A SURVEY OF THE USE OF MEDICATION WITH PROLONGED ORAL CLEARANCE IN THE ELDERLY IN NORTH EAST ENGLAND

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ABSTRACT

The elderly are increasingly retaining natural teeth into old age and many require regular long-term medication for chronic medical problems. If these medicines contain sugars and have a prolonged clearance time from the mouth, they may threaten dental health. The extent of regular and long-term use of these medicines in the elderly was the subject of this study comprising five surveys.

A general medical practice survey identified 2002 elderly patients aged ≥60 years taking 143 prescribed medicines with prolonged oral clearance (POC) long-term representing a prevalence of use of 9.8%, with females aged ≥75 years more likely to be taking POC medicines long-term ($p<0.001$). The main medical problems reported were cardiovascular and musculoskeletal, however antacids, laxatives and minor analgesics were the most commonly prescribed POC medicines. The prevalence of over-the-counter POC medicine use long-term was 1.1%.

Analysis of prescription numbers and quantities of medicines dispensed in primary care identified 613 POC medicines representing 13% of the 457 million items dispensed in England in 1994, of which 30.4 million items (51%) were for medicines potentially used regularly and long-term by the elderly. POC medicines prescribed in primary care represented the main area of use; secondary care accounted for only 1% of the overall quantities prescribed in the Northern Region and the contribution of OTC medicines to overall consumption of POC medicines was also low (<1%). The influence of generic prescribing and dose form on the sugar content of the medicines dispensed was substantial; over 80% of generic liquid oral medicines were sugars-containing compared with 7% of proprietary liquid oral medicines.

Efforts should be made to draw the attention of government, manufacturers, prescribers and dispensers as well as consumers to the major influences of dose form and specificity of prescribing on the sugars content of medicines. This is crucial in those increasing number of dentate individuals whose dental health is at risk through regular and long-term use of POC medication.

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CHAPTER 1
INTRODUCTION

The elderly are a growing population in the UK. In 1997 the population of the UK was 59 million individuals, of which 10.7 million (18%) were of a pensionable age, that is, aged 60 and over (Office of Population Censuses and Surveys, 1998). The elderly population of the Northern Region of England in 1995 was 0.62 million (21% of the overall Northern Region population), which had increased from 0.44 million in 1979, when the elderly represented 14.2% of the population (Office for National Statistics, 1995).

In a ten year period (1978 to 1988) the percentage of the UK population (16 years and over) who were edentulous fell from 30% to 21% (Todd & Lader, 1991). During the same period, the percentage of people aged 65 to 74 years, who were edentulous had decreased from 75% to 56% (Downer, 1991). The increase in the elderly population, together with improved dental health, has resulted in increased numbers of elderly persons retaining their own teeth.

The elderly suffer from more medical problems than younger members of the population; individuals over the age of 65 years report twice as much chronic or long-standing illness as persons under 65 years, however older people consult their doctor only one and a half times as often (HMSO, 1996). Medicines prescribed to the elderly in England accounted for 49% of all 500 million items dispensed in 1997 (Department of Health, 1998). These medicines are mainly administered orally, with the solid oral dose (e.g. tablets and capsules) being the most common formulation. However, solid doses are not always suitable and other oral formulations available for use include liquids, syrups, emulsions, pastilles, lozenges, chewable, buccal and sublingual tablets. These may be used because they are more acceptable to the patient, for example, when the patient may be too ill to swallow or if the solid oral dose causes local irritation. In addition, the efficacy of certain medicines is optimised with certain dose forms. Antacids offer fastest relief when formulated as liquids, and cough and sore throat products are most effective as pastilles and lozenges.

Medicines formulated as liquids, syrups, pastilles, lozenges, and chewable and effervescent tablets, buccal and sublingual oral slow release tablets all have an increased clearance time from

the oral cavity compared with oral doses designed to be swallowed immediately. For the purposes of this study they will be referred to as medicines with prolonged oral clearance (POC).

The role of sugar in the aetiology of dental caries has been well researched and it is clear that frequent intake of sugar may cause dental caries. Studies have also shown that liquid oral medicines which contain sugar and are used long-term, cause dental caries in children. If other medicines with prolonged oral clearance also contain sucrose or other sugars with acidogenic properties, they also may constitute a threat to dental health.

