Pharmacist participation in the private nursing home team: A study of the implementation of pharmaceutical services, based on the USA consultant pharmacist model.

A Thesis submitted for the Degree of

MPhil

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Abstract.

The pharmaceutical needs of 79 patients in two private nursing homes of good average standard have been assessed. A set of instruments has been devised and used to evaluate the prescribing of medicines in terms of patient diagnoses, health status and the patterns of medicine administration. Following the collection and analysis of baseline data, a number of recommendations for changes were made to the GPs and the nursing staff. Five further medication reviews were made at monthly intervals and additional recommendations made. The acceptance and implementation of all recommendations and their outcomes were determined. A total of 52% of all recommendations were accepted, though this differed in each nursing home. Some of the barriers to success in effecting these changes were identified.

Over the course of the study, there was a mean reduction in prescribing equivalent to 1.5 items per patient. In Nursing Home 2 there were significant differences in the prescribing of drugs for the alleviation of both constipation (P<0.006) and skin treatment (P<0.006) on an 'as required' basis. In Nursing Home 1, there were significant improvements in the patterns of medicine administration (P<0.05) by nursing staff. The prescribing of skin preparations appeared to rise overall by 3%, mainly due to the improved accuracy of recording these treatments. In both nursing homes, observed improvements in the health status of the patients included significant decreases in the incidence of health problems (P<0.05), pressure sores (P<0.05) and constipation (P<0.005). Following consultation with nursing staff, guidelines were agreed
which formalised a protocol for the prescribing and administration of laxatives; and the discretionary use by nurses of wound care products. The mean time involvement by the pharmacist to initiate and continue the process of monthly medication review on an individual patient basis is estimated at 1.4 hours and 8 minutes respectively.
Acknowledgements

I wish to express my sincere gratitude to all who have assisted in the completion of this project.

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Mrs C Ashworth, Matron, Badgerswood Nursing Home

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And finally, to the members of my family to have unswervingly supported me in everything that I have undertaken.
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<td>ASCP</td>
<td>American Society of Consultant Pharmacists.</td>
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<tr>
<td>BMA</td>
<td>British Medical Association. A representative body for doctors, involved in negotiations with the DoH concerning the GP contract of service within the NHS.</td>
</tr>
<tr>
<td>CCA</td>
<td>NHS &amp; Community Care Act.</td>
</tr>
<tr>
<td>CPPE</td>
<td>Centre for Pharmacy Postgraduate Education. Based at the University of Manchester, the centre prepares educational material for community pharmacists and primary care pharmacists.</td>
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<tr>
<td>DHSS</td>
<td>Department of Health and Social Security.</td>
</tr>
<tr>
<td>DoH</td>
<td>Department of Health.</td>
</tr>
<tr>
<td>DRR</td>
<td>Drug Regimen Review.</td>
</tr>
<tr>
<td>DSS</td>
<td>Department of Social Security.</td>
</tr>
<tr>
<td>GMS</td>
<td>General Medical Services. This refers to the contract that GPs have with the NHS to provide a range of services for patients registered with them.</td>
</tr>
<tr>
<td>GP</td>
<td>General Medical Practitioner.</td>
</tr>
<tr>
<td>GSL</td>
<td>General Sales List medicine. A medicine that may be purchased from any outlet without restriction.</td>
</tr>
<tr>
<td>HCFA</td>
<td>Health Care Financing Association (USA).</td>
</tr>
<tr>
<td>Homely Remedy</td>
<td>Term to describe medicines purchased by a care home for the immediate relief of mild to moderate symptoms.</td>
</tr>
<tr>
<td>ICF</td>
<td>Intermediate Care Facility (USA).</td>
</tr>
<tr>
<td>LTCF</td>
<td>Long-Term Care Facility (USA).</td>
</tr>
<tr>
<td>MAR</td>
<td>Medicine Administration Record.</td>
</tr>
<tr>
<td>NAHA</td>
<td>National Association of Health Authorities. This association was later named NAHAT; and then became the National Confederation of Health Authorities and Trusts.</td>
</tr>
</tbody>
</table>
NCSC  National Care Standards Commission.
NHA  Norwich Health Authority.
NHS  National Health Service.
Nightingale Ward: An NHS hospital ward characterised by two rows of beds opposite each other; each row arranged against a wall lengthwise down the ward.
P medicine A medicine that may only be purchased from a pharmacy supervised by a pharmacist.
PCG  Primary Care Group.
PCT  Primary Care Trust.
POM  Prescription Only Medicine. A medicine that may only be obtained on the written prescription of an authorised practitioner.
PRN  Abbreviation term for ‘as required’.
PPRRC  Pharmacy Practice Research Resource Centre. A joint venture between the College of Pharmacy Practice and the University of Manchester to support the Pharmacy Practice Enterprise Scheme.
PSNC  Pharmaceutical Services Negotiating Committee. The representative body for community pharmacy, involved in negotiations with the DoH concerning the pharmaceutical contract of service within the NHS.
RHA  Registered Homes Act 1984.
RHT  Registered Homes Tribunal.
R&I  Registration and Inspection Unit. The local or health authority section that deals with registration and inspection of either residential or nursing homes.
SNF  Skilled Nursing Facility (USA).
SPSS  Statistical Package for the Social Sciences.
UKCC  United Kingdom Central Council for Nursing, Midwifery and Health Visiting. The professional body responsible for retaining the register of practising nurses in the UK and also for issues of professional conduct.
Chapter 1

Introduction: Continuing Care Provision in the NHS and Private Care Industry.
Chapter 1: Introduction: Continuing Care Provision in the NHS and Private Care Industry.

It is acknowledged that civilised society has a moral obligation to provide care for the weak and vulnerable. Within the United Kingdom the responsibilities of the state in the provision of medical and social care were established with the National Health Service Act 1946 and continued with The National Health Service Act 1977. The ensuing years have seen many changes to the original concept of providing health care free to all and yet this fundamental belief is still maintained by government ministers to be the current perspective.

Private residential and nursing homes have become integral to the provision of healthcare in the UK. During the past decade the number, status and comparative importance of care homes have increased markedly. Hudson (1990) gave a clear outline of the problems associated with this increase in private sector homes. A major culture change was signalled with the introduction of the NHS & Community Care Act 1990 (CCA), enacted in 1993. Prior to this date, continuing care had been provided, to a large extent, by the NHS. From 1993, the focus of care delivery transferred to the client's own home. This may be considered a costly option in terms of care delivery, but a reduction in financial burden upon the NHS. The reality of modern day community care is the extensive use of private care homes. Thus those people who require continuing care have moved from NHS institution to private care institution. It is questionable whether this policy change has ultimately resulted in a benefit to patients.
One of the fundamental rights conferred upon the population by the NHS is the availability of healthcare services at no cost to the recipient. This was the case for patients who were cared for in NHS long-stay hospitals but does not apply to all clients in private care homes where those who claim state assistance are ‘means tested’. The issue has therefore assumed great importance because it affects the right of a person to claim care free at the point of delivery. It is possible to suggest that the ongoing debate about the precise definitions of ‘health care’ and ‘social care’ reflect the financial limitations of health and social care providers. This has been exaggerated by the difficulty in defining ‘nursing care’. This pattern of funding for England and Wales will alter in October 2001. Recommendations by the Royal Commission for Long Term Care (2000) were in part accepted by the government. Subsequently, the ‘nursing’ component of a client’s care will be the financial responsibility of the NHS once again, even when the patient is cared for in a ‘private’ nursing home.

Within this chapter a historical perspective of the changes that have occurred to the delivery of care through political change will be considered. A discussion about the manner in which care is delivered by medical, nursing and pharmaceutical practitioners will highlight the limitations of care in the community. And the involvement of the regulatory function is also considered, including the future of private care regulation.

1.1. Provision of Continuing Care.

The NHS once provided community hospitals whose principal function was to provide continuing care on a long-term basis. The patients were the elderly, the
mentally ill, those with learning difficulties and the chronically ill who could not be adequately cared for at home.

It is arguable that the demise of the community and 'cottage' hospital was for political reasons. Although, in 2001, there remains limited provision on a long-stay 'rehabilitation' basis, patients are now routinely transferred to both residential and nursing homes in the private sector unless they are able to establish a right to the continuing provision of NHS care. Even when the latter occurs, the health authority may elect to provide care at NHS cost through a private care home. This issue has been highlighted by the case of R v North East Devon Health Authority (1999). It is likely that the clinical status and needs of patients who occupy registered nursing homes differ little from those of similar patients who may previously have been cared for in NHS long-stay hospitals. The closure of community hospitals was driven by economic pressure on the NHS but in reality supported the philosophy of 'community care'. The result, however, was a tremendous weight of responsibility thrust upon primary care and scarce resources to meet demand.

The original NHS 'nightingale' wards, which characterised continuing care, were less than amenable for the identified client groups. It is therefore likely that, in addition to political changes, client and contractor expectations have dictated the provision of more suitable surroundings. It is also possible that relatives who were either unable or unwilling to offer care at home perceived a compromise situation in the private sector that provided more of a 'homely' atmosphere for the patient.
Prior to 1993, funds to support care in both residential and nursing homes were readily obtained for those who stated that they did not have the means to pay. The finance was originally provided through the Department of Health and Social Security (DHSS) and from 1984 through the Department of Social Security (DSS). There was no formal assessment of patient need. As a consequence, the admission of a client into a home was determined mainly by the client (or a relative) and the availability of a place in the chosen home. The weekly fees of some establishments exceeded the DHSS/DSS funding and occasionally a ‘top up’ fee was arranged with a relative. Some beds were offered at a lower cost to accommodate ‘DHSS’ and these may have been in multiple occupancy rooms. The actual ‘nursing’ needs of the patient were not always at issue and the patient population consisted of a mix of dependent and mobile patients. Within this financial climate, the home manager was in a strong position to select patients. Hence, the most seriously ill patients with a limited life expectancy remained within the NHS long-stay facility; and the more able patient was discharged to private care.

Whilst focussing upon financial and political influence, it is quite wrong to dismiss without comment the effect of changes on patients themselves. A study by Bowling et al (1991) concluded that patients within the nursing homes deteriorated more quickly than those in long-stay NHS hospital care. They also reported a higher ratio of accidents in the nursing home environment. Both of these indicators would appear to be a powerful argument for continuing care within the NHS. However, the authors also concluded that quality of life for a patient in the long-stay NHS geriatric ward was inferior to the private sector.
1.1.1. NHS & Community Care Act 1990.

The implementation of this legislation in 1993 had a major impact upon the private care industry and this has continued to the present day. The intended recipients of community care in the modern era are client groups who were previously accommodated within the NHS long-stay wards.

One aspect of the CCA was to place the funding for nursing and residential care with local authorities. Clients who require care are now subject to both 'needs assessment' and 'means testing', aptly described by Maclean (1997). The potential for a patient to self-fund still exists but does not represent the majority of nursing home admissions. Most patients are funded through local authority contracts and, in some instances, health authority contracts. In the case of the former, a specific fee for care is determined by the local authority annually. The public purse is never perceived to have sufficient to provide for all need that presents and social workers are faced with limitations upon the care that can be purchased.

Add to this scenario the pressures exerted upon the modern day NHS. The increased numbers of emergency admissions of elderly patients, particularly in the winter months, and an overall decrease in numbers of beds have combined to force the early discharge of patients from acute secondary care to prevent bed blocking. Hence, patients who need acute nursing care are being placed in care homes in the private sector as a necessity. Newer and more complex treatments are being provided in this care sector. This has increased the requirement of medical and nursing input to the nursing home and at times
these may not have been delivered in adequate measure. Indeed, the opinion has been forcibly expressed that there is a fundamental problem with this strategy both by Chambers (1991) and Crowe (2000).

1.1.2. Financial Limitations of Community Care.

The aim of CCA was to enable patients to be cared for at home and each client is entitled to a ‘package of care’. This has been achieved to a degree but inevitably the cost of a care package has had a defined limit. The process of client assessment was originally based upon the level of nursing care that was needed compared with the social care needs of the client. If minimal nursing intervention is required, the client may be cared for at home. When the cost of providing care in this way becomes prohibitive, the option for residential care is considered. This will also depend upon the extent of nursing intervention that can reasonably be delivered through the district nursing service. When the nursing needs of a client outweigh social care needs, a nursing home would be the appropriate provider.

Client assessments are conducted by trained social workers. Although some areas of the UK have involved registered nurses in this process, others have failed to do so. Some would argue that the process of assessment is therefore flawed due to the limited knowledge base of the assessor. A further consideration is the fund of available resources. Social workers have limited budgets and can often place three clients in residential care when for the same amount of money only two clients would be provided with a nursing home bed. The category of ‘highly dependent resident’ has emerged in recent years.
These clients are placed within residential care homes as a cost saving measure and require heavy input from the district nursing service. It is therefore possible to conclude that ‘care in the community’ has from its inception been driven by available resources.

The reality is that more able patients are supported within their own homes or in residential care homes and, as a result, there has been a polarisation of very dependent and vulnerable patients within private nursing homes. Few patients are self-caring; many are immobile; and clients are only admitted when there are funds to support the care. It would appear that since CCA was introduced there are no fewer patients who require nursing care but a paucity of finance to support them.

1.1.3. Changes in the Nursing Home Industry.

There has been a steady increase in the number of registered nursing home beds both prior to 1993 and to the present day. Statistics for England published by the Department of Health (DoH) in 1998 are reproduced in Table 1. The figures exclude premises registered as private acute hospitals and clinics.

<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>No. of nursing homes</td>
<td>5,132</td>
<td>5,332</td>
<td>5,535</td>
<td>5,568</td>
<td>5,786</td>
</tr>
<tr>
<td>No. of registered beds.</td>
<td>164,638</td>
<td>173,648</td>
<td>178,671</td>
<td>184,889</td>
<td>193,898</td>
</tr>
</tbody>
</table>
The 1998 Statistical Bulletin also identified that 159,600 beds were registered for care of the elderly, which was an increase since 1994 of 27%. The relative numbers of clients in defined groups are presented as Table 2.

**Table 2:** Number of registered beds in nursing homes by client group in 1998.

<table>
<thead>
<tr>
<th>Client Group</th>
<th>Number of beds</th>
<th>% change from 1994</th>
<th>% of total beds</th>
</tr>
</thead>
<tbody>
<tr>
<td>Elderly</td>
<td>159,600</td>
<td>+ 27%</td>
<td>82%</td>
</tr>
<tr>
<td>Adults with special needs</td>
<td>6,400</td>
<td>not reported</td>
<td>3%</td>
</tr>
<tr>
<td>People with Learning Disability</td>
<td>3,500</td>
<td>+ 28%</td>
<td>1.8%</td>
</tr>
<tr>
<td>People with Mental health problems</td>
<td>25,500</td>
<td>+ 48%</td>
<td>13%</td>
</tr>
<tr>
<td>Other client groups.</td>
<td>3,400</td>
<td>not reported</td>
<td>1.7%</td>
</tr>
</tbody>
</table>

Community care statistics for 1999 indicate that while the number of registered 'general' beds has fallen slightly there has been an increase in beds for mental health care. This also illustrates the determination during the last decade to close psychiatric institutions as part of the community care strategy. The population rise in the private sector can also be identified with the major increase in elderly people. Further DoH statistics state that the number of clients supported by local authority in total had risen from 149,000 in 1994 to 244,600 in 1998.

It has already been discussed that the dependency and mobility of the nursing home population has increased markedly in latter years. This must be viewed with some concern because there are distinct limitations within the private care sector to provide the necessary care. Prior to 1984 and the enactment of the
Registered Homes Act, the premises used as nursing homes were not usually custom built and in the main were conversions of large private dwellings. These were not originally intended to provide care on an 'acute' level. Recent trends are to construct purpose built premises which feature single accommodation. But this alone would be insufficient to ensure that patients receive adequate standards of care. (The standards that are required in the private sector are separately discussed in section 1.2.). Care homes require adequate funding and appropriate staffing. The former has already been highlighted as a source of concern. Fees have been set by local authority committee with little or no reference to the providers. Staffing issues are further considered in section 1.1.4. Therefore, although the numbers of beds are increasing and with it the cost of funding continuing care, the debate about sufficient resource continues.

1.1.4. Staffing of Nursing Homes.

Nursing homes are required in law to provide 24-hour nursing care. The skill mix of trained and untrained staff has been the subject of much controversy but is currently set through regulation on the basis of a minimum level for a specified number of clients. It is anticipated that the staff allocation will increase above the minimum when any patient is assessed as requiring a higher level of nursing care.

Recruitment of nursing staff is a major issue in 2001. In recent years, much media attention has been focused upon the lack of trained nursing staff in UK. This has been experienced by NHS provider and nursing home alike, resulting in a competition for agency staff. Many homes have been unable to recruit and
retain adequate numbers of registered nurses to provide care at the minimal level.

The provision of appropriate and current training for nursing staff is another limitation upon the care home. Insufficient funding for care from local authorities has reduced the real income of registered homes. In this economic climate, the continuing provision of training for staff has been carefully scrutinised by nursing home owners. The United Kingdom Central Council for Nursing, Midwifery and Health Visiting (UKCC) requires all registered nurses to remain up to date and to practice within their own limitations of professional expertise. Increasingly it seems that some homes leave it to the nurse to meet this obligation both in terms of time and funding. This can result in a nurse pursuing a course of training because it has ‘interest’ value rather than staff being appropriately trained to meet client needs.

The UKCC published a report in 1994 that highlighted grave concern about the standards of nursing practice within care homes. In the preceding year, 26% of matters brought before the Professional Conduct Committee were nursing home related and the UKCC took the unusual step of producing a summary of the issues discussed. This identified eight case studies of which five included incidents related to medicines and their administration.

When discussed in its wider context, this is rapidly providing a recipe for disaster. Homes are seeking to care for very ill patients often with insufficient registered nurses. The nursing staff that they recruit may not have recent
experience of acute nursing and may lack necessary skills to provide 'high tech' treatments.

1.2. Regulation of Private Nursing Homes.

The regulation of care homes has not been well understood by professionals and public alike. This can lead to the assumption that the regulatory process is sufficient in itself not only to ensure the overall protection of clients who are among the most vulnerable within our society but also to provide an element of pharmaceutical care. It would seem pertinent to consider the current and impending legislation; and to establish why pharmaceutical care cannot be delivered through the process of regulation.

1.2.1. Registered Homes Act 1984.

The separate roles of residential care home and nursing home in England and Wales were established in the Registered Homes Act, 1984 (RHA). Similar legislation has been enacted within Scotland. The RHA sets out the nature of regulation of the private care industry and this has been précised by Ward (1997). There are notable exceptions to care regulation: all premises owned or run by health authorities; all premises owned or run by local authorities; and homes granted a Royal Charter.

The Act has been written as two Parts: Part I relates to the regulation of residential care; and Part II to the regulation of nursing care. Hence, from the outset, there have been two separate inspectorates: one within the local authority framework and the other within the NHS establishment. Each local
authority and health authority in England and Wales has been required to support a Registration & Inspection Unit (R&I). In total this represents 250 individual units. One aspect that has been common to both regulators is the apparent ‘conflict of interest’. Health authorities and local authorities enter into contracts with nursing and residential care homes to a greater or lesser extent. Even when the department concerned with contracts is distinct from the R&I Unit, the ‘arms length’ activities of regulation have not been perceived as truly independent.

1.2.1.1. Residential Care Home.

A residential care home is defined as providing ‘....accommodation with both board and personal care....’ for clients who are elderly, disabled, have a mental disorder or are dependent upon alcohol or drugs. Residential premises are registered and inspected by local authority inspection officers, who monitor that registered owners are complying with the requirements of The Residential Care Homes Regulations 1984. It is exceptional if a local authority inspection unit contracts for pharmaceutical involvement in the regulatory process.

Residents are provided with medical and nursing care from primary care sources. Hence, the nursing care element, if required, will be delivered by district nursing staff. A dilemma can occur if a residential homeowner recruits and appoints a registered nurse to the staff of the home. The home is prohibited in law from advertising that a nurse is on duty; and the nurse may not deliver nursing care. Failure to comply with this proviso may render the owners liable to prosecution for running an unregistered nursing home.
1.2.1.2. Nursing Home.

A nursing home offers to provide patients with 24-hour nursing care and is regulated by health authority inspection officers. The legislation covers a very wide range of providers of health care. The majority of registered homes provide care for the elderly and/or mentally ill. In addition, the legislation covers acute independent hospitals; clinics where surgical procedures are carried out; maternity homes; clinics for termination of pregnancy; and other premises where specially controlled techniques are undertaken. When homes opt to provide both nursing and residential care - the dual registered home - there is a requirement to separately register with both regulatory bodies.

The registered person is required to comply with the Nursing Homes and Mental Nursing Homes Regulations 1984. Additionally, the Residential Care Homes and Nursing Homes (Medical Records) Act was passed in 2000, which enforces tighter requirements in record keeping to rectify an anomaly. The Residential Care Homes Regulations 1984 included a requirement for records relating to medicine receipt and disposal in a residential home (Regulation 6). An equivalent requirement was not included in the nursing home Regulations already referred to.

1.2.2. Pharmaceutical Inspection of Nursing Homes.

There had been a statutory duty upon district health authorities to annually conduct two inspections of nursing homes on behalf of the Secretary of State for Social Services since 1977. The role of pharmacists in the process of inspection has become an established principal in most health authorities through Section
54 of HC (81) 8, which states that every place where medicines are stored in a
nursing home must be regularly inspected by a pharmacist. This role originally
was undertaken by District Pharmaceutical Officers.

There is no reference within the Act itself to medicine management. The legal
requirement is set out in Regulation 12 (1)(o) of The Nursing Homes and Mental
Nursing Homes Regulations 1984:

'The person registered shall, having regard to the size of the home and the
number, age, sex and condition of the patients therein, make adequate
arrangements for the recording, safe keeping, handling, and disposal of
drugs'.

It is therefore the duty of the pharmacist inspector to monitor whether
arrangements for medicine management in the nursing home meet the test of
'adequacy'. The term 'adequate' poses some problems of interpretation and in
Regulation 2 has been defined as 'sufficient and suitable', which leaves wide
scope to both provider and regulator.

The earliest published guidance about inspection in general emanated from the
National Association of Health Authorities (NAHA) in 1985 and contained scant
information about the requirements for medicines and medicine management.
In 1988, the Guidance was extended with pharmaceutical input and has become
the foundation for most local standards. These have largely been focused upon
the elements of medicine procurement; medicine storage; medicine
administration; records of medicine receipt, administration and disposal; and medicine disposal.

It is particularly notable that the RHA neither specifies nor requires standards of patient care. The RHA does, however, stipulate that both the building that is used as a nursing home must be 'fit' for the purpose; and the people who are registered to carry on a nursing home must be 'fit' people. The suitability of medicine storage is incorporated into the overall 'fitness' of the registered premises. However, other aspects of medicine management within the home can only be tenuously attached to the 'fitness' of the registered person. The ultimate legal redress against a nursing home is to cancel registration. This can only be achieved on the basis of 'lack of fitness' and this is a difficult premise to prove.

Inspection is a legal process and it is therefore inevitable that any action that regulators may wish to take in order to protect vulnerable patients will be limited by the legislation in force at any given time. The pharmaceutical role in the inspection of private nursing homes and hospitals was described by Trice (1989). This included the manner of conducting inspections in West Berkshire Health Authority. The article did not reference the legal process by which change can be effected within a nursing home nor the limitations on professional influence.

It is worthy of note that there has been no requirement for pharmacists to undergo any specialised training in the process of inspection. For the majority, experience has dictated knowledge and, for some, expertise. This opens the
door to inequality in inspection technique and content. Some pharmacists have extended their role into 'generic' inspection as members of the health authority team. But for most, the inspection task is a part-time commitment while employed within an NHS Trust.

Guidelines for the pharmacist involved in inspection were developed by the Community Services Pharmacists group (now renamed 'Primary and Community Care Pharmacy Network', PCCP) through two sister publications (1990, 1992). Both of these have been reviewed in recent years. The publications have provided a standardised method of conducting inspections and yet there continue to be different approaches throughout England and Wales. This is because each registering authority has been required to establish and publish the standards that are deemed to fulfil the term of 'adequacy' in the nursing home.

1.2.2.1. Standards of Medicine Management.

The Registered Homes Act 1984 requires registering authorities to be 'reasonable' in their dealings with registered owners. Standards may only be enforced when they have been published to the appropriate people. Further to this, any published standard must be able to withstand scrutiny. Legal requirements pose no problem but even established professional standards may be subject to strident challenge if they represent a personal view of the inspector.
Many health authorities have modelled their own publications on the NAHA Guidelines (1988), though more recently the trend has been more towards 'standards' rather than guidance to registered owners. Some of the standards for medicine management are entrenched within UK law e.g. The Medicines Act 1968, The Misuse of Drugs Act 1971 and The Misuse of Drugs (Safe Custody) Regulations 1973. Others are referenced to good practice in pharmaceutical or nursing practice e.g. 'Duthie Report' (1988) and 'Standards for the Administration of Medicines' (UKCC, 2000). Once published by a registering authority as the requirement to meet Regulation 12 (1)(o), the standards are conferred with legal status and are enforceable. However, these standards can still be subject to legal challenge.

As previously referred to in section 1.2.1. there have been 250 R&I Units within England and Wales, and of these, 105 within health authorities to regulate nursing homes. The reality of current regulation is that each of these units has separately sought to define 'adequacy' of medicine management for registered providers. Thus, there has been the potential for lack of consistency between differing authorities.

1.2.2.2. Monitoring Standards of Medicine Management.

Once an authority has published the required standards, the inspection process involves monitoring a nursing home's compliance with those standards. Any perceived deficiencies must be brought to the attention of the registered person and sufficient time allowed for the matter to be rectified. Continuing failure to meet required standards may result in legal action being taken by the registering
authority either by prosecution under the RHA in a Magistrates' Court or through the cancellation of registration. Either action depends upon sufficient evidence being presented by the registering authority to prove 'beyond reasonable doubt' that the owners have failed in their duty. Such evidence must be to the standard collated by the police force and the requirements of the Police and Criminal Evidence Act 1984 (PACE) applies.

When a registering authority proposes to cancel registration, the homeowner may appeal to the Registered Homes Tribunal (RHT), including when the authority is granted an Urgent Cancellation by a Justice of the Peace. In the RHT, the level of evidence is 'on the balance of probabilities' and the proceedings are considered to be case law. Many of the judgements have involved issues relating to medicines and their management and these are listed in Table 3. This information has been compiled by Birkett (2000).

Given that the registering authority's requirements relate only to the basic management of medicines and not to good principles of prescribing practice, comment on individual patient's medication review by the inspecting pharmacist is clearly inappropriate. Far from providing the pharmacist with a clinical involvement in the home, the inspection role is principally concerned with the collection of evidence and the application of a legal process. This model of professional activity may well place the pharmacist in an ethical dilemma should the inspection identify issues of clinical importance that are out with the scope of the pharmacist either for direct comment to the prescriber or for resolution.
Table 3: Registered Homes Tribunal Judgements relating to Drugs Issues.

<table>
<thead>
<tr>
<th>RHT Judgement No.</th>
<th>Issue</th>
</tr>
</thead>
<tbody>
<tr>
<td>76</td>
<td>Conviction for a drug offence.</td>
</tr>
<tr>
<td>110, 264</td>
<td>Administration of a drug without a prescription.</td>
</tr>
<tr>
<td>67, 95</td>
<td>Mishandling of drugs.</td>
</tr>
<tr>
<td>17, 34</td>
<td>Drugs missing.</td>
</tr>
<tr>
<td>46, 59, 79, 170, 187, 218, 244, 398</td>
<td>Lack of proper procedure for the administration of drugs.</td>
</tr>
<tr>
<td>26, 250, 372, 373</td>
<td>Poor Records relating to drugs.</td>
</tr>
<tr>
<td>255</td>
<td>Serious maladministration of drugs.</td>
</tr>
<tr>
<td>67</td>
<td>Storage of drugs.</td>
</tr>
<tr>
<td>192, 219, 222, 253, 256, 291, 297, 322, 340, 345, 351, 398</td>
<td>Lack of medication procedures; failure to make adequate arrangements for drugs; poor control of drugs.</td>
</tr>
<tr>
<td>87</td>
<td>Use of unsigned prescriptions.</td>
</tr>
<tr>
<td>79, 154, 187, 218</td>
<td>Inadequate drug management.</td>
</tr>
</tbody>
</table>

1.2.2.3. Authorisation of Inspectors.

All persons who inspect nursing homes must be duly authorised by the registering authority. The inspector who holds, and indeed carries, such authorisation must be granted access to the registered home. Any attempts to obstruct an inspection, either by refusing entry or failing to produce the necessary documents that the inspector has a right to view, is liable to prosecution under the RHA. The pharmacist inspector is therefore given an unrivalled opportunity and professional privilege, which is not a ‘right’ purely because of professional status. It is vital that the pharmacist inspector does not abuse this right in law by entering into activity that is not within the scope of the RHA.
1.2.3. Future Regulation.

The Care Standards Act 2000 has received Royal Assent and is due to be fully implemented in April 2002. It had long been identified that the RHA had weaknesses, including the separate regulators for residential and nursing care and the lack of consistency between differing R&I units. The greatest impact of the new legislation is that all care homes will be covered by one regulatory authority, the National Care Standards Commission (NCSC). The NCSC will have a headquarters based in Newcastle, 8 regional offices and a network of 71 area offices that will cover work previously conducted in 250 R&I units. The new commission will be a separate body from both local and health authorities. This will resolve the problems that have occurred when a statutory body has been required to place contracts of care and at the same time regulate the care provider.

The Registered Homes Act 1984 had carefully defined the difference between residential and nursing provision. The new legislation considers 'care homes' which will help to resolve the issues arising from dual registered homes. The implementation of the Care Standards Act 2000 is progressing at pace as outlined in 'Regulating Private and Voluntary Healthcare: Developing The Way Forward' (2000). The changes in regulation have also been cited in the government's response to the Royal Commission on Long Term Care (2000).

Amongst many changes in legislation it is useful to consider the National Minimum Standards that will be applied to all care homes. The first consultation document 'Fit for the Future' was published in 1999. The standards were
related to care homes for the elderly. Similar documents were also planned for other client groups but are as yet to be published. The intention was to provide standards that were '.....robust, measurable and enforceable.....'. It has been commented that the changes have a strong 'social' rather than 'health' bias.

The National Minimum Standards for Care Homes for Older People were published in March 2001 under section 23(1) of the Care Standards Act 2000. It is anticipated that these nationally agreed standards will be of major benefit to regulator and provider. Medication is included as Standard 9. Strong emphasis has been placed upon the self-administration of medicines by clients and also upon protection of clients through policies and procedures set by the registered home.

At present it is hard to speculate on the influence of pharmacists in the future regulatory process. Although nothing has been written into the legislation to ensure the continuation of pharmaceutical inspection, the preparatory work for the NCSC has included reference to an appointed pharmacist within each 'area' office.

1.3. Prescribing of Medicines in Private Nursing Homes.

The private sector cannot be perceived as wholly private and independent. With the exception of private acute hospitals and hospices, patients in nursing homes usually receive medical and para-medical services through the National Health Service, including the provision of prescribed medicines. Prescriptions (FP10) are written by General Practitioners before being dispensed by a supply
(community) pharmacist or dispensing GP. As a general view, it is difficult at times to convince carers in both residential and nursing homes that medicines belong to the clients and not 'the home'.

There is extensive prescribing of medicines for nursing home patients and particularly the elderly. Furniss has enlarged upon this theme with particular reference to the number of prescription items that elderly clients in nursing homes receive (2000). Weedle and Parrish (1984) raised early concerns about the repeat prescription system; and concern among pharmaceutical advisers at health authority, Primary Care Group (PCG) and Primary Care Trust (PCT) level still exists as discussed by Lawson (2000).

