmacists did discuss the issue of concordance, but for the other healthcare professionals this was an unfamiliar expression and only a minority were able to define what concordance meant. Others did explain that they would talk to the older person about their medication. A study investigated whether it was possible, by using extended consultations, to achieve concordance with ‘non-adherent’ patients (Dowell, Jones and Snadden 2002). This study was unusual because the researchers combined a qualitative study of extended consultations with “Balint” style clinical meetings (Balint 1969). These “Balint” style meetings, enabled the clinicians to discuss

the transcripts of the consultations allowing development of the consultation strategy. As a result of the qualitative study the researchers developed a model for undertaking this type of consultation. The researchers noted the limitations of their study but stated a belief that this type of consultation was likely to improve clinical outcomes.

The lack of understanding of the term concordance among the majority of the healthcare professionals suggests that more education needs to be undertaken possibly at undergraduate level. A training plan for healthcare professionals has been suggested (Weiss 2004) which focuses not only on developing communication skills but also requires the professional to reflect on the influence of personal values on patient relationships.

The subject of concordance has been discussed in a number of articles and editorials in the medical press, often with a less than favourable tone (White 2003; Ferner 2003). In an education and debate article (Heath 2003), the author argues that although compliance can be seen as embodying the belief that ‘doctor knows best’, concordance, while paying lip service to mutual respect between the prescriber and the patient, actually conceals a level of coercion. Therefore there is still resistance and a lack of understanding of the nature of concordance.

The final key finding relates to age and ageism. I have previously discussed the fact that relying on chronological age as a marker for “being old” is unreliable. We are frequently told both by government organisations and the press that we live in an aging society and that this will cause financial problems in years to come. In Sections 1.6.1 and 1.6.2. I have described the increase in the elderly population and the level of medication use by older people. These figures can lead to the assumption that as we age we will succumb to poor health and increased medication use, leading to concerns

regarding the cost to the NHS of an ageing population. However this picture of a large population of chronically sick older people may be a misconception. Tallis in his book (2004) states:

the vast majority of people in later life enjoy excellent health or have health problems that are sufficiently under control not to be a barrier to the enjoyment of a reasonably full life. P. 226

Linked to this discussion concerning the health of older people is the concept of the “medicalisation of old age”. Medicalisation is a term used to describe a process through which a largely social problem is re-defined as a medical one. Therefore ageing is seen as a problem which needs to be solved by medical intervention rather than a natural process which occurs throughout the lifespan. It has been suggested that this biomedical approach is responsible for a construct of ageing as a time of decay and decline (Koch and Webb 1996). Healthcare professionals who concur with this model may succumb to negative stereotyping of old age. However the opposite opinion is held by others within the medical professions who see medicalisation of old age as something to be encouraged (Ebrahim 2002). Ebrahim states that although medicalisation should be encouraged it can also be dangerous. He continues that there are legitimate concerns concerning over-prescribing, hospital acquired infections and the use of tranquillisers for restraint, but concludes that: “Attempts to ration such care on the grounds of the fair innings argument or by chronological age are flawed” p863.

How do these arguments impact on the issue of MCAs? From Koch’s (*op. cit.*) point of view biomedicalisation leads to negative stereotyping and this may well lead to the inappropriate issue of a MCA. In contrast, Ebrahim (*op. cit.*) would argue that older people are entitled to all medical interventions irrespective of chronological age or age stereotyping and therefore the issue of a MCA may assist an older person to organise what may inevitably become a complex regime.

The healthcare professionals interviewed held the belief that older people were more forgetful despite the fact that this has not been conclusively proved by research. This negative stereotype of the forgetful older person is common in our society and there is evidence to suggest that older adults respond to these attitudes by altering their behaviour (Hess 2006). Therefore the older person may expect to become more forgetful and accept the MCA despite being capable of managing without it. The underlying belief of healthcare professionals when a MCA is issued is that the device will assist the older person to take their medication exactly as intended by the prescriber. All the research undertaken attempts to discover if the compliance rate improves when a MCA is supplied. This suggests that the underlying reason for issuing an older person with an MCA is to ensure that medication is taken as directed.

What seems clear is that healthcare professionals should not base the treatment of older people purely on the grounds of chronological age but on the assessment of their individual risk (Grimley-Evans 1997). A concordant or shared decision making approach should be taken with all possibilities discussed, this should lead not only to better and more appropriate treatment but the more appropriate use of MCAs.

Key messages for staff and policy makers.

Figure 19: What was known about this subject prior to this work being undertaken

MCAs assumed to be the ideal solution for older people having problems managing medication.

There was very little evidence to support this view.

The numbers of MCAs issued was unknown.

Figure 20: What information has this work added to what was already known

The preliminary study indicated that large number of MCAs were being issued to patients despite little evidence for their use.

The literature review in the main study revealed a lack of robust studies on the use of MCAs and little evidence of effectiveness

The main study has provided the following information:

For older people the need to remain in control of their lives and maintain their independence is of great importance. The effect of this is often under estimated by healthcare professionals

There was evidence of ageism within the NHS despite all healthcare professionals being aware of the problem. The issue of a MCA could be seen as ageist by some older people and there was little evidence to show that people were consulted about the issue of a device.

Paternalistic ways of working were much in evidence and this was admitted by the healthcare professionals. In particular as pharmacists we must learn to look beyond the medication and our desire to ensure that all medication is taken exactly as prescribed and consider the older person in a more holistic way.

Healthcare professionals must question their own beliefs about compliance with medication. Do we allow older people to make their own decisions about taking their medication? Are MCAs used to ensure that older people follow our instructions? Are they in fact a means of social control?

MCAs are too often seen as a quick and relatively easy method of hastening hospital discharge and providing evidence for other healthcare professionals that the older person's ability to manage their medication has been addressed.

8.5 Limitations of the thesis findings.

The preliminary study aimed to provide a picture of the supply and use of MCAs in one health authority area at one moment in time. The response rate from part one of the study was sufficiently high to provide an indication of the numbers of MCAs which might be in use in the country as a whole. The randomly selected sample of community pharmacists was small but representative of the pharmacies providing this service across the health authority area. The structured nature of the questionnaire limited the information provided by the pharmacists. Although the final question asked the pharmacists if they would like to provide any additional information about the use of MCAs this did not allow for an in-depth discussion. Therefore the information obtained from the pharmacists concerned who requested the issue of a MCA to a patient, and the procedures that followed such a request. This information highlighted further areas for research. The results from part three of the preliminary study were limited by the very low recruitment rate which has been discussed in Section 2.6.3. In addition the structured nature of the questionnaire meant that the data obtained was limited to a narrow field mostly concerning the interviewees' ability to use the MCA and their knowledge of the medication regime. However the results from this study did suggest further areas for research.

Chapter 3 comprises a detailed review of the literature concerning the use of MCAs. This review was undertaken in order to determine the depth of evidence concerning the efficacy of MCA use. The review of the literature undertaken before the start of the preliminary study had indicated that the evidence was limited but it was necessary to establish, as far as possible, the full extent of the evidence. The literature review was limited to studies which had MCAs as the main focus. The main study in this thesis

was undertaken using Grounded Theory methodology and followed the methodology of Strauss and Corbin (Strauss and Corbin 1998) which allows for a limited review of the literature to be undertaken prior to the start of the research. However, as recommended by Strauss and Corbin, I did not review all the literature in the field of compliance prior to starting the main study. Instead, as each interview was undertaken and analysed and new themes emerged, I searched for literature in these areas. The research studies were then woven into the discussion of the analysis. Carrying out the main review of the literature in this way allows for flexibility in literature searching, but does not provide a formal description and discussion of the search methods and results.

The main study was undertaken using Grounded Theory methodology which allowed for much more flexibility in the interviews. The number of older people interviewed was small, however according to grounded theory methodology it is only necessary to continue sampling until theoretical saturation is reached and no new themes developed. This had occurred in these interviews and therefore a sample of fifteen was considered sufficient. Only two male patients were interviewed and this is not representative of the proportion of men in the over 65 population. Therefore it is not possible to detect from the data if gender has any influence on older people's attitudes and beliefs. The percentage of male interviewees in the preliminary study was 32% however the age range in that study was wider.

The sampling of healthcare professionals was theoretical, based on information obtained in the older peoples' interviews. Interviewees represented the three healthcare professions most likely to be involved in the issue of MCAs to older people and were working in primary, intermediate and secondary care. Any problem with these interviews may be due to the difficulties of interviewing fellow healthcare professionals

especially those from the same profession as the interviewer. There is a possibility for bias and this was discussed in Section 5.4.1.

8.6 Implications for policy and practice.

The findings of this body of work have some important implications for policy and practice.

8.6.1 The evidence for the use of MCAs by older people living in the community

The literature review described in chapter 3 concluded that the evidence for the use of MCAs by older people living in the community was inconclusive. This finding agreed with that of other systematic reviews which had investigated the same topic (Haynes *et al.* 2005; Heneghan, Glasziou and Perera 2006). It would appear, therefore, that a large number of older people are being issued with devices which have no evidence base for their use. In a short article a pharmacist posed the question “Is it ethical to use monitored dosage systems when efficacy is questionable?” (Gartside 2005)

This must surely be of concern to all healthcare professionals. The evidence for the use of these devices is very tenuous and it would be foolish to place too much reliance on their ability to improve compliance with medication.

On the practical side however, there is no doubt that these devices are popular with older people who find them convenient and easy to use and because of this factor medication compliance may improve. Equally, other older people do not like the devices or find them difficult to use and therefore, in these cases the use of a MCA provides a barrier to the appropriate use of medication.