The elderly, who have higher morbidity and take more medicines are already a vulnerable group of the population. Good oral health has many positive benefits including improved general health as individuals with an intact dentition are able to consume healthier foods such as fibre. As more elderly individuals retain their natural teeth into old age, dental health concerns which have previously not required consideration are increasingly having to be addressed. The effects of the long-term use of medicines upon dental health is just one of these concerns.

"I do not want two diseases: one made by nature and one made by the doctor'" (Napoleon Bonaparte 1820). The role of the health professionals is to cure and treat disease to the best of their ability and use a holistic approach to treatment, considering all aspects of the patients health. There are a number of issues to be considered with regard to medicine use in the elderly.

- Do medicines with prolonged oral clearance form a significant part of the overall consumption of medicines in the elderly?

- Is the use of medicines with prolonged oral clearance restricted to acute short-term treatments or are such medicines being used long-term on a regular basis?

- What are the prescribing and dispensing issues relating to medicines with prolonged oral clearance?

- What proportion of medicines with prolonged oral clearance currently used overall and by the elderly are sugars-containing and pose a threat to dental health?

- Are there any wider general health and dental health concerns resulting from the use of medicines with prolonged oral clearance in the elderly?

The use of liquid oral medicines and dental health in children has been studied previously but research on the overall use of medicines prolonged oral clearance and their use in the elderly is sparse and mainly anecdotal. An assessment of the prevalence of use of all medicines with prolonged oral clearance in the elderly would provide valuable information which has been previously unavailable.

These issues formed the background to the planning and the subsequent undertaking of the series of surveys, which comprised this study.

CHAPTER 2

OVERVIEW OF MEDICINES CONTROL IN THE UNITED KINGDOM

2.1 INTRODUCTION

This chapter will give an overview of the control of medicines in the United Kingdom (UK) and mechanisms behind prescribing and dispensing in the UK.

2.2 REGULATION OF MEDICINES USED IN THE UK

The pharmaceutical industry is the UK's largest manufacturing industry, accounting for a gross output of over £6500 million per year (Stone & Curtis, 1995), with sales to the British National Health Service (NHS) of £2927 million, representing 10% of the gross cost of the NHS (Association of British Pharmaceutical Industry, 1992). Medicines manufactured by the pharmaceutical industry are subject to strict regulations and controls to ensure that the final product is safe. A major catalyst for the imposition of these strict regulations was the 1961 thalidomide tragedy when it was discovered that the drug thalidomide prescribed for morning sickness during pregnancy, caused foetal abnormalities (Ministry of Health, 1964). As a result of this and other adverse events due to drug therapy, the government implemented medicines control through the publication of the Medicines Act 1968 (HMSO, 1969).

Currently a new drug has to undergo a series of studies and clinical trials before it is granted a product licence by the Licensing Authority (via the Department of Health) (Figure 2.1). Initially a drug undergoes Phase 1 studies to look at biopharmaceutical data such as stability and formulation, as well as the drug's toxicology and pharmacology (Harman, 1999). Once these data have been collected and analysed, they are presented to the Medicines Control Agency, who can allow Phase 2 and 3 studies (clinical trials on human subjects) to begin. Once these are complete, evidence of safety and efficacy is submitted to the Committee on the Safety of Medicines (CSM) who can then recommend whether a drug should or should not be granted a product licence by the Department of Health.

The CSM is an independent advisory committee established under the Medicines Act 1968 (HMSO, 1969) which advises the UK Licensing Authority (Government Health Ministers) on the quality, efficacy and safety of medicines in order to ensure that appropriate public health

standards are met and maintained. The Committee's responsibilities are broadly, two-fold; to provide advice to the Licensing Authority on whether new products (new active substances) submitted to the UK Medicines Control Agency (MCA) should be granted a marketing authorisation, and to monitor the safety of marketed medicines, in close association with the MCA's Post-Licensing Division to ensure that medicines continue to meet acceptable standards of safety and efficacy. This is achieved through a system of licensing and monitoring medicines after a licence has been granted. The MCA has separate divisions dealing with licensing, post-licensing, inspection and enforcement of medicines, executive support and finance.

Once a product licence has been obtained, the manufacturer may bulk produce their drug for distribution into primary and secondary care. These new drugs are subject to post marketing surveillance in the form of the Yellow Card Scheme, where prescribers are asked to report any adverse drug reaction (ADR) to the new drug. Data from these reports are analysed to assess the probability of a reaction being caused by the drug. The CSM provide regular bulletins for health care professionals, updating them on potential ADRs. Figure 2.1 shows the pre- and post-marketing controls on manufacturing and marketing of new drugs.