The medical perspective of repeat prescribing has been explored by Zermansky (1996) and McGavock et al (1999). One of the main findings in each publication was the failure on the part of some GPs to adequately review medication issued on repeat prescriptions. Main (1988) reported the considerable impact on repeat prescribing systems that can occur when GP-led medication review is inadequate. Pharmacists who work directly with GP practices may channel time into the review of the system of repeat prescribing but may have limited opportunity to review medication from a clinical perspective. It may be true to say that there is general concern about wastage of medicines through inappropriate prescribing, which places a burden upon the GP prescribing budget. This view is accentuated by pressure upon GPs from PCG and PCT.

The client groups cared for in nursing homes consume vast resources particularly in terms of GP time and the requirement for repeat medicines.
However, the registration of a nursing home does not take account of the willingness of GPs to provide care for these patients or otherwise. The prescribing patterns for care home residents were described by Petty and Scrivener (1998). GP prescribing budgets have been adjusted to cater for the extensive resources that nursing home patients can require utilising the Age Sex Temporary Resident Originated Prescribing Unit (ASTROPU). This system of weighting has been subject to revision as described both by Lloyd et al (1997) and Lloyd and Scrivener (1998). In 1997, Corbett reported that the weightings thus applied were still insufficient to meet the demands on the drug budget of GPs caring for nursing home patients in Northamptonshire.

What has not been provided for is the time for GP consultation that will inevitably be required for very ill patients. Groom et al (2000) compared the cost of providing medical care to nursing home patients with those based in their own homes. They reported that the majority of home visits, out of hours visits and telephone calls were identified to nursing home patients. As a result, the workload monthly cost per patient was more than twice that of a community based patient. These figures did not include prescribing costs.

Some homes have paid a ‘retainer’ fee to the GP practice. This has raised concerns within the British Medical Association (BMA). The view has been expressed that GPs are expected to deliver care in line with General Medical Services (GMS) expectation and further payment must only relate to ‘additional services’. One such service may well be the regular review of repeat medicines prescribed for patients.
A further factor to take into account is the prevalence, and necessity in the rural areas of UK, of GP dispensing services. Nursing and residential homes do obtain medicines from dispensing GP practices. This can occur even when a community pharmacist is within reasonable distance due to the regulations that cover GP dispensing.

1.3.1. Patterns of Prescribing.

The majority of medicines are prescribed for patients through NHS FP10 forms. As previously stated, the clients who reside in care homes are high users of medicines and many of these will be on a repeat prescription basis.

There is a high expectation that prescribers will respond to the requests of nursing staff. As a pattern of behaviour emerges, a nurse may ask for a drug to be prescribed and this is particularly likely to occur when the patient is confused or unable to offer an opinion about his/her care needs. Relatives may or may not become involved in this process. It is therefore possible for poly-pharmacy to occur because of carer rather than client request.

Once items become listed on the GP computer, it is up to the nursing staff to make requests for further supplies. It is usual for the supply to last for one month though some homes are encouraged by GP practices to retain a larger stock. There are, however, other options for a registered nursing home to obtain all categories of medicines and these are now discussed.
1.3.1.1. Purchase of Medicines.

The Medicines Act 1968 and the Misuse of Drugs Regulations 1973 provide for the matron of a nursing home to obtain Prescription Only Medicines (POM), including controlled drugs, by means of a 'signed order'. It is a system that is employed in hospices whose medicines are funded by health authorities and may be supplied from a hospital pharmacy department; and also in private acute clinics and hospitals. Purchase of POM rarely occurs in private nursing homes because the cost would have to be passed to patients, and the current nursing home clientele are usually exempt from NHS prescription charges. Additionally, nursing staff would require a written 'prescription' before the POM may be administered to a patient. The medicines that are commonly purchased, although not classified as POM, are 'homely remedies' and these are further considered in section 1.3.2.

1.3.1.2. Private Prescription.

There may be some instances when a patient is provided with a private prescription for medicines. This is rare but may occur when a patient wishes to continue with a blacklisted medicine.

1.3.1.3. Bulk Supply.

A medicine that is not POM may be supplied to a residential or nursing home as 'stock' under certain conditions. The home must provide care for at least twenty residents; the GP must provide medical care for at least ten of these patients; and at least two of the GPs registered patients require the medicine in question.
1.3.2. Administration of Non-Prescribed Drugs.

It is inherent in the Medicines Act 1968 that a prescribed medicine may be administered by anyone so long as the medicine has been prescribed and is administered in accordance with the prescriber's intention (Section 58 (2)(b)). As the legislation relates to drugs classified as Prescription Only Medicines (POM) this leaves a wide range of products classified 'General Sales List' (GSL) or 'Pharmacy only medicine' (P), which may legally be purchased by carers as well as patients. In some respects a care home may be considered lacking in its duty of care to clients if non-prescription medicines are not purchased for occasional use. But this opens up the opportunity for client abuse if not carefully controlled.

Non-prescribed drugs are frequently referred to as 'homely remedies'. Guidance concerning their use in the care home was included in the RPSGB publication 'Guidelines for the Administration and Control of Medicines in Residential Homes' (1986) and also the later edition that encompassed Children's Homes (1994). The content was largely based upon work undertaken in Derbyshire (Pharmaceutical Journal, 1987). The homely remedy has also been the subject of other writers. The findings of Weedle et al (1987) were particularly alarming because residential care homes held a wide selection of POMs for this purpose. In a nursing home, this could occur either when it is wrongly perceived that medicines are the property of the home; or if medicines are retained for communal use after the death/discharge of a patient. In such circumstances, the home's policy for medicines must be unequivocal in its statements about ownership of medicines in the home.
The move to reclassify POM as P medicines has widened the opportunity for carer purchase of medicines. However, since the patients in nursing homes are generally exempt from prescription charges, it is unlikely that the homeowner will sanction the purchase of medicines. As identified in section 1.3.1.1. the burden of charging patients for their medicines is usually only undertaken by acute independent hospitals.

The decision by a carer to administer medicines without a GP prescription is further complicated when the client is unable to state a preference. The elderly population in nursing homes includes those who are confused or categorised as 'elderly mentally infirm'. To protect clients in these and other circumstances, regulators generally require written policy documents which have been prior agreed with GPs who care for patients in the home. Staff in homes may take the opposite view and only administer individually prescribed medicines. This gives little or no leeway for resident choice in the matter.

The interest in homeopathic and herbal remedies is increasing and these may be purchased by clients or their relatives. Some nurses do not have a clear understanding about alternative remedies and may be unwilling to oversee their administration. Or conversely, there is little to prevent the pioneering nurse who wants to introduce alternatives to clients in his/her care.

1.3.3. Inappropriate Prescribing of Drugs.
Inappropriate prescribing for the elderly has been the subject of much discussion. A report of the Royal College of Physicians (1997) particularly
highlighted the need for continuous re-assessment of medication regimes by prescribers. Hospital admission of the elderly due to iatrogenic disease has also been discussed by D'Arcy et al (1991). They attributed many orthopaedic admissions to poly-pharmacy, particularly with medicines affecting the central nervous and cardiovascular systems.

Few studies have centred upon the appropriateness of prescribing in care homes. An article by Weedle and Poston (1985) described the potential drug interaction rate of 9.2% in a group of 1,888 care home residents. The study reported by Monane et al (1993) identified the high incidence of prescriptions for daily laxative products in residents prescribed anticholinergic drugs. Lunn et al (1997) concluded that care home clients were subject to high risk of adverse drug reaction and in a population of 101, 53% were deemed to have at least one prescribed drug that was inappropriate. Later work by Oborne et al (1999) audited prescriptions for nursing home patients with airway obstruction and identified inappropriate prescribing.

The view has been expressed that the provision of some medicines to clients has been for the purpose of control and even restraint. The system of regulating prescribing of psychoactive drugs in USA nursing homes is considered in Chapter 2. However, it is important at this stage to consider research conducted in the UK. McGrath and Jackson (1996) used USA criteria to study the extent and nature of psychoactive drug prescribing in nursing home patients. Their findings were that 88% of prescriptions for this class of drug were inappropriately prescribed. Oborne et al (1998) documented similar
results to Lunn et al (1997) in relation to the inappropriate prescribing of neuroleptic drugs in 463 patients in 12 nursing homes.

In 1997, the Alzheimer's Society conducted a survey to establish any areas of concern in the care provided by care homes for clients with dementia. Relatives were particularly concerned about the lack of consultation about prescribed drugs (56%) and also the use of drugs for the purpose of controlling behaviour (54%). Hughes (2000) gives a broad overview of the current situation in the UK. It is possible to formulate the view that some prescribing in nursing homes may fall short of good clinical practice and may not be in the best interests of the patients.

1.4. Pharmaceutical Care in Private Nursing Homes.

It is a matter of some concern that despite the increase in patient dependency together with increased numbers of patients, it cannot be anticipated that patients in care homes in 2001 receive 'clinical' input by pharmacists which mirrors the service provided for continuing care in NHS trusts. Indeed, the clinical pharmaceutical picture has not altered markedly since the introduction of the NHS and Community Care Act 1990. The 'National Service Framework for Older People' (2001) has emphasised the significance of medicines in the elderly and suggested models of care delivery. The question must be raised whether it is feasible for a community-based pharmacist, within the current NHS contract for services, to provide pharmaceutical care to each patient in the nursing home. Elderly patients often have multiple pathologies. The number and cost of the drugs that they use are substantial and, as discussed by Trewin
et al (1991), adverse drug reaction is not insignificant. The patient who personally visits a pharmacy to collect medicines has the opportunity to access individual professional advice. How an equivalent service may be provided to the care population at large has not yet been resolved.

A pertinent problem within care homes is the extent to which clients are encouraged and supported to manage medicines for themselves. The view of local authority officers within residential care regulation is very definitely weighted towards this aim. Some registered nurses find it a difficult concept as discussed by Adie et al (1994) who reported a lack of self-medication schemes in the three homes studied. Where they existed, the involvement of the supplying community pharmacist was minimal. This leads to the possibility that clients in care homes obtain information about prescribed medicines through an intermediary, if indeed they obtain any at all.

The pharmaceutical profession also needs to carefully consider the expressed opinions of The Royal College of Physicians. The report 'Medication for Older People' (1997) was critical of the care delivered to older people and particularly in the care home. Although some criticism was directed towards prescribers there was comment about standards of medicine management within care homes and pharmaceutical influence upon these. A more recent report 'The health and care of older people in care homes' (2000) supports the ideal of employing specialist pharmacists to work in care homes. This prompts the question why a profession other than pharmacy is apparently taking the lead in this issue.
1.4.1. Pharmacy Contract to Supply Medicines.

It has already been emphasised that the majority of patients in a private nursing home obtain medicines on NHS prescription from a GP. For many community pharmacists, the main focus of service to a care home revolves around the mechanism to ensure that the supply of prescribed medicines is available when needed. Many homes have come to rely upon the provision of Monitored Dosage Systems while others continue to obtain medicines in traditionally dispensed containers. In all cases, the speed with which changes in drug therapy can be translated into actual medicines is crucial to nursing staff. It is therefore easy to understand why the issues of procurement of repeat and acute medicines can dominate discussions between nursing home staff and pharmacist.

The current community pharmacist contract is based upon payment for dispensing alone and this situation has not encouraged activity to reduce the number of items prescribed for a patient.

1.4.2. Contract for Pharmaceutical Advice.

A role for pharmacists in both nursing homes and residential care homes was highlighted in the 'Nuffield Report' (1987) and also the 'Report of a Joint Working Party on The Future Role of Community Pharmaceutical Services' (1992). Neither report gave a lead to pro-active pharmaceutical participation in medication review or promoting cost-effective prescribing in the care establishment.
The Pharmaceutical Journal published the findings of a RPSGB Working Party (1988), which included the view that residents of registered homes would require a greater input of pharmaceutical care. The Society's official guidance concerning services to nursing homes was published in 1990. However, this does not imply any direct 'clinical' involvement at patient level. The professional lead in ethics (Medicines Ethics and Practice, 2000) indicates that medication review in a care home is an optional service, provided at the discretion of the pharmacist, rather than a professional obligation. This section is included as Appendix V.

Before a formal approach to pharmaceutical advice was adopted, there was evidence of good practice most notably in Derbyshire, as reported in the Pharmaceutical Journal (1987), where a pharmacist was jointly appointed by health authority and social services to spearhead safe practice in residential care homes. In Barnet, Beaman (1987) reported the adoption of a standard approach but this was restricted to care homes owned and managed by the local authority.

The additional contract to provide advice relating to supply, storage and administration of medicines to residential care homes was instituted nationally by the publication of HC (FP)(89)13 during 1989. This Health Circular also announced payments for the retention of Patient Medication Records (PMR) by community pharmacists. Payment for advice was based on the number of beds in the establishment and restricted to homes registered under Part I of the RHA. At that time, the contract excluded private nursing homes that are registered under Part II of the Act and also premises exempt from registration as described
in section 1.2. It is commendable that similar service was often provided to nursing homes even though there was no financial incentive to do so.

In 1994, FHSL(94)59 titled 'Local Pharmacy Budgets' announced that the pharmacist contract for advice was extended to include homes registered under Part II of the RHA. Non-registered homes were still excluded. To qualify for the additional funding, pharmacists were required to complete the distance-learning course 'Residential Homes' published by the Radcliffe Medical Press (1989). This course was further developed by the Centre for Pharmacy Postgraduate Education (CPPE) in 1994 entitled 'The home away from home' and published as the second edition in 2000. This, together with the agreement of the homeowner, was and still is sufficient to initiate payments from the relevant health authority for advice. The original requirement was set out in the Drug Tariff. Pharmacists were required to make four visits annually to advise on the 'safekeeping and administration of drugs'; and to keep records of the dates of visits and nature of the advice offered.

The present contract has two fundamental weaknesses:

i. there is no professional requirement for a pharmacist to offer the service;

ii. there is no legal requirement for a home to accept or implement the pharmaceutical advice offered.

The contract is agreed on an annual basis with the owner of a care home and formally notified to the health authority; and may only be provided by a contracted community pharmacist. Provision of a 'clinical' service either from a hospital trust or independent pharmacist was not envisaged.
The health authority is responsible for monitoring the contract and the RPSGB inspectorate may undertake this. Large companies and specific groups including the National Pharmaceutical Association (NPA) have produced 'checklists' for the pharmacist to complete. It is hardly surprising that many registered homes have come to view the pharmacist input as another 'inspection' visit in addition to the regulatory function described in section 1.2. A leading article in the Pharmaceutical Journal by Taylor, Rihal and Iles (1995) identified the differences between 'inspection' under the RHA and 'advice' by the community pharmacist. Despite fundamental differences, the roles have become confused both within and without the profession of pharmacy.

From the outset, the contract for pharmaceutical advice did not specify involvement in the process of medication review for individual patients. The professional aspect of dispensing which requires the pharmacist to carefully assess whether there are contra-indications to the concurrent use of medicines is anticipated. But this does not extend to the formal clinical review in liaison with the prescriber. It can be strongly argued that the level of advice provided to a home cannot match the pharmaceutical input that patients would have received as an inpatient in an NHS long-stay ward. Clinical pharmaceutical input to such wards would be anticipated at least on a weekly basis.

A further change has occurred in this contract with the publication of HSC 1999/076. It is now the responsibility of a health authority to determine how the devolved fund of finance for additional pharmaceutical services will be distributed. Although many health authorities have not altered the previous arrangements, some have adopted a novel approach such as in the Isle of
Wight. Here the health authority has appointed a pharmacist to provide advice to all registered homes. It is hardly surprising that the response of community pharmacists to this initiative has been negative as reported in the Pharmaceutical Journal (2000) entitled 'IoW pharmacies to withdraw services from residential homes'. Very recently, Tees health authority has awarded a contract for medication review in care homes to a multiple community pharmacy also reported in the Pharmaceutical Journal under the title 'Moss wins Homes Contract' (2001).

In spite of the limitations of current contracts, studies have shown the benefits to the residential home of registration with a community pharmacist. Norman and Scrimshaw (1994) reported that residential care homes who had regular pharmaceutical advice exhibited higher standards of medicine management than those who did not. Statistical analysis identified significant differences when a care home had a pharmaceutical advisory contract. However, the study criteria did not include involvement of the pharmacist in medication review of individual clients.

It is interesting to note the outcome of a survey of residential care homes in the West Midlands prior to introduction of the advisory contact. Haines and Bradley (1990) reported that there was a high level of interest amongst the home managers/owners for advice about storage; pharmacist check of drug interactions; and a delivery/collection service.

Although there were varied problem areas, both homes experienced a greater number of problems associated with record keeping and also medication regimes. It would appear that pharmacist involvement is not only essential in relation to appropriate prescribing but also in assisting care staff to safely manage medicines for clients.

Additionally, the report of Duggan et al (1992) highlighted that the provision of services varied according to the motivation of the pharmacist concerned. The uptake of the advisory contract in West Sussex was researched by Stewart (1993). It was again recorded that pharmacists were not involved in medication review. It must be a matter of concern that one third of the homes who responded to the questionnaire had felt that the pharmacist input had achieved no change! This and other studies also identified that home owners would welcome the pharmacist involvement in training. The training package ‘Take Good Care with Medicines’ written by CPPE and distributed in 1991 has formed the basis of training for care staff. However, the extent of pharmaceutical involvement in providing training has yet to be assessed.

It is useful at this stage to consider the uptake of the advisory contract. The DoH report for the year to March 1999 states that 36% of pharmacies received payment for this service to both residential and nursing homes. The number of homes included in the scheme was 15,358 of which 3,468 were nursing homes. Further DoH statistics indicate in the same year that there were 6,100 registered nursing homes, hospitals and clinics. The only conclusion that can be drawn from these figures is that there is an appalling gap in the provision of pharmaceutical advice to registered nursing homes.
1.5. Research Methodology.

The question of whether a pharmacist could positively influence the process of prescribing for nursing home patients through a structured approach to medication review spurred the decision to conduct this study. The project was planned by initially setting the key objectives that are outlined in section 1.6. This was followed by consideration of the methods by which data relating to prescribing for patients in nursing homes may be captured and analysed. Consideration was given to the selection of a group of nursing home patients to base the study upon. The decisions about recruitment were influenced by the nature of nursing homes registered with Norwich Health Authority; and the willingness of proprietors, nursing staff and GPs to cooperate in what would be a lengthy process.

When a selection of the study sample had been agreed, the nature of data capture was determined. To provide evidence of change, the researcher required access to records that would identify the medicines that were prescribed for patients; and the pattern of administration of those medicines either by patients or nursing staff. The records that were required included those maintained by nursing staff in home. Access to GP medical notes was also considered essential for the process of medication review to be comprehensive. The study would thus be able to give an appreciation of the nature and extent of diagnoses relative to the study sample. A number of other variables were also included in the study and these were largely determined from documentation used in USA. This type of study had not been prior conducted in the UK and it was an important feature to develop documentation
that the researcher would use. It thus became another facet of the project to judge whether the documentation was entirely suitable for the intended tasks.

The study involved more than the recording of data from GP and nursing records. The decision to interview patients using a structured format was to gain an understanding of the level of patient dependence upon nursing staff. This approach also proved beneficial in providing unsolicited comments about medicines. These descriptive statements were not subject to analysis but have been included as an important feature of the project. Another different mode of research was the Observation of nurses when they were undertaking the drug round in each nursing home. A specified set of criteria was used to identify whether the observed practices met with standards published by the UKCC.

To place the methodology employed within this study in context, the varying methods by which practice research may be conducted are now considered.

1.5.1. Pharmacy Practice Research.

There has been rapid development in the field of pharmaceutical practice research in the past decade. One of the foremost requirements of any study is that the research protocol is based upon sound principles of research methodology. The actual design will be influenced by the number of variables being measured, including the setting that the study will be conducted in. Time and financial resources will also be factors for consideration. In fact, these may dictate to a degree the sample size even though, in the ideal study, this will be decided on the basis of confidence in the results that are obtained. Essentially,
the research project should be designed so that the results will be applicable to a wider population than that selected.

Pharmaceutical practice research is frequently constructed as a scientific model of quantitative measurement, including the current study. However, Smith (1997) comments that qualitative study methods are also widely used. It is arguable that the mix of both types of research enhances a study and Goldstein (1995) argues that this approach has been useful to identify how a pharmacist interacts in a multi-disciplinary health setting.

1.5.2. Quantitative Research Methodology.

In some respects it can be argued that quantitative research is easier to comprehend and produces measurable outcomes such as the average number of prescription items per patient. Tulley (2002) gives a clear account of differing methods of conducting such a study, as do the publications of the Pharmacy Practice Research Resource Centre (PPRRC, 1992). One such study design is the Before/After study. Although this may be designed as a single set of measurements pre- and post-intervention, this type of study can also be employed within a controlled study, that is one in which the study population has been allocated to a control or intervention group. Tulley comments that one of the problems of using single measurements is that there can be wide variation in the results due to anomalies. The nature of allocation can be random or non-random and may involve the matching of patients.
The use of Interview or Questionnaire is common in quantitative design. Each requires similar skill to formulate questions that are relevant to test the study hypothesis; and also to convey the true meaning of the question to the respondent. Interview technique can be structured, semi-structured or informal. The results may suffer from interviewer bias and particularly so when an interviewee makes responses that he/she feels the interviewer would wish to hear. Questionnaires are a relatively inexpensive means to collate data. There are differing methods for capturing the opinions of respondents including two-way question; differential scale from 'agree' to 'disagree'; and the option to rank listed responses in order of importance. Such studies are totally dependent upon the rate of response and this variable is difficult to manage effectively.

Another study method is to utilise a survey instrument or research tool. In this instance, it is important to have a validated tool, that is one that has been tried and evaluated prior to use in a project. Day (1995) gives a clear outline of this process through the development of the Liverpool University Neuroleptic Side Effect Rating Scale (LUNERS). In the second of two linked papers, Smith (1997) reviews the development of a range of survey instruments and comments on their reliability and validity.

Study design may also incorporate peer review of researcher input. This approach has been noted in the study conducted by Rees et al (1995) where a team of medical and pharmaceutical experts graded recommendations made by the community pharmacists during the study as potentially life-saving through to potentially life-threatening. The use of an independent panel in this manner contributes to the reliability of the results.
1.5.3. Qualitative Research Methodology.

Qualitative research provides a description rather than numerical analysis of the subject and this approach to research has also been described by in two related papers by Smith (1998). The approach may be through Focus Groups, which is a useful tool to generate ideas prior to commencing a research project. These groups may consist of a cross section of up to twelve participants who may have never met before the session. A moderator usually identifies themes for discussion and facilitates the session, which is taped and then produced as a transcript. As many as four groups will usually discuss the same topics. The merit of this approach is that the participants will state their own views and will not be subject to bias as a result of a researcher's interview technique. One of the limitations, however, is that a strong voice may emerge within a group and this may inhibit the opinions of others. From the written transcripts the researcher identifies hypotheses that can be followed up as a further element of research.

Another approach to qualitative research is Observation. This may be undertaken without the knowledge of the people who are being observed (covert study) or with the agreement of participants (overt study). In either case, the researcher is reporting what actually happens rather than what a participant states happens; and the results are less likely to be contaminated by researcher prejudice, which can occur in the Interview scenario. However, when the study is overt, and the researcher is recognised as a member of the team being observed, the researcher can introduce a bias because of prior knowledge of
people and situations; and the participants may act differently because they know they are being watched. Observation is a technique that can be effectively used alongside other methodologies to supplement quantitative data and this has occurred in the current study. As a technique it cannot provide a random sample and is not suitable for statistical analysis. The researcher can present the findings as summaries of responses, using quotations to illustrate the points raised.

1.5.4. Sampling for Practice Research.

Irrespective of the style of study design, adequate sampling of the studied population is a major component. This can be empirically described as 'Probability' or 'Non-Probability' sampling. In probability sampling, all members of a given population may in theory be selected for a study. This can be an expensive option for research and has greatest use when Questionnaires are the chosen mode. In contrast, a non-probability sample may be described as a 'typical' group of the people that the research is focussed upon. Such studies are based upon 'units' of the research population that are readily accessible.

The size of the study sample will affect the degree of confidence that can be placed in results. When surveys are conducted, the researcher may employ a sampling frame to select the study population. Due to the complex nature of this topic, the researcher is well advised to seek expert guidance from a statistician when determining the sample size appropriate to the subject under study. The current study used a non-probability sample and this has restricted the potential for wider generalisation of the results.

The principal aim of the study was to identify whether there was a measurable difference in the number of prescribed medicines for selected patients within UK nursing homes when a pharmacist conducted regular medication review. The study was related to the practice of consultant pharmacists in USA and this is described in more detail in Chapter 2.

It is relevant to question whether such a study was necessary. Prior to 1993, published work had not sought to mirror the USA model. In fact, USA consultant pharmacist activity was largely unheard of in the UK. A short report in the Pharmaceutical Journal 'Servicing US nursing homes' (1990) was not followed up by significant debate. A review of literature produced much to commend pharmaceutical influence on prescribing behaviour for patients in private nursing homes but was largely focused upon practice in the USA. Hence, a valid question for this study was to establish whether the type of healthcare provision had an influence upon the effectiveness of pharmacist-led medication review.

There are few examples of clinical pharmaceutical involvement in care homes. Provision of a clinical pharmacy service to nursing homes was described by Lapsley in 1988. Interventions, which were made in a 'ward type' service, were classified and illustrated a wide range of pharmaceutical needs. The service was described as 'prescription monitoring' which activity may reasonably describe ward pharmacy at that time. The service was provided from a hospital base.
Further research into community pharmacist involvement in care homes has been undertaken by Wright et al (1994). The potential benefit to clients when pharmacists undertake regular review of medication was analysed. As with Lapsley, the study did not involve analysis of baseline data prior to pharmacist interventions. However, the study highlighted the reduction in prescribing and therefore a cost saving to the NHS.

A report of the work of Wright and Chrystyn (1994) into therapeutic and biochemical monitoring in care home patients has also indicated the major benefit to patients that can occur when pharmacists become involved in a clinical activity.

Further work by Rees et al (1995) confirmed the potential benefit to patients of pharmacist intervention in medication review. But this study also highlighted the difficulties of adequate communication with prescribers and the somewhat disappointing GP response (54%) to recommendations.

The work of Furniss et al (2000) describes pharmaceutical intervention by review of patient medication. The study compared results from an intervention group in which reviews were conducted with a control group that had no pharmaceutical intervention. There was a decrease in prescribing and prescribing costs in the intervention group. Rather surprisingly, the authors reported that the intervention group exhibited cognitive deterioration that was greater than the control group.
Another insight into clinical involvement by community pharmacists has been offered by Hemmings et al (1991). In this case residential care units were owned and operated by the health authority and as such were not registered. However, the decision to contract pharmaceutical supply and clinical service to a community pharmacy was explored. The conclusions drawn from this arrangement were very positive but highlighted the importance of training for the community pharmacist.

It is indeed interesting to note that differing models of pharmaceutical care are emerging through the introduction of Primary Care Groups and Primary Care Practice Pharmacists. Klepping (2000) gives a clear description of medication review in care homes. It is likely that the impetus for such activity was financial since the main focus of activity by pharmaceutical advisers at health authority, PCG/PCT and practice level has been to reduce prescribing costs. However, it is also possible that pharmacists working in this field may achieve what community pharmacists have failed to explore due to lack of financial support.

A report in the Pharmaceutical Journal (02/06/2001) was particularly encouraging. A GP in Birmingham who addressed a meeting of the UK Drug Utilisation Group stated that the care of patients in a nursing home was improved by pharmacist-led medication review. The short report appeared to indicate that the pharmacist involvement was focused on cost savings to the GP budget.

The conclusion can be drawn that despite the fundamental changes in the delivery of continuing care, clinical pharmaceutical involvement in the care home
has not developed to meet the challenges of care provision. To further identify whether such involvement would prove beneficial both to nursing home residents and the NHS in general, the current study was established.

Taking account of other work in this field, the hypothesis was formed that there was opportunity for pharmaceutical involvement in medication review of nursing home residents in the UK. The study design and methodologies that were employed are described in Chapter 3. The study comprised three distinct phases, each of which had key objectives. To test the hypothesis, the decision was taken to conduct an interrupted time-series survey on the same group of nursing home patients, designed to assess the impact of pharmaceutical recommendations. Measurements were made of the time input to achieve each of the elements of medication review. In an attempt to reduce the potential for sampling error, the study sample was recruited from two nursing homes.

The first phase was to establish from prescribing patterns at baseline what level of need existed for pharmaceutical intervention in a sample of nursing home residents. The key objectives of this phase were:

i. To establish the nature and extent of prescribing for patients in the private nursing home setting.

ii. To investigate the administration of medicines within private nursing homes relative to the prescriber's intention.

iii. To investigate the quality standards of medicine management within private nursing homes.

iv. To establish whether pharmaceutical advice should be provided to nursing homes, and the nature of such advice.
The second phase was to quantify and classify the pharmaceutical interventions made in respect of these residents; and further to record the rate of acceptance and implementation by appropriate practitioners. The key objectives of this phase were:

i. To establish the nature and extent of pharmacist recommendations concerning the prescribing and administration of medicines in a discreet group of nursing home patients.

ii. To investigate the level of acceptance of pharmacist interventions both by medical practitioners and nursing staff.

iii. To establish the nature of any patient outcomes from implementation of pharmacist recommendations.

The third phase was to repeat the study of prescribing patterns and make comparisons about the nature of prescribing with the baseline. The key objectives of this phase were:

i. To establish the nature and extent of changes in prescribing of Regular and PRN medicines in two nursing homes following pharmaceutical intervention.

ii. To investigate the changes in patterns of medicine administration following pharmaceutical intervention.

iii. To investigate whether the provision of pharmaceutical advice contributes to individual patient benefit.

iv. To investigate the investment of pharmacist time that was necessary to provide this level of service.
Chapter 2

The USA Model of Pharmaceutical Care in Nursing Homes.
Chapter 2: The USA Model of Pharmaceutical Care in Nursing Homes.

The majority of published information in the field of nursing home pharmaceutical care has emanated from the USA. Chapter 2 incorporates an overview of consultant pharmacist involvement in USA nursing homes together with comment upon the influence this has had upon practice in other western countries. The nature of care provision and the regulatory influence upon nursing care will also be discussed.

2.1. Provision of Nursing Care in USA.

Nursing facilities in USA provide for the full spectrum of nursing care. There are three basic categories of provider:

- Skilled Nursing Facility (SNF) – which may equate with the UK model of acute care in private hospitals and clinics.
- Long-term Care Facility (LTDF) – which can be considered the closest equivalent to private nursing homes for continuing care in UK.
- Intermediate Care Facility (ICF) – providing specifically for the needs of mentally ill or learning disabled clients, which in the UK may be categorised as either a nursing home or a residential care home.

The number of beds in a facility varies but in general is higher than the equivalent provider in UK. The patients that these facilities accept may be self funding, supported through insurance cover or state funded by Medicaid or Medicare. Irrespective of the source of patient funding, the facility administrator has a
concern about the cost of prescribed drugs, which must be purchased by the facility.

2.2. Pharmaceutical Involvement in Nursing Facilities.

A clear exposition of pharmacist involvement in USA nursing homes has been described by Bryan and Martin (2000). The term 'consultant pharmacist' was introduced during the 1950's to identify those pharmacists who engaged in a wide provision of services to nursing facilities. It is interesting to note that pharmaceutical services are provided from a variety of sources: community pharmacy, closed pharmacy and hospital pharmacy. The nursing facility will only be directed to a source of supply if the patients' insurance cover has dictated this.

Early in 1990, Webster made a presentation to the PSNC conference in London about the practice of consultant pharmacists in USA, reported in the Pharmaceutical Journal under the title of 'Servicing US nursing homes'. This gave a broad overview of dispensing and consultant services, particularly the process of Drug Regimen Review (DRR) discussed more fully in section 2.2.2.