8.6.2 Assessing the medicines management abilities of older people

The older people interviewed in this study gave no indication that their abilities to manage their medication had at anytime been assessed. The healthcare professionals

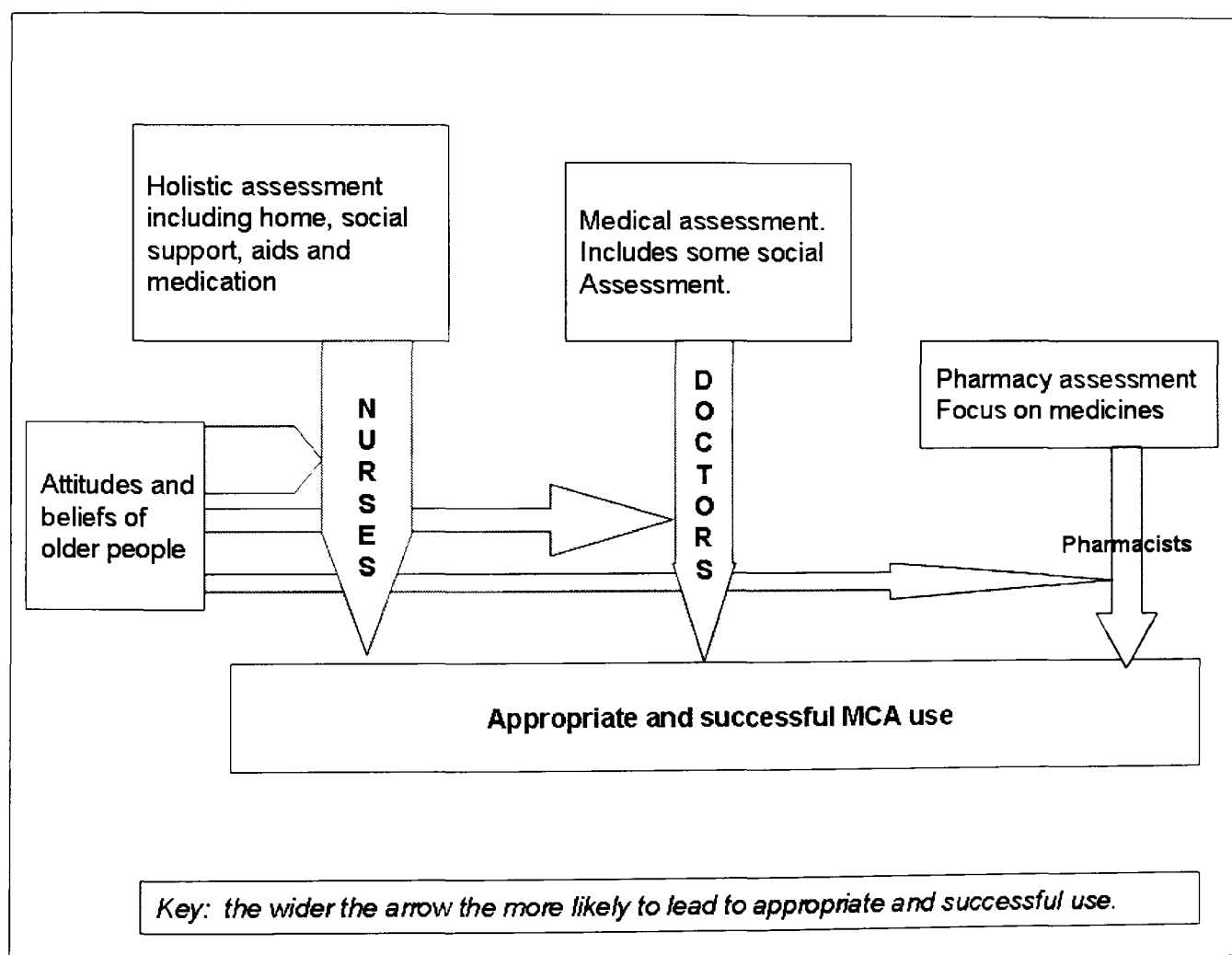
did indicate that some form of assessment took place under certain circumstances, with the staff working in Intermediate Care appearing to have the most robust systems. There were complaints from half of the healthcare professionals interviewed that they had observed older people who were unable to use the MCA which had been issued to them. The healthcare professionals concluded that in these cases no assessment had been carried out. However the data which emerged from the main study indicated that the assessment should not only include the physical abilities of the older person to manage the packaging, there must also be assessment of their understanding of the medication regime including names of drugs, therapeutic actions and possible side effects. Equally important are the older person's beliefs about their medication because, as has already been discussed, these beliefs can influence the older person's medicines management. Finally any assessment needs to be undertaken within the older person's own home, where the healthcare professional can place medicines management within the older person's daily routines.

Figure 21 shows diagrammatically the situation regarding the assessment of older people as discovered during both the preliminary and main studies. When a holistic assessment took place which covered not only the older persons' medication regime and their medical condition but also their lifestyle, social circumstances and concerns, then this contributed to more appropriate MCA use. If alongside this holistic assessment the older person was given the opportunity to have a major input into discussing their care then this led to even more appropriate use. The interviews with the healthcare professionals indicated that this type of approach was most likely to be taken by the Intermediate Care Team nurses. When a more medically orientated assessment took place by a doctor then the assessment was likely to be less holistic and the older person was likely to have less opportunity to express their own point of view. The least holistic

assessment appeared to be undertaken by pharmacists who focused on medication review, and in some cases but not all, to assessing the ability of the older person to use the device. The older person had least opportunity to put their point of view forward with the pharmacist.

This suggests that there needs to be a much more multi-disciplinary approach to assessment with more opportunity for the older person to express their own attitudes and beliefs.

Figure 21: Diagrammatic representation of the assessment carried out by the different healthcare professional groups



Although within secondary care the healthcare professionals discussed that the decision to issue a MCA would be taken by the multi-disciplinary team there seemed to be little opportunity for the older person to put their point of view. The older person would then

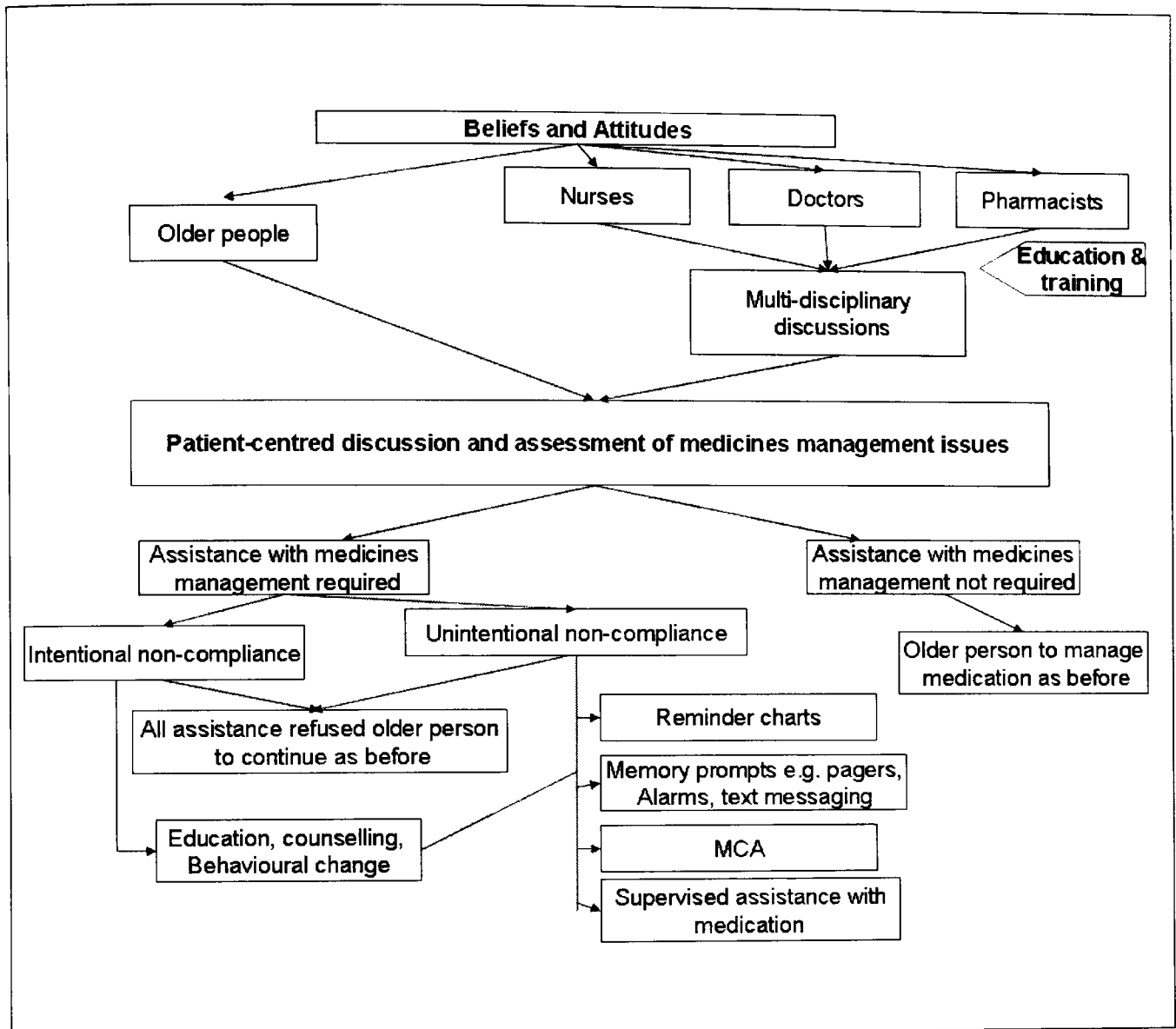
be discharged from secondary care and the provision of the MCA would pass to the community pharmacist. The MCA provided might be the same as the one provided on discharge or a different type. There was little evidence of further assessment or discussion with the older person. Therefore the community pharmacist needs to be included within the multi-disciplinary holistic assessment, which might also need to include the GP and primary care nurse. At all steps on the way the older person needs to be involved.

The Intermediate Care Team staff who were interviewed, described their assessment process, and this did approach the ideal format. However there still needed to be more multi-disciplinary discussion. One ICT where staff were interviewed had a pharmacist on the team as part of a research project. This provided the opportunity for medication reviews and pharmacist input but still left a gap regarding the provision of the MCA by the community pharmacy.