2.3 CLASSIFICATION OF MEDICINES USED IN THE UK

2.3.1 Prescription only medicines (POM)

Prescription only medicines (POM) are usually potent drugs which have to be prescribed by a qualified medical or dental practitioner in the UK. These medicines are generally available to the UK public, prescribed on a NHS prescription. However in April 1985, in a bid to reduce costs, the government selected a list of medicines it felt were not efficacious and created a NHS blacklist of drugs it was not prepared to fund using budgets and amended the NHS Regulations to limit the range of preparations available within therapeutic groups (Department of Health, 1995). As well limiting the range of drugs in a therapeutic section, drugs with limited clinical value were also blacklisted. Blacklisted products cannot be prescribed on NHS prescription forms. They have to be prescribed privately on a private prescription and the patient will usually incur a fee for this service.

2.3.1.1 Branded and generic medicines

All new medicines are generally manufactured by large multinational companies who either produce and sell the medicine directly or sell the chemical entity or product to another company. These medicines are assigned brand or proprietary names. As well as this name, the medicine will also have a chemical name which can be either the British Approved Name (BAN), recommended International Non-proprietary Name (rINN) or the scientific name (Kopp-Kubel, 1995). This chemical name is generally referred to as the generic name and the Medicines Act 1968 (HMSO, 1969) states that it must be included on the medicine label.

Most new medicines are given a patent for a number of years (usually 10 to 15 years) so that the developers of the drug can recoup the research and development costs incurred in getting the drug licensed for use. Once the patent expires, any pharmaceutical manufacturer can produce the drug as long as it complies with strict quality guidelines regarding bioavailability, stability and palatability. These generic formulations are also subject to the strict regulations and control imposed on new medicines, however, as these generic manufacturers have not incurred the research and development costs, they tend to be cheaper than the proprietary equivalent. Although there may be many generic formulations of a medicine, not all companies distributing them are the manufacturers; some buy the product and then pack it into their own packaging and it may be that the source of the raw material for the medicine may vary from time to time. Currently, European Community guidelines do not require the excipients (the inert ingredients in the formulation) in generic formulations to be identical (Feely, 1996).

The spiralling costs of the NHS drugs bill has forced government to seek ways of reducing this expenditure and this prompted the publication of the 1982 Greenfield report, which stated that there were advantages to be gained from generic prescribing but, in particular, highlighted the cost savings (Greenfield, 1982). As a result of this, generic prescribing and dispensing has increased dramatically over the last 15 years, with 60% of all prescribing in England in 1997 being generic compared with 39% in 1987 (Department of Health, 1998). The proportion of drugs generically dispensed however, forms a lower proportion of use since not all drugs prescribed generically are available in a generic form.

2.3.1.2 Parallel imports

The manufacture of medicines in other countries is sometimes considerably cheaper than in the UK and this has led to their increased import into the UK for dispensing. This has obvious financial advantages for community pharmacists in that they can buy a branded product more cheaply abroad and be paid the higher price of the original UK brand. This loophole in NHS regulations has necessitated further control of these medicines and now only those with a Parallel Importing Product License (PL[PI]) can legally be dispensed. Pharmacists using unlicensed products are open to disciplinary action for professional misconduct (Royal Pharmaceutical Society of Great Britain, 1998).

2.3.2 Over the counter (OTC) medicines

Medicines that can be bought 'over the counter' (OTC) are generally safe, well established preparations, many of which have been available for a number of years. OTC medicines can be classified either as 'pharmacy only' (P) or general sales list (GSL). Pharmacy only (P) medicines are those that can be bought without a prescription but have to be sold under the supervision of a pharmacist. GSL medicines can be sold in any retail outlet without any restrictions or supervision from a healthcare professional.