The provider of clinical pharmaceutical services – the consultant pharmacist – is not necessarily associated with the supply of medicines. There is concern in USA about conflict of interest and in some states there is a requirement for the consultant to be entirely independent of the supply function. The consultant may be a pharmacist owner or employee but equally may be an independent practitioner or an academic. In 1990, it was suggested to the author that a full time consultant pharmacist would carry a caseload of 1,000 to 1,200 patients.
There are responsibilities that the consultant pharmacist is associated with in addition to medication review. These encompass the policies and procedures for medicine management within the facility and training of the facility’s staff in medication-related subjects. The American Society of Consultant Pharmacists (ASCP) Guidelines anticipate that the consultant pharmacist will be active in preparing the facility to meet the stringent requirements of legislators as well as ensuring the safe prescribing and administration of medicines within the facility (1981). The nature and extent of consultant pharmacist involvement is variable and will be determined by the individual contracts for service with facilities.

2.2.1. American Society of Consultant Pharmacists.

In 1968 the American Society of Consultant Pharmacists (ASCP) was established and currently has in excess of 7,000 members in USA and other countries worldwide. The history of ASCP has shown that change in the practice of pharmacy occurred due to the commitment of individual pharmacists who perceived that there was a need for pharmaceutical care in the nursing home environment. Walker (1971) described ways in which a pharmacist could become involved in LTCFs.

In 1972, Bennett made a strong argument that community pharmacy techniques were not suitable for the provision of pharmaceutical care to nursing home patients and that the service must alter to meet need. He identified an 18% medication error rate related to three key factors: inadequate consultant pharmacist involvement; high number of occasions each day that nurses selected a medicine dose for patients; and clinical rooms that were poorly designed. He advocated the use of monitored dosage systems and drug trolleys to transport
medicines direct to patients as a safety measure that community pharmacists were able to provide.

ASCP produces guidelines of best practice; provides education and training, which is a requirement for continuing membership; and has established a research foundation particularly in the care of elderly people. High on the agenda of ASCP is the lobbying of legislators to achieve change and this has been a very successful strategy as outlined in section 2.3.2.

2.2.2. Drug Regimen Review.
The main service provided to nursing facilities by consultant pharmacists is the monthly review of medication - referred to in USA as the 'Drug Regimen Review' (DRR). This is closely associated with the responsibility of the pharmacist to communicate any problems either to the appropriate prescriber or the director of nursing. This activity has been incorporated into legislation as discussed in section 2.3.

Many papers have described the benefits that have accrued to patients as a result of DRR and also the cost benefit of pharmaceutical intervention. These are discussed later in this section. It must be considered that nursing facilities have a high interest in the overall cost of drugs for patients due to the manner in which private care is delivered. The concern about cost is equally of concern to government at state and federal level; and to insurance companies whose budgets are not open ended.
Dyer et al (1984) give a broad overview of the earlier literature. A reduction in the number of drugs prescribed for patients as a result of regular DRR has been published, amongst others, by Cheung and Kayne (1975), Cooper and Bagwell (1978) and Young et al (1981). Dyer also highlights that reduction in the cost of drugs is the subject of other studies, the most notable being Kidder (1982) who placed a monetary value on the annual savings to state funded care schemes (Medicare and Medicaid) by pharmacist-led DRR.

Rawlings and Frisk (1975) described the range of services that pharmacists may provide to SNFs. The regular review of medication was reported to be effective in reducing the average number of prescribed drugs per patient from 7.7 to 6.1.

Work by Thornley et al (1992) described the effect of withdrawing the clinical pharmacy service in a nursing home care unit over a period of 2 weeks. The result was an increase in prescribing which was reversed when the service was reinstated. They concluded that the service must be provided on a continuous basis to achieve good prescribing practice.

A decrease in the number and hence the cost of prescription drugs in LTCFs as a result of DRR was described by Strandberg et al (1980). The results indicated a decrease in the monthly bill for medicines of 29% per patient. In 1979, Aycock et al had published research into the prescribing and administration of PRN drugs in LTCFs. A high percentage were not utilised which resulted in wastage and unnecessary costs to the facility. The paper also clearly identified that there was insufficient funding from the Health Care Financing Administration (HCFA) at that time to enable further pharmacist involvement in nursing homes.
In 1991, Obenchain published a retrospective review of consultant pharmacist recommendations in a Kentucky nursing home of 130 beds. The recommendations were either to discontinue or reduce the dose of medication during a 12-month period. Of 135 interventions, 51 patients whose medication was discontinued remained stable; and 27 whose medication dose was reduced also remained stable. Only 12 patients were reinstated to original doses.

Further work has established patterns of poor prescribing which, without intervention, may result in drug interactions. Miller et al (1993) identified 1,087 potential drug therapy problems in a population of 315 patients during a 13-month period. Of the recommendations made, 81% were accepted, resulting in cost savings totalling $44,000 during this period. More recently, researchers have focussed upon specific issues such as ‘unacceptable’ medications for the elderly. Byars et al (1999) concluded that 43% of identified unacceptable medicines were either reduced in dose or discontinued following pharmacist intervention.

The impact of medication on risks to residents has also been the result of consultant pharmacist involvement. Cooper (1997) reported that a range of medicines were associated with a risk of falling. The number of falls experienced by patients decreased when physicians accepted pharmacist recommendations.

The importance of team working between pharmacist, physician and nurse was researched by Karki et al (1991). This study compared 2 workstations in an ICF, one of which was the baseline. The number of prescribed drugs/doses decreased in the station selected compared to the baseline station and this resulted in cost savings to the facility.
2.2.3. Quality Control Report.

The remit of the consultant pharmacist extends beyond the monthly DRR to assist the facility to meet other requirements of regulation. This activity may be closely affiliated to the community pharmacist 'advisory' role in the UK. During a visit by the author to USA in 1990, consultant pharmacists in two separate companies described the provision of a quality control report on a quarterly basis. An example of this report is attached as Appendix II.

The style of report may identify when required standards are complied with, partially complied with or not complied with. Much of the written information supplied by the consultant pharmacist identifies a measure of compliance with acceptable practice and can be expressed as a percentage of all required standards. The issues that may be focussed on include the availability of medicines; the storage of medicines; the system of medicine administration; record keeping; and correct disposal of medicines. This corresponds to the content of UK standards published by R&I units to specify the nature of 'adequate arrangements' under the RHA.

In particular, consultant pharmacists observe the 'med-pass' - the term used to describe administration of medicines. This aspect of care is observed during regulatory visits (ref. section 2.3.) and staff are also observed regularly by the consultant pharmacist to ensure that the correct procedures are being observed. The findings from this exercise have been utilised as a training tool within the facility.
2.2.4. Training in Medication Issues.
Staff training has been given a high priority by consultant pharmacists. This was not solely focussed on medicine administration when monitored dosage systems were in use. Training materials also related to clinical pharmacy issues, regulatory requirements and the use of non-drug interventions. As in the UK, nursing staff in USA are required to participate in continuing professional development in order to retain professional status. It would appear that consultant pharmacists have successfully marketed their expertise in training; and this element may well be costed into the total consultant service.

2.2.5. Cost of Consultant Pharmacy Services.
It is also useful to consider the cost of providing consultant pharmacy services. Due to the manner of health care provision within the USA the costs of purchasing medicines, and also of employing a consultant pharmacist, rests with the facility concerned. The costs will mainly be passed to patients but this is a complex model of care that has become more complicated with the advent of the Prospective Payment Scheme (PPS).

Malone and Gym (1997) surveyed 800 facilities and identified that the costs ranged between $3 and $4 per patient per month for consultant pharmacist services. This would appear to be a modest cost for the reported benefits to patients, which have resulted from DRR.

2.3. Regulation of USA Nursing Facilities.
The regulatory mechanism is invoked when any nursing facility accepts clients who are funded by individual state welfare schemes of Medicare or Medicaid.
The system of regulation is very prescriptive upon the facility. Each state regulates the facilities within it based upon core requirements imposed by federal law. Additionally, a state may choose to impose further regulations. When a facility fails to comply with requirements a citation is issued and this may result in a financial penalty.

Each state appoints 'surveyors' to monitor nursing facilities, a similar system to the UK. The state may well have a pharmacist as part of the team but surveyors who are not pharmacists undertake the process of monitoring medicines and their use in the facility. The specific nature of regulation is signified by the use of clinical indicators, designed to ensure that the care provided meets with best practice. One example of this is the nature and extent of psychoactive drug prescribing within the facility, also discussed in section 2.3.2.

2.3.1. Regulation of Medication Review.

Regular DRR by a pharmacist was included in legislation for Skilled Nursing Facilities in 1974 and was extended initially to Long-Term Care Facilities in 1985 followed by Intermediate Care Facilities in 1987/1988. In essence, the rules require that a pharmacist conducts medication review for each patient at least once a month; and further that the pharmacist is responsible for bringing to the attention of the prescriber or director of nursing any perceived problems with the drug regimen. The legislation also requires the responsible physician or director of nursing to respond to the pharmacist's intervention. This does not impinge upon clinical responsibility because the regulator does not insist that the pharmacist recommendation is accepted and implemented but monitors whether
this has been duly considered. This is a major role for the consultant pharmacist but also a legislative responsibility.

2.3.2. The Omnibus Budget Reconciliation Act 1987.

Further regulation of medicines was contained within this legislation, often referred to as OBRA, which was enacted in 1990. The main focus of OBRA was the preservation of patient's rights within nursing care facilities. In relation to medicines, this specified the right to be free from any chemical restraint imposed for the purpose of convenience of the facility and not directly required to treat one of the 13 defined diagnoses.

The literature has many references to the work conducted by consultant pharmacists following the implementation of OBRA. Neel et al (1993) reported that the percentage of residents prescribed psychoactive drugs in a population of 9,000 in long-term care reduced from 78.3% in January 1990 to 47.3% in December 1990 due to the implementation of OBRA regulations. In addition to the financial benefits of reduced prescribing, the authors concluded that there would potentially be a reduction in the number of falls suffered by patients. This would further reduce the costs of hospitalisation, rehabilitation and other professional input. Avorn et al (1993) compared the programme to reduce psychoactive drugs in six matched pairs of nursing homes using one group as baseline. They reported higher levels of drug discontinuation in the experimental nursing homes with less deterioration of cognitive function than the control nursing homes.
Posey (1995) concluded that the introduction of governmental measures had improved care of patients in LTCFs when previous initiatives had not been able to achieve changes in prescribing habits. O'Brien et al (1991) reported that the effective reduction in prescribing of psychoactive drugs was also largely dependent upon in-service training for nursing staff as well as physicians.

As with the UK, the problem of inappropriate prescribing is not confined to nursing establishments. Rest homes in USA may be considered as equivalent to residential care homes and do not have the rigorous regulations of nursing faculties. Barker and Solomon (1992) reported a 40% decrease in the use of chlorpromazine in a 60-bed rest home directly as a result of pharmacist involvement in DRR and the introduction of OBRA requirements.

2.3.3. Quality Indicators.

The Health Care Financing Administration (HCFA) introduced the most recent changes in legislation in July 1999. These have been summarised in two ASCP documents, accessed from the website, entitled ‘HCFA Revision to Nursing Facility Survey Procedures’ and ‘Quality Indicators and the Nursing Facility Survey: Implications for the Consultant Pharmacist’. Each facility must complete a Minimum Data Set for individual residents and this is electronically submitted and available to the regulator. Prior to surveyor visits, the data is analysed and particular features that emerge are followed up during the visit.
There are 24 indicators and 5 of these refer directly to prescribing:

- Symptoms of depression that have not been treated with anti-depressant therapy;
- Number of residents who are prescribed 9 or medications;
- Prescribing of anti-psychotic drugs and diagnoses;
- The extent of prescribing of hypnotic/sedative drugs;
- The number of residents receiving a hypnotic drug more than twice in the previous week.

Within other indicators there are further indirect references to prescribing.

The consultant pharmacist is now expected to identify when a prescribed medicine may cause a problem that may trigger one of the indicators. The emphasis has clearly moved from retrospective DRR to prospective identification of risk factors for the resident. ASCP has, through its research and education foundation, embarked upon the 'Fleetwood Project'. Phase 1 was conducted by Bootman et al (1997). This work identified and estimated the national cost of drug related problems during 1994. In a publication about Fleetwood, Erwin (1999) described that reduction in the costs associated with medicines had hitherto focussed solely upon the cost of medicines whilst the first phase of Fleetwood identified the overall cost to a facility of medication-related problems. The value of consultant pharmacy input was thus identified. Fleetwood postulates that there is a 40% increase in optimal patient outcomes when consultant pharmacists are involved in DRR. When compared with the estimated cost of drug related problems, the continued employment of consultant pharmacists is considered to be favourable financially.
2.4. Acceptance of Consultant Pharmacist Recommendations.

It is important to consider how physicians have responded to these legislative requirements. In 1991, Brown reported 89.5% acceptance rate when pharmacist recommendations were communicated in writing. The acceptance rate reported by Williams et al (1992) was lower (67%). However, this paper also identified that, of those recommendations which were accepted, 33% were of clinical significance. A further study by Ellis and Ellis (1994) reported 63.6% acceptance of recommendations when a severe drug-drug interaction was highlighted.

2.5. Conclusions about Consultant Pharmacy Practice.

The literature researched presents a clear view of clinical pharmacy input in the nursing facilities within the USA. The activities are diverse but the majority of papers discuss the influence of DRR on prescribing, risk benefit, costs and physician acceptance. Legislation since 1974 has required nursing facilities to utilise the skills of clinical pharmacists and the most recent legislative changes have increased the role to a prospective rather than retrospective activity.

The literature also shows that an increasingly dependent elderly population is not a phenomenon of British culture alone. Nor are the financial pressures on pharmaceutical involvement. It is useful to note that work in other western countries has mirrored the USA model. In South Africa, Bellingan and Wiseman (1996) described the impact of regular pharmacist-led medication review in a facility for elderly care. This study reported a reduction of drug related problems, which was significant. A study by King in Australia, reported in the Pharmaceutical Journal (2000) under the title 'Team working in residential homes improves care', highlighted the potential for pharmacist involvement in multi-
disciplinary case conferencing in care homes. One area of concern was the lack of information that the pharmacist was able to access and hence that some recommendations for changes to the drug regime were inappropriate.

It cannot be said that all practice within the USA follows best practice at all times. A recent report by Gutwitz (2000) indicates that nursing home patients continue to be affected by medication errors, 50% of which could have been prevented. However, the overall impression is one of a better structure of clinical pharmacy input to nursing homes than can be depended upon within the UK.
Chapter 3

Study Design and Methodology.
Chapter 3: Study Design and Methodology.

The study was formulated to investigate whether the USA consultant pharmacist model would provide comparable patient benefit in the UK private nursing home. However, in advance of this it was considered necessary to determine whether a need existed in private nursing homes for pharmaceutical involvement that exceeded current provision.

The format of the project was therefore designed to make comparisons between selected criteria, measured pre- and post-intervention by a pharmacist. This was conducted in two nursing homes providing a discreet sample of patients. The criteria on which the study relied were:

i. The prescribing of medicines.

ii. The administration of medicines.

iii. The health status of each patient.

The third criterion was included to investigate whether the provision of pharmaceutical care was perceived to impact upon individual patient health status.

This chapter provides a general overview of the study. The objectives, methodology and results of the Baseline, Intervention and Post-intervention phases are reported in Chapters 4, 5 and 6 respectively.

3.1. Study Format.

The project was conducted in five phases, each of which were carefully designed to meet the requirements of the key objectives. The initial phase of three months
incorporated the complex negotiations to conduct the research and this is detailed in section 3.3.

The second phase involved an intensive collation of data to establish a baseline reference of prescribing and medicine administration. The researcher also undertook observational studies of quality issues related to medicine management; interviewed staff regarding patient's health conditions; and interviewed patients included in the study. Two months were provided for this phase.

The Baseline data were analysed in phase 3 using the Statistical Package for the Social Sciences (SPSS) and a written report was constructed for participants in the study. A period of 2 months was allocated for this element of the study.

Phase 4 was the Intervention phase, which comprised the monthly review of medication for each patient in the study over a period of six months. The investigator's recommendations for changes in prescribing and other medicine-related issues were directed either to the appropriate GP or the nurse in charge of the home.

The final phase (Post-intervention) comprised the analysis of phase 4 and a comparison statistically between baseline and endpoint of the study. The analysis also sought to identify how much time had been expended to establish a profile for each patient and thereafter conduct a monthly review. This element was costed to estimate whether similar activity can be considered to be cost effective when compared with any financial benefits that would accrue through
reduction in prescribed medicines. Four months were allocated to the final phase of the study.

Throughout the study, reference was made to the ASCP publication 'Drug Regimen Review: A Process Guide for Pharmacists' (1992). Recommendations relating to drug interactions and therapeutic drug monitoring were therefore based upon the standards set for USA consultant pharmacists.

3.2. Patient Sample.
Selection was made on the basis of a 'specific patient group' from nursing homes registered with Norwich Health Authority (NHA). There were 49 registered homes providing 1560 beds and 80% of these were for care of the elderly. It was determined to recruit a sample of at least 100 patients from nursing homes registered to care for elderly people. This would represent 7% of the total population of nursing home patients within the health authority.

The selection was by necessity a 'convenience' sample due to limitation of resource and the extensive negotiation of access for each establishment included in the study. To avoid bias, patients were recruited from more than one nursing home.

Access to an adequate sample of patients in 'typical' nursing homes was of prime importance. The criteria that determined the choice are described below.
3.2.1. Standard of Medicine Management within Selected Nursing Homes.

There was a deliberate choice of establishments that were considered by the investigator to be of 'good average standard'. The main purpose of this criterion was to exclude any distortion that could occur as a result of poor management of medicines within the home.

Prior to the research, the investigator had undertaken pharmaceutical inspections of all nursing homes registered with NHA for a period of four years. During this period a broad overview of the prevailing standards of medicine management within each of these homes had been formulated. It was therefore possible to select nursing homes for the study on the basis of this experience.

The selection ensured that legal action under The Registered Homes Act 1984 had not been instituted within a home during the previous four years; and that there had been no major concerns regarding medicine management resulting from pharmaceutical inspection. The investigator had utilised a uniform approach to all inspections in line with the recommendations of NAHA guidelines. (To avoid any conflict of interest, the researcher was not involved in the pharmaceutical inspection for NHA within the selected homes for the duration of the study).

It is anticipated that the standard of medicine management within an establishment will depend to a large extent upon the staff that are employed
within it. It was useful to consider only those homes with a relatively stable workforce and where the policy for staff recruitment was sound.

3.2.2. Nursing Home Location.

Within actual premises, the major impact upon medicine management would be the suitability of storage facilities and whether or not the use of a mobile drug distribution system was practical. The nature of the building itself i.e. whether the home was purpose built or adapted from a previous use as a private dwelling would not necessarily be anticipated to affect medicine management.

The choice of nursing homes needed to take into account the rural aspect of Norfolk County. This single element has a major effect upon the provision of pharmaceutical services. Medicines may be provided to many nursing homes from a dispensing GP surgery with no pharmaceutical involvement other than the twice-annual inspection by the investigator. It was determined that this should not be included as another variable but that a nursing home would not be excluded from the study on this basis alone.

Further to this, the location must provide ease of access for the investigator. The rural nature of NHA did present a challenge in practical terms and it was necessary to minimise the time that could have been lost through travel. The ideal location was felt to be no more than 10 miles distant from the investigator's base.
As already stated, successful maintenance of good standards is dependent upon staff within the nursing home. The nursing home's ability to recruit and retain suitable staff may well be affected by location. It was determined that the ideal choice of nursing homes must include both rural and urban locations.

**3.2.3. Size of Selected Nursing Homes.**

Many of the registered nursing homes had a patient population of less than 50. To achieve the required patient population of 100 it was necessary to locate the study in more than one establishment. This was a limiting factor in the choice of nursing homes. The level of interest shown by nursing and managerial staff in advance of any firm negotiations was also taken into account.

A considerable amount of time was anticipated to gain the cooperation of GPs who provided medical services for patients in the selected nursing homes. This was a major factor in the decision to limit the number of establishments to the least number that would provide the required sample size. Hence, two larger homes were considered to be more suitable than three or more smaller homes to deliver the same number of patients. The decision was taken to centre the study within two nursing homes owned and managed by the same company. This was theoretically beneficial because both homes were standardised in terms of procedures and policy documents relative to medicines. Each had a patient population in excess of 50, and was located within a reasonable distance of the investigator's base hospital. One nursing home was purpose built and within the city limits. The second home was a property conversion and located in a rural setting. The homes will now be referred to as Nursing Home 1 (NH1) and Nursing Home 2 (NH2).
All patients who were resident in the selected nursing homes at the commencement of the study were included as the population. The study was by nature longitudinal. New patients were not included after the Baseline data collection phase. From a potential population of 110, 81 patients agreed to be included. Due to discharges and deaths, there were 60 remaining patients at the conclusion of the study.

3.3. **Negotiation of Access.**

Although the study was 'pharmacy based' it was entirely dependent upon multidisciplinary support involving patients, nursing staff and GPs. An initial phase of three months was planned for the complex negotiation.

3.3.1. **Nursing Homes.**

It was necessary to have the explicit written consent of the registered owners of the two nursing homes before any detailed negotiations could commence. Once this was achieved, it was of equal importance to have the co-operation of all nursing staff in both homes.

Senior nurses were keen to become involved in the study. However, it was considered important to provide a presentation in each nursing home that was aimed specifically at the trained nursing staff. This was deliberately designed to promote discussion about concerns that the nursing staff may have held, including the planned observation of medicine administration rounds and access by the researcher to all nursing care notes held within the home.
3.3.2. General Medical Practitioners.

Co-operation of the medical practitioners was a vital component of the study, particularly since the investigator required access to patients' medical notes. Early discussion was held with the chair of the Local Medical Committee who was willing to support the aims and objectives of the study.

Of the two nursing homes selected, one received medical services from one GP group practice, and the other from two rural group practices, which, although they did not provide medicines to the nursing home, were dispensing GP practices. The investigator visited each practice and presented the aims of the study. Of the three practices, two agreed to participate in the project, one per nursing home. Patients under the care of the third practice were therefore excluded from the study. This was a minority group of patients, the main medical provision being provided by the participating practice. It was important to note that a lead practitioner provided the majority of medical input from each of the participating practices.

Although access to patients' medical notes was agreed, the provision differed in each home. NH2 retained patients' notes on site and these were available throughout the study to the researcher. The GP who was responsible for the patients in NH1 provided a computer printout at the commencement of the study and this was not updated throughout the Intervention phase. This issue was a limitation upon the pharmacist researcher.
3.3.3. Community Pharmacists.

Each home was provided with medicines from a local community pharmacy. The investigator visited and discussed the project with each pharmacist prior to commencement.

3.4. Ethical Committee Approval.

A research protocol for the study was submitted and approved by the NHA Ethical Committee. Although it was planned that prior patient consent would be obtained wherever possible, the committee agreed that confused patients could be included if permission were granted by a near relative. In such cases the relevant general practitioner was requested to ensure that the medical notes did not contain information which the patient might be unwilling for a third party to be aware of.

3.5. Patient Consent.

Patients receiving medical services from participating GPs were given a Patient Information Leaflet (Appendix I) and invited to take part in the study. When a patient was considered unable to offer informed consent, this permission was requested from a relative or representative who was also provided with written information about the study. In one of the nursing homes, making an informal presentation to the relatives at an evening meeting facilitated this.

In each home, the practical management of obtaining consent and therefore recruiting patients was managed, at their request, by nursing staff. The Consent Form is included in Appendix I.

Particular attention was given to aspects of the study that it was anticipated might be problematic. One such area of concern was the means of communicating effectively with other professionals throughout each phase. Documents were designed for the study based upon examples used by consultant pharmacists in USA. These are considered in detail and reproduced in Appendix II.

3.6.1. Patient Profile.

This document was used throughout the study to record all pertinent details of prescribed medicines, laboratory tests/monitoring, interventions made following the initial review, subsequent monthly reviews and prescriber response and the time required for the researcher to achieve each element. In respect of each prescribed medicine a record was included regarding the pattern of administration, and whether this had been in accordance with the prescriber’s intention.

To enable the Patient Profile to provide a focus for data collection about each patient, the above data was supplemented by details of diagnosis, health status and patient awareness of drug therapy. This was adapted from the USA Minimum Data Set and contained a number of ‘triggers’.

It was also considered essential to include details of drug or dietary allergy and any adverse drug reactions reported during the study. Some elements of the profile were given a notional rating system e.g. to identify whether there had been any measurable change in health status of a patient as a result of pharmaceutical intervention. The survey instrument was not, however, validated.
3.6.2. Audit Documents.
Two documents were designed to establish drug trolley and drug cupboard contents at the baseline data collection. These incorporated checklists for problems. The contents were cross-referenced with information collated in the Patient Profile.

3.6.3. Observation of Medicine Administration.
A checklist was designed for observation of medicine administration by nursing staff. A series of criteria were listed as either being 'met' or 'not met'. This was associated with the quality control report (section 3.6.4).

3.6.4. Quality of Medicine Management.
The adequacy of arrangements for the safe handling and administration of medicines was assessed using the monthly quality control report. This was intended to give an overview of registration issues that would be useful to enable the nursing home to meet the requirements of pharmaceutical inspection by NHA. Each selected criterion was identified to be undertaken consistently, inconsistently or never.

3.6.5. Communication Documents.
Two documents were designed for communication: one specific to the responsible GP; and the other to the nurse in charge of the home. Appropriate recommendations were made with rationale for changes on a named patient basis. Sufficient space was provided on the form for the GP/nurse to record the response to the recommendation, whether negative or positive.

A form was devised to summarise all recommendations for change that were made at the time of the monthly review. It was also possible to record the outcome of each recommendation consequent upon acceptance of the advice or the reason for non-acceptance.

3.7. Statistical Analysis.

The term 'null' hypothesis is defined as the belief that there is no change whatsoever between the variables that are being compared in a study. To accept or reject a research hypothesis, which by definition is the opposite of the null hypothesis, the study results must be tested for statistical significance. This is achieved through statistical analysis. In this study, the application of statistical tests will determine whether or not the differences in the results obtained pre- and post-intervention have occurred only by random chance; or whether any correlation may be made with the researcher's interventions.

Statistical significance, represented in this study as a 'P' value, is a measure of probability that the null hypothesis holds true. Therefore, the absence of statistical significance confirms that any differences that have been observed are of a minor nature and can only be attributed to random chance. A high level of significance indicates that the research hypothesis is more likely than random chance.

The probability (P) value describes how rare an event is whilst taking account of the normal distribution of results. The level of probability that has been employed in this study is 0.05. When the P value is expressed as less than 0.05 this means
that the probability of the null hypothesis being true is less than 5 out of 100. As the value of $P$ decreases, the level of significance that can be attributed to acceptance of the research hypothesis increases. It is, however, recognised that tests of statistical significance cannot be interpreted as proof of the practical importance of any research findings.

The current study was designed to report on the differences that were observed in the measurement of variables, pre- and post-intervention, in a sample of nursing home patients that were divided into two subsets. Statistical tests were applied to identify whether there was any significant difference between the results; and hence whether there was a relationship between the results obtained and pharmaceutical intervention.

The patient recruitment to this study represented a sample of the population of all patients within nursing homes, subdivided into two subsets. Statistical analysis was therefore appropriate in relation to the sample population in total; and also to any measured variation between and within the individual nursing home subsets. The reliability of results and the wider generalisation to the patient population is related to the sample size, and this has already been discussed in section 1.5.

Statistical tools that are available to the researcher have been described by Healey (1999). Conventional analysis of quantitative data was employed using chi-squared test, paired t-test and ANOVA using the Statistical Package for the Social Sciences (SPSS) computer programme. The respective characteristics of these tests are now summarised.
3.7.1. Chi-Squared Test.

This statistical test is stated by Healey (1999) to be the most commonly applied in analysis of social science research and is described as a test of independence. It is a non-parametric test on data presented in the format of a table; and is particularly useful because there are no assumptions made about the distribution of the study sample and whether it reflects adequately the population that is being studied. It is useful when the measured variables have more than two categories; and there is a study population that is divided into two or more subsets. In this respect, it has similar test properties to ANOVA (section 3.7.3.). The test is reputedly less reliable as the sample size decreases; but inappropriate conclusions may also be drawn from a very large sample.

The test is based upon the assumption that random chance produces an expected frequency of result when two or more variables are involved. (In his publication, Healey draws the analogy of tossing a coin and expecting equal frequencies of ‘heads’ or ‘tails’ to fall). Application of the chi-squared test compares expected frequencies with the observed results; and also measures the significance of any difference between these values. The null hypothesis that is tested is that two measured variables are totally independent of each other. If that were the case, the chi-squared expected results would not differ significantly from observed results. The possibility of rejecting the null hypothesis and therefore adopting the research hypothesis increases as the differences between expected and observed results increases.

The chi-squared test was the most frequently employed statistical tool in this study. The research hypothesis was that changes in the prescribing of medicines
over time are related to the involvement of a pharmacist through structured medication review. Support of this hypothesis would be delivered by a chi-squared test result of $P<0.05$ for any of the variables measured. A result of $P>0.05$ would conversely indicate that the measurements were the result of random chance.

3.7.2. Paired t-Test.

The t-test is a statistical tool that is employed when the sample size is small (defined as less than 100) and when the value of the population standard deviation is an unknown quantity, both of which were features of this study. The test is a simple measure that identifies whether there is a significant difference between the results obtained from differing subsets of the sample population.

Because there were differing systems of care within each nursing home in this study, the research hypothesis represented that the results relating to the prescribing of medicines and medicine administration by nursing staff may be significantly different in one nursing home subset when compared with the second nursing home subset. To test this hypothesis, evidence of change following intervention ought to be sought in the individual subsets. The test was applied during the analysis of the number of items prescribed for Regular and PRN administration in each nursing home (section 6.3.3).

3.7.3. ANOVA.

The term 'ANOVA' is an abbreviation of the analysis of variance. Although the test has some qualities that are similar to the chi-squared test, it is a sophisticated extension of the t-test, designed to test whether there are
significant differences between subsets of the study population. It not only compares the variables between two or more subsets but also compares the results within each of them. The null hypothesis in this test represents that the samples are equal. This view would be rejected should the test reveal that the subsets exhibit great differences but also exhibit little difference within each subset.

In this study, ANOVA has been used to identify whether there is any significance in the difference between results obtained from each of the nursing home subsets. The benefit of such a test is to enable the aggregation of data from both subsets when the difference is not significant (P>0.05); and thereby to increase the reliability of the statistical analysis of a particular variable. This was employed for the analysis of pharmacist time involvement (section 6.3.5.).

3.8. Source of Funding.

Funding was obtained through the Pharmacy Practice Research Enterprise Scheme, operated by the Pharmaceutical Division of the Department of Health and was concluded in December 1993.
Chapter 4

Establishing the Baseline.
Chapter 4: Establishing the Baseline.

4.1. Key Objectives.

A baseline for the study was constructed by investigation of each of the following key objectives.

i. To establish the nature and extent of prescribing for patients in the private nursing home setting.

ii. To investigate the administration of medicines within private nursing homes relative to the prescriber’s intention.

iii. To investigate the quality standards of medicine management within private nursing homes.

iv. To establish whether pharmaceutical advice should be provided to nursing homes, and the nature of such advice.

4.2. Methodology.

A key element of the project was to obtain a comprehensive baseline of information including details of all prescribed medicines, and all medicines administered; patient diagnoses; any health related problems experienced by the patient; the cognitive and physical status of the patient; the patient’s understanding of the medicines he/she was given and attitude to self medication.

Such data was recorded in the Patient Profile (Appendix II). It was also during this phase of the study that the quality aspects of medicine management by nursing staff were established. Throughout the study, accurate records were maintained of the time involvement.
The collection and analysis of baseline data was a lengthy process but imperative to the whole research project. To obtain this, the two nursing homes were visited on alternate days over a period of two months, commencing in October 1992.