The interviews with the older people provided little evidence of a patient-centred approach when assessing their medicines management abilities. It has to be remembered that the issue of a MCA may not be the best solution for a particular person for a great many reasons and healthcare professionals should be prepared to consider alternative strategies.

Figure 22 below represents a method of approaching older people's medicines management issues, derived from the data obtained from both preliminary and main studies, and suggested as a way forward.

Figure 22: Diagram detailing a proposed method of approaching older people's medicines management.



The implications for both policy and practice can therefore be seen from Figure 21 above:

The beliefs and attitudes of both older people and healthcare professionals need to be taken into consideration. For the healthcare professionals this may mean more education and training around the issues of concordance, shared decision making or patient-centred approaches. Further training may also be needed to address stereotypical images of older people. For the older people more education on their illnesses and the place of medication.

Policies need to be put into place to allow more multi-disciplinary discussion of older people's medicines management within all sectors of the NHS. In particular these discussions should include the community pharmacist irrespective of which sector the discussions are held in. The community pharmacist has in the past been mainly seen as the provider of these devices and has had little input into the more holistic approach to an older person's medicines management. However the community pharmacist needs to be included in the discussion as he or she will be responsible for the ongoing provision of the device and will be the point of contact for the older person.

The assessment of older people needs to become much more patient-centred with the older person's point of view welcomed and valued. There needs to be acceptance of the fact that some older people can manage perfectly well and wish to continue with their own medicines management routine. Assessment also needs to identify the reasons for non-compliance (if it exists) as the strategies which can be used are different depending on the type of non-compliance, with a key difference being between intentional and non-intentional non-compliance.

Finally it should be recognised that some older people will resist any offer of help and advice and if this occurs after careful assessment and discussion then their wishes should be respected.

The assessment process I have described above is complex and will require changes in both policy and in practice. It should also be remembered that healthcare provision is a dynamic situation and the older people will not remain in the same condition after an initial assessment. Therefore arrangements must be put in place to revisit the assessment at regular intervals.

8.7 Implications for future research

Various implications for changes to policy and practice have been made in Section 8.6 and although these suggestions have been made based on the findings of this thesis it will be necessary to undertake further research to ascertain if these changes are effective.

The more holistic, multi-disciplinary assessment which I suggest will provide better medicines management for older people needs to be investigated thoroughly.

During the course of this thesis I have indicated that there is a lack of robust research into various aspects of the use of MCAs. The literature review in chapter 3 concluded that the standard of the few RCTs which looked at the ability of MCAs to improve medication compliance was poor. Therefore further studies, which are well constructed and conducted, are needed.

There are also other areas of MCA use which are under researched:

New studies are needed to assess the abilities of older people to remove the medication from the newer sealed disposable devices. The two studies identified which looked at ability to use (Atkin *et al.* 1994; Nikolaus *et al.* 1996) only investigated refillable MCAs.

The safety of MCAs has not been investigated in this country despite there being anecdotal evidence that serious problems do occur. The only study identified in the literature review (Levings, Szep and Helps 1999) was undertaken in Australia and therefore the level of errors is not directly applicable to the UK.

All the studies which investigate the use of MCAs do so in the short term, there is a need for a longitudinal study to investigate how a patient's ability to use the device may deteriorate over time.

8.8 Conclusion

This thesis has provided further insight into the use of MCAs by older people living independently in the community. The preliminary study highlighted the increased use of these devices in primary care. The interviews with both the pharmacists and the MCA users in the preliminary study indicated that little assessment was undertaken to determine the patients' medicines management requirements, few alternative strategies were suggested and there was little evidence of matching the MCA to the need of the patient.

The majority of previous research in this field has attempted to determine the ability of MCA use to improve compliance with medication and this research has been discussed in detail in Chapter 3. The literature review, however, highlighted that very little research had been undertaken to determine the attitudes and beliefs of both the older people who use these devices and the healthcare professionals who recommend the use of MCAs. This thesis aimed to rectify this situation.

The findings from the main study reveal that the beliefs and attitudes of the older people can influence not only their use of MCAs but also the role of medication within their daily lives.

The healthcare professionals were revealed, in some cases, to possess stereotypical views concerning older people and their ability to manage their medication. Despite having reservations concerning the use of MCAs, the healthcare professionals still recommended the use of these devices by older people.

This study challenges the view that what is required is more rigorously conducted RCTs of MCA use, which will provide a definitive answer to the question "do MCAs improve compliance?" The reality is much more complex with healthcare professionals and

policy makers alike needing to think beyond the simple action of issuing a MCA to providing more detailed assessment of older people's medicines management skills. In addition there needs to be a more concordant or Shared Decision Making approach with older people having the right to choose not to take their medication if that is their wish. Further research is therefore required to test out this new method of assessment and to develop a framework for assisting older people with their medicines management.

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Appendix 1. Preliminary Study

Self-administered pharmacist questionnaire

Administered pharmacist questionnaire

Administered patient questionnaire.

Patient leaflet and consent form

Community Pharmacists Questionnaire
Use of Multicompartment Compliance Aids (MCAs) in
Primary Care

Question 1.

Do you dispense medicines in MCAs to any patients living in their own homes?

Yes	
No	

If YES - about how many patients do you have at present?

If NO - Give reasons if possible

Question 2.

**Approximately how many patients living independently
at home do you have using each system?**

Dosett	
Medidos	
Nomad	
Other (specify)	

Question 3.

Would you be prepared to be involved further in the research?

Yes	
No	

Name and Address

Please return in the SAE provided

Thank you for your time.

**Use of Multicompartment Compliance Aids (MCAs) in
Primary Care**

Pharmacist's follow up questionnaire

1. In your experience who is the person who usually requests the dispensing of medicines in MCAs for patients living in their own homes?

doctor

carer

patient

social services

district nurse

hospital

yourself

Please rank the above answers 1 - 7 (1 is most often 7 is least often)

2. Once a request to dispense medication in an MCA has been received what procedure do you follow?

subsidiary questions to be asked if not found out above.

2a Is the patient assessed for ability to open the aid and remove medication?

YES NO

If YES - how?

2b Is the patient assessed for reading ability i.e. can the patient read the days of the week and the times?

YES NO

If YES - how?

2c. Do you counsel the patient about using the aid or is the aid delivered by the driver in the usual way?

ALWAYS

SOMETIMES

NEVER

2d. Do you first try to simplify the regime?

YES NO

2e. Do you check the drugs for stability in the aid?

YES NO

If YES - what information do you use?

2f. Does the pharmacy have a written procedure?

YES NO

3. Have you ever been pressured by other healthcare professionals to dispense medication in an MCA even when you know that the use is inappropriate; or has this not happened?

If yes:

how often does this happen?

what action would you normally take?

4. Have you ever been pressured by the patients family to dispense medication in an MCA?

if yes:

how often?

what action would you normally take?

5. Who fills the MCAs?

- pharmacist
- qualified dispenser
- unqualified dispenser
- counter assistant

6. Who checks the dispensing if this is not carried out by the pharmacist?

7. Do you have any problems or concerns about the checking procedure?

8. How much time approximately is taken up with dispensing drugs in MCAs for patients at living independently at home?

a. on the first occasion

b. on subsequent occasions

9. Who delivers or collects the MCA.

- pharmacist
- driver
- other (specify)

10. Do you obtain weekly scripts from the GP for these patients?

- always
- when GP agrees
- never

9. Do you usually order the repeat prescriptions from the GP. or does the patient make the request?

- pharmacist
- patient
- other (specify)

11. What procedure do you follow if the MCA is returned with tablets still in it?

12. Who decides which make of MCA to use?

- pharmacist
- depends on patients needs
- other (specify)

13. Do you have a preferred MCA?

- YES NO

if YES a. which make? _____

b. why?

14. Who pays for the MCA?

- patient
- pharmacy
- other

15. Is there anything else you would like to say about MCAs for patients in their own homes?

GALEN STUDY

PATIENT QUESTIONNAIRE

Patient Details

Patients name	
Address	
Telephone	
Date of birth	

Gender

Male

Female

Type of accommodation

own home

sheltered housing

Living arrangements

alone

with partner

with son / daughter

with other relative / friend

with paid carer

Support Services

Home help

District nurse

Relative / friend who visits

Warden

General Practitioner

Name	
Address	
Telephone	

Additional Information

For example name and address of carer, access to home, preferred time for visit.

--

Agreement to Visit

Date consent form supplied	
Date consent form signed	
Date & time for visit	

Hello, I'm Jacky Nunney from the University of Leeds. Do you remember I spoke to you about some research we are doing into the use of special containers for medicines?
Are you still willing to answer some questions for me? Can I come in?

Have you got all your medicines here for me to see?

Have you got the patient information leaflet which I gave you?

Have you signed the agreement at the back of the leaflet?

This is what I am going to do

- Ask you about your medicines
- Talk about any problems you might have

So first of all a few questions about your medicines

Section A Review of medication.

1. Can you show me which medicines you take?

(Patient can look at MCA and any bottles if necessary.)

- What is the name of the medicine?
- How much do you take?
- How often do you take it?
- What is it for?

Do you take it every day or just when you need it?

Fill in answers on chart.

Section B: Review of medicines by other professionals

Obtaining repeat prescriptions

Has anyone talked to you about your medicines recently?

e.g. GP. Hospital Doctor, Practice Nurse

YES NO

If YES give further details if possible including when.

3. Does anyone help you with your medicines at home?

- Nobody
- Relative
- Nurse
- Home care
- Other (specify) _____

What do they do to help?

- Comes into home & puts tablets out
- Gives medicine to patient
- Fills monitored dosage system
- Writes a chart
- Other (specify) _____

4. Who orders your repeat prescription from the Doctor's surgery?

- Myself
- Relative
- Home care
- Other (specify) _____

5. When do you order your repeat prescription?

- When medicine has run out
- When a few days supply left
- When a weeks supply is left

- Every 4 weeks
- Pharmacy does it
- Other (specify) _____

Who collects your medicines from the pharmacy?