All P medicines are governed by strict regulations compiled by the Royal Pharmaceutical Society of Great Britain which states that a pharmacist must at all times be on the premises during the sale of a P medicine (Royal Pharmaceutical Society of Great Britain, 1998). The pharmacist does not have to be directly involved in the sale as long as a pharmacy sales assistant has been trained to a National Vocational Qualification (NVQ) level and there is a protocol on the sale of P medicines displayed in the pharmacy. However, the pharmacist must also be present to deal with any problems associated with the sale. P medicines are price protected by the Resale Price Maintenance (RPM) scheme which, as the name suggests, maintains the cost of all P medicines to ensure community pharmacies cannot compete with each other and that smaller rural pharmacies providing a vital service to the community can continue as a viable business.

To optimise the use of general medical practitioners time and cut down on waiting times, patients are being encouraged to seek advice from community pharmacists on healthcare matters (National Pharmaceutical Association, 1990). Pharmacists are being encouraged to assess a medical complaint identifying any serious underlying problems, in which case the patient would be

referred to the general medical practitioner. If the condition was minor then the pharmacist could treat it using the appropriate OTC medicine with counselling and guidance. OTC medicines sold to patients are not currently recorded, although some of the latest computer software used in some pharmacies can record a sale of a OTC medicine in a patients record. This allows the pharmacist to check any interactions with prescribed medicines, ensuring that the OTC medicine is safe for that patient.

Medicines classed as GSL medicines can also be bought at supermarkets and other retail outlets and are normally sold without any supervision or counselling. Recent pressure from the pharmaceutical profession led to reclassification of two such GSL medicines (paracetamol and aspirin) as P medicines, so that packs of 16 and above could only be bought from pharmacies (National Pharmaceutical Association, 1998), requiring pharmacists to supervise the sale and appropriate use of these potentially harmful products.

2.4 PRESCRIBING AND DISPENSING OF MEDICINES IN THE UK

2.4.1 Primary health care (Figure 2.2)

In the UK, the National Health Service allows the public access to free healthcare from their general medical practitioner. The patient will present with a complaint and after assessment, the general medical practitioner may prescribe a treatment with a medicine by issuing a prescription to the patient. This is usually a NHS prescription which is taken to a community pharmacy for dispensing. The pharmacy must have a contract with the Family Health Services Association (FHSA) before it can dispense a NHS prescription, the most common of these being the FP10 which is the script used by general medical practitioners for prescribing in primary care. The dentist uses the FP14 and the FP10(HP) and FP10(S) are used by hospital doctors and the armed forces, respectively.

If a general medical practitioner prescribes a proprietary product, then the dispensing pharmacist must dispense that brand. If the medicine is prescribed by the generic name then any brand which is chemically equivalent may be dispensed.

The pharmacist is responsible for ensuring that the prescription has been correctly written, with the correct dose, that the drug does not interact with other therapy and that the drug has not been blacklisted, after which the medicine is dispensed and the script filed. Most pharmacies keep

patient medication records (PMRs) for each patient, however this is not a requirement within the terms of NHS pharmacy services and the quality of information recorded can vary from pharmacy to pharmacy.

The NHS prescription will either be exempt from the NHS prescription charge or the patient will have to pay this charge (currently £5.80) for each item dispensed. Those exempt must indicate on the back of the script the reason for their exemption; for example, being aged over 60 years, or being entitled to income support. Some medicines prescribed are 'over the counter' (OTC) products; if their cost is less than the prescription charge and the indication is appropriate, a pharmacist will usually suggest that the patient buy the OTC pack and will give the appropriate counselling regarding to administration and dosage.

At the end of each month the NHS scripts (e.g. FP10 and FP14) from each community pharmacy are sent to the Prescription Pricing Authority (PPA); the special health authority responsible for paying community pharmacy contractors. The PPA calculates the cost of the drugs dispensed and this fee is reimbursed to the pharmacy contractor along with a dispensing fee for each item dispensed. Additional fees for prescriptions for controlled drugs and extemporaneous dispensing are also paid where the pharmacist has endorsed the prescription to claim these fees. Once payment has been made, the PPA collate the data to produce prescribing reports called Prescribing Cost and Analysis (PACT) and Prescribing Cost Analysis (PCA) reports. PACT reports are produced quarterly for each general medical practitioner and give a summary of the prescribing costs for that quarter. They are also available six monthly and yearly and are available to various health professionals for prescribing research.