Data collection for each Patient Profile comprised the following elements:

i. Recording details of medicines from the nursing home records of medicine receipt, administration and disposal.

ii. Listing medicines that were available within the home either in drug trolley, medicine storage or patient’s own room.

iii. Identifying current diagnoses from the GP medical notes.

iv. Identifying health related problems from the nursing care notes and by discussion with nursing staff.

v. Conducting a structured interview with the patient.

vi. Reviewing each patient’s drug therapy in relation to diagnoses and health conditions.

For the Quality Control audit, all aspects of medicine procurement, storage, recording and disposal were recorded.

4.2.1. Prescribing and Administration of Medicines.

Data were compiled on an individual patient basis utilising the records of medicine receipt, administration and disposal retained by the home. A variety of other records were also accessed to obtain full details of all medicines prescribed and administered including nursing care notes and care plans; GP medical notes; nursing records relating to wound care, patients’ bowel activity and bladder washout administration.
Medicines were categorised as Regular or PRN and the administration patterns were recorded. Nursing staff were observed during several drug administration rounds, and a comparison was made between the documented prescription and the actual administration of medication.

An audit of all medicines, both in the drug trolley and in storage cupboards, was carried out. A further comparison was made between those drugs that were available and those that had been prescribed.

4.2.2. Diagnosis.
Each patient's recent medical history was accessed from the medical notes and a list of diagnoses compiled within the Patient Profile. A comparison was made between disease state and prescribed medicines in the initial assessment.

In NH2 the GP medical notes were kept on the premises and were therefore readily available throughout the study. Initially, complete medical notes were not available for two patients, highlighting the lengthy delay that can occur in forwarding documents when patients are transferred from one GP to another. In one of these cases, the medical notes were eventually seen in June 1993, several months after the patient had been admitted.

Full medical records of patients in NH1 were held at the Health Centre but a computerised summary was made available at the commencement of the study.
4.2.3. Health Status.
Details of health conditions, cognitive function and physical function were included in the patient profile. Information was obtained, as far as possible, from the nursing documents held in each home. When these did not provide a complete picture, the investigator discussed individual patients with nursing staff who were available at the time.

4.2.4. Patient Awareness.
With the exception of those who were very confused or unable to communicate, patients were interviewed to establish awareness of drug therapy. This was recorded in the Patient Profile. Additionally, the interview helped to establish whether the patient suffered from side effects as a result of drug therapy; and the patient perception of nurse administration of medicines. Questions concerning the motivation, or lack, for a patient to self medicate were also included.

The comments that patients made were noted and have been included as descriptive statements within section 4.3.4.6. but have not been the subject of detailed analysis.

4.2.5. Other Parameters.
When the information was available, a record was made in the Patient Profile of allergies, diet and evidence of patient monitoring, e.g. blood pressure, for each patient.
4.2.6. Quality Audit.

After collation of the baseline data, the researcher completed the quality audit form, which encompassed all aspects of medicine management within the nursing home.

i. Medicine procurement criteria were determined by whether prescribed medicines were available for patients at all times.

ii. The provision for storage was monitored against NHA standards for registration.

iii. Record keeping was observed in relation to standards set by the UKCC.

iv. All medicines within the home were checked for their suitability and appropriateness for use. Particular attention was paid to the expiry date of medicines, including limited life products. It was also pertinent to ensure that medicines retained in the nursing home were appropriate to current therapy and kept only for current residents of the nursing home.

v. A major part of the data collection was the observation of medicine administration by nursing staff. This occurred on five occasions, three in NH1 and two in NH2. The researcher accompanied the nurse throughout each medicine round and subsequently completed the written record of observations.

4.2.7. Analysis of Data.

Before proceeding to the Intervention phase of the study the data was collated and analysed using the Statistical Package for the Social Sciences (SPSS). A report summarising key elements of the baseline data was presented to the nursing staff and an action plan was agreed. Conclusions were drawn at this
stage concerning the necessity for pharmaceutical advice in nursing homes and target areas for concern.

4.3. Results.

Eighty-one patients were entered into the study by the nursing staff. Thirty-one patients (six male, twenty-five female) were recruited from the first nursing home (NH1) and fifty patients (eleven male, thirty-nine female) from the second (NH2). The distribution of the age range of the patients in years is shown in Chart 1. Before the completion of the Patient Profiles, two of the patients had died. Thus, the remainder of the data presented relates to 79 patients.

Chart 1: Baseline Data - Age distribution of patients in years.
4.3.1. **Patient Diagnoses.**

Details of patient diagnoses were accessed from both GP medical and nursing care notes. Table 4 is a summary of the recorded diagnoses for seventy-nine patients in two nursing homes. The GP medical notes were not available for two patients in NH2. Although most patients were in the category of 'elderly', NH2 was also registered to care for patients in the 'young chronic sick' classification. The information on diagnosis was utilised at the outset to make an initial assessment of potential pharmaceutical problems on an individual patient basis.

Most patients had multi-pathology. Within NH2 there were more patients who had previously experienced a cerebro-vascular accident and also suffering from arthritis. The layout of this nursing home gave better access for wheelchairs and this may have contributed to these results. In other respects, the incidence of particular diagnoses was very similar.
<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Number of Patients</th>
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<tr>
<td></td>
<td>NH 1</td>
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</tr>
<tr>
<td>Arrhythmia</td>
<td>6</td>
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<tr>
<td><strong>Sensory</strong></td>
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</tr>
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<td>Cataracts</td>
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<tr>
<td>Conjunctivitis</td>
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<tr>
<td>Glaucoma</td>
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<td>Arthritis</td>
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<td>Diabetes</td>
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<td>Hiatus Hernia</td>
<td>4</td>
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<td>Hypothyroidism</td>
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</tr>
<tr>
<td>Liver dysfunction</td>
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<td>Osteoporosis</td>
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<td>Psoriasis</td>
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<td>Ulcer, Gastric/Duodenal</td>
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<tr>
<td>Urinary Tract Infection</td>
<td>2</td>
</tr>
</tbody>
</table>
4.3.2. Patient Status.

Data were collected in relation to each patient's cognitive and physical status. Each identified element was given a notional rating and this contributed to an overall assessment score.

4.3.2.1. Cognitive Function.

There were no comatose patients and forty-one (52%) were considered to be alert. Forty-four (56%) of the patients enjoyed a pattern of sleep that was normal for their age. Chart 2 summarises the initial information collected.

**Chart 2: Baseline Data - Cognitive function.**
A significant number of patients had a 'memory' problem (75%) and only thirty-seven (47%) were able to make decisions independently. As anticipated in a group of elderly and highly dependent patients, there was a heavy reliance upon nursing staff for all aspects related to medicines and their administration.

4.3.2.2. Physical Function.

The physical function of the patient, particularly in respect of mobility and continence, can have a major bearing on the effects of drug therapy. Only seven (9%) patients could walk unaided and this lack of mobility probably contributed to the problems of constipation and skin care. Thirty-three patients (42%) were totally incontinent. A summary is included in Chart 3.

Chart 3: Baseline Data - Physical function.
4.3.3. Patient Health Conditions.

It was vital in this study to obtain details of those health problems that might be resolved with additional pharmaceutical help. To this end, such problems were initially identified in patients who entered the study. It was found that of the seventy-nine patients, only two presented with no problems whatsoever.

Problems in the remaining patients occurred with a frequency that ranged from one to seven (Chart 4). Data of this type was gathered using a variety of sources that had been compiled over a considerable period of time. In this sense, the incidence of problems was cumulative and would not necessarily have arisen within the period October/November 1992. Nevertheless it is a fair assessment of the status quo at the two nursing homes when the study commenced.

Chart 4: Baseline Data - Distribution of the frequency of occurrence of health related problems.
Table 5 identifies the number and nature of the problems that the patients experienced at the time baseline data were collected. Constipation was the most common problem that affected more than half of the patients. It was notable that 34% of patients suffered problems with pressure sores. Both of these problems would be anticipated in a group of elderly dependent patients.

Table 5: Baseline Data - Health Conditions

<table>
<thead>
<tr>
<th>Problem</th>
<th>No. of patients</th>
<th>% of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Constipation</td>
<td>47</td>
<td>59.5</td>
</tr>
<tr>
<td>Diarrhoea</td>
<td>8</td>
<td>10.1</td>
</tr>
<tr>
<td>Dizziness/vertigo</td>
<td>6</td>
<td>7.6</td>
</tr>
<tr>
<td>Faecal impaction</td>
<td>6</td>
<td>7.6</td>
</tr>
<tr>
<td>Hallucinations</td>
<td>4</td>
<td>5.1</td>
</tr>
<tr>
<td>Joint pain</td>
<td>7</td>
<td>8.8</td>
</tr>
<tr>
<td>Oedema</td>
<td>27</td>
<td>34</td>
</tr>
<tr>
<td>Pain</td>
<td>23</td>
<td>29</td>
</tr>
<tr>
<td>Pressure Sores</td>
<td>27</td>
<td>34</td>
</tr>
<tr>
<td>Shortness of breath</td>
<td>14</td>
<td>18</td>
</tr>
<tr>
<td>Skin problems</td>
<td>16</td>
<td>20</td>
</tr>
<tr>
<td>Syncope</td>
<td>1</td>
<td>1.2</td>
</tr>
<tr>
<td>Vomiting</td>
<td>7</td>
<td>8.8</td>
</tr>
<tr>
<td>Falls</td>
<td>27</td>
<td>34</td>
</tr>
<tr>
<td>Hip fracture</td>
<td>10</td>
<td>12.6</td>
</tr>
<tr>
<td>None of the above</td>
<td>2</td>
<td>2.5</td>
</tr>
</tbody>
</table>
4.3.4. Patient Knowledge of Drug Therapy

An important feature of the research was the opportunity to talk to individual patients and assess their knowledge of current drug therapy. In addition to gathering data, it was a salutary experience to hear first-hand how patients feel about the medicines they are given. Thirteen patients (17%) were excluded from interview for one of the following reasons:

- The patient was unwell and the interview might have caused distress.
- The patient was too confused to understand the questions.
- The patient was aggressive.
- The patient had a communication problem and an interview might have caused embarrassment.

In general, patients were extremely pleased to have the opportunity to discuss their medicines, and a variety of other subjects. The relative of one patient requested an interview with the investigator in addition to the patient interview.

4.3.4.1. Patient Knowledge of Prescribed Medicines.

When asked if they knew which medicines they received, ten patients (13%) were able to list or describe all of them. Seven of the patients interviewed were sure that they never took medicines (9%), although the records indicated otherwise. One patient was able to describe her medicines by colour and another patient, though not on any regular medication, had a good understanding of the homely remedies he occasionally required. However, 36% of the patients had no knowledge of their medicines. These data are shown in Chart 5.
Patients were then asked if they knew why their medicines were prescribed and only nine were confident about this. One patient described her anti-diabetic medicine as being for 'dizzy spells'. Another patient was emphatic that she would like to be informed about her medicines and this request was relayed to nursing staff. Nursing staff assured the researcher that there were frequent discussions, particularly about laxatives, but the patient had some problems with memory.

It was fascinating to talk with another patient, who gave a graphic description of the past, including her experiences as a nurse. Although she was well informed about her disease state, she only knew two out of the eight drugs she received. She also recognised that there had been a time when she would have known what each of them was. These data are shown in Chart 6.
The language in these discussions was an important factor to consider. The term 'medicine' was taken to imply 'liquid mixture' by many of the patients and it was necessary to explain that the term encompassed tablets, capsules, creams and ointments.

4.3.4.2. Self-Medication.

Very few patients (5%) were sufficiently motivated to administer their own medicines. Some had successfully managed their medicines prior to admission but no longer wished to be responsible for them. One patient was very keen to keep the medicines that had been prescribed for himself and his wife prior to admission to the nursing home. This was mainly due to the fact that whilst at home he had apparently been taking his wife's co-proxamol but within the nursing home, he had only been receiving the paracetamol that was prescribed for him. The degree to which patients wished to self-medicate is summarised in Chart 7.
Chart 7: Baseline Data - Patient preference for self-administration of medication.

17% 5% 3%
75%

[Chart showing preferences for self-administration of medication]

It was evident that some patients had their own purchased remedies that were not included in any documentation. This aspect was not followed up.

4.3.4.3. Patient Knowledge of Side-Effects.

Many patients were aware of the side-effects associated with their medicines. In extreme cases, there was a reluctant acceptance of the situation and a belief that quality of life could not be improved, due to the process of disease. This was particularly notable in patients suffering from Parkinson's disease. Section 4.3.9. includes descriptive statements about side effects experienced by these patients that were drawn from patient interview, discussions with nursing staff and the nursing care notes.
4.3.4.4 Refusal of Medicine.

Forty-nine patients (65%) stated that they did not refuse medicines, although at least one patient was documented as doing so. These data are presented in Chart 8. There were varying reasons for refusal. Some patients disliked the side effects whilst others perceived that the medicine was ineffective. Some patients expressed a preference for the medicine to be administered at a different time. It was noted that confusion or aggression were contributory factors in the refusal of medicines.

Chart 8: Baseline Data - Patient refusal of medicines.

4.3.4.5 Nurse Administration.

Patients were asked if they could recall medicines not being given when they expected them. Many could not understand the question but of those who did, three patients believed that medication was sometimes missed, whilst two thought that they frequently failed to receive their drugs.
A similar response was recorded when patients were asked if they could recall being asked not to take a medicine. Without exception, patients praised the care that they received from nursing home staff.

4.3.4.6. Other Issues.
Several patients expressed concern about the number of medicines they were given and that they would prefer to have fewer. This is a significant comment in relation to patient choice within the nursing home setting. A frequent comment was that the medicines 'do no good'.

One patient was very concerned about substitution of a different drug to one she had received for many years. Her perception was that the current therapy did not work as well as the previous therapy.

Some patients had strong feelings about independence and privacy and it was difficult to see how these could easily be accommodated within the establishments' arrangements for medicine administration. When discussing aperients with one patient, she explained that prior to admission, her diet was based on fresh vegetables and fruit. Although the nursing home did provide fresh food, it clearly differed from the diet she normally ate.

An unusual comment from one patient related to physiotherapy, which she had anticipated but not received. During subsequent discussions with the nursing staff, it became clear that the patient was reticent to talk with them and they had not realised how she felt about this. This incident highlighted the positive
aspects of another care professional contributing to the total team effort in caring for patients.

4.3.5. Allergic Reaction to Medicines.

A drug related allergy was recorded for seventeen patients, the most frequently recorded being Penicillin (7 patients). Other allergies were noted for Septrin, Stemetil, Aspirin/NSAID, Streptomycin, Ephedrine and Temgesic. Additionally, three patients were allergic to skin preparations/dressings, one to metallic products and another to fish.

It is pertinent to note the difficulty the investigator experienced in obtaining this information. Although the drug administration chart had a box in which to record 'known allergies', this section was often left devoid of comment. Both nursing homes had encouraged GPs to write new prescriptions onto the medicine administration chart (MAR) and information relating to patient susceptibility to allergies would be an important detail to include. It would have been equally useful to record 'no known allergy' in the box provided when a patient did not have any documented allergies.

4.3.6. Diet.

Details of patients' diets were included in the Patient Profile when a reference was found in either the nursing care notes or the Medicine Administration Record chart.
In NH1, 24 (77.4%) of the patients recruited to the study had a normal diet. Three patients (9.7%) were diabetic; three patients (9.7%) were provided with liquidised food; and one patient (3.2%) was on a fat free diet.

In NH2, 35 patients were stated to have a normal diet (70%). Seven patients (14%) were diabetic; one patient (2%) was prescribed a dietary supplement; one patient (2%) had liquidised food; and there was no record of diet for 3 patients (6%). Of the remaining patients (6%), two were on a reducing diet and one frequently refused food.

4.3.7. Prescribing of Medicines.

Collection of data relating to the Drug Profile of each patient took considerable time. Although the drug administration chart contained details of current medicines which were given on the drug round, the record of administration of previous PRN medicines, items for self-medication, medicines for external use and medicines which were administered during other routine tasks, e.g. bladder wash-outs were invariably missing. There were also differences between the records kept in the nursing home and those kept by the GP.

To compile a complete data set, it was necessary to access all available records and also to audit the contents of cupboards. Table 6 gives a summary of the total items prescribed in each nursing home, both Regular and PRN. A detailed analysis of the data gave a breakdown in each nursing home of the total prescribing patterns for individual drug groups. A summary is included in Chart 9.
Table 6: Baseline Data - Items prescribed for patients.

<table>
<thead>
<tr>
<th></th>
<th>NH 1</th>
<th>NH 2</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of patients</td>
<td>30</td>
<td>49</td>
<td>79</td>
</tr>
<tr>
<td>Items - Regular</td>
<td>155</td>
<td>217</td>
<td>372</td>
</tr>
<tr>
<td>Items - PRN</td>
<td>108</td>
<td>105</td>
<td>213</td>
</tr>
<tr>
<td>Items - Total</td>
<td>263</td>
<td>322</td>
<td>585</td>
</tr>
<tr>
<td>Average items per patient</td>
<td>8.7</td>
<td>6.6</td>
<td>7.4</td>
</tr>
</tbody>
</table>

Chart 9: Baseline Data - Prescribing in two nursing homes by pharmacological classification.
It was found to be more useful to analyse the data into prescribing patterns of medicines for Regular or PRN use. The categories of medicines that were only prescribed for regular administration were anti-infective, endocrine, urinary/gynaecological, malignancy, nutrition and eye. The remaining pharmacological classifications are summarised in Chart 10.

Chart 10: Baseline Data - Comparison of the prescribing of Regular and PRN medicines by pharmacological classification in two nursing homes.
From the results of this analysis it was decided to investigate those classes of medicines with a high incidence of use and which were administered PRN. Those groups were GI, CNS and Skin. Additionally, an analysis was made of the different prescribing patterns in the two nursing homes, in which Regular and PRN prescriptions were compared.


Medications used for the treatment of gastro-intestinal problems were classified into groups similar to those defined in the British National Formulary. The relative frequency of administration of the different drug groups is shown in Chart 11.

Chart 11: Baseline Data - Prescribing of GI medicines in two nursing homes.
It will be seen that laxatives were the most frequently prescribed group either when administered on a Regular or PRN basis. It is also interesting to note that only 3% of medicines prescribed on a Regular basis were for ulcer healing. There were sixty-six patients (84%) receiving laxatives, some patients receiving as many as five different products. The distribution is shown in Chart 12.

**Chart 12: Baseline Data - % of patients receiving Laxatives, Regular and PRN in two nursing homes.**

<table>
<thead>
<tr>
<th>Number of laxative items</th>
<th>% of patients (n=79)</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>4</td>
<td>3.8</td>
</tr>
<tr>
<td>3</td>
<td>6.3</td>
</tr>
<tr>
<td>2</td>
<td>12.6</td>
</tr>
<tr>
<td>1</td>
<td>55.6</td>
</tr>
</tbody>
</table>

Records of administration had been maintained for oral dosage items but reference to suppositories and enemas more commonly occurred in the nursing notes. A comparison of the prescribing patterns between the nursing homes is shown in Chart 13.
The incidence of laxative use was less in NH2 than NH1 for both Regular and PRN use; and the PRN use of laxatives exceeded Regular administration in both homes. The difference in laxative prescribing and administration between the homes was also supported by informal discussions that the investigator had with nurses. From this, it was identified that, in both nursing homes, the selection of a laxative product, together with the dose and frequency of administration, had been recommended to the prescribing GP by nursing staff.
In NH1, nurses stated that the GP actively encouraged nurse discretion in this aspect of patient care. This nursing home utilised a separate chart for laxatives and combined it with a record of bowel movement. However, the decision to administer a laxative did not appear to be related to recorded bowel activity. All patients who were deemed by nurses to be constipated had a laxative regime of senna (three times weekly) and 'as required' lactulose written onto this chart.

In NH2, the approach to laxative prescribing and administration was more on an individual patient basis. However, nurses stated that the request for a prescribed product was influenced by successful treatment of other patients.

4.3.7.2. Central Nervous System Prescribing.

The frequencies of administration of drugs affecting the CNS, classified into groups, are shown in Chart 14.

High levels of prescribing occurred only in the case of PRN analgesics. Thus it was not considered appropriate to target CNS drugs in general. A reduction in the use of hypnotics and anti-psychotics following admission was evident in both nursing homes. Patients who had previously received regular anti-psychotics were managed satisfactorily using PRN regimes.
Chart 14: Baseline Data - Prescribing of CNS medicines in two nursing homes.

- Anti-parkin: 0% Regular, 4.3% PRN
- Anti-epilep: 1.4% Regular, 1.4% PRN
- Analgesic: 4.9% Regular, 21.3% PRN
- Nausea: 0.9% Regular, 0.3% PRN
- Anti-depress: 0% Regular, 4.1% PRN
- Anti-psych: 1.9% Regular, 2.7% PRN
- Hypnotic: 5.7% Regular, 6.5% PRN

% of all prescribed items
Chart 15 provides a comparison between the two nursing homes of the Regular and PRN prescribing patterns.

**Chart 15: Baseline Data - Comparison of Regular and PRN prescribing patterns of CNS medicines in two nursing homes.**

4.3.7.3 Prescribing for Skin.

Skin products were used most frequently on a PRN basis (Chart 16). There was a distinct lack of accurate records and in some cases little continuity of treatment. Medicines in this group were prescribed for forty-two patients.
This data highlights the extent to which nursing staff influence when and why external medicines are applied. Accordingly it was decided that some input to policy making would be appropriate. A comparison between the two nursing homes of the Regular and PRN prescribing patterns of medicines applied to the skin is shown in Chart 17.
4.3.8. Administration of Medicines.

In addition to obtaining details of prescribed medicines, a careful record was made of whether the administration accurately reflected the prescriber's intention. Initially, it was intended that this issue would be documented by using a 'Yes' or 'No' response. However, the varied reasons for non-administration of medicines prompted the decision to distinguish between negative responses. The extended criteria are set out in Table 7.
There were two stages to the analysis, the first being to establish whether there were different patterns of administration for medicines that were given on a Regular as distinct from a PRN basis. This comparison is shown in Table 7.

**Table 7:** Baseline Data - Patterns of medicine administration for Regular and PRN use.

<table>
<thead>
<tr>
<th>Patterns of medicine administration</th>
<th>Regular (%)</th>
<th>PRN (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Administered as prescribed</td>
<td>78.8</td>
<td>20.7</td>
</tr>
<tr>
<td>Not administered</td>
<td>9.4</td>
<td>15.5</td>
</tr>
<tr>
<td>Self-medication</td>
<td>1.6</td>
<td>1.9</td>
</tr>
<tr>
<td>No record of administration</td>
<td>2.7</td>
<td>18.8</td>
</tr>
<tr>
<td>No record of FP10</td>
<td>5.6</td>
<td>33.3</td>
</tr>
<tr>
<td>Nurse prescribed</td>
<td>0.3</td>
<td>8.9</td>
</tr>
<tr>
<td>Different dose from prescription</td>
<td>1.1</td>
<td>0</td>
</tr>
<tr>
<td>Infrequent admin./refusal</td>
<td>0.5</td>
<td>0.5</td>
</tr>
<tr>
<td>Patient's own purchase</td>
<td>0</td>
<td>0.5</td>
</tr>
</tbody>
</table>

When medicines were given on a Regular basis, 79% were administered in accordance with the GP's instruction. Of the remainder, 10% were not given at all. The pattern of administration for PRN medicines was markedly different. Only 21% of PRN medicines were administered in accordance with recorded GP instruction.

Even when those medicines within the group of 'nurse discretionary medicines' were excluded, 33% of medicines had been administered in the absence of any GP instruction, some of which were 'Prescription Only Medicines' (POM). Furthermore, 19% of the medicines given PRN were not recorded formally on the
MAR charts, although reference was made to them in the nursing notes. In 9% of the PRN medicines administered, it was clearly identified that nursing staff had initiated the therapy.

In the second stage of this analysis, any differences in the overall patterns of administration of medicines between the two nursing homes were investigated. The percentage of Regular and PRN medication that was administered in accordance with GP directions was less (45%) in NH1 than in NH2 (68%). This difference was highly significant (P <0.0001: chi-square). A similar scenario was observed in the incidence of medicines being administered when there was no record of GP prescription in the two nursing homes: 27% in NH1 and 6.5% in NH2. The results are shown in Table 8.

The results highlighted the differences that existed between GP medical notes/computer printout and actual drug administration. It became evident that a considerable degree of nurse decision was actively encouraged by the GPs, most commonly in the areas of laxative and wound care. It was also apparent that alterations to the drug regime were not always reflected in the GP documentation, resulting in items remaining on the surgery computer profile even when the GP had taken the decision to discontinue treatment. Consequently, there were supplies of drugs in the nursing homes that were no longer appropriate to individual patients' treatment.

The analysis indicated a need for intervention to encourage accurate recording of all medicines and define the limitations of nurse discretion in relation to prescribing issues.
Table 8: Baseline Data - Comparison of medicine administration in two nursing homes.

<table>
<thead>
<tr>
<th>Pattern of medicine administration.</th>
<th>NH1 (%)</th>
<th></th>
<th>NH2 (%)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Reg.</td>
<td>PRN</td>
<td>Total</td>
<td>Reg.</td>
</tr>
<tr>
<td>Administered as prescribed</td>
<td>67.1</td>
<td>13.9</td>
<td>45.2</td>
<td>87.1</td>
</tr>
<tr>
<td>Not administered</td>
<td>14.2</td>
<td>13.9</td>
<td>14.1</td>
<td>6.0</td>
</tr>
<tr>
<td>Self-medication</td>
<td>0</td>
<td>1.9</td>
<td>0.8</td>
<td>2.8</td>
</tr>
<tr>
<td>No record of administration</td>
<td>2.6</td>
<td>13.0</td>
<td>6.8</td>
<td>2.8</td>
</tr>
<tr>
<td>No record of FP10</td>
<td>12.9</td>
<td>47.2</td>
<td>27.0</td>
<td>0.5</td>
</tr>
<tr>
<td>Nurse prescribed</td>
<td>0.6</td>
<td>10.2</td>
<td>4.6</td>
<td>0</td>
</tr>
<tr>
<td>Different dose from prescription</td>
<td>2.6</td>
<td>0</td>
<td>1.5</td>
<td>0</td>
</tr>
<tr>
<td>Infrequent admin./refusal</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0.9</td>
</tr>
<tr>
<td>Patient's own purchase</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

4.3.9. Side Effects.

There was no section within the Patient Profile to record side effects of current therapy but the interview stage with patients did identify some notable instances. In section 4.3.4.3, it has already been cited that patients who suffered from Parkinson's disease exhibited some of the well-documented side effects of L-Dopa. These are now described.

Hallucinations: One patient, the sole occupant of a room, was able to conduct a conversation with the investigator but described the 'other' people in the room and always placed left-over food on the floor for 'the dog'. The drug history revealed that the night-time dose of Madopar had been changed to the CR formulation but the original Madopar dose had not
been discontinued. Both doses had been administered concurrently, resulting in a daily dose of 1250mg daily instead of the intended 1000mg.

**Falls:** One patient was mobile with a walking aid but frequently fell. The nursing home policy was not to restrict patients but consequent upon each fall the patient was examined and sometimes taken to the hospital A&E department. The same patient exhibited amorous suggestive behaviour towards nursing staff.

**Rigidity:** One patient had regular spasms of rigidity and during one such incident, prior to this project, fell and suffered a fractured hip. On admission to the nursing home the Madopar regime had been altered from 125mg every three hours to 375mg in a controlled release formulation eight hourly.

**Muscle Weakness:** One patient understood the nature of the disease and the need for medication but deplored the weakness that the drugs caused. She described the ideal drug for her condition: "When my arm starts to shake, the drug should be injected into the arm directly and then my whole body would not be affected".

4.3.10. **Quality Control.**

A summary of the quality issues observed by the researcher was collated and provided to senior nursing staff. This incorporated the observation of medicine administration by nursing staff. The findings are presented as Table 9.
Table 9: Baseline Data – Quality Control.

<table>
<thead>
<tr>
<th>Quality Standards</th>
<th>Consistently undertaken</th>
<th>Inconsistently undertaken</th>
<th>Never undertaken</th>
</tr>
</thead>
<tbody>
<tr>
<td>NH1</td>
<td>54%</td>
<td>18%</td>
<td>28%</td>
</tr>
<tr>
<td>NH2</td>
<td>65%</td>
<td>22%</td>
<td>13%</td>
</tr>
</tbody>
</table>

4.3.10.1. Observation of medicine administration:

Administration of medicine was evaluated using twenty different criteria that were based on previously established good nursing and pharmaceutical practice (Appendix II). Any consistent failure by nursing staff to undertake an activity or adopt procedures in accordance with the nursing home’s written policy was recorded.

The observation was conducted on five occasions: three times in NH1 and twice in NH2. On average, only 58% of the medication was being administered in accordance with the defined criteria. The most common errors were:

- Failure to witness drug administration before recording the fact. In most cases, the record was signed when the nurse placed the dose unit into a medicine glass.
- Administration of medication without prior formal identification of the patient concerned.
- Nurse signing the administration chart and therefore accepting responsibility, even though a second nurse had observed the patient taking the medicine.
- Medicines left for the patient to take later.
- Medicines that were formulated as suspensions not sufficiently shaken.
- Inappropriate crushing of some oral dose forms.
4.3.11. Time Involvement of the Pharmacist.

During the Baseline phase the pharmacist carefully noted the time requirement to collate information on an individual patient basis. On analysis it was found that the value mean (± SD) per patient was 84.1 (± 26) minutes per patient. A record was also kept of other time commitments including completion of the Quality Control report and Observation of medicine rounds. Because these elements were additional to the requirements of medication review they were not featured within the quoted figure.

4.4. Summary of the Baseline Phase.

The Baseline phase of the study identified aspects of medicine management that would potentially benefit from further pharmaceutical involvement. The analysed data identified areas of concern that were broadly classified as Prescribing, Medicine Administration and Quality.

4.4.1. Prescribing.

Although the researcher had been aware of nurse influence upon prescribing, the data confirmed that this was a considerable issue in the day-to-day operation of a private nursing home. Many items were apparently prescribed by the GP at nurse request. However, it was a matter of some concern that POMs were administered to patients, ostensibly when there was no written prescription from the GP, in addition to medicines identified for use at nurse discretion. The researcher also had a particular concern about the high usage of uro-tainer products.
High rates of prescribing and administration of PRN gastro-intestinal and skin products combined to identify specific areas for pharmacist involvement in prescribing. These were considered as ‘target’ areas for the development of policies for use of laxatives and wound care products. Due to the low use of psychoactive drugs, further targeting of CNS medicines was not considered appropriate.

4.4.2. Medicine Administration.
The accuracy of medicine administration, or otherwise, was a matter of some concern. Some of the adopted procedures were considered by the researcher to be unsafe. Added to this was the poor standard of record keeping by nursing staff in some instances. Many medicines had not been formally recorded. These were identified primarily as training issues.

4.4.3. Quality Issues.
The quality issues were fundamentally associated with each nursing home’s registration with NHA. Although failure to meet these criteria was not considered an unacceptable risk to patients, the issues were of sufficient importance to be required standards under the Registered Homes Act 1984.

4.4.4. Report and Agreement to Proceed.
An interim report was constructed which set out the major issues already referred to and this was discussed at a meeting with the matron of each nursing home and a senior nurse within the company whose remit was Quality Control. A summary report was tabled and discussed.
There was consensus agreement to proceed to the next phase of the study with pharmaceutical involvement in the following issues:

i. Review of policy documents relating to medicine management within each nursing home.

ii. Provision by the researcher of a written policy for laxative use.

iii. Provision by the researcher of a written policy for wound care.

iv. Review of the medicine storage arrangements in each home.

v. Review of the procedures for recording medicines in each home.

vi. Provision by the researcher of 'in service' training for nursing staff.

vii. The institution of a monthly meeting with the matron in each nursing home to discuss pharmacist recommendations.
Chapter 5

Pharmaceutical Intervention.
Chapter 5: Pharmaceutical Intervention.