- Myself
- Relative
- Home care
- Other (specify) _____

Section C Assessment of physical abilities / disabilities

Now I would like to ask you about how you manage your medicines

7. Do you have a problem using the (type of MCA)

YES (has a problem)

NO (no problem)

State problem if there is one _____

8. Ask patient to demonstrate opening and removing a tablet from the MCA

YES NO

9. Show patient card with days of week and times written on and ask patient to read it.

YES NO

10. Do you have any problems swallowing your tablets?

YES NO

11. If you are going to be out of the house when you need to take a medicine what do you do?

Section D

12. How well do you think you would be able to remember to take your medicines if you had your medicines in bottles?

- | | |
|------------|--------------------------|
| very well | <input type="checkbox"/> |
| quite well | <input type="checkbox"/> |
| not well | <input type="checkbox"/> |
| not at all | <input type="checkbox"/> |

13. Do you have any ways of reminding yourself to your medicines?

14. Do you remember who first suggested that you had your medicines put in a (type of MCA)?

15. There are a few different types of special container, did the pharmacy let you choose which type?

- NO YES

16. Is it a problem that some of your medicines are in the box and some are not?

- NOT APPLICABLE

17. How does the (type of MCA) compare with ordinary bottles for you

- Is it -----much better
- a little better
- no different
- a little worse
- much worse

19. Is there anything else you would like to tell me about how you get on with your (type of MCA)?**Research pharmacist's personal assessment of patient's ability.**

My assessment of the patient's ability to manage their medication is -

- Patient could manage very well with medication in bottles
- Patient could manage reasonably well with medication in bottles
- Patient could manage with difficulty with medication in bottles
- Patient could not manage at all with medication in bottles

University of Leeds
Division of Academic Pharmacy Practice

0113 3926737

Patients managing their medicines at home project

We would like to invite you to take part in the above research project

What is the project about?

- In this research project pharmacists (chemists) have been asked to find patients who have their medicines dispensed in special containers (compliance aids.)
- These patients are being asked if they would like to take part in the project.
- If you agree a research pharmacist will visit to talk to you about your medicines.

The pharmacist will ask you about your medicines and the compliance aid.

What will I have to do?

The research pharmacist will ask you for a good time to visit you at home.

She will:

- talk to you about everything to do with your medicines.
- ask you some questions about how you manage your medicines.

All the information which you give to the pharmacist will be confidential and only used for the research project.

What is the project for?

- We will be visiting about 100 patients like you across Leeds. At the end, we will look to see how people cope with their medicines in special containers (compliance aids)
- This will help us find the best way to help people manage their medicines at home.

Do I have to take part?

- No, you do not have to take part. If you do not, it will not affect the way your doctor or chemist treats you in any way.

Can I change my mind?

- Yes, you can change your mind at any time. Just call in at the pharmacy or you can phone and tell us.

What do I do now?

If you want to take part in the project, please read the consent form below and sign at the bottom.

Consent Form

I have read and understood the patient leaflet about the managing medicines at home project.

I agree

- to have a visit from the Research Pharmacist.
- I understand that the information which I give the pharmacist will be used in the research project

Patient's signature _____

Patient's name _____
(block capitals)

Date _____

Mrs J Nunney (Research pharmacist)
Division of Academic Pharmacy Practice
University of Leeds
0113 3926737

Appendix 2. Literature review

Literature search details

Literature Search details

All searches limited to Human, English language and years 1982 - 2003

Medline

Keyword or phrase	Number of references identified by search	No retained for further scrutiny	Number retained in review
Patient compliance and compliance aids	15	10	1
Patient compliance and reminder systems limit to all over 65	33	6	1
Patient compliance and drug packaging limit to all over 65	29	27	8

Embase

Keyword or phrase	Number of references identified by search	No retained for further scrutiny	Number retained in review
Compliance aid\$	10	7	3
Patient compliance AND drug packaging	11	11	2
Patient compliance & reminder systems	4	4	0

CINHAL

Keyword or phrase	Number of references identified by search	No retained for further scrutiny	Number retained in review
Compliance aid\$	19	0	
Patient compliance & reminder systems	14	0	
Patient compliance & drug packaging	1	1	1

PsycINFO

Keyword or phrase	Number of references identified by search	No retained for further scrutiny	Number retained in review
Compliance aid\$	1	1	
Patient compliance & drug packaging	0		
Patient compliance & reminder systems	0		

International Pharmacy Abstracts (IPA)

Keyword or phrase	Number of references identified by search	No retained for further scrutiny	Number retained in review
Compliance aids & elderly	10	4	
Drug packaging and patient compliance	55		
Reminder systems and patient compliance	6		

Pharm-line

Keyword or phrase	Number of references identified by search	No retained for further scrutiny	Number retained in review
Compliance aids & elderly	45	12	7
Drug packaging and patient compliance	34	4	3
Reminder systems and patient compliance			

Appendix 3. Older people's interviews

Pharmacist introduction letter

Older person information leaflet and consent form

Topic guide

Please reply to:

Pharmacy Practice & Medicines Management Group
Room 2.23

Tel: Direct Line: 0113-3431232 or 3431340

E-Mail: J.M.Nunney@leeds.ac.uk

To Community Pharmacists
X Primary Care Trust

Our Ref: JN

10 June 2004

Dear Colleague

Research into the use of Multicompartment Compliance Aids in Primary Care

Some of you will know me from my previous research in this field supported by Galen Awards from the Royal Pharmaceutical Society and from my time as C.P.P.E. tutor for Leeds. I am now working as a part-time lecturer in the School of Healthcare Studies and also studying for a PhD. The aim of the research for my PhD is to study the use of Multicompartment Compliance Aids (Dosett, Medidos, Nomad, Venalink and similar) by older people living in the community and to try to find if the attitudes and beliefs of healthcare professionals and older people influence the decisions to use these devices.

I intend to carry out interviews with a number of different healthcare professionals both in Primary and Secondary Care. I also want to discover what the older people themselves think of the devices and I intend to interview older people who have their medicines dispensed in this way. I have ethical and research governance approval for this study however because of tighter controls put in place by ethics committees I am not allowed to approach patients directly and this is the reason for my letter to you. I am looking for a number of community pharmacists who regularly dispense medicines to patients in MCAs who would be willing to approach their patients on my behalf. The patients must be able to read, understand and sign a consent form (which does exclude many of the patients)

I am enclosing a sheet which gives more details of the procedure for obtaining consent from patients, if you feel able to help, please sign the enclosed slip and return to me in the freepost envelope provided. I will provide consent forms and further details to those pharmacists who offer to help.

Thanking you in anticipation.

Best wishes

MRS JACKY NUNNEY
PHARMACY LECTURER and PhD STUDENT.

Older People Managing their Medicines at Home

What is it all about?

My name is Jacky Nunney and I am a researcher and associate lecturer at the University of Leeds.

I have been researching into the use of Multi-compartment Compliance aids by older people living in their own homes for a number of years. The current research project will form part of my PhD thesis.

I am inviting healthcare professionals to discuss their views on the use of Multi-compartment compliance aids by older people, how effective these aids are and what problems older people experience when managing their medicines.

I am inviting you to take part in the study.

What will be involved?

- The discussion will take the form of an interview, which will last between 30 and 45minutes
- You will be asked before the interview if you agree to being tape-recorded. This will help me to remember the main points of the discussion. I will listen to the tape myself, the recording will be transcribed and then destroyed. You may decline to answer a question at any time during the interview.
- The discussion will take place at a time and venue convenient for you.

Confidentiality

All recordings will be kept in a secure place, transcribed notes will be kept in a secure filing cabinet or on a password protected computer. I will not discuss your views with anyone else and it will not be possible to identify any participant in any publications or presentations.

Do I have to take part?

Taking part in this research project is entirely voluntary. You do not have to participate if you do not want to.

What do I need to do now?

- If you would like to take part please complete the attached consent form and return it to me in the envelope provided. I will contact you to arrange an appointment.
- If you do not wish to take part there is no need to take any further action.
- If you would like further information you can contact me,

Jacky Nunney tel: 0113 3431232 or e-mail: J.M.Nunney@leeds.ac.uk

You can also write to me at:

Pharmacy Practice and Medicines Management Group

School of Healthcare Studies

Baines Wing

University of Leeds

PO Box 214

Leeds LS2 9UT

Patient Identification Number for this Study:

CONSENT FORM FOR RESEARCH STUDY

Title of Project: Managing your medicines at home

Name of Researcher: **Jacqueline Nunney, University of Leeds**

**Please
tick to
say yes**

- I have read the information sheet for the above study.
- I have had the opportunity to ask questions about the study, and to discuss it with family and friends.
- I understand the purpose of the study, and how I will be involved.
- I understand, and accept, that if I take part in the study I will not gain any direct, personal benefit from it.
- I understand that all information collected in the study will be held in confidence and that, if it is presented or published, all my personal details will be removed.
- I confirm that I will be taking part in this study of my own free will, and I understand that I may withdraw from it, at any time and for any reason, without my medical care or my legal rights being affected.
- I agree to take part in the above study.

Signed

Date

Person taking consent

Date

Researcher Jacqueline Nunney

Researcher (if different Date
from above)

Multi-compartment compliance aids study

Individual interviews with Older People who have their medicines dispensed in or use a Multi-compartment compliance aid

Topic guide

Can you think back to the time before you had your medicines put into a special box?

1. *Can you tell me how you managed your medicines?*
2. *Did you ever have a special way of reminding yourself to take your medicines?*
 - **Prompt** *Some people put the containers in special places*
 - **Prompt** *Some people make charts*
 - **Prompt** *Some people put the medicines in other containers.*
3. *Does anyone help you with your medicines at home?*
 - *What do they do?*
4. *Do you remember who first suggested that you had your medicines in this type of box?*
 - **Prompt** *Can you tell me who it was?*
 - **Prompt** *Do you know why they suggested it*
5. *Were you asked if you wanted your medicines dispensed in this way?*
 - **Prompt** *Would you have said no if asked?*
 - **Prompt** *Were you offered a choice of box?*
6. *How do you manage with your box?*

- **Prompt** *Can you describe how you remove the medicines from the box.*

7. *What benefits are there in having a box?*

8 *I would now like to talk to you about taking medicines in general*

- **Prompt** *Is taking medicines correctly important*
- **Prompt** *Do you think you take too many*
- **Prompt** *Do you hold any personal beliefs about medicines*

9 *Can I ask you now about being independent, is that important*

10. *Finally can I ask about the relationship you have with healthcare professionals for example your GP or hospital doctor , your pharmacist and any nurses.*

- *As an older person do you think your age affects this relationship?*

Appendix 4. Healthcare professional Interviews.