5.1. Key Objectives.

The Intervention phase of the project was constructed to fulfil the following key objectives:

i. To establish the nature and extent of pharmacist recommendations concerning the prescribing and administration of medicines in a discreet group of nursing home patients.

ii. To investigate the level of acceptance of pharmacist interventions both by medical practitioners and nursing staff.

iii. To establish the nature of any patient outcomes from implementation of pharmacist recommendations.

5.2. Methodology.

The intervention stage of the project began at the end of March 1993. Each nursing home was visited and an initial medication review conducted for each patient in the study. Written recommendations were made to both GPs and nursing staff (section 3.6.5.). At the outset, communication of matters related to prescribing was made to the GPs and those related to procedure or quality issues to nursing staff. Each group thus had a different set of recommendations but the investigator held a total profile (section 3.6.6.). This was one aspect of the project that was altered in the light of experience and is discussed further in Chapter 7.
The Communication forms (Appendix II) included a section for written responses relative to individual patient recommendations. These responses were used to identify the acceptance or not of any pharmacist recommendation.

One month after the initial medication review the researcher commenced a series of monthly visits to each nursing home. On each subsequent visit, a medication review was conducted and any new or continuing recommendations made. This was achieved by:

i. Discussing with the matron or nurse in charge any changes that had occurred in relation to prescribing and medicine management within the home. The discussion took due note of any changes in the health status of patients in the study.

ii. Recording details from the nursing home records of any changes in prescribed medicines relative to the preceding medication review.

iii. Reviewing any changes in prescribing not related to the previous review.

iv. Identifying any results of therapeutic drug monitoring.

v. Identifying any new diagnoses from the patient’s medical notes.

vi. Identifying any alterations in health conditions from the nursing notes.

vii. Conducting a medication review on the basis of available information.

In addition, it was possible to record the degree of uptake of previous recommendations and assess any outcome where changes had been made. The nature of the interventions made was defined to enable statistical analysis as described in section 5.3.2.
The Intervention phase continued for a total period of six months. During visits to the nursing homes a record was made of any perceived outcome for patients, whether positive or negative. These data were analysed statistically using SPSS.

5.3. Results.
The Intervention phase was the most difficult to manage. There was no response from one GP at the time of the second medication review to recommendations that had been made in the previous month and these were only obtained after a further month. However, this delayed response coincided with a request from the senior nurse manager within the company for a review meeting with the investigator and the matrons. A key problem had arisen due to lines of communication. To address this issue, it was decided that a month should be allowed to elapse before any further medication reviews were attempted. Consequently, the project had five rather than the six reviews that had originally been planned. Furthermore, for reasons that are explained more fully in Chapter 7, it was agreed that recommendations from the investigator should first be conveyed to the nursing home matrons for information and comment, prior to being passed on to other nursing staff or the caring physicians. This procedure avoided a possible situation where the nursing staff could have felt that their status was being undermined. This situation provided a valuable outcome of the project.

The data have been represented to describe the frequency, nature and acceptance rate of interventions by the pharmacist.
5.3.1. Frequency of Interventions.

New patients were not accepted into the study after the baseline data collection. A total of 173 recommendations were made during five medication reviews. Forty-two recommendations were made to GPs: 18 in NH1 and 24 in NH2. Recommendations to nursing staff numbered 131, of which 56 were to NH1 and 75 to NH2.

The number of interventions showed a tendency to decline at the time of the second review but later increased so that on occasions it was equal to the initial level (Table 10).

Table 10: Intervention Data – Number of interventions per month in each nursing home.

<table>
<thead>
<tr>
<th>Nursing Home</th>
<th>Number of Interventions/month</th>
<th>Total Interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>NH1</td>
<td>27</td>
<td>5</td>
</tr>
<tr>
<td>NH2</td>
<td>30</td>
<td>10</td>
</tr>
</tbody>
</table>

A continuing need to intervene as the study proceeded was due to:

- Lack of response to previous recommendations and a concomitant requirement to reinforce previous advice.
- The introduction in one nursing home of a monitored dosage system that was set up using patient data that was no longer accurate.
5.3.2. Nature of Interventions.

A series of seventeen classifications was applied to interventions. This was an extension of the initial classification, based upon the findings during medication reviews. These are listed in Table 11.

**Table 11: Intervention Data - Classification of pharmacist interventions.**

<table>
<thead>
<tr>
<th>Interventions related to prescribing</th>
<th>Interventions related to medicine management.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Potential drug interaction.</td>
<td>9. Records indicated that the drug was not administered to the patient as prescribed by the GP.</td>
</tr>
<tr>
<td>2. Recommendation to change the dose of a prescribed medicine.</td>
<td>10. Records of medicine administration inadequate e.g. missed signatures, variable dose not recorded.</td>
</tr>
<tr>
<td>3. Recommendation to alter the frequency of administration of a prescribed drug.</td>
<td>11. Administration of a prescribed Regular drug had been omitted.</td>
</tr>
<tr>
<td>4. Recommendation for a review of drug therapy in total.</td>
<td>12. Recommendation to change the time of dose administration.</td>
</tr>
<tr>
<td>5. Recommendation to undertake a laboratory investigation e.g. U&amp;E, Digoxin level.</td>
<td>13. Recommendation that patient monitoring introduced e.g. regular B.P. for patient prescribed antihypertensive therapy.</td>
</tr>
<tr>
<td>7. Recommendation to prescribe a different product.</td>
<td>15. Specified drug held in the nursing home was beyond the expiry date.</td>
</tr>
<tr>
<td>8. Recommendation to discontinue the prescribed drug.</td>
<td>16. Recommendation to dispose of specified drug because it was 'out of date' or no longer appropriate to therapy.</td>
</tr>
<tr>
<td></td>
<td>17. Quality issues related to Registration e.g. medicine storage arrangements; procedure for obtaining repeat medicines.</td>
</tr>
</tbody>
</table>
A summary of the nature and frequency of interventions is shown in Charts 18 and 19. Reference has previously been made to the original intention to refer all matters related to prescribing to GPs. From the second medication review, this decision was revised with the knowledge that the nursing staff had been delegated responsibility for some prescribing decisions. Hence, a number of interventions regarding prescribing were made to nursing staff, many of which related to the use of laxative and wound care products.

Chart 18: Intervention Data - Nature of interventions relating to prescribing issues.
5.3.3. Acceptance of Interventions.

Out of the total of 173 recommendations made, 96 were accepted and acted upon. In NH1, recommendations to the GP were accepted in 45% of the cases; and recommendations to nursing staff were accepted in 66% of the cases. In NH2, the proportions were: GP 70% acceptance and nursing staff 45% acceptance. Taking all the interventions, the acceptance rate was 55.5%. This data is shown in Chart 20.
5.3.4. Outcome of Interventions.

As an outcome of the medication reviews, it was possible to draw a distinction between those recommendations for change that would have a direct impact on therapy and those associated with quality issues.

5.3.4.1. Interventions having a Direct Impact on Therapy.

The occasions where implementation of a recommendation produced a positive outcome are listed in Table 12.
Table 12: Intervention Data - Positive outcomes of recommendations related to drug therapy.

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Number of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>New laxative regime</td>
<td>14</td>
</tr>
<tr>
<td>Time of dose altered</td>
<td>7</td>
</tr>
<tr>
<td>Dose increased</td>
<td>6</td>
</tr>
<tr>
<td>Maintain therapy following laboratory test</td>
<td>5</td>
</tr>
<tr>
<td>Medicine discontinued</td>
<td>4</td>
</tr>
<tr>
<td>Dose reduced</td>
<td>2</td>
</tr>
<tr>
<td>Medication regime altered</td>
<td>1</td>
</tr>
<tr>
<td>Medicine given as prescribed by GP</td>
<td>1</td>
</tr>
<tr>
<td>Dose frequency changed</td>
<td>1</td>
</tr>
<tr>
<td>Medicine reinstated</td>
<td>1</td>
</tr>
<tr>
<td>Medicine disposed of</td>
<td>1</td>
</tr>
<tr>
<td>Monitoring instituted</td>
<td>1</td>
</tr>
</tbody>
</table>

The most notable change was in the acceptance of new laxative regimes in the case of fourteen patients. In addition, the following six cases are of particular interest.

**Case 1**: When interviewed, this 80-year-old lady with a diagnosis of Parkinson's disease complained of difficulty with bowel movement. The alteration of her laxative regime not only produced a good outcome in relation to constipation but also led to the discontinuation of Gaviscon which had been taken regularly four times daily for several years with no documented diagnosis to support its use.
Case 2: This 80 year old lady had senile dementia and some incidence of fitting. A recommendation was made to discontinue bendrofluazide since there was no supportive diagnosis and this was accepted. There was no evidence of any negative outcome to the drug being discontinued.

Case 3: This gentleman was a 75-year-old Parkinsonian patient who presented with poor mobility and also suffered from frequent hallucinatory episodes. The recommendation to reduce the amount of L-Dopa given to this patient was accepted. Nursing staff were of the opinion that the patient's hallucinations had subsequently decreased and he had become more mobile.

Case 4: At the commencement of the study, this 72-year-old lady was recovering from a fractured neck of the femur. On entering the nursing home, the therapy for her Parkinsonian symptoms had been changed from a three hourly regime to three Madopar CR capsules at eight hourly intervals. Although this had potential advantages for the nursing staff and the patient, she continued to suffer from severe spasmodic attacks of rigidity, which may have contributed to her injury. A recommendation was therefore made to re-instate her pre-admission therapy. No negative consequences arose from this change, although it was not possible to observe any change in the frequency of her rigidity spasms.

Case 5: This 75 year old lady with learning disabilities had, for many years, been immobilised following hip and leg fractures. She had been prescribed antidepressant therapy for some considerable time but the
caring physician had recently discontinued this. During this study, it became clear that her problems of constipation were related to her previous intake of antidepressant therapy. A recommendation was therefore made to discontinue the continual laxative administration that subsequently proved to be unnecessary.

**Case 6:** This 84 year old lady was immobile because of a below-knee amputation. Nursing staff reported that constipation was a continuing source of distress to this patient and she was receiving a regular dose of Co-Danthrusate. A recommendation was made to check potassium levels. The laboratory results indicated a lowered potassium level. The Co-Danthrusate was discontinued and a new laxative regime initiated.

Conversely, a negative outcome occurred on seven occasions when recommendations were implemented. Three cases are of particular interest. In each case the outcome is separately discussed in Chapter 7.

**Case 7:** This 82-year-old lady was prescribed ranitidine, together with several other drugs. A search of all available documentation did not reveal a diagnosis to substantiate the therapy. A recommendation was made to discontinue the drug and this was accepted. The patient became very ill, complaining of epi-gastric pain. Ranitidine was re-instated.

**Case 8:** An elderly frail 96-year-old lady was prescribed a high dose of frusemide. A recommendation was made to review the dose. This was
accepted and the dose was reduced. The patient rapidly produced a blistering oedema and the dose was reinstated.

In the same patient, the recommendation was made to review the prescription for Slow-K in the light that a combination potassium sparing diuretic may be as effective and less cumbersome of swallow. In conjunction with reducing the frusemide, the GP stopped Slow-K and did not provide any potassium supplement. Subsequent communication reinforced the advice relating to potassium but rather than altering the diuretic, the decision was made to reinstate Slow-K but at a lower dose.

**Case 9:** A recommendation was made to review the antidepressant therapy for this 93-year-old gentleman as his regime included two different tricyclic antidepressants. The recommendation was accepted but although one drug was discontinued, the dose of the other was not increased and the patient became distressed. It was unfortunate that the patient's general condition deteriorated and he died before any further recommendations could be made.

### 5.3.4.2. Interventions that had an Impact on Quality Issues.

During the course of the study, a number of supply issues were resolved, inappropriate drugs were returned/disposed of and patient monitoring relevant to their drug therapy was initiated. Although an improvement in the completeness and accuracy of the record keeping was evident by the end of the intervention phase, some errors and omissions were still occurring, which suggests that continual monitoring of these aspects would be highly desirable.
Although quality issues may not have a direct bearing on prescribing, they do have an impact on the quality of patient care in the nursing home and therefore have a place in this research project.

5.4. Summary of Intervention Phase.

During a period of six months the researcher made pharmaceutical recommendations to prescribers and nursing staff. The manner of communication was revised in the light of experience. Responses to these recommendations varied between the differing professionals and the two nursing homes.

When a final report was prepared in 1993 for the DoH, each GP was provided with a copy, including a request for comments upon the findings. Neither GP responded to this request.
Chapter 6.

Post - Intervention Analysis.
Chapter 6. Post - Intervention Analysis.

6.1. Key Objectives.

Future investment of time and money in the development of the pharmaceutical advisory role in nursing homes requires evidence that this investment will produce more cost effective treatment for patients. To enable conclusions to be drawn from the whole project, the following key objectives were identified:

i. To establish the nature and extent of changes in prescribing of Regular and PRN medicines in two nursing homes following pharmaceutical intervention.

ii. To investigate the changes in patterns of medicine administration following pharmaceutical intervention.

iii. To investigate whether the provision of pharmaceutical advice contributes to individual patient benefit.

iv. To investigate the investment of pharmacist time that was necessary to provide this level of service.

6.2. Methodology.

To enable a comparison with the Baseline data, it was essential to make a final data collection following the Intervention phase. The elements that were followed up included the current drug regimes for those patients who remained in the study and the pattern of administration of Regular and PRN medicines. These factors were evaluated in the light of pertinent health conditions of each patient.
During the final visit to each nursing home an evaluation of the health condition of each patient was established during interview with the matron or nurse in charge. The decision was taken not to re-interview patients but to obtain a subjective view of outcome from nursing staff (section 6.3.1.).

The final phase of the study was devoted to statistical analysis. A comparison was conducted of the pre- and post-intervention data to establish whether any significance could be placed upon changes in prescribing and medicine administration that had occurred during the study.

A careful analysis of time was also undertaken. This identified the time commitment a) to set up a medication review service; and b) to conduct monthly medication reviews and liaise with nursing staff. These data have been extrapolated to give an overview of the potential cost-benefit of introducing pharmacist-led medication review in private nursing homes.

6.3. Results.

Post-intervention data were collected one month after the final medication review. As a result of discharges and deaths, the patient population at the end of the study comprised 60 patients: in NH1 there were 22 patients (2 male and 20 female); in NH2 there were 38 patients (6 male and 32 female).

6.3.1. Patient Status.

The Patient Profile was completed at the end of the study, following discussion with nursing staff. Even after a cursory review of these data, it was apparent...
that there had been little or no change in physical and cognitive status. It was therefore considered inappropriate to re-interview the patients.

6.3.2. Health Conditions.

As with the status of each patient, the nurse perception of health conditions was discussed and a summary is presented in Table 13. These results correlate to baseline data set out in Table 5 (page 108).

**Table 13: Post-intervention Data – Health Conditions.**

<table>
<thead>
<tr>
<th>Problem</th>
<th>No. of patients</th>
<th>% of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Constipation</td>
<td>11</td>
<td>18.0</td>
</tr>
<tr>
<td>Diarrhoea</td>
<td>1</td>
<td>1.7</td>
</tr>
<tr>
<td>Dizziness/vertigo</td>
<td>2</td>
<td>3.3</td>
</tr>
<tr>
<td>Faecal impaction</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Hallucinations</td>
<td>1</td>
<td>1.7</td>
</tr>
<tr>
<td>Joint pain</td>
<td>3</td>
<td>5.0</td>
</tr>
<tr>
<td>Oedema</td>
<td>13</td>
<td>22.0</td>
</tr>
<tr>
<td>Pain</td>
<td>9</td>
<td>15.0</td>
</tr>
<tr>
<td>Pressure sores</td>
<td>3</td>
<td>5.0</td>
</tr>
<tr>
<td>Shortness of breath</td>
<td>7</td>
<td>11.7</td>
</tr>
<tr>
<td>Skin problems</td>
<td>6</td>
<td>10.0</td>
</tr>
<tr>
<td>Syncope</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Vomiting</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Falls</td>
<td>10</td>
<td>16.7</td>
</tr>
<tr>
<td>Hip fracture</td>
<td>1</td>
<td>1.7</td>
</tr>
<tr>
<td>None of the above</td>
<td>21</td>
<td>35.0</td>
</tr>
</tbody>
</table>
There were 21 patients who were reported as not having any of the recorded problems. The distribution of health problems is shown in Chart 21. The corresponding Baseline data are included as Chart 4 (page 107).

**Chart 21: Post-intervention Data - Distribution of the frequency of occurrence of health related problems.**

There were some evident improvements in the health conditions of the patients when these were compared for the Baseline and Post-intervention phases. Initially only two of the 79 patients were free of the health problems that were being monitored. At the end of the study, no less than 21 of the 60 remaining patients were problem-free. Furthermore, where they occurred, initial incidence of problems was in the range one to seven whilst post-intervention the range was one to four. When the percentage occurrence of health problems was compared pre- and post-intervention for both nursing homes, improvement was
significant for absence of any health problem (P <0.05), decrease of pressure sores (P <0.05) and decrease in the incidence of constipation (P <0.005).

6.3.3. Changes in Prescribing.

In addition to recording the outcome of previous recommendations, a record was made of the current drug regime for each remaining patient, including an audit of drug trolley and cupboard contents. An analysis of the total items prescribed in each nursing home was undertaken and is shown in Table 14. These correspond to the Baseline data in Table 6 (page 117). It is important to emphasise that the GPs who offered medical services to patients in each of the nursing homes were the same throughout the entire study.

Table 14: Post-intervention Data - Items prescribed for patients

<table>
<thead>
<tr>
<th></th>
<th>NH 1</th>
<th>NH 2</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of patients</td>
<td>22</td>
<td>38</td>
<td>60</td>
</tr>
<tr>
<td>Items - Regular</td>
<td>90</td>
<td>149</td>
<td>239</td>
</tr>
<tr>
<td>Items - PRN</td>
<td>29</td>
<td>61</td>
<td>90</td>
</tr>
<tr>
<td>Items - Total</td>
<td>119</td>
<td>210</td>
<td>329</td>
</tr>
<tr>
<td>Average items per patient</td>
<td>5.4</td>
<td>5.5</td>
<td>5.5</td>
</tr>
</tbody>
</table>

6.3.3.1. Changes in the Number of Items Prescribed.

The average number of items prescribed per patient in the Baseline and Post-intervention stages of the study is compared in Table 15. The number of PRN and Regular items are shown separately for each nursing home.
Table 15: Comparison between Baseline and Post-Intervention data of average number of prescribed items per patient.

<table>
<thead>
<tr>
<th></th>
<th>Baseline data: Average no. of prescribed items per patient.</th>
<th>Post-Intervention Data; Average no. of prescribed items per patient.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Regular</td>
<td>PRN</td>
</tr>
<tr>
<td>NH1</td>
<td>5.1</td>
<td>3.6</td>
</tr>
<tr>
<td>NH2</td>
<td>4.4</td>
<td>2.1</td>
</tr>
</tbody>
</table>

Since the systems of nursing care differed in each nursing home, it was decided that evidence for change due to the provision of pharmaceutical advice should be sought within each establishment. The data was therefore not pooled prior to analysis. The respective changes in prescribing for each nursing home are also presented as Charts 22 and 23.

Chart 22: Comparison of changes in the average number of prescribed items per patient, pre- and post-intervention, in NH1.
Baseline and Post-intervention data were compared using a paired t-test. Firstly the difference in the number of items per patient prescribed on a Regular basis was tested. In NH1 the mean value (± SD) was 4.6 (2.7) before and 4.3 (2.2) after intervention. This difference did not reach statistical significance (P >0.05). In NH2 the mean value was 4.4 (2.8) before and 4.1 (2.9) after intervention. This difference was statistically significant (P <0.05).

Secondly, the test was applied to items prescribed for PRN administration. The reduction in the number of items pre- and post-intervention was even more marked. In NH1, there was a significant decrease in the mean number of items per patient from 3.4 (1.4) to 1.4 (0.8) (P <0.001). In NH2, the mean number of
items per patient decreased from 2.3 (1.5) to 1.7 (1.2) which was significant at $P = 0.0006$.

Overall, in both nursing homes and considering Regular and PRN medicines, there was a reduction in the average number of prescribed items per patient from 7.4 to 5.5. It was also determined that there was a reduction in the mean number of prescribed items per patient of 1.5.

The data has been collated and analysed solely on the basis of the number of prescribed items and no attempt was made to identify the actual cost savings associated with reduced prescribing. In the absence of accurate costs, it has not been feasible to predict the potential for making cost savings in relation to the GP prescribing budget and from this to establish whether it would be cost effective to employ a pharmacist to undertake medication review in nursing homes. This is further discussed in section 7.8.

6.3.3.2 Prescribing by Pharmacological Classification.

A detailed analysis of total prescribing by pharmacological classification was also conducted. This analysis is presented in Chart 24. An inspection of the data shows a similar breakdown to the Baseline data presented in Chart 9 (page 117). The most frequently administered drugs on both a Regular and PRN basis were for the treatment of gastro-intestinal, central nervous system and skin conditions.
Following the analysis carried out for Baseline data, a distinction has been made between the separate prescribing patterns of Regular and PRN medicines. The results of this classification are shown in Chart 25 and these should be compared with Chart 10 (page 118).
A more detailed analysis of the indications for the use of GI, CNS and skin medications was then undertaken and this identified similar patterns for the most frequently prescribed medicines as had been noted during the Baseline phase.
In the gastro-intestinal classification, laxatives were the most commonly prescribed items for both Regular and PRN administration. Chart 26 contains details of the Post-intervention data. This corresponds to Baseline data in Chart 11 (page 119).

A comparison with Baseline data indicated that for laxatives there had been an increase in the percentage of total prescribing from 17 to 18% for Regular items; and a decrease from 22.7 to 15.6% for PRN administered items.
It was also considered appropriate to ascertain the number of laxative items administered to patients Post-intervention. This information is included in Chart 27. The corresponding Baseline data is presented as Chart 12 (page 120).

**Chart 27: Post-intervention Data - % of patients receiving Laxatives, Regular and PRN in two nursing homes.**

There were no patients receiving in excess of three laxatives. When the differences were compared using a chi-squared test for each nursing home there was no significant difference pre-and post-intervention for GI medicines prescribed for Regular use. There were, however, significant differences for PRN medicines (P <0.006). In NH2, after intervention, the percentage of drugs prescribed PRN for GI treatment (many of them laxatives) fell from 19.2% to 8.2%.
Medicines prescribed for the central nervous system were also analysed post-intervention (Chart 28). This corresponds with Baseline data set out in Chart 14 (page 123).

**Chart 28: Post-intervention Data - Prescribing of CNS medicines in two nursing homes.**

Using a chi-squared test to make comparisons, it was established that neither nursing home showed any significant difference, pre-and post-intervention, in the percentage of drugs prescribed on a Regular basis in this category (P >0.05). There was similarly no difference in the PRN prescribing of CNS drugs in both nursing homes (P >0.05).
The third category of medicines (skin) did produce significant results post-intervention for PRN medicines (P<0.006). The data are represented in Chart 29 and should be compared with Baseline data in Chart 16 (page 125).

![Chart 29: Post-intervention Data - Prescribing of Skin medicines in two nursing homes.](image)

The prescribing of Regular medicines showed no significant difference pre-and post-intervention (P >0.05). The percentage of drugs administered PRN for the treatment of skin complaints rose from 27.9% pre-intervention to 46.6% post-intervention. This is a reflection of better record keeping of the topical applications in use post-intervention rather than an indication that more patients were receiving these medicaments.
A further comparison was made between the patterns of Regular and PRN prescribing post-intervention for the three categories of medicines in each nursing home. The results are presented in Chart 30. These should be compared with the results set out in Charts 13, 15 and 17 (respectively pages 121, 124 and 126).

**Chart 30: Post-intervention Data - Comparison of Regular and PRN prescribing patterns of Laxatives, CNS and Skin medicines in two nursing homes.**

It is interesting to note that in contrast to other drugs, the administration of drugs for treatment of CNS had been satisfactory in both nursing homes at the pre-intervention stage.
6.3.4. Changes in Administration of Medicines.

The criteria used to describe the administration of medicines at Baseline were also used to make comparisons between the administration of Regular and PRN medicines Post-intervention. These data are presented in Table 16 and correlate with Baseline data presented in Table 7 (page 127).

**Table 16:** Post-intervention Data – Patterns of medicine administration for Regular and PRN use.

<table>
<thead>
<tr>
<th>Pattern of medicine administration</th>
<th>Regular (%)</th>
<th>PRN (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Administered as prescribed</td>
<td>85</td>
<td>28</td>
</tr>
<tr>
<td>Not administered</td>
<td>3.6</td>
<td>10.8</td>
</tr>
<tr>
<td>Self-medication</td>
<td>3.2</td>
<td>1.1</td>
</tr>
<tr>
<td>No record of administration</td>
<td>2</td>
<td>12.9</td>
</tr>
<tr>
<td>No record of FP10</td>
<td>2.8</td>
<td>6.5</td>
</tr>
<tr>
<td>Nurse prescribed</td>
<td>2</td>
<td>39.8</td>
</tr>
<tr>
<td>Different dose from prescription</td>
<td>1.2</td>
<td>1.1</td>
</tr>
</tbody>
</table>

A further comparison of these patterns of administration was made between NH1 and NH2 and the results are listed in Table 17. The corresponding Baseline data is set out in Table 8 (page 129).
Table 17: Post-intervention Data – Comparison of medicine administration in two nursing homes.

<table>
<thead>
<tr>
<th>Pattern of medicine administration.</th>
<th>NH1 (%)</th>
<th>NH2 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Reg.</td>
<td>PRN</td>
</tr>
<tr>
<td>Administered as prescribed</td>
<td>79.6</td>
<td>26.7</td>
</tr>
<tr>
<td>Not administered</td>
<td>3.2</td>
<td>13.3</td>
</tr>
<tr>
<td>Self-medication</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>No record of administration</td>
<td>1.1</td>
<td>3.3</td>
</tr>
<tr>
<td>No record of FP10</td>
<td>7.5</td>
<td>16.7</td>
</tr>
<tr>
<td>Nurse prescribed</td>
<td>5.4</td>
<td>36.7</td>
</tr>
<tr>
<td>Different dose from prescription</td>
<td>3.2</td>
<td>3.3</td>
</tr>
</tbody>
</table>

6.3.4.1. Results for NH1.

In NH1 there was an increase in the percentage of Regular drugs that were administered in the same dose and frequency as prescribed by the GP. The observed rise from 67.1% at Baseline to 79.6% Post-intervention was significant (P <0.05: chi-square test). There was also an increase in the number of medications administered PRN on the specific directions from a GP. The pre-and post-intervention levels were 13.9% and 26.7% respectively and this change was significant (P <0.05: chi-square test). These results are presented in Chart 31.

The percentage of drugs that were prescribed by nurses on a Regular and PRN basis rose from 0.6 to 5.4% and 10.2 to 36.7% respectively. The effect of intervention has been to rationalise the guidelines within which such discretionary prescribing was undertaken.
6.3.4.2. Results for NH2.

In NH2, there was no significant difference pre-and post-intervention in the percentage of drugs prescribed by a GP on a Regular basis and correctly administered and also those administered PRN following explicit directions from the GP (P > 0.05). The changes are represented in Chart 32.

As at the Baseline stage, there were no Regular drugs prescribed by nurses; whilst the percentage of drugs administered PRN rose significantly from 7.6 to 41.3% (P < 0.05). As in NH1, the discussions between the investigator and the
nurses over the course of the study had resulted in a more careful selection of drugs that could be used PRN.

![Chart 32: Comparison of Regular and PRN medicine administration in accordance with the GP prescription, pre- and post-intervention, in NH2.]

6.3.5. Pharmacist Time Commitment.

The final objective of the Post-intervention phase was to identify the time that a pharmaceutical service, similar to that provided in the USA, would require; and to compare the findings to the reference in section 2.2.

Careful records were maintained throughout the project and the time involvement is presented as three separate elements. An SPSS statistical analysis and comparison (using ANOVA) of the mean time required to accomplish each of the
stages described below was undertaken for each of the nursing homes. These times were not found to be significantly different (P >0.05). It was therefore decided to summarise the data in terms of a total time commitment per patient.

The first element of the analysis related to the initial collation of Baseline data. This represented the major time commitment. As identified in section 4.3.11., this had a mean value (± SD) of 84.1 (± 26) minutes per patient. Identifying diagnoses from the handwritten medical notes was time consuming. A further extensive time commitment was necessary to obtain information from nursing records, which complemented the GP records and, in some cases, were essential because the transfer of medical notes were delayed. This is further discussed in section 7.6.1.

The second time element related to the monthly medication review. It must be emphasised that the pharmacist did not obtain an update of the medical notes in NH1 during each of the monthly reviews. From the data, it was calculated that a medication review for one patient would take a time mean (± SD) of 7.9 (± 4.4) minutes. This would appear to confirm the information obtained from USA consultant pharmacists that the ongoing medication review for a caseload of 1,000 patients represents at least full time commitment (section 2.2.).

The final time element that was recorded during the study was the monthly conference time in each nursing home when the pharmacist met with nursing staff subsequent to the medication review. Due to the importance of inter-professional communication, which is discussed in Chapter 7, a time must be set aside for team meetings. In this study, a further commitment for the
pharmacist of two hours per month within each nursing home has been necessary.

On the basis of the study results, pharmacist time can be estimated on an individual patient basis to be 171 minutes during the first twelve months of the service; and 94.8 minutes per annum in ensuing years. A more detailed breakdown of pharmacist time was not undertaken and this is discussed in section 7.5.

6.4. Summary of Post-intervention Phase.

The analysis of Post-intervention data and comparison with the Baseline has led to the conclusion that measurable changes occurred in relation to prescribing of medicines, administration of medicines and health conditions of patients in two nursing homes following regular medication review by a pharmacist.

The time involvement of the pharmacist has been identified both to introduce and provide a continuous service for patients in nursing homes. However, the actual savings that were generated by a reduction in prescribed items was not identified.
Chapter 7

Discussion
Chapter 7: Discussion.

The study was designed to identify whether the practice of USA consultant pharmacy was appropriate in the UK environment of the National Health Service. The stated aims of this research project have been achieved. The activity of a USA consultant pharmacist has been mirrored in a UK setting. The nature and extent of prescribing in two nursing homes, selected because of their history of good medicine management when inspected under the auspices of The Registered Homes Act 1984, was established in relation to the patients and their health needs. During a period of six months the investigator conducted monthly medication review for a discreet group of patients. Recommendations for changes in drug therapy were communicated to both nursing staff and GPs, after which a comparison of the prescribed items for patients indicated an mean reduction of 1.5 items per patient.

In this Chapter, the discussion will focus upon important issues that have emerged during the course of the study, including the challenge of working in a multi-disciplinary setting and the appropriateness of pharmacist-led medication review for patients in nursing homes. The study design is critically discussed to judge the reliability of the study findings and the potential for wider generalisation of the results to the UK as a whole. Finally, proposals for change are discussed in the light of potential financial and health-related benefits.
7.1. **Prescribing of Medicines.**

At the beginning of the study, the average number of prescription items per patient was 7.4, and may well be considered to be unremarkable. Nevertheless, following pharmacist-led medication review, there was a reduction in prescribing in both homes based upon the mean number of prescribed items per patient. A literature summary published by the American Society of Consultant Pharmacists (ASCP) in 1986 detailed a range of results for similar studies of between 20 and 517 patients. The average number of prescribed items ranged from 2.4 to 9.6 per patient at baseline; and following pharmaceutical intervention identified a reduction of prescribed items ranging from 0.9 to 4.1 items per patient. When a basic comparison is made between these results and the mean reduction of 1.5 items per patient in the current study, it can be postulated that the influence of pharmacist recommendations in private care is not dependent upon the nature of health care service.

The investigator made a total of 173 recommendations to either prescribing GP or nursing staff. The acceptance rates differed between the two nursing homes but the overall rate of acceptance and implementation was 55.5%. The most marked changes in prescribing were noted for those groups of drugs that were identified as being the most problematical during the collection of Baseline data.

The study data shows that the GP responsible for NH1 accepted and implemented 45% of the pharmacist’s recommendations; and the GP responsible for NH2 accepted and implemented 70% of the pharmacist’s recommendations. The resistance of some medical practitioners to pharmaceutical involvement at the prescribing interface was clearly demonstrated by the refusal of one practice
to participate in this research. Those GPs did not see any reason, at the time, why pharmacists should be commenting on their prescribing practice. To overcome these concerns, which may in part be linked with freedom to exert clinical judgement, pharmacists must clearly demonstrate positive benefits to patients as a result of interventions. Since the introduction of PCG and PCT this attitude may have altered with the increasing emphasis upon appropriate prescribing together with prescribing costs.

Wright et al (1994) reported a total of 177 interventions over a six-month study period. Of these, 123 were implemented (69%). The patient population differed from the current study: there were 216 patients in nursing homes and 96 residents in residential care homes. The main reported reason for intervention was un-necessary medication. The associated study by Wright and Chrystyn (1994) focussed upon biochemical and therapeutic drug monitoring to influence prescribing decisions. A patient population of 319 was recruited, all of whom were resident in nursing homes. A total of 31 recommendations were made subsequent to sample analyses; and 18 of these were actioned (58%). One of the issues discussed was the inappropriate prescribing of diuretics.

The study by Rees et al (1995) was conducted in nine residential care homes. They recruited 160 residents, all of whom were over 75 years of age. There were 35 recommendations to change therapy but only 11 of these were agreed with the prescribers. However, they reported a 54% response (6) to these agreed changes one month after discussion with the relevant GP. The actual result represented 17% implementation of the original recommendations and this was a low response rate when compared with USA studies. Although the study
employed a test and control group of residents, the results suggested that the difference in the number of medication changes between these groups was not statistically significant. It is relevant that the study identified inappropriate prescribing of diuretics, hypnotics and laxative medicines.

The study by Furniss et al (2000) included 330 patients, recruited from 14 nursing homes. This study also employed test and control groups. The interventions were conducted over a four-month period but were also followed up within one month of the recommendations for medication changes. A total of 261 recommendations were made and 239 of these were accepted by GPs. However, only 144 (60%) of these were subsequently implemented. This is a similar response to that reported by Rees et al (1995). The reduction in prescribed medicines in the intervention group was not statistically significant. Additionally there was a reduction in prescribed items in the control group, though this was less than the intervention group. The study also found that there were high levels of prescribing of laxatives, diuretics and hypnotics.

The methodologies of the studies by Rees et al and Furniss et al do raise a major concern because follow-up of recommendations was within one month of the medication review. As repeat prescriptions are commonly provided for 4 weeks, the changes may not have been actioned within this timeframe. In the current study, the researcher did not prior discuss recommendations with the GPs. The reported acceptance of interventions is synonymous with implementation of the recommendations.
The results from these later studies prompt a conclusion concerning the prescribing practice of GPs in the current study. The prescribing of medicines in the cardio-vascular classification was not remarkable and, with minimal exception, the pharmacist did not recommend changes in diuretic therapy. Prescribing of hypnotic medicines and laxatives are considered separately in sections 7.1.3. and 7.1.1. respectively. A comparison of the current study with other studies confirms the view that the standard of prescribing for patients was of a good standard but even so provided scope for pharmaceutical intervention.

7.1.1. Prescribing of Laxatives

A notable outcome of this study was the reduction in the prescribing of gastro-intestinal drugs on a PRN basis in NH2. Most change was effected in the laxative group of drugs. In addition to improving the health condition of the patients, it had a further benefit of contributing to the patients' privacy and dignity. Pharmaceutical interventions were reinforced by the production of an Information Bulletin relating to laxative use (Appendix IV) and the matron in each home distributed this to trained nurses.

The GPs in the study had delegated choice of products to nursing staff and the selection was different in each nursing home. Registered nurses had accepted bowel management as their province of care and did not respond enthusiastically to pharmaceutical intervention in the first instance. Despite the fact that both nursing homes were in the same company, there were widely differing approaches to the problem of bowel management. The emphasis upon the topic was highlighted by the use of separate books to record whether a problem existed for each patient and also what treatment was selected. The policy in NH1
was to offer senna to every patient three times weekly combined with lactulose on a daily basis. This was recorded on a document separate from the MAR; and all aperients were offered at lunchtime in a manner, as observed on one occasion by the investigator, which did little to promote the dignity and privacy of patients. When this combination did not work effectively, several other agents were tried in an unstructured way and this approach resulted in some patients receiving as many as five different laxatives. The other home (NH2) employed a patient-focused regime but when success was achieved with one patient, it led to the same product being used on a wider scale. The product that was used to a great extent prior to the project was co-danthrusate.

Many elderly people have great concerns about inefficient bowel activity, particularly those with poor mobility. There is anecdotal evidence to suggest that older people have traditionally used laxative products to excess. The investigator observed that when patients were not necessarily concerned about this aspect of health, nursing staff exhibited great concern. A discussion relating to the use of laxatives was a feature of every post-medication review conference and was arguably the most contentious issue to deal with.

The study by Furniss et al (2000) reported that 49% of patients were prescribed laxative medication; but the study by Rees et al (1995) only identified laxatives for 20% of residents. In this study, 84% of patients were prescribed laxatives and this may be a marker of the influence of nurse discretion that is further discussed in section 7.1.4.
7.1.2. Prescribing for Skin Care.
The number of prescriptions for skin preparations apparently increased after pharmaceutical intervention and this has been attributed to a more formal approach to the recording of all external medicines by the nursing staff. The use of skin care products was not addressed in the same depth as laxative use. A Wound Care policy was written by the matron for use in NH2 as a direct result of the pharmaceutical report following the Baseline collation of data. In this instance the investigator was able to encourage and support the development of nursing policy within the home. It is considered important for the staff themselves to formulate policy and procedures and therefore to have ownership of them. The study thus identified a pharmaceutical role of influence rather than control of the process.

It is important to recognise that pharmaceutical intervention has the potential to result in increased prescribing in care homes and thereby to increase prescribing costs. In relation to the skin medicines identified in this study this was not felt to be the case, because the main outcome was better recording of activity that the nursing staff were already undertaking.

7.1.3. Prescribing of Psychoactive Drugs.
Changes were not particularly notable for psychoactive drugs and this was potentially due to the good medical and nursing care already in place in these homes. The results from this study underline the view that inappropriate prescribing of psychoactive drugs is not a feature of every care home. It is important at this stage to emphasise that the chosen nursing homes, prior to the study, were considered to be of good average standard in relation to the
management of medicines. In addition, each home was, in the main, provided with medical care continuously by the same GP. The commitment of these doctors was evident and visits to the home were regularly scheduled as well as in response to specific requests. This pattern of medical support is not notable in every care home.

In both nursing homes, the use of sedative medicines was minimal and as far as possible nursing staff encouraged the reduction of regularly prescribed medicines. This was evident from the Baseline data relative to cognitive function (section 4.3.2.1.). It was a nurse perception that 31 patients (39%) had a pattern of moderately disturbed sleep; and 4 patients only (5%) had severely impaired sleep patterns. However, the level of sedative prescribing was only 6.5% on a Regular basis and 5.7% PRN. Conversely, there was no evidence that the decision to restrict the use of sedatives was detrimental to patient care.

It is pertinent to note that, in the study by Furniss et al (2000), there was a strong focus on the appropriateness of psychoactive drug prescribing in nursing homes. The research incorporated a measurement of the mental status of patients, pre- and post-intervention by a pharmacist and highlights the importance of multidisciplinary research methodologies.

In retrospect, the current study would have been strengthened by the inclusion of a validated tool to establish actual cognitive ability of patients. At the planning phase, the opportunity for involving specialist medical assistance was not actively considered and it must be queried whether a pharmacist would have been sufficiently skilled to apply such an instrument and thereafter correctly interpret
the results. The results obtained in the current study indicated little or no change in cognitive function whereas Furniss et al (2000) have demonstrated deterioration in mental status over time.


The influence of nursing staff in prescribing decisions was one of the major enlightenments of this study. Nursing staff frequently made requests for medicine to be prescribed by the GP and had wide scope for discretion, not only in choosing to institute treatment involving medication but also in altering the dose and/or frequency of existing therapy. The researcher has formed the opinion that the continuing care of clients in nursing homes was dependent to a large extent upon nurse discretion.

The use of discretion in the routine management of bowel problems and wound care appeared to be encouraged by the GPs involved in this study. Communication difficulties occurred when the investigator addressed recommendations concerning prescribing to the GP, unaware that the treatment had been initiated or altered by nursing staff. The nurse insistence that any changes had occurred with GP approval was not documented. The introduction of a system of pharmaceutical advice must carefully account for any existing inter-disciplinary procedures.

The data in this study were collated before the enactment of legislation to facilitate nurse prescribing. The frequency and nature of the discretionary decisions that were made by nurses had not been anticipated, even though there
was awareness that professional judgment was permitted in the use of some medicines, based on previous experience of inspecting nursing homes.

Whilst nurses were exercising their professional judgement in these circumstances, the possibility existed that sufficient consideration may not be given to patient choice, including the right of the patient to have personal access to the prescriber, and the provision of adequate information about any prescribed medicines. The short time that GPs can spend in a care home on each visit may be perceived to be best utilised by dealing mostly with the nurse rather than the patient, particularly if the patient has cognitive impairment. Thus the patient's accessibility to the GP becomes very limited by circumstance, and with it patient choice.

From the observations of requests for prescriptions by nursing staff during this study combined with nurse decision to initiate therapy, it is possible to conclude that patients themselves may not be adequately consulted about new prescriptions. This concurs with the findings of the Alzheimer's Disease Society questionnaire (1997). It is also pertinent to discuss the fact that the majority of clients in care homes are not given the opportunity to speak with a pharmacist about their medicines.

The Medicines Control Agency requirement for every medicine to have a Patient Information Leaflet (PILs) was not an issue at the time of data collation. PILs may be perceived by nursing staff as a source of information to the carer but it is probably true to conclude that few are provided or indeed explained to the clients themselves.
Consequent upon these findings, it is considered necessary for individual nursing homes to have a clearly defined written policy for medicine management that incorporates the nature and extent of nurse discretion. A pharmaceutical adviser would be ideally qualified to provide pertinent information and training on the use of drugs and also facilitate the formulation of such policy.

7.1.4.1. Homely Remedies.

Under present regulations nurses within care homes are not permitted to prescribe for patients in their care nor apparently is this intended for the future following a press release about an extension of the nurse prescribing scheme (2001). And yet, nursing staff do prescribe homely remedies and make discretionary use of other medicines that may be required on a continuing basis. A GP response to this issue that the researcher has frequently observed is that patients may elect to self-treat with such medicines and therefore there is no necessity for the GP to become involved in the decision.

The issue regarding nurse discretion becomes more pertinent when patients have impaired cognitive function and are not able to give informed consent to treatment. It is strongly argued that the administration of any homely remedy, together with alterations of drug therapy, must be with the express agreement of the patient and must not solely depend upon the nurse perception of the patient’s condition. The construction of written protocols for the administration of medicines when a patient is unable to give informed consent must surely prove beneficial to patient care.
The publication in April 1998 of 'Review of Prescribing, Supply & Administration of Medicines' has proved beneficial in the nursing home sector even though it relates to the provision of Prescription Only Medicines in the NHS. The report includes guidance in the construction of Patient Group Directions and this can be extrapolated to the use of homely remedies in the care home setting.

It is very likely that the source of funding for homely remedies will also determine how and when they are used. The GP may be reluctant to bulk prescribe such products due to increasing limitations on drug budgets in primary care. If GSL and P medicines are purchased for use in the home, the home would be expected to sustain the cost. In the absence of 'free' medicines, the decision may be taken to restrict or even prevent the use of homely remedies within the home. It is highly probable that contracting authorities will assume that all medicines for the client are included in the general contract for services and requests for funding for simple remedies that the GP refuses to prescribe may not be treated favourably.

Registered owners have a duty of care to patients and are expected to provide necessary basic items. But the private care home is ostensibly a business venture and any provision must submit to the financial test of feasibility. Added to this is the fact that the Registered Homes Act 1984 includes no reference to standards of care that must be provided. Regulators are therefore unable to require that homes make specific provision of either consumables or equipment; and a homeowner may elect to refuse to purchase and provide such a service. For nursing staff, this may pose a professional dilemma if they are unable, through lack of non-prescribed medicines and wound care products that they may
deem necessary, to deliver appropriate care. The decision to provide homely remedies, or not, has the potential to become a matter of professional ethics and may place the nurse's registration with the UKCC in jeopardy.

The later studies already referenced in this Chapter have made no comment about the use of Homely Remedies nor indeed to the influence of nursing or care staff in discretionary use of medicines in care homes.

7.1.5. Medical and Pharmaceutical Services.

Whilst the study has focussed upon medication review, it has also provided valuable insights into the way that medical and pharmaceutical services continue to be provided for nursing home patients. For the vast majority of private care homes, all medical and pharmaceutical services are accessed from the NHS; and are anticipated to mirror the provision patients would obtain in their own homes. It is difficult to accept that this is indeed private provision of care.

It is also a tragic fact that whether the clients in a care home are able to access appropriate medical and/or pharmaceutical services that equate to their individual needs is a matter of chance. The medical profession, through the BMA, has been vociferous in stating that care of patients in communal homes represents a greater workload and requires appropriate funding. The incidence of retainer fees paid to GP practices in lieu of additional services is not inconsequential. Yet there has been little comment from the pharmaceutical profession on this issue. The anomaly may accurately reflect that, to the supplying pharmacy, there is no work distinction that differentiates where a patient lives.
Even though the current system of contracting assumes NHS medical and pharmaceutical services are included, there is no reason why this should not be challenged at some future time. It is therefore an interesting exercise to question what changes within the UK system would be necessary should the USA model of private care become a reality in this country.

Firstly, a nursing home would have the responsibility of contracting medical care directly from doctors, or may indeed set up a system to grant 'admission rights' to specified doctors. Is it not clear whether this would ultimately lead to better medical care for patients in the nursing home. In truth, the UK system already partially supports this model by the payment of retainer fees to GP practices for services that exceed general medical services.

This model would allow a GP to select whether or not to offer medical services to nursing homes instead of the current system where there is no choice. With contracted agreements, the GP practice would be able to apply the necessary resources to the task, including the resource of time. Additionally, the GP would select to offer care within the scope of professional practice that he/she has. Under current arrangements, it is indeed remarkable that, in spite of the GPs inability to determine whether to provide care for large numbers of vulnerable and often acutely ill patients, many continue to give an excellent service to nursing homes as was evidenced in this study.

Secondly, a nursing home would be responsible for purchasing supplies of medicines, either as individually dispensed items by means of a private prescription or as stock supplied against a signed order. The only necessity in
law would be for the home to retain a written record, which would effectively be the prescription order to nursing staff, signed by the medical practitioner in advance of the administration of any medicine to a client. Prescription charts would thus replace the MAR charts.

This situation would potentially impact upon a supplying pharmacist who would in theory be subject to competition from other suppliers. In addition to pharmaceutical wholesalers, PCT may elect to explore the option of supplying nursing homes from a hospital trust pharmacy department and thus capitalise on the potential for bulk purchase. All parties would be faced with the need to market a pharmaceutical service to a care home and this may ultimately result in realistic professional fees. As has happened in USA, the provision of medication review for nursing home patients could be associated with a contract to supply medicines.

There are differing options for finance of private health care in UK without reliance upon the NHS:

- A charge directly to the patient. This system already operates in acute private hospitals within UK and there are nursing homes that effectively market themselves to private paying clients.
- Greater use of insurance policies. There are companies who already market these in UK but the cover has been to provide the residence and not the health care services.
- The emergence of more bulk contracts with care providers including health authority organisations and local authorities.
True privatisation of continuing health care in UK would result in a shift of financial accountability from State provision to personal payment for all aspects of care and not only the medical and pharmaceutical service. Given that this is a politically sensitive subject, there appears little determination to change the status quo that all UK citizens are entitled to receive free healthcare. To the interested observer, the current provision is a compromise situation.

7.2. Administration of Medicines.

Administration of medicines in accordance with prescriber’s instructions improved during the study and there was a decrease in the incidence of medicines that were not administered as directed. This occurred for medicines in both Regular and PRN categories. The incidence of nurse discretionary use of bulk supplied medicines increased and this was attributed to a clearer identification of the role of the nurse in initiating certain treatments. There was also an improvement in the process of recording the administration of medicines.

The importance of administering medicines in accordance with the prescriber’s direction was pertinent, given the status of the patients in these nursing homes. Patient interviews, together with the data relating to cognitive status, indicated that patients were highly dependent upon the nursing staff for all aspects relating to the administration of medicines. A pharmaceutical advisory role should ensure that the standards published to all nurses by the UKCC are practised within the home environment.

The majority of medicines were administered by nursing staff and this is further discussed in section 7.2.2. The researcher was concerned by the Baseline data,
particularly that of PRN prescribed medicines (section 7.2.2.2.). The areas of discussion relate principally to procedures, time of drug administration and crushing of oral dosage forms. The study has also identified the low incidence of self-administration of medicines by patients.

7.2.1. Authority to Administer Medicines.

One of the fundamental issues identified from the Medicine Act 1968 is that a third party may administer a POM to a patient provided that the medicine has been prescribed, labelled and supplied for that patient. In a sense, the authority that permits a nurse to undertake this task is that he/she has been able to substantiate exactly what the GP prescribed for the patient. It can be assumed that this is specified on the label of the dispensed medicine. However, this assumption becomes flawed when changes to dose or frequency are effected and the nurse is expected to give the altered regime from a container bearing the original (and now incorrect) information.

A further concern is whether the MAR chart used in the care home is an exact replica of the original prescription and therefore proof of the prescription for the purpose of nurse administration of the medicine. In this study, charts were hand written by nurses and neither of the homes retained photocopies of original FP10 prescriptions for reference. When a monitored dosage system was introduced to NH2, the MAR charts were printed by the supplying pharmacy. Such charts were constructed from the written FP10 prescriptions that the chemist received and would not necessarily include PRN medicines that had not been prescribed that month. This facet of the study was not developed.
In the intervening years since the study, the provision of printed MAR charts from supplying pharmacies has increased, the chart being produced from the same computer software as the product label. In theory there should be no difference between MAR chart and medicine label. In reality, the dose of a product may alter at any time during the timescale of the chart. Under such circumstances, the MAR chart would also include the incorrect information unless changed manually by care staff. This highlights the potential for medication errors that can occur in the care home setting.

7.2.2. Nurse Administration of Medicines.

The observation of drug rounds within the study identified areas of concern. Some of the nursing staff were not only failing to meet the standards published by the health authority but also exhibited practices that were at variance with those published by the nurse professional body, the UKCC.

In both homes there was frequent use of a ‘runner’, that is a second person who took the prepared medicines to the patient. In NH1, the drug trolley was not routinely taken throughout the home and the second person, usually a care assistant, was invariably not within the sight of the registered nurse who prepared the dose and who also signed the MAR chart. This differed from NH2 where two registered nurses undertook drug rounds by taking the drug trolley to patients. One of the nurses prepared the medicine, signed the MAR chart and remained with the drug trolley while the second nurse took the medicine to the patient. Both the UKCC and the regulator under the RHA hold the person who signs a chart responsible professionally for the medicine administration. The nurses involved did not seem unduly perturbed about the legal implication of appending
their signatures to MAR charts when they had not witnessed the patient taking the medicine.

7.2.2.1. Timing of Medicine Administration.

There is a real danger that the timing of medicine administration may be selected to meet the needs of staff or to fit into the established routine of the home. In each of the nursing homes, medicine administration rounds were frequently undertaken at meal times. Thus, when medicine administration was indicated at other times, there was the potential for doses to be missed unless nursing staff employed a defined strategy for 'ad hoc' medicine administration. The drugs most likely to be affected included those indicated for administration in advance of meals; antibiotic courses; and dosage formulations that were unsuitable for administration when a patient was eating food. The problem was exacerbated when the dosage form was stored somewhere other than the drug trolley e.g. refrigerated items.

In the USA the time commitment for drug administration has been carefully identified. Little account is given to such measurement in the UK and indeed did not feature as an issue in this study. The prescribing of Madopar for one of the patients evidenced a problem that can be attributed to nurse organisation of medicine administration; and illustrates how the time required for medicine administration may also be an important factor in nurse requests to the prescriber. The issue described in section 5.3.4.1. (case 4) occurred prior to the study. It was therefore not possible for the investigator to make comparisons about the rigidity this patient experienced with that pertaining before the introduction of the controlled release dosage form of the anti-parkinson drug.
When the patient was prescribed Madopar 125mg capsules three-hourly, it was necessary for a nurse to prepare and administer a dose seven times in 24 hours. This was inevitably more time consuming for the nurse than the administration of a controlled release capsule (375mg) three times in 24 hours. Not only did the latter regime benefit from corresponding to the traditional drug rounds of medicines for other patients; it also lessened the potential for missing a dose, a situation that may have been the cause of great worry, particularly for a Parkinson's patient. It is possible that nursing staff themselves requested the altered drug regime for this patient that was in reality less onerous for nurses to administer. Whatever the reason, the sustained release formulation did not meet the patient's needs and this was resolved with GP approval.

Another pertinent concern about this intervention is the apparent lack of understanding of the nursing staff in some aspects of the treatment of Parkinson's disease, even though the nursing home in question (NH2) cared for several patients with this diagnosis. This incident illustrates the lack of appropriate training for nursing staff in the private sector.

7.2.2. PRN Medicines.

The analysis of patterns of medicine administration produced results that were startling to the investigator, particularly those relating to PRN administration. As already discussed in section 7.1.4. the influence by nurses on prescribing was extensive and this may in part have been effected through the actual medicine administration.
When the study commenced, the researcher was concerned to note that only 21% of PRN medicines were administered in the same dose and frequency prescribed by the GP. The data did not provide evidence of whether this was attributed to nurse influence or to a deliberate decision of the patient concerned. Although nursing staff were observed to ask patients whether they required PRN medicines, some were included in MAR charts in a dose and/or frequency that differed substantively from the original prescription and this is further discussed in section 7.2.2.4. It is possible that the MAR charts reflected the pattern of administration that had been established over time. This may inadvertently be a disadvantage to patients. If the records used by nurses are altered in accordance with nurse perception, the patient may be deprived of medicines at a time when the patient feels that they are indicated.

7.2.2.3. Crushing Medicines.

The issue of crushing medicines is also worthy of discussion. Medicines were apparently crushed to assist patients who had difficulty in swallowing but this practice may have be used to disguise the fact that a medicine has been added to food. The UKCC has made a public statement about the covert administration of medicines (2001). In some respects this must be welcomed because it identifies that the practice has occurred. It is noteworthy, however, that the statement does not give absolute sanction or guidance to a registered nurse about the nature and extent of this practice. It must be concluded that disguising medicines from patients remains a problem area for both nurse and patient.

The investigator witnessed a nurse attempting to crush a co-proxamol tablet using a mortar and pestle with limited success. Such activity would not normally
come to the attention of the supplying pharmacist. The nurse probably believed that she was serving the best interests of the patient and had not considered making a request for a comparable product in a more suitable dosage form. Following pharmaceutical intervention the matter was resolved and the GP prescribed a soluble paracetamol-based analgesic. This incident highlights the necessity for pharmacists to engage in observational exercise when providing an advisory service to a care home.

7.2.2.4. Nursing Home Records.

During the study, the researcher noted that standards of record keeping frequently fell below those published at that time by the UKCC (1993). All registered nurses are expected to practice professionally and keep accurate records including those relating to medicines. In the UK, nurse training is mainly associated with the NHS. It is therefore reasonable to assume that patterns of nursing practice previously learned in the NHS are subsequently observed in the private sector. This leads to the conclusion that poor practice in record keeping may also occur in NHS hospitals and yet not be identified by hospital pharmacists. The provision of a stock of medicines to a hospital ward is not dependent upon documentary evidence of use for patients. Hence, the administration of products given at the discretion of nursing staff may not be adequately recorded in the NHS situation.

It was swiftly realised by the researcher that nursing records were frequently recorded as 'task' rather than patient focussed. This was a major factor in the time involvement to establish which medicines were routinely administered to patients. The first impression gained from viewing MAR charts was that
prescribing was minimal in both nursing homes. Careful research of all available records indicated a different picture, namely that some medicines were never recorded, even though they had been administered to patients, whilst other medicines were mentioned in different records.

Frequent omissions included:

i. Suppositories and enemas used for laxative purposes, occasionally mentioned in the nursing notes or 'bowel' book.

ii. External medicines, frequently included in the patient's nursing care plan and also recorded in a daily 'dressing book'.

iii. Homely remedies, especially if the item was not included in the nursing home's list and therefore not provided as a bulk prescription. In such instances, it was possible that another patient's supply had been used.

A comparison with recording systems in the USA reveals a very different scenario. In 1990, the researcher undertook a Travelling Fellowship to Texas and California, USA to study the marketing of professional pharmaceutical services to nursing homes. During the course of the study it was noted that records were maintained for every aspect of nursing and social care and that these were the main sources of information for the accounting system. It may be possible to conclude that when a facility constructs invoices using medication records as a marker for the care provided, the resulting standard of record keeping is higher. It therefore follows that poor record keeping may be a product of the NHS policy of 'free' care; and also because poor attention is paid by some practitioners to professional accountability.
Some of the later study data are important to discuss in relation to records maintained in a care home. Wright et al (1994) reported an average of 3.98 prescribed items per patient per month in the nursing home population studied. Rees et al (1995) reported the mean number of items per patient as 4. In the study by Furniss et al (2000), details of prescribed medicines were obtained from the MAR charts. The mean number of prescribed items was 4.9 per patient in the control group, and 5.1. in the intervention group at the study commencement. These figures differ greatly from the current study findings. It is unclear whether any of these studies took account of other care records or actual medicines in the care home in addition to those listed in MAR charts and/or GP records of repeat prescriptions. There is also no comment in these studies concerning medicine administration when compared with the prescriber's intention.

The current study has also highlighted the potential for poor record keeping by nursing staff to impact negatively on patient care, briefly discussed in section 7.2.2.2. The investigator recorded the GP prescription either directly from medical notes or, more commonly, from the label attached to a medicine by the supplying pharmacist. The directions often differed from the MAR chart record that was hand-written by nursing staff. These discrepancies were most frequent when nurses used their discretion to modify patient medication. For example, there were several instances where nurses had failed to include PRN medications in the MAR; or modified the dose or frequency of existing drug intake. This was particularly notable for analgesic products. Many of these decisions were no doubt justified. Unfortunately they gave rise to the inconsistency in record keeping that has been noted. It was not possible to judge from available documentation whether such decisions had at any stage been
discussed with or communicated to the prescriber. Nor was there any record to identify whether the individual patient had agreed to changes in drug therapy.

The investigator was able to ascertain this information solely because supplies of some medicines that were not included in the MAR chart were retained in the home. It must be a matter of concern that a patient may be denied an appropriate dose of prescribed therapy because of poor record keeping; or because carers perceive that the medicine is no longer required.

The variety of records, their variability and often frequent absence, made it very difficult for the investigator to access details relating to previous monitoring of the patients, e.g. blood pressure, potassium levels, etc. This is an obvious area for development and improvement and was one of the areas researched by Wright and Chrystyn (1994).

The converse argument to the anomalies in record keeping should also be considered. Nursing staff frequently made records about medicines and their administration in the manner that they found most useful. Hence, a number of entries were identified in the daily statements written by nurses in the care plans and the separate record books for bowel and skin care. The latter records were used as a practical tool at differing times of day to the traditional drug rounds. At the time, each nursing home identified a trained nurse to deliver the wound care to all patients in the home. Thus, the single source of information about each patient who required nursing intervention was more easily provided for the nurse concerned. Essentially, the responsible nurse had made an adequate record of medicine administration even though it was not centralised with other medicine
administration in the MAR chart. In future work of this nature, it is probably more important for the pharmacist to recognise the existence of such records and their relative importance to the practitioners using them rather than to attempt to incorporate all records into the MAR chart.

7.2.3. Self-Administration of Medicine by Patients.

The results of patient motivation, or lack, to self medicate were particularly relevant. At the time of Baseline data collection, only 5% of the patients in this study expressed the desire to manage their own medicines. It is possible that patients felt intimidated to a greater or lesser extent when they were admitted to the nursing home; and may not have felt empowered to exert the right to Self-administer medicines. As set out in the first chapter, clients in care homes are vulnerable people who are dependent for most, if not all, aspects of daily living upon their carers. Many may not complain or exert individuality because they are fearful of the outcome. Poor media presentation may exacerbate this view and there have been well-publicised incidents of resident abuse by staff. Another feature of the elderly population is that they have lived through times of austerity during world conflicts and have learned to accept situations that are less than favourable.

The level of patients' understanding of their prescribed medicines was lower than might have been envisaged. A comparatively small number were able to name the medicines that were prescribed for them and even less knew what each of these medicines had been prescribed for. Nursing staff judged that 48% (38 patients) were impaired cognitively, of whom 17% (13 patients) were considered unable to participate in the patient interview element of the study. The Baseline
data resulting from the patient interviews identified that 37% had no knowledge of the medicines that were prescribed for them, a higher figure than might have been anticipated. These results support the view that patients may not be competent to self-administer medicines even if they wished to do so.

The results may also have been influenced by the opinion of nursing staff when patients were initially admitted to the home. Some nurses may not acknowledge the right of a patient to self-administer medicines and may even have held the view that it was prohibited in a nursing home. There are several likely influences on nurse attitudes to self-administration. Such schemes were rarely encountered within the NHS at the time of the study and nurses may have lacked the practical experience of patient assessment and also of medication compliance systems. It must be considered that the majority of nurses were themselves assessed for competence in medication administration using stock bottles in traditional drug rounds. The community system of supply for individual patients instead of bulk supply is still a difficult scenario for many nurses to accept.

The UKCC (1993) statement of professional conduct may also be an influencing factor because nurses are held accountable for medicine administration to clients in their care. It is therefore easy to understand the reluctance of some nurses to facilitate patient control of medicines, particularly if the nurses felt that patients did not fully understand what they were taking. These professional influences may have contributed to the low patient interest but interviews were not sufficiently detailed to enlarge on the responses.

It is also possibly true to conclude that issues concerning medication may not feature as major for relatives and friends to intervene on a client's behalf.
Although the Information Leaflet (Appendix I) was provided to relatives, only one requested to speak with the researcher directly.

The sociological view continues to be biased towards self-medication in all types of care homes as stated in the National Minimum Standards for Older People (section 1.2.3.). The standard for medicines places heavy emphasis upon self-medication as a first line approach in medicine administration for all care homes. This may be due to a determination to preserve patients' rights. It is an important outcome of this study that the patients themselves did not wish to exercise the right to self-administer medicines. If the study gives a true picture of patient choice in this matter, the National Minimum Standards relating to medicines must be viewed sceptically as theoretical and potentially unrealistic.

7.3. Health Conditions of Patients.

The over-riding purpose in providing a clinical pharmacy service to any patient should be to contribute to an improvement in the patient's condition. During the course of the project, positive improvements in patient's health conditions have been demonstrated.

The possibility exists that there is a difference between the perceptions of carer and patient in respect of Health Conditions. In spite of this, the investigator obtained some of the Baseline and all of the Post-intervention data by discussion with registered nurses and did not refer directly to patients themselves. It is true, that it would have been difficult to assess the patient's view of Health Conditions, particularly when some were cognitively impaired.
The investigator does not claim that the reported improvements (section 6.3.2.) in Health Condition of patients were directly attributable to pharmaceutical intervention. It is considered to be a reasonable conclusion that pharmaceutical intervention contributed to the changes that were reported.