Healthcare professional introductory letter.

Healthcare professionals information sheet and consent form

Topic guide

Please reply to: Pharmacy Practice & Medicines Management Group Room 2.23

Tel: Direct Line: 0113-3431232 or 3431340

E-Mail: J.M.Nunney@leeds.ac.uk

Our Ref: JN/HCP2

26 January 2006

Dear

Research into the use of Multi-compartment Compliance aids by older people living independently at home.

I am a pharmacy lecturer at the University of Leeds and I am currently undertaking research into the above topic for a Doctor of Philosophy degree. I have interviewed a number of older people who regularly have their medicines dispensed in Multi-compartment compliance aids (Nomad®, Venalink® or similar) and would now like to interview healthcare professionals who may request the provision of this type of device for older people in their care. The research study has full ethical approval from X East and X West Ethics Committees and I hold an Honorary NHS contract with all five X Primary Care Trusts. I have informed X Local Medical and Pharmaceutical Committees of my research and have been given their support.

I would like to interview General Practitioners and Practice Nurses about the use of Multi-compartment compliance aids, the benefits to older people and the possible disadvantages. Interviews can take place at a venue and a time to suit the interviewee and should last no longer than 30 minutes, interviews will be tape recorded for ease of transcription.

I am enclosing a number of copies of the Information Leaflet, which gives more details about the research, and copies of the formal consent form. Anyone who is willing to participate should complete the consent form and /or reply slip enclosed with this letter and return it to me in the freepost envelope provided. I will then make contact directly to arrange an interview. Please ask if you would like a copy of the research protocol that includes some details of the work completed so far. I will telephone in a few days time to answer any queries.

Thank you for your time and consideration.

Yours sincerely

MRS JACKY NUNNEY

PHARMACY LECTURER

Older People Managing their Medicines at Home

What is it all about?

- My name is Jacky Nunney and I am a researcher and associate lecturer at the University of Leeds.
- I have been researching into the use of Multi-compartment Compliance aids by older people living in their own homes for a number of years. The current research project will form part of my PhD thesis.
- I am inviting healthcare professionals to discuss their views on the use of Multi-compartment compliance aids by older people, how effective these aids are and what problems older people experience when managing their medicines.
- I am inviting you to take part in the study.

What will be involved?

- The discussion will take the form of an interview, which will last between 30 and 45minutes
- You will be asked before the interview if you agree to being tape-recorded. This will help me to remember the main points of the discussion. I will listen to the tape myself, the recording will be transcribed and then destroyed. You may decline to answer a question at any time during the interview.
- The discussion will take place at a time and venue convenient for you.

Confidentiality

- All recordings will be kept in a secure place, transcribed notes will be kept in a secure filing cabinet or on a password protected computer. I will not discuss your views with anyone else and it will not be possible to identify any participant in any publications or presentations.

Do I have to take part?

- Taking part in this research project is entirely voluntary. You do not have to participate if you do not want to.

What do I need to do now?

- If you would like to take part please complete the attached consent form and return it to me in the envelope provided. I will contact you to arrange an appointment.
- If you do not wish to take part there is no need to take any further action.
- If you would like further information you can contact me,

Jacky Nunney tel: 0113 3431232 or e-mail: J.M.Nunney@leeds.ac.uk

You can also write to me at:

Pharmacy Practice and Medicines Management Group

School of Healthcare Studies

Baines Wing

University of Leeds

PO Box 214

Leeds LS2 9UT

Healthcare professional Identification Number for this Study:

CONSENT FORM FOR RESEARCH STUDY

Title of Project: Older people Managing your medicines at home

Name of Researcher: **Jacqueline Nunney, University of Leeds**

**Please
tick to
say yes**

- I have read the information sheet for the above study.
- I have had the opportunity to ask questions about the study.
- I understand the purpose of the study, and how I will be involved.
- I understand, and accept, that if I take part in the study I will not gain any direct, personal benefit from it.
- I understand that all information collected in the study will be held in confidence and that, if it is presented or published, all my personal details will be removed.
- I confirm that I will be taking part in this study of my own free will, and I understand that I may withdraw from it, at any time and for any reason.
- I agree to take part in the above study.

Signed

Date

Person taking consent

Date

Researcher Jacqueline Nunney

**Appendix 5. Original Paper. The Pharmaceutical Journal
December 2001**

How are multi-compartment compliance aids used in primary care?

By Jacky M. Nunnery, DipCommPharm, MRPharmS, and D. K. Theo Raynor, PhD, MRPharmS

AIM • To determine the scale of dispensing in compliance aids to patients at home, how community pharmacists provide this service and the extent to which patients' needs are met.

DESIGN • Self-completion questionnaire to contracted pharmacies, administered questionnaire to 10 randomly selected community pharmacists and administered questionnaire to patients using a compliance aid at home.

SUBJECTS AND SETTING • The study was conducted in the Leeds Health Authority area. Pharmacists were interviewed in their community pharmacies and patients in their homes.

RESULTS • Responses were received from 123 pharmacies (80%), of whom 95 (77%) supplied 1,328 patients with a multi-compartment compliance aid (MCA). Most commonly used were the Nomad (694; 52%), Dosett (363; 27%) and Medidos (116; 9%). 7 of the 10 pharmacists interviewed required 7 day prescriptions and 8 paid for the aid themselves. 5 would make an initial visit to assess patients and 8 supplied their preferred device without reference to the patient. I had a written procedure and in 2, an unqualified assistant filled the devices. In 4 pharmacies delivery

was by a non-qualified person. Of the 169 eligible patients, 56 patients were interviewed (33%). In total 48 (86%) had no input into ordering their prescription and had their device delivered by the pharmacy. The names of their medicines were not known by 38 (68%) and 10 (18%) said they had difficulty using the device; 22 patients (39%) thought they would be able to remember to take their medicines if still in conventional containers.

CONCLUSION • Large numbers of patients living at home have their medicines in an MCA, but initiation and supply appears not to be focused on their needs. MCAs can take away a key link between the patient and their health professional. They can also cause patients to lose some responsibility for their own medicines. Before supply, an assessment should determine individual needs and the appropriate intervention — supply of an MCA is only one option. Lack of a payment mechanism makes the need for appropriate targeting urgent; pharmacists are expected to provide the service without support or resources, placing a strain on inter-professional relationships. An evidence-based mechanism for use, targeting those who really need an MCA, should be sustainable through implementation of medicines management, as a result of the NHS National Plan.

Multi-compartment compliance aids (MCAs) are widely used for patients perceived as having problems with medicine taking at home. The aids hold seven days of a patient's medicines in 28 inner compartments, four for each day. They appear to be accepted by many health care professionals as a solution for patients having problems managing their medicines at home. This is despite there being little evidence for their effectiveness.^{1,2} A recent development is that traditional MCAs (such as Dosett and Medidos) have been overshadowed by monitored dosage systems (MDSs) which, although initially designed for institutional use, are also promoted for use by patients in their own home.³ The main advantages and disadvantages that have been associated with the use of MCAs are described in Panel 1.

What is the evidence? The most commonly used and studied MCA is the Dosett (known as Mediset in the United States) and it has been the subject of a number of trials with conflicting results. Some have been reported as being little more than a collection of anecdotal reports,¹ others have included too few patients to detect

statistical significance⁴ and one author concluded that it was only of limited value.⁵ Some workers have found that the Dosett is rarely suitable for the elderly⁶ and Atkin⁷ found that 24 per cent of elderly patients could not open a Dosett box. Crome *et al*⁸ found no significant improvement in the compliance of elderly patients who used the Dosett device. There have been more rigorous trials of MCAs when used as part of a multiple intervention in the US.^{9,10} However it is difficult to assess the individual roles of the various interventions employed. In the latter study, only half of the patients were still using the Dosett after six months.

Some work has compared various MCAs, mostly using a criterion of patient acceptability. Wheel-based devices appear least popular¹¹ and Walker's series of studies found the Medidos most popular over-

all,¹²⁻¹⁴ although in one study 35 per cent of patients could not remove the tablets "quickly, with ease".¹¹ A trial of the Dosett and Medidos devices in a self-medication scheme was unsuccessful because of the difficulty patients had in opening the devices.¹⁵ Sweeney *et al* found the Medidos "extremely useful" in selected patients (although it had been incorrectly refilled by two patients).¹⁶ A *BMJ* review¹⁷ of compliance aids for the elderly included no critical analysis of their role or effectiveness.

There are few published controlled studies of the use of MDSs as compliance aids. A study in 1982 of a system with some similarities to an MDS showed the same level of compliance as with patients using ordinary bottles.¹⁸ However, initiatives have been undertaken locally in the UK, with systems set in place by health authorities to use MDSs as compliance aids in this way.^{19,20} Ryan-Woolley recently researched the use of an MDS to monitor medicines wastage and facilitate concordance.²¹ Tablet counts in two studies in the 1980s appeared to show improved compliance rates in elderly patients. However, the authors concede that removal of doses before repeat prearranged visits may have

Ms Nunnery is a visiting research associate and Professor Raynor is Professor of Pharmacy Practice, Medicines and their Users at the Division of Academic Pharmacy Practice, School of Health Care Studies, University of Leeds LS7 9JT. Correspondence to Professor Raynor (e-mail D.K.Raynor@leeds.ac.uk)

occurred (the visual nature of an MDS or MCA makes such adjustments more likely than with conventional containers).^{22,23} There are no published comparisons of patient acceptability between MCAs and MDSs.