7.4. Time Involvement.

The nursing homes in this study were considered to be of good average standard, a factor that may have influenced the time for a pharmacist to initiate and subsequently undertake regular patient medication reviews. Based on this study, it would require a mean time of 70 hours direct contact with nursing home records and GP medical notes to establish a medication review service for fifty patients (section 6.3.5). This assumes that the pharmacist would have ready access to all of the necessary documents and incorporates time for discussion with individual patients.

To closer predict the impact on pharmacist time of establishing a medication review service, further costs must be considered:

- Time allocation for a case conference at the conclusion of the medication reviews. This can be estimated, on the basis of the study, as 2 hours.
- Allocation of time for Travel. The total contact time of 70 hours will need at least 10 working days to complete, resulting in at least 10 return journeys from base. An allowance of 1 hour/day is incorporated into the equation.

By aggregation of all of these factors, the estimated total time commitment is 82 hours. Taking an hourly rate of £25.00 per hour, the pharmacist time costs of introducing a medication review service to a nursing home with 50 patients

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amounts to £2,050. Consider an example of a nursing home 10 miles distant from base, the travel expense is estimated as £100.00 (Whitley Council rate of £0.493/mile). In this size of establishment, the cost per patient of the initial medication review is therefore £43.00.

Using the same formula, the provision of a continuing medication review service in the same group of patients would require approximately 10½ hours per month, including the review, time for travel and case conference. The pharmacist time and travel expenses may therefore realise £282.50 per monthly session, which is a total cost per patient of £5.65.

These estimates have not incorporated consumable items such as stationery and telephone calls to arrange visits and consultations. It has already been highlighted that the pharmacist needs access to the GP medical notes and this may incur more time than was identified in the study. Even so, the experience of this study prompts the view that an unstructured service of ‘one off’ medication review is a costly option and may not result in optimal patient benefit.

The selected pharmacist fee of £25.00 per hour is probably realistic for 2001 but does not account for variation between practitioners. A community pharmacist may charge on the basis of locum fees; while a hospital pharmacist or PCG/PCT employee may command remuneration related to Whitley Council grading. Use of an independent pharmacist may be on another fee structure.

One conclusion that may usefully be drawn from the data is that the cost of the service will differ according to the variables that have been discussed; and also
that the service charges would need to be individually determined for specific care facilities. This aspect of the study is a suitable subject for further research.

Neither of the costing examples can be taken as a quotable figure for this service, though. The frailty of the nursing home population has been ably demonstrated in this study. The population at Baseline was 81, of whom 2 died during the initial data collation; and a further 19 died or were discharged by the end of the study. It must be anticipated that every pharmacist visit to the home will incorporate a mix of initial collation of information for new patients as well as continuing medication review for existing patients.

The time required to undertake medication review was judged to be similar to the USA model of care. However, this calculation did not allow for the different type of nursing home provision in the UK. In 1990, McCulloch, a USA Consultant Pharmacist employed by Instacare Pharmacy Services in San Antonio (Texas, USA) informed the researcher that care facilities in the USA were large businesses, providing care for several hundred patients on one site. The UK situation is very different to this. Within Norfolk and Cambridgeshire the number of nursing homes providing care for 100 patients or more is very few. Home sizes vary widely from as little as 6 beds in specialised units while the majority of nursing homes have between 40 and 60 beds. Because of the variables, it is not possible to conclude with confidence that a pharmacist in the UK may on a full time basis provide a comparable service to the USA model for 1,000 patients.
7.5. Frequency of Visits.

Although the study was set up initially to provide one medication review per month, it was intended that this frequency should be reviewed for its appropriateness as the work progressed. In fact, given that recommendations from the investigator were accepted gradually and implemented even more slowly, this frequency of input would seem to be appropriate.

An important issue for discussion is whether a service should be provided as a ‘one off’, that is a single medication review that is not followed up by continuing monthly reviews by the pharmacist. There may well be occasions when a pharmacist selectively provides this type of service by targeting patients prescribed a high number of items each month. This would appear to be a costly service in pharmacist time because, as discussed in section 7.4., the major time commitment is for the initial set-up.

Good practices are constantly emerging and it is vital that the pharmacy profession as a whole grasps the opportunity to become involved in this most important field. One of the important outcomes of the National Service Framework for Older People (2001) has been the explicit milestone that is due to be delivered by 2002.

‘All people over 75 years should normally have their medicines reviewed at least annually and those taking four or more medicines should have a review 6-monthly’.
In this study, more than 73% of the patients were aged over 75 years; and the average number of prescribed items per patient was 7.4 pre-intervention and 5.5 post-intervention. Thus, the application of current DoH standards to the study sample would result in the majority of patients having their medication reviewed at least every six months. The NSF commended the ideal of pharmacist involvement in the process of reviewing medication, particularly in care homes. Medicine Management pilot schemes have commenced but there is no definition of how a medication review service should be provided or financed.

It is useful to consider what benefit would attach to less frequent medication review as recommended in the NSF for Older People. Commendable though such a standard may be, it may not result in optimal patient benefit. There is little doubt that the standard approach reflects limited resources in the NHS to conduct more frequent medication review and also the lack of manpower. It can be argued that the recommendations included in the NSF for Older People make the assumption that clinicians will respond positively when medication review highlights the need for change. The outcome of this study challenges that view. Throughout the review phase of the study, the researcher reinforced earlier recommendations and these were only gradually accepted and implemented.

Reference has already been made in section 7.1. to the follow-up time within which the studies of Rees et al (1995) and Furniss et al (2000) were constructed. Both studies were based upon a single medication review. The impact upon prescribing for patients was limited, even though the recommendations had been prior agreed with GPs. When contrasted with the study of Wright et al (1994), where visits to care homes continued for a period of six months, the response to pharmacist recommendations was higher (69%).
This leads to two conclusions; firstly that a single medication review is not only a costly option in financial terms but also represents a poor outcome for the patient concerned; and secondly that pharmacist visits should be more frequent than 6-monthly to achieve cost-effective medication review.

7.6. Access to Patient Information.

The study has identified that the effectiveness and quality of pharmaceutical intervention is dependent upon the accuracy and timeliness of appropriate information. The process of retrieving necessary and relevant information for the Baseline data was lengthy and at times tedious. When medication review is conducted in the nursing home it is essential to have patient-focused information relating to both medical and nursing records readily available.

7.6.1. Access to GP Medical Notes.

At present, comprehensive medical information is rarely available unless the pharmacist works within a GP surgery. However, medication review that is conducted solely in the GP practice may be less effective because the pharmacist would not be able to judge the pattern of medicine administration to individual patients.

The co-operation of the GPs who participated in the study is gratefully acknowledged. Their willingness to allow access to patients' medical notes was not common to all practices that provided care for patients in these nursing homes. Clinical pharmacy practice in NHS hospitals has long been afforded this access and indeed it is widely considered to be a pre-requisite for meaningful pharmaceutical advice. Such access could not, at the time of the study, be
assumed within the community situation. Even now the issue of access to patients' medical notes has not been resolved and community pharmacists may still experience difficulty gaining access for ongoing clinical pharmaceutical care. More information is being provided for the practice-based and PCG/PCT pharmacist. Until such time as both GPs and community pharmacists have a unified access to computerised notes this situation is unlikely to change.

The inclusion of relevant data in computerised files of GP surgeries has wide variation. Written notes by the GP remain the mainstay of documentation in many practices and the location of handwritten medical notes had a major impact on the study. Where it existed, the 'on site' notes provided up to date information relating to the patient's status and treatment but this facility was only available in one of the nursing homes (NH2). In NH1, where a copy of the computer record was made available to the investigator at the outset, subsequent medication reviews were conducted without an update to these records and this was a major drawback. Use was made of other information sources within the nursing home to obtain an updated picture. In retrospect, the provision of a monthly update of this information was a necessity. Visits to the GP surgery to access notes would have added to the time element but may have promoted better communication links. In this respect, a GP practice-based pharmacist will have a major advantage over a community pharmacist. The computerised notes were easier to read but often omitted important information, e.g. allergy, blood pressure. However, in spite of the limitations, the relationship between researcher and GP for this nursing home was perceived to be good; and the GP provided succinct and timely responses to the pharmaceutical recommendations.
Information relating to laboratory results presented other difficulties. These results were always sent to the GP surgery. In NH2 there were delays before results were transferred for inclusion in the medical notes kept on site. In NH1 the laboratory results were usually communicated verbally to nursing staff. In either case, it is anticipated that the GP will take any required action and then communicate it to nursing staff retrospectively. At present, if a pharmacist wished to have access to this information, a visit to the GP surgery would be involved. Since this information could be pertinent to the quality of advice that the pharmacist was able to provide, these data should be more readily accessible.

An area of concern that became evident during the study was the inadequate prescribing information that accompanied the transfer of patients between different care providers and also between GPs. The investigator was aware of delays in transferring the 'Lloyd George' patient notes from one GP to another. Some patients were resident for a number of months before the transfer was achieved and information relating to diagnosis and prescribed medicines was sparse. A dilemma for both nursing staff and researcher occurred in relation to one patient in NH1 who had been resident for some months in that nursing home. It was identified that a letter from the previous GP, retained in the nursing home file, indicated that the patient should be receiving a regular dose of Neo-Cytamen. This information had not been included in the transfer letter from the previous nursing home and there was no supply available for the patient. The omission had not been previously challenged or investigated. The GP was asked to check the original medical notes and this identified that Neo-Cytamen had not at any time been prescribed and hence the reference in the letter from the
previous GP was an error. The patient had not been given Neo-Cytamen but this case highlights the possibility of errors that can occur when patients are transferred between GPs and nursing establishments.

During the Intervention phase of the study, the inaccuracy of GP medical notes precipitated negative outcomes for two of the patients referred to in section 5.3.4.1. (Cases 7, 8). For each pharmacist recommendation to discontinue a drug, the GP had also verified that the medical notes contained no reference to a supportive diagnosis. This serves to illustrate a major clinical concern for prescribers when patients are admitted to care homes from another area.

In the 1995 study by Rees et al, the authors acknowledged the problems of accessing information in the care homes, particularly a medication history.

The modern methods of communication through computer links would seem to be worthy of discussion. To date, the intended computer links within the NHS have not included community pharmacists. The use of computer technology does raise a concern about patient confidentiality and whether this would be compromised should patients' medical notes be accessed from an external venue. This once again supports the view that a pharmacist engaging in this type of work will by necessity be required to access confidential patient information at the GP surgery.

It is important to comment on the way in which changes to repeat prescriptions are managed in a GP practice. Any decisions to alter therapy that are taken by a prescriber in the nursing home will ultimately need to be entered into the
computer records after the consultation. When this does not occur promptly, future issues of prescriptions will still contain the original directions for dose and frequency of dose and may also continue to list a drug that has been discontinued. The supplying pharmacist has a legal and ethical obligation to dispense items exactly as they are printed on the FP10. Thus the nurse in the nursing home, whose responsibility it is to administer the medicines, is placed in a vulnerable situation. In the absence of any written 'prescription' in the home, the only 'authority' on which the nurse can rely is the product label, which contains the patient name and details of the drug and dose. If these details are incorrect compared with the verbal instruction of the prescriber, patient care in the home is compromised as previously discussed in section 7.2.1.

7.6.2. Access to Nursing Records.

There has been prior discussion about the reliability of records kept in the nursing home in section 7.2.2.4. and how the manner of recording medicine administration may have an impact on actual administration by nurses. In this section, the nursing notes that are referred to are the patient's care plan, principally used to record the nature of care that is delivered to the patient.

In this study, some of the nurses in NH1 expressed concern that a pharmacist had access to care plans and yet the researcher gained much information about medicine prescribing and administration from these records. Some of the information was recorded solely in this manner and not included in the MAR chart. Despite this, other research projects have focussed solely upon the MAR chart as the source of information about prescribed medicines.
The question of access to the care plan by a pharmacist may not have been tested out with this study because pharmacists in general may not seek to use such documents. It is a nursing tradition that the content of a care plan is a matter of confidence between nurse and patient. It cannot therefore be assumed that a pharmacist will have ready access to nursing documentation in the process of conducting medication review. The findings of this study emphasise that meaningful pharmaceutical intervention relies upon all pertinent facts about the patient's medicines; and that this data is at times only accessible through nursing documents.

7.7. Communication.

Innovative work may well challenge the attitudes of patients and other professionals and this was clearly demonstrated during this project. It is very important to encourage an atmosphere in which a pharmacist can contribute to the care team without disrupting the existing relationships between patient, GP and nursing staff.

At each stage of the project the researcher was particularly sensitive to the attitudes of other professionals and this perception was frequently uncomfortable. Medical and nursing staff may have felt that their respective positions had been compromised; and it was the responsibility of the researcher to nurture new ways of working with them for patient benefit.

This work has re-emphasised the need for effective inter-professional collaboration and in particular, communication. The issues that presented were solved in an ad-hoc manner in this study but provide scope for research in this
all-important area. Any future schemes of this nature will require careful planning and management of all the issues related to communication.

It has been encouraging to note that 55.5% of all recommendations were accepted and implemented. There were, however, differences between the nursing homes. Although some recommendations may not have been acceptable because of communication problems, some were discounted because of 'historical' precedents. The reasons for non-acceptance of recommendations would be a valuable project for further study.

It is probably true to conclude that the study outcomes were heavily dependent upon successful methods of communication between differing professionals. After the initial interview phase, the investigator had little or no formal contact with any of the patients in the study; and although the two community pharmacists who respectively supplied each home had been made aware of the study there was similarly no further formal contact.

The major communication channels were established between the researcher and senior nursing staff due to the pharmacist attendance within the nursing homes. There was less verbal communication with the GPs. The vast majority of interventions were therefore presented in written format to both medical and nursing staff. These issues are now considered further.

7.7.1. Communication with Patients.

The opportunity for the pharmacist to meet most patients in the study was a rewarding experience. None of the patients gave the impression that the
pharmacist was interfering in any way. For the most part, patients were pleased
to have a visitor who signalled a change from routine in the home.

The most striking impression from this exercise was the resignation of patients to
their current status in care. Few identified that they had chosen to reside in these
nursing homes and for many their only social interaction occurred within the
home itself. The questions about medicines seemed to come as a surprise to
most. This is probably due to the fact that they no longer had control over
medicine administration and were content to leave this to the nursing staff. In this
respect, the nursing home was closer to the institutional concept of care than a
homely setting.

The low uptake of self-administration by patients has already been discussed in
section 7.2.3. It was disappointing that so few expressed an interest in managing
their own medicines. A higher response had been anticipated but the researcher
was aware that some patients were relieved to pass responsibility for medicines
to a nurse. Such patients may have experienced difficulty in their own homes in
managing medicines safely. It was not possible to establish how many of the
patients were subject to iatrogenic disease prior to entering the nursing home.

The question that the investigator put to patients concerning refusal of medicines
was non-controversial. Most of the patients were willing to take medicines as
offered to them by nursing staff, even though some were unhappy about the side
effect profile. It is possible that many of the patients were unwilling to complain
either to the nurse or the GP but this facet was not pursued.
It is regrettable that the researcher did not interview patients at the study conclusion as initially planned. This has created a void in patient opinion regarding pharmaceutical involvement and undoubtedly denied participants the opportunity to commend or complain about any change in drug therapy.

7.7.2. Communication with the Community Pharmacist.
The investigator was able to outline the aims of the project to each of the community pharmacists prior to conducting the research. Neither expressed any concerns about the outcome in relation to changes in prescribing, even though this may have resulted in reduced income through a reduction of prescribed items. The contact was a matter of courtesy rather than formalisation of a communication route.

In retrospect, the study may have benefited from further contact between investigator and pharmacist. The community pharmacist's perceptions of any changes in prescribing would have been useful to record. Should an independent pharmacist deliver pharmaceutical care in the future, continuing dialogue with the supplier would be considered essential.

7.7.3. Communication with Nurses.
At study conclusion, the pharmacist's recommendations to nurses had been accepted in NH1 in 66% of cases; and in NH2 in 45% of cases. Early in the project, nursing staff had clearly stated the hope that the pharmacist would support them when they considered that the GP was prescribing medicines inappropriately or failing to respond positively to the issues identified by nurses. During the course of the study it became apparent that the nurses had not
considered that any interventions would relate to their own professional practice and sphere of influence.

From the outset, the investigator had greater opportunity to establish good communication links with nursing staff. Even so, relationships were strained in the early stages of the Intervention phase because some recommendations were perceived as 'criticism'. The investigator made every effort to rectify this situation. This sensitivity illustrates the problems that can arise when communications are conveyed solely in writing.

Although there had been a useful meeting with senior nurses after analysis of the Baseline data, it was necessary early in the Intervention phase to call a further meeting to discuss issues relating to communication and training. It was immediately evident that the structure of communication with GPs would need to be adjusted by including nursing staff in the process if the study were to continue to its conclusion. The agreement reached was that after each medication review the investigator would meet the relevant matron to discuss the recommendations. Pharmacist and matron would together determine which issues would be carried forward by nursing staff; and which recommendations would be referred to the GP, either by written communication as before or communicated verbally by nurses.

Communication was successful in one nursing home (NH1) for the remainder of the research. In the other nursing home, there was a period of difficulty due to illness among the nursing staff and these conferences had to be postponed on two occasions. Consequently, some interventions were only discussed fully
during the final data collection and no further response was obtained in these cases. This set of circumstances undoubtedly affected the final results of the study. More than this, they served to highlight the extreme importance of well-constructed communication links, which must operate as a two-way system.

It is interesting to note that the report of work by Wright et al (1994) also incorporated discussion with the home manager before any recommendations were made to the prescribing GPs.

7.7.4. Communication with General Practitioners.

The experience gained in this study underlines the importance of providing suggestions for change in such a manner that it assists the GP in making clinical judgements. It must be commented that there were delays both in obtaining the GP response to recommendations; and also to the implementation of changes when these were accepted. Pressure upon GP time may have contributed significantly to these delays.

It has already been outlined that there was limited communication with GPs during the study. The only direct method of communicating recommendations to the GPs was in writing. The limitations of this method and the importance of clear and unambiguous communication were highlighted in section 5.3.4.1. when the apparent misunderstanding of pharmacist recommendations led to a negative outcome for two patients (Cases 8, 9).

The compromise structure of communication outlined in section 7.7.3. presented limitations to the investigator. Pharmaceutical advice was in the first instance
being subjected to another opinion before being presented through an intermediary, indeed, in some cases was not therefore presented to the intended recipient. It is highly probable that this procedure slowed down the rate of acceptance and implementation of interventions within the two nursing homes.

It is concluded that the most successful means of communication will always be direct between pharmacist and relevant professional but this may not always be practicable. Both nursing homes were frequently visited by the GPs, and in NH2 there was an arrangement for a regular weekly visit. In contrast, the Intervention phase of the study involved the pharmacist visiting each home for one day per month. The GP visits were time-limited and only those situations that required immediate attention were dealt with. Case conferences on a regular basis between pharmacist, GP and nursing staff would be desirable but it is difficult to postulate that these would be feasible given time constraints. The study has identified that communication conducted only with one or other professional is inadequate for the full implementation of pharmaceutical advice. A more acceptable means of written communication that includes all interested parties is essential and further work is required to establish what form this should take. A triplicate written communication would be more useful to all professionals to provide access to the full range of recommendations and this is further discussed in section 7.9.2.2. The decision to provide a separate set of written recommendations to nurses and GPs was potentially flawed and may have contributed to the problems encountered during the study.

The studies undertaken by Rees et al (1995) and Furniss et al (2000) both report that even when GPs have agreed the validity of pharmacist recommendations,
the rate of implementation was low. This suggests that the problem of making changes in medication is not wholly related to GP acceptance of pharmacist recommendations but depends upon the method of implementing the changes in the GP surgery. It is also notable that both of these later studies relied upon verbal communication with GPs, either by a visit to the GP surgery or by telephone. Thus it is possible to conclude that communication solely by the verbal route no more effective than communication solely in writing.

The inadequacy of written communication in this study also prompts the view that future projects should provide for a combination of verbal and written communication. A compromise situation may entail the exchange of verbal information by telephone rather than face-to-face conference. Above all, the pharmacist who undertakes this type of activity must be flexible enough to ensure adequate communication links.

In recent years, the emergence of the primary care pharmacist has signalled a change in the attitudes between GP and pharmacist. There is no doubt that resistance still exists but the way to more profitable joint working is opening. The excellent work undertaken by McGregor, reported in the Pharmaceutical Journal under the title ‘Pharmacy project wins Golden Helix Award’ (1998) and Bradley (1999), amongst others, has highlighted the nature and extent of pharmaceutical involvement in the GP surgery.

In the current study, the overall acceptance rate of recommendations was not high compared with USA studies; but comparable with other UK studies. This was in part attributable to lack of response from the GP in NH2 and may indeed
have been influenced greatly by the manner of communication. The USA publications indicate an acceptance rate that was higher. A study by Brown (1991) was conducted over 12 months and included 987 patients in a Skilled Nursing Facility. Recommendations relating to drug therapy (237) were accepted in 89.5% of cases; and those relating to laboratory investigation (153) were accepted for 89.7%. The communication was provided in written format in patients' notes. The type of facility may have influenced the high level of response in addition to the OBRA requirements outlined in Chapter 2.

Williams et al (1992) reported retrospective pharmacist review of recommendations made by other consultant pharmacists, and the consequent physician responses, in fifty Long Term Care Facilities in Oregon and Washington. No time frame was identified but a total of 1,282 recommendations were reviewed. The acceptance rate to the written communications was 67%.

The research by Ellis & Ellis (1994) was also a prospective study of patients in a Skilled Nursing Facility over a period of 12 months. The interventions were specifically concerned with drug-drug interactions and 63.6% were subsequently implemented by physicians.

When considering these results, it must be borne in mind that the consultant pharmacist has become well accepted and valued in the USA; and that federal law requires the physician to make a timely response to pharmaceutical recommendations.
7.8. Cost Effectiveness of Medication Review.

With the information available, it has not been possible to arrive at an estimated cost saving when a pharmacist conducts medication review for nursing home patients. Any savings that may accrue to the GP prescribing budget as a result of this service must be considered in the light of pharmacist costs both to introduce and maintain the service.

The study has identified a reduction in the mean number of prescribed items per patient of 1.5. The recommendations were not achieved during the first month but were gradually implemented over a period of six months. It has therefore been difficult to make assumptions about the potential for reduction of prescribing costs. The data analysis was not sufficiently sensitive to cost each of the discontinued items; nor to identify the stage of the study when each item was discontinued.

Some of the discontinued medicines may have been prescribed for PRN use and therefore requested minimally; while other medicines may have been continued for some months following the recommendation. It may be reasonable to suggest that, once altered, the reduction in prescribed items would be a cost saving because without the pharmacist involvement such items would continue to be prescribed and may be requested by nursing staff. On reflection, an accurate costing of the medicines that were discontinued would have been a useful addition to the study had time permitted.
However, it is reasonable to suggest that there is the potential to save money through medication review but that this must be balanced against pharmacist fee and the time that it will require of both GPs and nursing staff in case conference.

Consultant pharmacists in USA have been particularly successful in making a case for continued involvement in the nursing home team, principally because they have been able to demonstrate actual cost savings to the nursing facility. This has been in three main categories: the savings in the cost of drugs purchased by the facility; the saving in nurse time because fewer doses are administered to patients; and the saving in hospitalisation costs that are incurred by the facility when a patient is transferred for emergency care due to adverse drug reaction. These are powerful cost indicators and have persuaded the owners of facilities to accept the burden of financing pharmacist input.

Such a comparison is hardly credible within the UK. Any reduction of drug costs is a saving to the NHS. The nursing home owner does not purchase drugs, with few exceptions, and therefore the cost benefit may appear to be negligible. Similarly, the cost of transferring a patient to acute NHS care does not have a financial implication for the care home. This leaves the argument about saving small amounts of nurse time as a limited means of persuasion. It would therefore seem to be a lost cause to attempt to cover the cost of pharmaceutical service from within the private care industry. The true cost of providing medical and pharmaceutical services to private care homes has been a burden sustained by the NHS and therefore the cost effectiveness of pharmacist-led medication review must be identified in general terms to the NHS.
Wright et al (1994) conducted a cost-benefit analysis for medication review by community pharmacists, principally because they acknowledged that community pharmacy remuneration did not recognise the benefits of reduced prescribing.

The study by Furniss et al (2000) incorporated an overall cost comparison that encompassed the cost of drugs together with aspects of primary and secondary care resources used by all patients in a nursing home, equally distributed between all of the patients in the home. This approach to cost analysis is a major benefit of multi-disciplinary approach to practice research.

The study has not sought to identify the time element for GPs or nursing staff and this can be considered a weakness of the original design. Unlike the USA, where pharmacists are able to demonstrate financial benefits through reduced drug costs, reduced costs of hospitalisation and reduced time for nursing staff to administer medicines, this study cannot effectively show reduction in costs that will have a direct impact upon either the prescriber or the carer. There may be a benefit to the identified drug budget of the GPs but that fact may not in itself be sufficient spur to encourage the GP time commitment that would be necessary.

7.9. Limitations of the Study Design.

It is a strong commendation of the project that at each stage the stated objectives were achieved within the planned timescale. This study has provided the opportunity for quantitative data collection, some of which has depended upon structured interview with both nursing staff and patients. However, the majority of data collection has relied upon the survey of GP medical notes and a variety of records of medicine administration to patients. It must also be acknowledged that
much of the data collated was utilised to give an overall picture of each client rather than provide for quantitative analysis. The study has also incorporated observational activity and case description, though this was not subject to data analysis.

The data in this study was collated in 1993/94 and this may prompt questions about current validity. However, the strength of this data is three-fold:

i. Patients were not prior selected by the investigator, neither were they referred to the study by a GP or nurse on the basis of perceived need for medication review. The inclusion of a patient was totally dependent upon residency within the selected nursing homes and the express agreement of the individual concerned or a representative.

ii. The study was designed to provide Baseline data for each recruited patient in the nursing home against which to compare prescribing of medicines after a pharmacist had conducted medication review each month for six consecutive months. The later studies by Rees et al (1995) and Furniss et al (2000) have not reproduced this type of study.

iii. The results that were obtained regarding the mean number of prescribed items per patient and the mean reduction of the number of prescribed items per patient per month are consistent with previous results published in USA for similar pharmaceutical input.

It is possible to suggest that the results remain valid and are potentially of interest within the UK. There are, however, a number of aspects related to the study design that prompt the conclusion that the findings are not sufficiently robust to warrant wide generalisation. These issues are now separately considered.
7.9.1. Patient Population.

The study did not provide a random selection of patients. The selection was carefully considered as described in Chapter 3 but, by necessity, the study was small and localised geographically. The decision to recruit a sample of 100 patients was determined on the basis of available resources rather than to provide confidence in the results obtained and this aspect alone has impaired a wider generalisation of the results. The total number of registered beds in the two nursing homes was 103 and therefore the agreement of 81 patients to participate represents 83% of the potential patient population. This figure corresponds well to the research by Furniss et al (2000) where the patient response was 78%.

The recruitment of patients was managed, at their request, by the nursing staff in each home. This proved to be a further limitation on the study and in NH1 was less successful than NH2. Although the focus of the study was patient benefit, it could not be assumed that all patients would be willing to be involved. This was carefully planned, taking account of the ethical committee requirements for patient recruitment. Even so, it appeared that some patients refused to take part because of peer opinion and also poor presentation of the project. One patient declined to participate because he considered that his doctor knew and understood his medical needs and he did not wish any third party to interfere. The target patient population of 100 was not achieved within the recruitment phase of the study and this may have been affected by the procedures for recruitment.
As commented in section 7.6.1., access by a pharmacist to patient's medical notes, and pharmaceutical contribution to decisions has become generally well accepted in hospital practice. And yet, it is doubtful whether anyone has questioned the patient's view of this process. Professional people may be inclined to believe that the patient's best interests justify the means and that benefit outweighs any (potential) objection. This study has demonstrated that patients do have an opinion about such matters, though this was not analysed. The publication by the DoH of '12 key points on consent: the law in England' (2001) states in the first article that a health professional needs to obtain consent from a competent adult before providing 'care'. It therefore cannot be assumed by pharmacists that every nursing home client wishes to have pharmaceutical care thrust upon him/her; and future projects must leave room for this eventuality.

Higher patient numbers may have been achieved had the study design provided for continuous recruitment of patients. Due to death or discharge of patients after the Baseline data collection there were only 60 remaining patients at the end of the study. Despite the low numbers, the benefit of this type of study is that the data pre- and post- intervention relates to the same cohort of patients. It is difficult to postulate whether continuous recruitment beyond the time set for the Baseline data collection would have contributed to the results. The time limitation of the study was certainly prohibitive to this type of research.

The study conducted by Wright et al (1994) included patients that were recruited by referral from GPs and therefore did not by intention include all of the residents in selected care homes. The total study population was 312 within homes for residential or nursing care. Wright and Chrystyn (1994) studied a population of
319 patients in 8 nursing homes. The methodology suggests that there was GP referral rather than patient choice to participate in the study. Neither study compared the findings to a baseline or control group.

In contrast, studies by Rees et al (1995) for a population of 160 in 9 residential care homes and Furniss et al (2000) for 330 patients in 14 nursing homes compared an intervention group of patients with a control group. The patient recruitment was similar to the current study in that all patients in the selected care homes were given the opportunity to participate.

7.9.2. Study Documentation.

The range of documentation used in the study was based upon those used by consultant pharmacists in Texas and California, USA in 1990. These can be broadly classified as the research tool, referred to as the Patient Profile; documents for communication with medical and nursing staff that would also provide a vehicle for recording their responses; documents retained by the researcher to enable comprehensive data analysis; and information documents. The design and content of these documents is presented in section 3.6. These documents will be discussed in terms of usefulness.

7.9.2.1. Research Tool.

The Patient Profile was a useful tool for the researcher to summarise pertinent information on a patient focused basis throughout the study. The instrument, as described in section 3.6.1., was based upon a working document from the USA, the components of which were input into a computer programme that a consultant pharmacist utilised.
The relative usefulness of all parts of this tool was an additional insight that the study provided. The Patient Profile included a wide range of data but during the study it became evident that not all of it was relevant. Although it was acknowledged that this could have a pertinent effect on medicine usage, the recording of diet did not contribute anything of relevance to this study. More importantly, it was noted that the notional scale of rating which combined evaluations of the health condition, cognitive function (already discussed in section 7.1.3.), physical function and awareness of the patient, contained parameters which changed little, if at all, during the study period. After the final data collection, it was realised that changes had occurred only in the health condition of patients and hence a comparison was made solely on this basis. However, one should not conclude that the recording of the other parameters was unnecessary as these contributed to a greater understanding of each patient's status.

The Patient Profile was not a validated instrument. The criteria and scoring system favoured the Barthel style that Bowling (1997) states has limitations as a measure of 'outcome' because it is not a 'continuous scale'. It is deemed to be useful for comparative studies of pre- and post- intervention and therefore is considered to have some validity for this study.

Smith (1997 (2)), who gives a clear evaluation of instrument validation including the survey instrument used in this study, determines that the study tool was useful in describing the patient population rather than predicting prescribing characteristics based upon patient health status. The validation of this instrument would have been a useful addition to the project.
7.9.2.2. Communication Documents.
The Communication Documents were unnecessarily lengthy. The format was cumbersome and wasted paper. It would be useful to revise the layout for further work. A more suitable format to develop would be a self-carbonating system in triplicate that would provide a copy for GP, nursing staff and pharmacist for all interventions. Adoption of this style would remove the necessity for a Consultant Report (separately discussed in section 7.9.2.3.) and would also provide full details of pharmaceutical recommendations to all interested parties. The issue of communication has also been discussed in section 7.7.

During the course of the study, the opinions of GPs and nursing staff were not canvassed on the suitability of communication documents. In hindsight, this would have been a valuable additional insight into the opinion of other professionals.

7.9.2.3. Documents Retained by the Investigator.
The Consultant Report was more helpful to the researcher than might have been envisaged. It provided a means by which changes in the medication of each patient could be summarised on a monthly basis, whether or not interventions had been made, and retained as a master document by the pharmacist. As with the communication documents, the format was found to be unnecessarily lengthy. The development of a better communication tool (as described in section 7.9.2.2.) would render this document redundant.

The Quality Control documentation was intended as an indicator of training needs of nursing staff, as were the Observations of Medicine Administration. These
were successful in meeting this aim even though the offer of training was subsequently declined.

7.9.2.4. Information Documents.

An Information Bulletin on Laxatives was provided to the matrons at the beginning of the Intervention phase for distribution to nursing staff. Clearly there is a role for pharmacists to provide information of this type for dissemination by nurses to nurses. It would also be desirable for pharmacists to participate in inter-professional teaching programmes, although the offer to provide such an input was not taken up by the nursing homes on this occasion.

The concept of providing information that would assist the nursing homes in aspects relating to registration with the Health Authority was not well received. This may have been due to the status of the investigator. During the course of the study pharmaceutical inspections of the two nursing homes had been suspended. However, all concerned were aware that the resumption of inspections by the investigator would occur after the study. Hence there may have been reluctance by the matrons to acknowledge shortcomings that may be followed up subsequent to the study.

7.9.3. Overview of the Study.

The study provided wide scope for the researcher to investigate how medicines were handled within two nursing homes. On reflection, the project may have been easier to manage if there had been fewer variables to be measured. However, the breadth of this project has enabled the researcher to formulate
opinions about a wide range of issues that impact on prescribing and administration of medicines in nursing homes.

The chosen methodology did deliver measurable data which, when analysed, supported the research hypothesis that patient care in a nursing home can be improved by pharmacist involvement in medication review on a regular basis.

7.10. Proposals for Change.

This study has demonstrated that the implementation of a pharmacist advisory service in two nursing homes has made a significant contribution to the quality of care a patient receives. This has occurred in homes considered to be of a good average standard and already benefiting from a good relationship with the GPs that the patients were registered with; and the community pharmacists who undertook a supply function. It is significant that a pharmacist who attempted to become part of a multi-disciplinary team within the nursing home made the interventions; and that the pharmacist was also independent of the supplying pharmacy.

A time of reflection on the study outcomes raises further important questions:

i. Should a pharmacist or other health professional conduct the review of medication?

ii. Is the proposed provision of a medication review service for nursing home patients the responsibility of the NHS or private nursing homes?

iii. What impetus exists to secure the necessary resources for introduction of regular medication review for nursing home patients?
These can best be considered by critically examining where the responsibility for safe and effective prescribing truly lies.

7.10.1. Clinical Governance.
Risk management is high on the agenda of health care strategists. The Audit Commission report *A Spoonful of Sugar* (2001) was principally concerned with medicine management in NHS hospitals. However, it is rapidly becoming clear that minimisation of risk to patients through clinical governance is vital wherever health care is provided. Added to this, it can only be a matter of time before the requirement to report medication errors to the National Patient Safety Agency is extended beyond the NHS to the private care industry.

Clinical governance is concerned with successful team working to the ultimate benefit of patient care. Although this concept has been embraced within the culture of the NHS, the acceptance within the private care sector is likely to be variable. In fact, it is possible to conclude that issues of clinical governance are not yet well understood outside the NHS. The multi-disciplinary team that provides care for nursing home patients is a mix of private and NHS staff. One of the major anomalies in the make-up of the team is that the key player, the GP, does not choose to provide the service as described in section 7.1.5. Thus, the optimal conditions for team working are hardly a foregone conclusion; and good working practice may occur by chance or because of the dedication and commitment of the participants.

Pharmacists have not naturally been considered as part of the primary care team or as a member of the nursing home team. The task to establish a pharmacist
as such should not be underestimated. This leads to the question whether medication review is best provided by a pharmacist or other healthcare professional. There is no doubt that clinical responsibility rests with the clinician who has prescribed the medicine. The study has identified that, for optimal patient outcome, medication review may be more effective when a professional who is not the prescriber conducts it.

A common response from nurses in private nursing homes is that they are more likely to take the lead and request that a GP reviews medication, based upon a perceived problem with the current regime. This occurs despite GP computerised systems that may offer a prompt that medication review is due at the point of issuing repeat prescriptions. The resulting reviews may be less than optimal because they are neither structured nor regular. An emerging model of medication review has been the deployment in the nursing home of the GP practice nurse who reports any findings to the GP to action. The question must arise whether a practice nurse is sufficiently skilled to conduct medication review.

There is a major cost implication in utilising a pharmacist to conduct medication review as identified in section 7.4. Further study would be appropriate to relate the comparative benefits of medication review by a GP, pharmacist and nurse.

If the recommendations of the NSF for Older People are implemented, there will be more pharmacist involvement in patient medication review. This project sought to establish whether the practice of 'consultant' pharmacy was applicable within the UK culture of health provision and did not aim to identify additional roles for specific groups of pharmacists. The data has shown that the need of
patients rather than the system of healthcare delivery is the determinant factor. The practice base of the pharmacist may have some impact on how medication review is delivered but does not limit the patient outcome. The conclusion is therefore drawn that the pharmacist does not need to be based in a community pharmacy to be effective in this role.

The studies of Wright & Chrystyn (1994) and Wright et al (1994) appear to be structured to confirm an extended role for community pharmacists. It is undoubtedly possible for a pharmacist whose practice base is within community pharmacy to make a valuable contribution to medication review in care homes. However, until the structure of the community pharmacy contract changes, there is a potential conflict of interest for the supplying pharmacist. In this study, the community pharmacists received no additional payments for servicing the nursing homes and yet were reputed to be wholly supportive and professional in their dealings with staff. But the supply function had not been extended to provide a medication review service.

Debate within the pharmaceutical profession is currently concerned with 'Pharmacy in the Future – Implementing the NHS Plan' (2000). This does provide the potential for pharmacists to explore new models of care. One such model for consideration is the ‘closed pharmacy’ scheme through which community-based pharmacists may elect to provide a service solely to care homes from premises that are not open to the public. Such premises have been extensively developed in USA to prepare and supply medicines in MDS systems.
The response to directing pharmaceutical services elsewhere than the community pharmacy has at times been negative as reported in the Pharmaceutical Journal (2000) entitled ‘IoW pharmacies to withdraw services from residential homes’. Teeside health authority has also awarded a contract for medication review in care homes to a multiple community pharmacy, also reported in Pharmaceutical Journal (2001) under the title ‘Moss wins Homes Contract’. In each case, it has been a bold scheme to finance innovative work.

Other modes of delivery of the service must be explored. Due to the importance of accessing the patient’s medical notes, and being able to communicate directly with a GP, the most ideally situated pharmacist to conduct this type of work is the primary care pharmacist in the GP surgery, and not the freelance or community pharmacist. This is not an ideal situation, however, because many care homes receive medical input from more than one GP surgery.

There is also no barrier to the hospital-based pharmacist offering a medication review service. One might argue that the knowledge and skills of pharmacists who work continuously in a ‘clinical’ environment are well suited to the work in primary care. This would seem an unlikely solution however, because hospital pharmacy departments have found it difficult to recruit sufficient pharmacists to provide clinical services for in-patients.

7.10.2. Responsibility and Accountability.

While the medical and pharmaceutical responsibility for a nursing home patient rests with the NHS, so also does the responsibility for safe prescribing practice. It is possible that a PCT could be found lacking in a duty of care to nursing home
patients if such patients were discriminated against by any decision to restrict the provision of medication review to NHS Trusts.

Whilst not discounting the potential for a future private health care model as discussed in section 7.1.5., the practical reality is that nursing home patients are entitled at present to receive medical and pharmaceutical services from the NHS. Possible models for providing pharmacist-led medication review within the structure of NHS provided health care services are:

- Model A. Financed through PCT.
- Model B. Financed by the Nursing Home.
- Model C. Financed by the Contractor who has placed the patient in the nursing home; or the patient him/herself.

It is a matter of logic that the cost of providing a service should fall to the body where the financial benefit will accrue. Hence, unless there is a fundamental change in the way that medical and pharmaceutical services are provided to nursing homes, the burden of financing medication review should properly be borne by the NHS and in particular the local PCT. But in the current financial climate, there is a very real danger that a cost effective service that is intended to promote the well being of vulnerable people in care will be subject to local priority.

By the same reasoning, it cannot be reasonably expected that UK nursing homes bear the cost of the medication review service. This said, it is possible that the best outcome of the service will only be realised when the nursing home is responsible for funding it and is required to do so by regulation under NCSC.
7.10.3. Resources for Medication Review.

Finance initiatives are useful in the execution of pilot studies but until and unless real finance is consistently designated to the review of medication the type of benefit shown by this study will not be realised. Even though the results of this study were reported to the DoH in 1994, the practice of regular medication review in nursing homes by clinical pharmacists has not been implemented to date.

There is opportunity for GPs to conduct medication review and this is a recognised clinical responsibility when providing repeat prescriptions for patients, irrespective of where the patient lives. But this has not been regarded as high priority when viewed alongside the many demands upon a GP’s time. Hence, in an attempt to meet with PCT expectations in terms of prescribing budgetary control, GPs have at times involved practice nurses to undertake the task.

Community pharmacists have had the opportunity since 1994 to provide additional pharmaceutical services to private nursing homes. The pharmaceutical press has not carried any publications to suggest that the contract has been developed to provide medication review for patients though there have been two publications by Sommerville (1996, 1997) that outlined ways of achieving this outcome.

It would appear that the NHS agencies at present do not have allocated resources for medication review and yet there is the potential to reduce prescribing costs. The future success of this important field will require the allocation of new funds at a time when competition for resources is fierce.
7.11. Summary.

The outcome of this study has been to demonstrate a reduction in the number of prescribed medicines and from this to conclude that a systematic approach to medication review would be financially beneficial to the NHS, though this has not been quantified. Additional to this finding is the benefit of a pharmacist contributing to the multi-disciplinary environment of the nursing home; and closer communication with GPs.

It is possible to postulate that, as there are ever increasing demands upon GP time, the involvement of nursing staff in prescribing decisions will increase. A close working relationship between nursing staff and pharmacist in the care home will help to minimise the risk of medication errors to a greater extent than if the pharmacist is only available to speak with by telephone. Added to this, a PCT may be better able to meet the milestones published in the NSF for Older People.

The final discussion point to raise is whether there are sufficient pharmacists who are appropriately trained, motivated and willing to offer nursing homes a medication review service.
Chapter 8

Conclusions
Chapter 8: Conclusions.

The study has successfully achieved the stated aim that was presented in Chapter 1. The manner of introducing pharmacist-led medication review into two nursing homes was based upon the successful practice of consultant pharmacy in the USA. The study results have confirmed that the outcome of this activity was comparable to published work within the USA. It has therefore been concluded that the effectiveness of pharmacist involvement in private nursing homes is not dependent upon the nature and funding of the health care system.

The key findings have been presented and discussed in Chapter 7. Based upon analysis of data collated pre- and post-intervention by a pharmacist, the study has reported a reduction in the mean number of prescribed items per patient of 1.5; and an overall improvement in the way that medicines were administered to patients by nursing staff, compared with the prescriber's intention. In achieving these outcomes, the report has included the nature of interventions made to GPs and nursing staff; and the level of acceptance and implementation. Additionally, the study has reported the pharmacist time involved in setting up and conducting a monthly medication review service; and has made suggestions concerning the frequency of medication review. The report has also included important findings about the accessibility of records to a pharmacist conducting medication review; and reviewed the methods of communicating with patients, community pharmacists, nurses and GPs. Finally, as a result of this study, a number of recommendations for change have been formulated.
The project was wide-ranging and ambitious. There were limitations and it has been possible to track issues in the original study plan that were inadequate, some of which were identified during the course of the project. When compared with similar research conducted within the UK, both prior to and subsequent from the current study, there have been no comparable projects.

This study has highlighted the fact that a pharmacist other than the supplier of prescribed medicines can contribute to patient care. The GPs who provided medical services to the patients in this study were reputed to be interested in care of the elderly; the nursing staff were also noted to be well motivated; and both homes already benefited from a community pharmacy supply service. These may be considered to be near ideal circumstances for care of vulnerable people in the private sector and yet the study has demonstrated that targeted monthly medication review by a pharmacist makes a positive contribution to the nursing home team. The mean reduction of prescribed items per patient was significant statistically, a result that has not been mirrored in other UK studies where cost reductions were frequently cited as the major outcome. These results alone are of vital importance to NHS strategists who are concerned not only to limit spiralling health care costs but also to promote cost-effective evidence based prescribing in primary care.

Recent publications have highlighted the importance of safe and effective prescribing; and the NSF for Older People lists a milestone in 2002 for medication review. Primary Care Trusts will be expected to review prescribing practice in primary care to deliver the required standards. The study supports the
view that pharmacist-led medication review within nursing homes should be undertaken monthly to ensure the optimal outcome for patients.

Consultant pharmacists in USA have undertaken this type of activity over a period of at least 30 years and other countries have commenced similar developments. In spite of the weight of publications in the USA, and the fact that the current study findings were reported to the DoH in 1994, clinical pharmacy practice in nursing homes has not as yet become a reality in the UK.

The regular review of nursing home patients' medication will require substantial input from experienced pharmacists who are clinically skilled. The patients in nursing homes are deserving of good quality pharmaceutical care, funded by the NHS. However, the successful development of this initiative must first of all be allocated adequate resources if the anticipated benefit to patients and reduction in prescribing costs to the NHS are to be realised.
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Appendix I

Information Leaflets.
Patient Information Leaflet

Patient Medication in Private Nursing Homes.

Whilst in your nursing home, it may be necessary for you to take a number of tablets and mixtures. Just occasionally, these medications may cause unexpected problems.

With the knowledge and support of your GP, Dr ................, I am carrying out a study which will investigate:

1. How many medications you are taking each day.
2. What they are for.
3. When you are taking them.
4. Whether they are causing any problems such as indigestion.

If you would like to help me with this study, I would like you to answer some questions about your medication and I will need your permission to look at your medical notes. Such information will be treated as strictly confidential.

Your participation in this study is entirely voluntary and your refusal will not affect any other medical treatment. If you wish to participate you are free to withdraw from the study at any stage without any medical treatment being affected.

Hazel Sommerville.
Information Leaflet for Patient's Representative.

Patient Medication in Private Nursing Homes.

Whilst in .................... nursing home, patients are often taking a number of tablets and mixtures. Just occasionally, these medications may cause unexpected problems.

With the knowledge and support of Dr .........................., I am carrying out a study which will investigate:

1. How many medications each patient is taking each day.
2. What they are for.
3. Whether they are causing any problems to the patient such as indigestion/diarrhoea etc.

In this connection it would be helpful if I could include Mr/Mrs .............. in this study. To do this, I would need your permission to look at his/her medical notes. Such information will obviously be treated as strictly confidential.

Although I hope that you will give me this permission, your refusal will not affect the medical treatment that Mr/Mrs .............. is receiving in any way. Furthermore, you would be free to withdraw this permission at any stage without their medical treatment being affected.

Hazel Sommerville.
Norwich Health District Medical Ethics Committee.

Consent Form.

TITLE OF PROJECT

(The patient should complete the whole of this sheet himself/herself)

Have you read the patient Information Sheet?  

Have you had an opportunity to ask questions and discuss this study?  

Have you received satisfactory answers to all your questions?  

Have you received enough information about the study?  

Who have you spoke to?  Dr / Mr / Mrs / Miss  

Do you understand that you are free to withdraw from the study:

- At any time
- Without having to give a reason for withdrawing
- And without affecting your future medical care?  

Do you agree to take part in the study?  

Signed  

Date  

(Name in BLOCK letters)  

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Appendix II

Documentation.
**REGULAR MEDICATION**

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<th>Dose and Frequency</th>
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**PRN MEDICATION**

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**ALLERGIES**

1 2 3

**Diet**

1 2 3
### CARDIOVASCULAR
- Hypertensive disease
- Atherosclerotic disease
- Congestive Heart Failure
- Hypertension
- Peripheral Vascular Disease

### NEUROLOGICAL
- Alzheimer’s
- Transient Ischemic Attack
- Multiple Sclerosis
- Parkinson’s

### PULMONARY
- Asthma
- Emphysema

### PSYCHIATRIC/MOOD
- Depression

### HEALTH CONDITIONS
- PROBLEMS
  - Stomach/indigestion
  - Constipation
  - Incontinence
  - Fatigue/vertigo
  - Constipation
  - Bowel impaction
  - Fainting

- COGNITIVE FUNCTION
  - Status
    - Independent
    - Moderately impaired
    - Severely impaired
  - Memory
    - Normal
    - Some disturbance
    - Always disturbed

- VISION
  - Fully sighted
  - Partially sighted
  - Blind

- HEARING
  - Fully hearing
  - Partially hearing
  - Blind

### DISEASE DIAGNOSES
- 4.5 SENSORY
  - Cataracts
  - Glaucoma
  - 4.6 OTHER
    - Allergies
    - Anaemia
    - Arthritis
    - Cancer
    - Diabetes
    - Hypothyroidism
    - Osteoporosis
    - Seizure control
    - UTI

### 4.7 OTHER CURRENT DIAGNOSES

### 5.2 ACCIDENTS
- Falls
- Emergency care
- Hip fracture

### 6.4 DECISION MAKING
- Independent
- Moderately impaired
- Severely impaired

### 6.4 SLEEP
- Normal
- Some disturbance
- Always disturbed

### 7.3 MOBILITY
- Walks unaided
- Walks with aid
- Unable to walk

### 7.4 CONTINENCE
- Continent always
- Continent sometimes
- Incontinent
8 PATIENT KNOWLEDGE OF DRUG THERAPY

Does the patient:

8.1 Know which medicine [s]he takes:  
- All: a 0 
- Some: b 1 
- None: c 2 

8.2 Know what the medicine is for:  
- All: d 0 
- Some: e 1 
- None: f 2 

8.3 Prefer to self-medicate:  
- Always: g 0 
- Sometimes: h 1 
- Never: i 2 

8.4 Refuse medicine:  
- Never: j 0 
- Sometimes: k 1 
- Frequently: l 2 

Reasons for refusal:  

8.5 Ever notice that a dose of medicine has been missed *  
- Never: m  
- Sometimes: n  
- Frequently: o  

8.6 Recall being asked NOT to take a medicine *  
- Never: p  
- Sometimes: q  
- Frequently: r  

* Do not include within rating score

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<td>Initial</td>
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<tr>
<td>Follow-up</td>
<td>/18</td>
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9 PHARMACIST INITIAL ASSESSMENT

Date ........................................

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<th>Recommendation</th>
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### 10 ADVERSE DRUG REACTIONS

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<th>Date</th>
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<th>Severity</th>
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### 11 NURSE MONITORING/LABORATORY TESTS

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<tr>
<th>Date</th>
<th>BP</th>
<th>Pulse</th>
<th>Weight</th>
<th>Hgb</th>
<th>Cr</th>
<th>Dig</th>
<th>Theo</th>
<th>Lith</th>
<th>Na</th>
<th>K</th>
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### 12 DRUG REGIMEN REVIEW

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<th>Intervention</th>
<th>Comments</th>
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</table>

### 13 TIME ALLOCATION [HOURS]

<table>
<thead>
<tr>
<th>Drug Profile</th>
<th>Patient</th>
<th>Kardex</th>
<th>Medical Notes</th>
<th>Assess</th>
<th>Regimen Review</th>
<th>Total</th>
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<tr>
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RESEARCHER: ........................................................................................................................................260
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<tr>
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<tr>
<td>Altered Dose</td>
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<tr>
<td>No Current Prescription</td>
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<tr>
<td>No Medication on Trolley</td>
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<tr>
<td>Expired</td>
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<td>Date Opened</td>
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<td>Quantity Problem</td>
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<td>CONSULTANT TROLLEY AUDIT</td>
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<td>Date:</td>
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<tr>
<td>Location:</td>
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<tr>
<td>Medication</td>
<td>Patient</td>
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Nursing Home: ..................................  Date: .............................
Observation of Medicine Administration by Nursing Staff.

<table>
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<th>Criteria</th>
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<th>Not Met</th>
<th>Comments</th>
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</thead>
<tbody>
<tr>
<td>Procedure is Prep/Admin/Record</td>
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</tr>
<tr>
<td>Checks chart and label</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clean technique</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Patient identified</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Appropriate monitoring</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medicines not left</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Observers patient taking</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Offers sufficient fluid</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Uses/records PRN appropriately</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Maintains security of trolley</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Records doses given/not given</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Records refusals</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Suspensions shaken</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Accurate measurements</td>
<td></td>
<td></td>
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<tr>
<td>Only appropriate drugs crushed</td>
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<tr>
<td>Eye drops properly instilled</td>
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<tr>
<td>Inhalers properly administered</td>
<td></td>
<td></td>
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<tr>
<td>Injections properly administered</td>
<td></td>
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<tr>
<td>CD recorded/witnessed</td>
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<tr>
<td>No interruptions</td>
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Observed by: 263
CONSULTANT PHARMACIST MONTHLY QUALITY CONTROL REPORT

Nursing Home: ..........................  Date of Report:  ...............  

I DRUG THERAPY REVIEW:
1 Dates of visits.  
2 Pharmacist hours spent in nursing home.  
3 Number of patients reviewed.  
4 Number of interventions.  
5 Other pharmacist activities.  

II SUPPLY OF MEDICINES:
1 FPIO forms are supplied according to the needs of the home.  
2 Prescriptions are supplied without delay.  
3 Supply is available without interruption or delay.  
4 Ordering procedure followed correctly.  
5 Returnable medicines are promptly sent to the pharmacy.  
6 Current drug references are available.  

Comments/Recommendations:  

III ACCOUNTABILITY OF MEDICINES:
1 Orders correctly transcribed to charts.  
2 Orders for new medicines recorded.  
3 Orders for repeat medicines recorded.  
4 Medicines received from pharmacist recorded.  
5 Medicines brought in with patient recorded.  
6 Repeat medicines are ordered in time.  
7 Medicines are sent with patient on discharge.  
8 Medicines issued on discharge recorded.  
9 Medicines disposed of regularly.  
10 Medicines not kept past their expiry date.  
11 Disposal record easily retrievable.  
12 Medicines sent with patient on outings recorded.  
13 Quantity of medicine is consistent with directions for use.  
14 There is not an excessive quantity in the back-up stock.  

Comments/Recommendations:  

IV MEDICINE PACKAGING AND LABELLING:
1 Pharmacy labels are complete and accurate.  
2 Labels have not been altered.  
3 Bulk medications are properly labelled.  
4 Medication containers are intact.  

Comments/Recommendations:  

____________________________________________________________________

264
### V ADMINISTRATION OF MEDICINES:

1. New prescriptions are started timely.  
2. Stat prescriptions are administered timely.  
3. Medications not administered are recorded.  
4. Routine medicines are recorded.  
5. PRN medicines are recorded.  
6. Self-medication by patients is recorded appropriately.  
7. Household remedies are recorded.  
8. Appropriate monitoring for selected drugs.  
9. Medicines withheld if appropriate.  
10. Medicines Administration Policy is followed.  
11. Proper medication technique is followed.  
12. Medicines reviewed for appropriateness of crushing.

### Comments/Recommendations:

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<th></th>
<th>C</th>
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<th>N</th>
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### VI MEDICATION STORAGE:

1. Security of trolleys and cupboards well-maintained.  
2. Security of refrigerated items well maintained.  
3. Medication storage areas are neat and organised.  
4. All storage areas are clean.  
5. Refrigerator temperature suitable.  
6. Clinical room temperature suitable.  
7. Separation of internal and external medicines.  
8. Patient's medicines storage separately.  
10. No deteriorated medicines.  
12. No storage of non-medication items.  
13. Proper storage/disposal of syringes.  
14. An in-house trolley audit system is in place.  
15. Self-medication items are securely held.  
16. Key held by the nurse-in-charge.

### Comments/Recommendations:

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<th>I</th>
<th>N</th>
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### VII CONTROLLED DRUGS

1. Controlled drugs are properly stored.  
2. Controlled drugs records are complete.  
3. Controlled drugs correct.

### Comments/Recommendations:

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### VIII SUMMARY:

1. Total Consistent (C).  
2. Total Inconsistent (I).  
3. Total Never (N).
Consultant Pharmacist Recommendations to Patients’ GP.

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<tr>
<th>Patient</th>
<th>Recommendations</th>
<th>GP Response</th>
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Thank you

Hazel Sommerville
Whitlingham Hospital

0603 611911 ext. 261
Consultant Pharmacist Recommendations to Nursing Staff

To:                      Date:                      

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<tr>
<th>Patient</th>
<th>Recommendations</th>
<th>RGN Response</th>
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Thank you

Hazel Sommerville
Whitlingham Hospital

0603 611911 ext. 261
Consultant Report.

Nursing Home: Date:

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Appendix III

Sample of Baseline Data.
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<thead>
<tr>
<th>Horse</th>
<th>Patient No</th>
<th>Date of Birth</th>
<th>Date of Prescription</th>
<th>Item</th>
<th>Frequency of Administration</th>
<th>Pattern of Administration</th>
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<tbody>
<tr>
<td>2</td>
<td>1</td>
<td>24.11.14</td>
<td>02.10.92</td>
<td>Moduratic</td>
<td>1 - OD</td>
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<tr>
<td>2</td>
<td>1</td>
<td>24.11.14</td>
<td>02.10.92</td>
<td>Pilocarpine 4% Eye Drops</td>
<td>1 - QDS</td>
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<tr>
<td>2</td>
<td>1</td>
<td>24.11.14</td>
<td>02.10.92</td>
<td>Tinsoptol 0.5% Eye Drops</td>
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<tr>
<td>2</td>
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<td>24.11.14</td>
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<td>2</td>
<td>09.09.11</td>
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<tr>
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<td>2</td>
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<td>02.10.92</td>
<td>Lasoride</td>
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</tr>
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<td>2</td>
<td>3</td>
<td>16.12.23</td>
<td>02.10.92</td>
<td>Losuc 20mg</td>
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<td>1</td>
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<td>2</td>
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<td>16.12.23</td>
<td>02.10.92</td>
<td>Sultospan 10mg</td>
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<td>2</td>
<td>3</td>
<td>16.12.23</td>
<td>02.10.92</td>
<td>Co- Hydramol</td>
<td>2 - nocte</td>
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<td>3</td>
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<td>Paracetamol 500mg</td>
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<td>03.10.92</td>
<td>Fluclotalic Eye Gint</td>
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<tr>
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<td>3</td>
<td>16.12.23</td>
<td>02.10.92</td>
<td>Gaviscon</td>
<td>10ml - QDS</td>
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<td>2</td>
<td>3</td>
<td>16.12.23</td>
<td>14.12.92</td>
<td>Furmi L5</td>
<td>1 - OD</td>
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</tr>
</tbody>
</table>

0 - Not Given  
1 - Given as Prescribed  
2 - Self-medication
Appendix IV

Pharmacy Information Bulletin.
Laxatives

One of the most common complaints among the elderly population is constipation. There are wide ranging causes, including aging of the muscle, poor diet, physical inactivity, excessive use of laxatives over many years and side-effects of prescribed medicines.

Irrespective of cause, constipation is an uncomfortable situation, which can of itself contribute to pain and aggressive behaviour.

Non-Drug Approach.

The first step to relieving constipation should be the non-drug approach:

- Increase fluid intake.
- Increase fibre in the diet e.g. fresh fruit, more wholemeal bread
- Reduce sugar, fat and processed foods in the diet.
- Encourage mobility.

When these measures are not effective or inappropriate for a particular resident, it may be necessary to consider using a laxative to relieve the situation.

Laxatives:

There are five types of laxatives which have different pharmacological actions, four of which may be recommended for use:

- Bulk forming drugs
- Stimulant laxatives.
- Faecal softeners.
- Osmotic laxatives.
- Lubricants *

* The lubricant group comprises products which contain paraffin. Due to the possibility of serious side effects they are no longer recommended and should not be available direct to the public.

When choosing which laxative to use, it is important to adopt an 'individual' approach. The cause of each resident's constipation is unique to that resident. It is also important to understand the action of different laxatives.

e.g. Lactulose [osmotic]: when used on a regular basis may take up to seven days to exert its full action. It is therefore unsuitable for PRN administration.
The following Table is intended to clarify the Action, Dose, Advantages and Disadvantages of the differing categories of Laxatives.

<table>
<thead>
<tr>
<th>Type</th>
<th>Examples</th>
<th>Dose</th>
<th>Action</th>
<th>Advantages</th>
<th>Disadvantages</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Proctofibe</td>
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<td>Normacol</td>
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<td>Celevac</td>
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<td></td>
<td>Diocetyl</td>
<td>Preferably given at night.</td>
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<td></td>
<td>Senna</td>
<td>Restricted use</td>
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<td>Picolax</td>
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<td>Co-Danthramer</td>
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<td>Glycerin supps.</td>
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<tr>
<td>Faecal softener</td>
<td>Diocetyl</td>
<td>Regular, Daily.</td>
<td>Softening stools.</td>
<td>As for stimulants</td>
<td>As for stimulants</td>
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<tr>
<td>Osmotic</td>
<td>Lactulose</td>
<td>Regular, Twice daily.</td>
<td>Draw water into the bowel to keep stools moist.</td>
<td>Useful in children. Tales 1-2 days to act. Useful for short-term</td>
<td>Unpleasant to take. Can cause flatulence, cramps, and diarrhoea.</td>
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<td></td>
<td>Epsom's salts.</td>
<td>As required</td>
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<td>Micralax</td>
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<td>Fletcher's Enemas</td>
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</table>
Appendix V

RPSGB Standards for pharmacists providing services to nursing and residential homes.
Provision of services

Pharmaceutical services for homes may include:
- Supply of medicines, dressings and appliances
- Out of hours services
- Advice on the administration, storage, disposal and record keeping for medicines, dressings and appliances
- Review of medication used in the home
- Input into medicines protocols
- Care plans for use in the home
- Contribution to training of carers in the home up to National Vocational Qualification level. This should be subject to a separate contractual arrangement.

The pharmacist is advised to liaise with:
- The relevant commissioning authority (to establish a contract for the service)
- The local community services pharmacist, if one exists
- The patient’s GP and other members of the primary health care team
- The home manager
- The officer in charge of medication at the home
- The hospital pharmacist if practicable (if the patient has recently been discharged from hospital)
- Social services (for training of care staff in residential homes).

Service delivery.

A community pharmacist is advised to negotiate a contract with the local health commissioning authority which specifies the number of homes to which pharmaceutical services can be provided.

An initial visit to the home should be carried out by the pharmacist and subsequent visits made at agreed intervals.

Pharmacists should be aware of any local practices for medicines administration and usage in homes.

Monitored dosage systems may be considered and if one is to be used it is advised that the Society’s detailed guidance on Monitored Dosage Systems be followed.

Further information can be found in Administration and control of medicines in care homes produced by the Royal Pharmaceutical Society.

Training for care staff includes:
- The continuing education resource pack entitled Take good care with medicines, available from the Society’s library.
- Scottish/national Vocational; training.
Evaluation.

It is advisable wherever possible that records of each visit made to the home be kept and include:

- The date on which the visit was made
- Names of individuals seen (patient, care staff and other health professionals)
- Clinical interventions made and advice given
- Training of care staff.

Such records should be made available for inspection by the commissioning authority.

Pharmacists are advised to develop methods to monitor the service, which might include:

- Analysis of visiting records and outcomes of advice
- Clinical intervention and training
- Maintenance of a record book in the home in which patients and care staff can comment on the service provided.

Training

Pharmacists are advised to complete:

- The distance learning course *The home away from home*, available from the Centre for Pharmacy Postgraduate Education, The Welsh Centre for Pharmacy Postgraduate Education or the Scottish Centre for Pharmacy Postgraduate Education.
- Any other necessary education and training as determined by the commissioning authority, under the terms of the contractual arrangement
- Specialist training needed for specific areas of service.