What are the alternatives? There are a number of alternative strategies for tackling unintentional non-compliance, some of which have a wider evidence base. Patients with unintentional non-compliance usually need help with:

- 1 Knowing when to take doses
- 1 Remembering to take doses
- 1 Coping with a complex regimen

The key approaches are simplification and rationalisation of the medicine regimen, cueing of doses and tailoring regimens,²⁴ medicine reminder charts,^{25,26} and various memory aids.²⁷ These are described in Panel 2.

Why do this study? The scale of use of MCAs is not known and methods of providing a service through community pharmacists have not been described in detail. MCAs may be useful for some patients, but the appropriate method for targeting is not known.

The report "From compliance to concordance" confirmed the need for research into interventions which address unintentional non-compliance, including compliance aids.²⁸

This study investigated the role of these aids in the wider picture of compliance support interventions and how their use can be targeted. The objectives were to:

- 1 Ascertain the current scale of dispensing of medicines in MCAs to patients living in their own homes in the Leeds Health Authority area
- 1 Determine how community pharmacists provide this service
- 1 Assess the needs of patients receiving medicines in MCAs and whether these were being met through their current medical and pharmaceutical care

We have adopted the term "multi-compartment compliance aid" to differentiate between devices designed to contain tablets and capsules from those which assist in the administration of non-oral dose forms, eg, eye-drops and inhalers. Both types of device have been referred to as "compliance aids". We chose to continue to use the term "compliance" in this report, rather than "adherence", due to the historical use of the former in relation to such aids.

METHODS

There were three phases to the study:

Self-completion pharmacy questionnaire A self-completion questionnaire was sent to all 152 contracted pharmacies in Leeds and asked:

- 1 Did they dispense medicines in MCAs to people living in their own homes?

1 December 2001

Panel 1: Proposed advantages and disadvantages of multi-compartment compliance aids

Advantages

- 1 Some at-risk patients on multiple medication may be able to be cared for at home
- 1 Patients who are generally alert but on complex regimens may be helped
- 1 May allow administration of medicines by carers (formal or informal) otherwise prepared (or allowed) to give medicines
- 1 Act as a reminder to patients who frequently forget to take doses of medicines

Disadvantages

- 1 The patient loses some responsibility for their medicines
- 1 The MCA may be filled incorrectly by a non-professional
- 1 Many dose forms are unstable outside their original packaging
- 1 Many dose forms cannot go into an MCA, eg, inhalers, liquids, drops
- 1 No recognised payment system for supply or filling
- 1 Cost (of device, and for professional refilling)

Comment

- 1 Could prevent the need for admission to hospital (or nursing or residential home)
- 1 Such practical assistance may be effectively provided by a reminder chart
- 1 Can result in a process focused on the needs of the carers, rather than those of the patients
- 1 There are other simpler methods such as reminder charts

Comment

- 1 May be inevitable in some patients with poor mental state
- 1 Already happens with transfer between bottles in the home
- 1 Unclear whether of real significance in short term
- 1 Such dose forms often constitute a significant part of a patient's regimen
- 1 Can lead to inter-professional dispute and misunderstanding in an area where a multidisciplinary approach is essential
- 1 Cost-effective analyses need applying to determine optimum use

Panel 2: Interventions to support patients having problems with unintentional non-compliance

Regimen rationalisation/simplification

Before other interventions, make the regimen as simple as possible.

Reduce the number of medicines to a minimum and dose frequencies to once or twice daily where possible.

Tailoring regimens and cueing doses

Tailoring dose-taking times to fit in with a patient's daily routine can be helpful.

Doses can also be linked to events in patients' daily routine, eg, meal times and bedtime. This helps the patient to remember to take their doses.

Medicine reminder charts

Essentially two-dimensional MCAs which show what medicines to take at each dose taking time, but with the medicines remaining in their separate containers. Studies have shown that such charts can improve knowledge and compliance. They both help in general understanding of a complex regimen and act as a reminder or cue.

Memory aids

These include telephone reminders, timed alarms, refrigerator stickers, etc.

- 1 How many patients received their medicines in MCAs?
- 1 Which device(s) did they use?

Administered pharmacist questionnaire An additional questionnaire was sent to 10 ran-

domly selected community pharmacists who responded to the self-completion questionnaire and said that they provided medicines in MCAs. Before randomisation, the pharmacists were divided into groups depending on the number of patients receiving medi-

ORIGINAL PAPERS

TABLE 1: WHO MAKES THE DELIVERY OF THE MULTI-COMPARTMENT COMPLIANCE AID

Who makes delivery	Number of pharmacies
Driver	3
Pharmacist	2
Pharmacist or driver	2
Pharmacist or relative	1
Pharmacist or pharmacy assistant	1
Pharmacy assistant	1

TABLE 3: NUMBER OF PATIENTS USING EACH TYPE OF MULTI-COMPARTMENT COMPLIANCE AID (N=56)

Type of MCA	Number of patients
Dosett	20
Nomad	19
Medidos	6
Venalink	7
Manrex Sun & Moon	4

TABLE 2: PATIENT DEMOGRAPHIC DETAILS (N=56)

Sex	Female/male	38/18 (68/32%)
Age in years	Mean (range)	78.5 (46-93)
Housing	Own home	43
	Sheltered	11
	Warden controlled	2
Living arrangements	Alone	40
	With partner	12
	With relative/friend	4
Support services	Home care	40
	District nurse	8
	Relative/friend who visits	4
	No help	9

cines in MCAs from the pharmacy, ie, 1-10, 11-20, 21-30, over 30. Four were randomly selected from the first group, three from the second, two from the third and one from the fourth group (to help get a balanced picture across the spectrum of community pharmacies). The pharmacies were seven small independents (up to three shops), one from a small independent multiple and two from large multiples. The population served by these pharmacies was varied, ranging from inner city to the rural suburbs. Of the pharmacists involved, six were proprietors and four were employees.

The questionnaire was designed to answer the following questions:

- 1 Who requests the dispensing of medicines in MCAs for patients living in their own homes?
- 1 What method of assessment of the patient does the pharmacist use?
- 1 What verbal advice and information does the patient receive?
- 1 What procedures are in place in the pharmacy for dispensing in MCAs and is there a written protocol?
- 1 Did the pharmacists have any concerns about dispensing in MCAs?

Administered patient questionnaire All patients with MCAs supplied and filled by the 10 selected pharmacies were contacted by letter to seek consent and then by telephone to arrange a home visit.

A questionnaire, based on a previously validated questionnaire,²⁹ was designed to be used by the research pharmacist when interviewing patients in their own homes. The questionnaire was designed to answer the following questions:

- 1 Did the patient know the names of, and indications for, their medicines?
- 1 Could the patient manage to use the

MCA correctly and did they receive any assistance?

- 1 How did the patient obtain repeat prescriptions from the GP and further supplies of medicines?
- 1 How did the patient feel they would be able to manage if they did not have the medicines in an MCA?
- 1 How did the patient feel the MCA compared with medicines in ordinary bottles and packs?

Approval was obtained from Leeds Health Authority/United Leeds Teaching Hospitals Research Ethics Committee. A copy of the questionnaire is available on request from the authors.

RESULTS

Self-completed pharmacy questionnaire We received completed questionnaires from 123 of the 152 contracted pharmacies (80 per cent). Of these, 95 (77 per cent) dispensed medicines in MCAs to patients in their own homes. The total number of patients receiving their medicines in MCAs was 1,328 (average of 11 per pharmacy, range 1-70).

Most common was the Nomad (an MDS) which was used by 694 patients (52 per cent), followed by the Dosett with 363 (27 per cent) and Medidos 116 (9 per cent). Overall, 819 patients (62 per cent) were using an MDS, rather than a conventional MCA. Preliminary results for this questionnaire have previously been reported.³⁰ There were 28 pharmacies (23 per cent) which did not dispense in MCAs to patients living independently in the community. The reasons stated included: no demand (11); no remuneration (6); would dispense if given seven-day prescriptions (1); pharmacy not suitable (insufficient space) (1); no reason given (9).

Administered pharmacist questionnaire

The 10 randomly selected pharmacists ranked general practitioners (GPs) and hospital staff as the main initiators of requests for an MCA, closely followed by carers and social services' staff. The pharmacists rated themselves as being the least likely to initiate use of an MCA.

Seven pharmacists always requested seven day prescriptions from the GP and would not proceed if the GP refused. One would ask, but if refused would dispense in the MCA anyway. Two pharmacists requested 28-day prescriptions and dispensed four by seven days to the patient at one time. Six pharmacists stated that they would order the repeat prescriptions themselves (with the patient's approval) but two preferred the patient to order their own repeat prescriptions. In eight cases the pharmacy paid for the MCA. Two pharmacists stated that they did, on occasion, receive payment for the MCA from the patient.

Five pharmacists said they would make an initial visit to assess the patient before setting up the service and seven said they would check the patient's ability to use the MCA. Eight said that they would provide information and advice to the patient on first supply, but only one would suggest simplification of the regimen and assess patients' progress in conventional containers first. Eight of the pharmacists decided on the type of device without reference to the patient and each had a preferred MCA (six were MDS).

Seven pharmacists stated that they would check the stability of drugs in an MCA. Sources quoted for information were:

- 1 Pharmacist's own knowledge
- 1 Manufacturer's literature or Data Sheet Compendium
- 1 British National Formulary
- 1 Royal Pharmaceutical Society information

Three said that they did not think there was a problem, considering the short length of time the drugs were in the MCA.

One pharmacy had a written procedure in place, although most kept a file with the names of the patients receiving their medicines in MCAs. Two pharmacists always filled the MCAs themselves with five sharing the task with either a qualified dispenser or an unqualified assistant. In one pharmacy dispensing was always carried out by a qualified dispenser and in two by an unqualified assistant. The pharmacists who always filled the MCAs themselves did not get anyone to check them; in the other cases the pharmacist checked the dispensers' work. However, half of the pharmacists had concerns on the ability to check dispensing into MCAs properly. The average estimated time taken for dispensing a seven-day supply was 15 minutes on the first occasion, and six minutes on subsequent occasions. In four of the pharmacies, the MCA was delivered by a non-qualified person (Table 1).

Four pharmacists said there were occasions when they had been pressured by other

health care professionals to supply drugs in MCAs, when they felt this was inappropriate, but that this was not a frequent occurrence.

Administered patient questionnaire Of the 169 patients being supplied with a MCA from the above pharmacies, 61 (36 per cent) patients consented to being interviewed and 56 interviews were completed. They had a mean of six medicines in the MCA (range 1–12) and 52 per cent had other medicines not in the MCA. Table 2 shows demographic details of these patients.

When asked who had suggested the use of an MCA, patients' most common response was that it was hospital staff (22; 39 per cent) and GPs (9; 16 per cent). Only one patient said that they had been given a choice of MCA. For 48 patients (86 per cent), the pharmacy ordered their prescription and so the patient had no input. Again 48 patients (86 per cent) had the device delivered by the pharmacy. Most patients were using a Dosett (20; 36 per cent) or Nomad (19; 34 per cent) device (Table 3). All hospital initiated MCAs were the Dosett device.

The names of the medicines in the MCA were not known by 38 patients (68 per cent) and 10 (18 per cent) reported difficulty in using the device; 22 said they thought they would be able to remember to take their medicines if dispensed in conventional containers. A quarter of comments volunteered by patients related to the fact that the MCA allowed them to see if they had forgotten to take a dose. Over 90 per cent (52) said that the MCA was much better than ordinary bottles. However, a subjective assessment by the research pharmacist suggested that three could manage very well, and 26 reasonably well, with conventional containers.

DISCUSSION

This work suggests that (through extrapolation to Britain as a whole) there are over 100,000 patients living in their own home whose medicines are dispensed in MCAs.

The most widely used device was an MDS (Nomad) rather than a conventional MCA. This may relate to the MDS which individual pharmacies use for supply to residential and nursing homes. The most commonly used MCA was the Dosett, with significantly less use of the Medidos, despite some evidence that patients prefer it.^{10–12} Four-fifths of the pharmacists had a preferred MCA, though this was not an evidence-based decision. Only one patient said they had been able to choose the type of MCA. The use of Dosett devices for all those discharged from hospital sometimes led to a change to their pharmacist's preferred device once at home. It appears patients' needs are not the prime criterion for the choice of MCA.

Lack of payment as a barrier The main reason given by pharmacists who did not dispense in MCAs was the lack of payment, and this was the most common source of comment during interviews. Seven of the 10 pharmacists would not dispense in an MCA unless

the GP provided seven-day prescriptions. It is clear that the use of such surrogate payments to manipulate the remuneration system is inappropriate and can harm GP-pharmacist relationships. Problems also arise when the patient's local pharmacy will not dispense in MCAs, leading to two pharmacists being used (one for medicines in the MCA and the other, more local pharmacy, for incidental needs), neither with complete records.

Triggers for supply and patient assessment

It is of note that pharmacists named the GP as the person most likely to request the use of an MCA, along with hospital staff, and saw themselves as least likely to initiate use. This may be a result of pharmacists having a better appreciation of the advantages and disadvantages of MCAs. Training of health care professionals appears to be needed in supporting patients having problems with managing their medicines at home. This should include hospital and social services staff.

Only half of the pharmacists interviewed would visit the patient to assess their suitability for an MCA and only one would try out a simplified regimen first in conventional containers. However, the first question should be: "Is an MCA appropriate or would another option be more appropriate?"³¹ Patients' individual needs depend on their motivation, type of regimen, and physical and cognitive ability. As shown in Panel 2, the first goal is to ensure that the patient's regimen is as simple as possible, in traditional containers with appropriate labelling, along with appropriate advice and a reminder chart where necessary. If it is found that such a device is appropriate, then the next question should be: "Which MCA?" In many cases, this process would need a domiciliary assessment.

Procedures and protocols Only one pharmacy had a written protocol in place (Royal Pharmaceutical Society guidelines have limited use as they only apply to MCAs supplied to residential or nursing homes³²). Clinical governance requires that a protocol should be available and it should consist of two parts: patient assessment and dispensing and supply of the MCA.

Drug stability needs clarification, with practical guidance needed for pharmacists on the short-term transfer of medicines into MCAs. There is concern over the ability to check dispensing into MCAs and the use of unqualified assistants for MCAs is open to question. Pharmacists need to audit their dispensing and checking procedures and have clear protocols and documentation in place.

Low consent rate The low consent rate for the patient interviews (around one third) limits the wider applicability of these findings. The low rate could have been predicted in this group of elderly patients due to significant numbers of patients too confused to be able to give informed consent and patients who were reluctant to allow a stranger into their homes.

However, the comments of some patients suggested that they had detected an ulterior motive and that someone was "going to try to take their MCA away". This needs to be borne in mind if protocols which promote options other than MCAs are brought into use.

Patient ownership of medicines and patient-professional contact

Over two-thirds of patients did not know the names of any of their medicines in the MCA. These devices remove the ownership by some patients of their treatment; their medicines become an anonymous collection of variously coloured and sized tablets and capsules which they swallow in one go, at predetermined times. Separate tablets in different bottles help to maintain a link between the patient and their medicines, the patient retaining some responsibility for their own medication.

Most patients had their repeat prescription ordered by the pharmacy and then the device was delivered, frequently by an unqualified person. Thus the patient becomes not only divorced from their medication, but also from the doctor and pharmacist who prescribe and dispense it. In particular, the valuable link between the patient and pharmacist is lost. There is no opportunity for the patient to ask questions or opportunity for the pharmacist to assess patients' changing needs with respect to their medicines. Almost one-fifth of patients said they had some difficulty getting medicines out of the aid. Patients' medicines management needs may have changed after the MCA was initiated — hence the need for continual monitoring. Previous research has shown that housebound patients who rarely see a pharmacist often have a number of medication problems which need resolving.³³

Patients' information needs There was anecdotal evidence of patient and carer misunderstanding of the system for supply. This emphasises the need for precise and detailed information to be given at the beginning. Patients need the following verbal and written information when an MCA is first supplied:

- 1 How to use the aid
- 1 What to do if a dose is missed
- 1 Arrangements if away from the house
- 1 How to get further supplies

Assessment protocols for MCAs Over 90 per cent of patients said they preferred the MCA to conventional bottles. For many, the main benefit appeared to be that they could see if they had forgotten to take a dose; apparently a major concern. However, almost 70 per cent still relied on other methods to remind themselves to take their medicines and it was apparent at home visits that some patients or carers leave out tablets on the table for patients to take with their next meal. Others were taking them out to put in other containers. Perhaps for many patients — those who need to check whether they have taken a dose — what is

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needed is an aid with just four compartments into which the patient or carer could set out the daily doses each morning. This intervention could be part of a wider protocol to address the needs of patients with problems with unintentional non-compliance.

The research pharmacist's subjective assessment suggested that 29 of the 61 patients would be able to cope well or reasonably well without an MCA. Review of a patient's medicine regimen and consideration of other interventions (as described in Panel 2) needs to be part of a protocol for meeting the needs of patients with problems with unintentional non-compliance.²⁹ This assessment suggests that the number of patients using MCAs could be significantly reduced through such a process.

Remuneration A fundamental problem at the heart of the use of MCAs is the lack of remuneration. For this to be resolved, funders will need to be reassured that MCAs are being properly targeted. The level of remuneration will need to reflect the true time and resource commitment of a properly constituted service, ie, including recommendations made here regarding documentation, patient assessment, and the provision of information and advice. The publication of the National Plan for the NHS, with explicit support for medicines management and new methods of remuneration for pharmacists, is an opportunity to address this issue.³⁴

Limitations The questionnaires to the pharmacists depended on accurate self-reporting of their behaviour. It is possible that there was some over-reporting of the extent to which measures were in place to ensure appropriate use of MCAs. The results should therefore be taken as the most optimistic picture of the current situation.

The low consent rate to the patient interviews needs to be taken into account when looking at these responses. Some of the non-responders would undoubtedly be among the most vulnerable and most in need of monitoring and support for their medicine taking.

Future work This study has laid the foundations for further research into MCAs. Key questions are:

1. How acceptable are MDSs as devices for use by patients in their own homes?
1. Which MCA (including MDSs) do patients prefer?
1. Could a "single-day" MCA (filled by the patient or carer) be sufficient for those patients who just need reminding whether they have taken a dose?
1. How do MCAs, MDSs and other interventions, eg, regimen simplification, reminder charts and single day MCAs compare (through randomised controlled trials)?

It is important that any such studies are independent of the manufacturers of the

aids. Developmental work that needs to be done includes:

1. Testing of a protocol for intervening when patients have problems with unintentional non-compliance (The full range of non-MCA interventions should be considered and it should include a role for all stakeholders, [including hospital and social services].)
1. Guidelines for dispensing and supplying MCAs to patients at home (These should preferably be an extension of current Royal Pharmaceutical Society guidelines for residential and nursing homes. They should dovetail with the above assessment protocol, once a decision has been made to supply an MCA and should cover personnel, premises and equipment, production and procedures, method of supply and advice to the patient.)
1. A practical guide to which medicines can be placed in an MCA for up to four weeks
1. Development of a written guide for patients using an MCA

CONCLUSION

Health professionals need to know the place of MCAs in the wider context of medicines management for patients at home. The place of each intervention (including MCAs) needs determining, so that each can be targeted to those who would most benefit. Pharmacists need criteria to ensure that MCAs are only used when appropriate, and they need evidence on which to base their recommendation. If an MCA is the appropriate intervention, then evidence-based protocols are needed for the choice of MCA and the dispensing and supply of the device. The cost of filling and supplying MCAs, lack of a payment mechanism and the complications that arise from their use in practice make these needs more pressing.

It is of concern that over 100,000 patients living independently in the community in Britain are using MCAs, despite the lack of good evidence that such devices are effective.

Patients are receiving the devices largely without any assessment of whether their use is appropriate in their case. There is no proper referral or assessment mechanism between primary and secondary care. It

seems that the process is focused on the needs of professionals and carers and not on the patients' needs. This is in direct conflict with the concept of concordance in medicine-taking,³⁵ which is based on patients playing a full role in decisions about their medicines. An assessment of the patients needs should be the starting point.³⁵

Patients must not be issued with an MCA without first being assessed. The assessment should follow standard guidelines which are needed to ensure that all patients receive the intervention and care most suited to their needs. If the assessment indicates that an MCA is the most appropriate option, then the first delivery should always be made by a pharmacist or suitably trained technician. Verbal and written information should include how to use the aid, how to get further supplies and who to ask for further information.

The medicines management problems of many patients currently using MCAs may be able to be managed in another way. Simplification is the key strategy for unintentional non-compliance and may be sufficient on its own to meet patients' needs. MCAs can be useful in some patients, however they must be seen within the wider context of medicines management and pharmaceutical care. It is essential that all primary care professionals, social services and hospital staff are part of a wider managed mechanism.

Pharmacists have been placed in a situation where they are expected to provide a service for MCAs, but without the resources to do it. The current ad hoc mechanism for remunerating pharmacists for supplying and filling MCAs is insupportable and has a negative effect on pharmacist-patient and inter-professional relations. It is unlikely that sufficient NHS resources are available to fund all patients currently using MCAs at home, but an evidence-based mechanism for their use, for the smaller number who really need them, might mean that sufficient funding is available. This needs to be incorporated into the implementation of the medicines management initiatives arising from the NHS National Plan.

ACKNOWLEDGEMENTS This work was funded through the Galen Award 1998-99 of the Royal Pharmaceutical Society of Great Britain. We thank all the pharmacists and patients who gave up their time to allow this study to take place.

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**Appendix 6. Abstract British Pharmaceutical Conference
Cardiff 1999**

Multicompartment compliance aids in primary care: building an evidence base.

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Introduction

The profile of medication compliance in the 1990s has been increased by the “From Compliance to Concordance” report¹, which confirmed:

- the distinction between intentional & unintentional non-compliance².
- that compliance aids are often used for unintentional non-compliance i.e. by patients who wish to comply but have problems remembering and understanding complex regimes.

The report said that such aids must be carefully targeted to be effective.

There is little research associated with the use of compliance aids³ and so such targeting cannot at present be undertaken accurately.

Objectives

This work forms part of a larger study and aimed to answer the basic questions:

- How many patients living in their own homes are receiving their medicines in compliance aids from pharmacies in one Health Authority?
- What types of aids are used?
- We have used the term ‘Multicompartment Compliance Aids’ (MCAs) to distinguish these aids from mechanical administration aids.

Method

A questionnaire was sent to all 152 contracted pharmacies in Leeds. This included the questions:

Q 1. Does your pharmacy dispense in MCAs to patients in their own homes?

- (a) If so; how many patients?
 - (b) If not; why do you not use MCAs?
- Q 2. Which type(s) of MCA do you use?

Results

119 replies (78%) were received

92 (77%) pharmacies used MCAs for a total of 1327 patients at home.

The median number of patients with an MCA per pharmacy was 10 (range 2-70). See Table 1.

The most frequently used MCA was Nomad, followed by Dosett and Medidos. See Table 2

The most common reason for not dispensing in MCAs was lack of funding.

Table 1: Numbers of patients with MCAs per pharmacy

No. of patients with MCAs	No. of pharmacies
1-10	50
11-20	22
21-30	13
31-40	3
41-50	2
51-70	2

Table 2: Types of MCA used for all pharmacies

Type of MCA	No. of patients
Dosett	416
Medidos	116
Nomad	694
Manrex	40
Venalink	85
Other	30

Discussion

There is little data on the number of patients using MCAs at home.

Unpublished data suggest that the number of MCAs in use in Leeds was 5-10 per pharmacy

This survey shows that the actual range is 2 to 70, with a median of 10.

The dispensing of medicines in MCAs for over 1300 patients in one Health Authority represents a considerable investment in terms of both time and money for the community pharmacist.

These large numbers are a cause for concern because of the limited evidence for the benefits of MCAs.

Strategies for tackling unintentional non-compliance with a greater evidence base should be used first e.g. regime simplification & medicine reminder charts.

The place of each intervention (including MCAs) needs determining, so each can be targeted to those who would benefit most.

More work is needed so that MCAs can be effectively targeted. Only then is appropriate remuneration likely to become available.

Future Work

The next stage of this work involves undertaking a needs assessment of a random sample of patients using MCAs.

Who recommended the use of an MCA?

What was the basis for the choice of MCA?

Do they actually need an MCA or could other strategies be used?

ACKNOWLEDGEMENT. This work is supported by a Royal Pharmaceutical Society of Great Britain, Galen Award.

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**Appendix 7. Abstract Health Services Research and
Pharmacy Practice Conference London 2003**

WHAT IS THE EVIDENCE FOR THE USE OF MULT-COMPARTMENT COMPLIANCE AIDS BY OLDER PEOPLE LIVING IN THE COMMUNITY?

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Aim: A structured literature review was undertaken to investigate the evidence to support the use of Multi-compartment Compliance Aids by older people, living in the community.

Method: Systematic searches of Medline, CINHALL, EMBASE, PsychINFO, International Pharmaceutical Abstracts and Cochrane were carried out for the period 1982 to present. Both UK and international, English language literature were searched. Hand searches were undertaken within the same parameters, as were bibliographies of identified articles and colleagues' personal collections. The keywords used were patient compliance, compliance aids, drug packaging, reminder systems and searches were limited to age over 65 were possible. Key words were combined and not all keywords produced results in each database. Identified articles were reviewed and those in which Multicompartment Compliance Aids (MCAs) were the main or a major focus of the article were obtained for further review and analysis.

Results: Twenty eight articles were identified by the above method, these articles could be divided into a number of classifications as described in table1.

Table1.

Type of article	Number
Randomised controlled trial	7
Controlled trials	2
Trials without control	2
Descriptive articles	8
Experimental studies	9

The articles were critically evaluated and the result of the trial determined. Seven Randomised controlled Trials were identified and of these three found that the use of an MCA improved compliance and four found no improvement. All of the non randomised controlled trials and the non controlled trials stated that patient compliance was improved. Critical analysis of the trials revealed a number of problems which would have a bearing on the trial result. The method of randomisation was described in only two of the randomised controlled trials. Outcome measures varied from measurement of blood pressure and plasma drug levels to self reported compliance and pill counts. The number of patients enrolled in the studies varied from 12 to 297. The interventions described all included a MCA but often included counselling, charts or other instruction leaflets, therefore making it difficult to determine if the improvement was due to the MCA alone or the combination of interventions.

Discussion. A randomised controlled trial is often seen as the gold standard of research into a particular intervention. The randomised controlled trials investigated were divided in the conclusions obtained and because some of the trials were flawed it is impossible to draw a valid conclusion. The other trials although indicating that multicompartiment compliance aids improved compliance suffered from small numbers of patients or from multiple interventions which made it impossible to determine which intervention had caused the improvement.

Conclusion: The available literature describing trials of the use of Multicompartiment compliance aids does not provide sufficient evidence for the use of these devices in primary care.

**Appendix 8. Abstract British Pharmaceutical Conference
Manchester 2007.**

Multi-compartment compliance aids: Who gets the benefit? Who takes the risk?

Authors: Mrs J. Nunney. Prof. D.K. Raynor, Dr P. Knapp. Prof. S.J. Closs

Focal Points.

- Multi-compartment Compliance Aids (MCAs) are often seen by healthcare professionals as providing benefits to older people
- Older people and healthcare professionals agree on some of the benefits but recognise different risks.
- Healthcare professionals need to consider the older person's concerns if they use these devices.

Introduction: Multi-compartment compliance aids (MCAs) are issued to large numbers of older people despite little evidence for their effectiveness¹. This study aims to discover whether the attitudes and beliefs of older people and healthcare professionals influence the use of multi-compartment compliance aids. The findings discussed here focus on the risks and benefits which the interviewees identified.

Method: Semi-structured qualitative interviews were undertaken with a purposive sample of 15 older people aged over 65, taking more than 4 regular medicines and using a MCA and 17 healthcare professionals (doctors, nurses and pharmacists) from primary, intermediate and secondary care. Research ethics and governance approval was obtained for all stages of the research. All the interviews were taped, and transcribed. Preliminary analysis of the data has been undertaken using the grounded theory approach as described by Strauss and Corbin². Verbatim transcripts were analysed and emerging themes coded. As further transcripts were analysed the themes were constantly compared and similar themes were then grouped into categories.

Results. Convenience and ease of use was the benefit most frequently cited by the older people; although a minority of interviewees thought the MCA did help them take their medicines correctly. The main benefit identified by the healthcare professionals was also ease of use although some stated that the MCA could aid memory. Both groups agreed that it was easier to remove all the medication to be taken at one dosage time, at once from a MCA, rather than have to open a large number of original packs.

The biggest risk identified by the older people was receiving the wrong medication in the MCA or receiving a medicine which they could not identify. Taking a whole day's or week's supply of medication at one time was the most serious risk the healthcare professionals identified.

Healthcare professionals also discussed dispensing errors stating these posed a risk to older people and that dispensing medicines in a MCA might lead more frequently to these errors.

Non-compliance itself was considered a risk by the healthcare professionals leading, in their opinion, to repeat hospital admissions. MCAs are seen by some healthcare professionals as the answer to the problem of non-compliance and therefore could be viewed as a benefit.

Discussion. This study has shown that MCAs may make the process of medication easier for some older people. It is possible that medication compliance may be improved through the use of MCAs especially if the regimen is complex and the older person is at risk of taking the medication incorrectly. The link between medication compliance and memory is complex involving both retrospective and prospective memory³. Therefore the MCA may help by removing the need to remember the medication regimen but may not help with the prospective component. Non-compliance may lead to an increase in hospital admissions⁴ and therefore issuing a MCA could be seen as providing a benefit, but healthcare professionals must not ignore the risks involved.

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