2.4.2 Secondary health care

In hospitals the control and dispensing of medicines is managed by the hospital pharmacy service. For inpatients, the hospital pharmacy dispenses to wards following requests from doctors or nursing staff. The ward pharmacist consults with doctors and is responsible for checking the dose and any interactions or contraindications for use. For outpatients, following a consultation and a change in medication, a first prescription is issued for 7 days, which is dispensed at the outpatients pharmacy in the hospital. If the treatment is long-term, the consultant will write to the general medical practitioner, who will continue prescribing the medicine. Unlike community

pharmacies, dispensing information in hospital pharmacies is not recorded and there is no equivalent information on prescribing or dispensing.

Figure 2.1 Pre- and post-marketing control of new drugs.

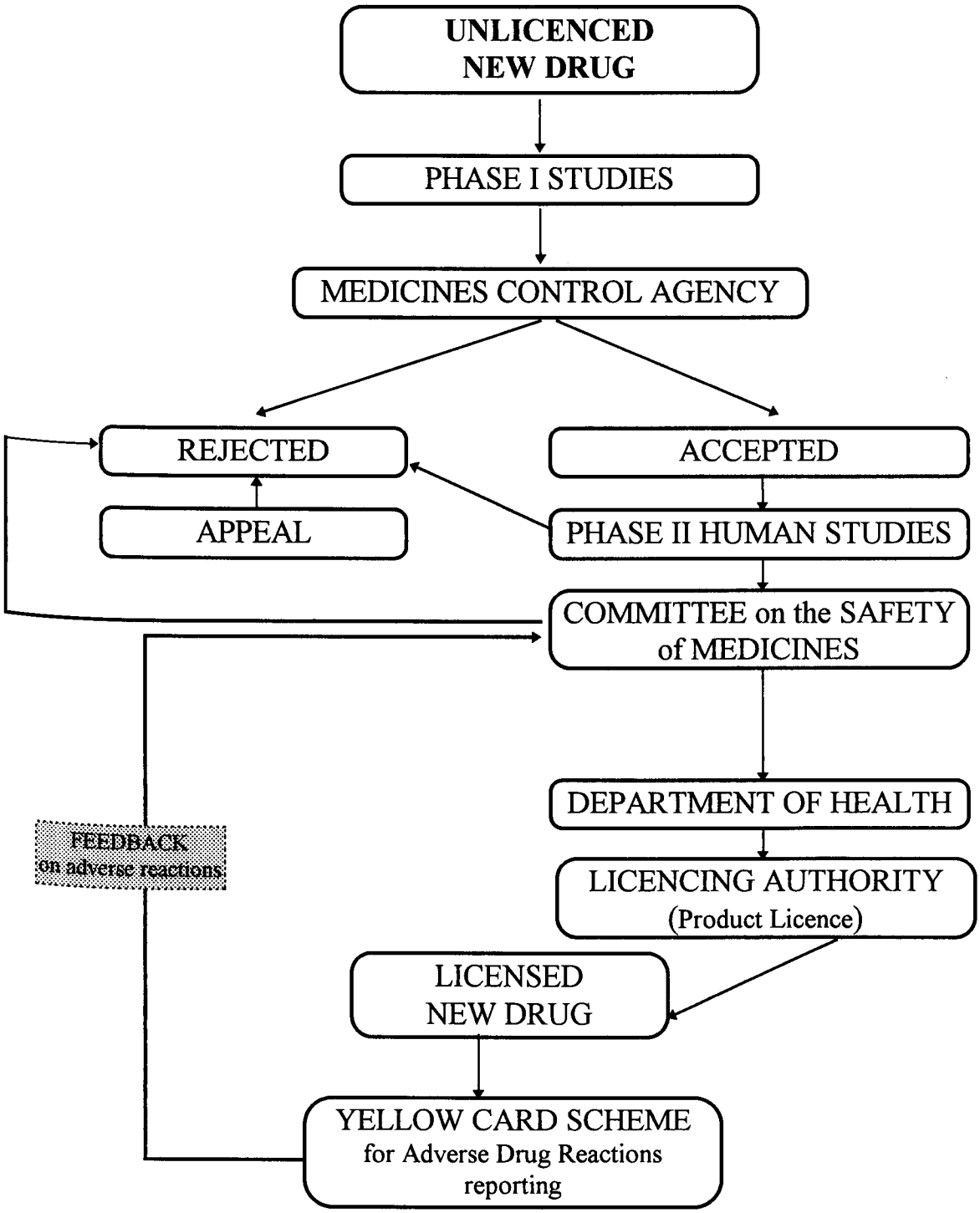
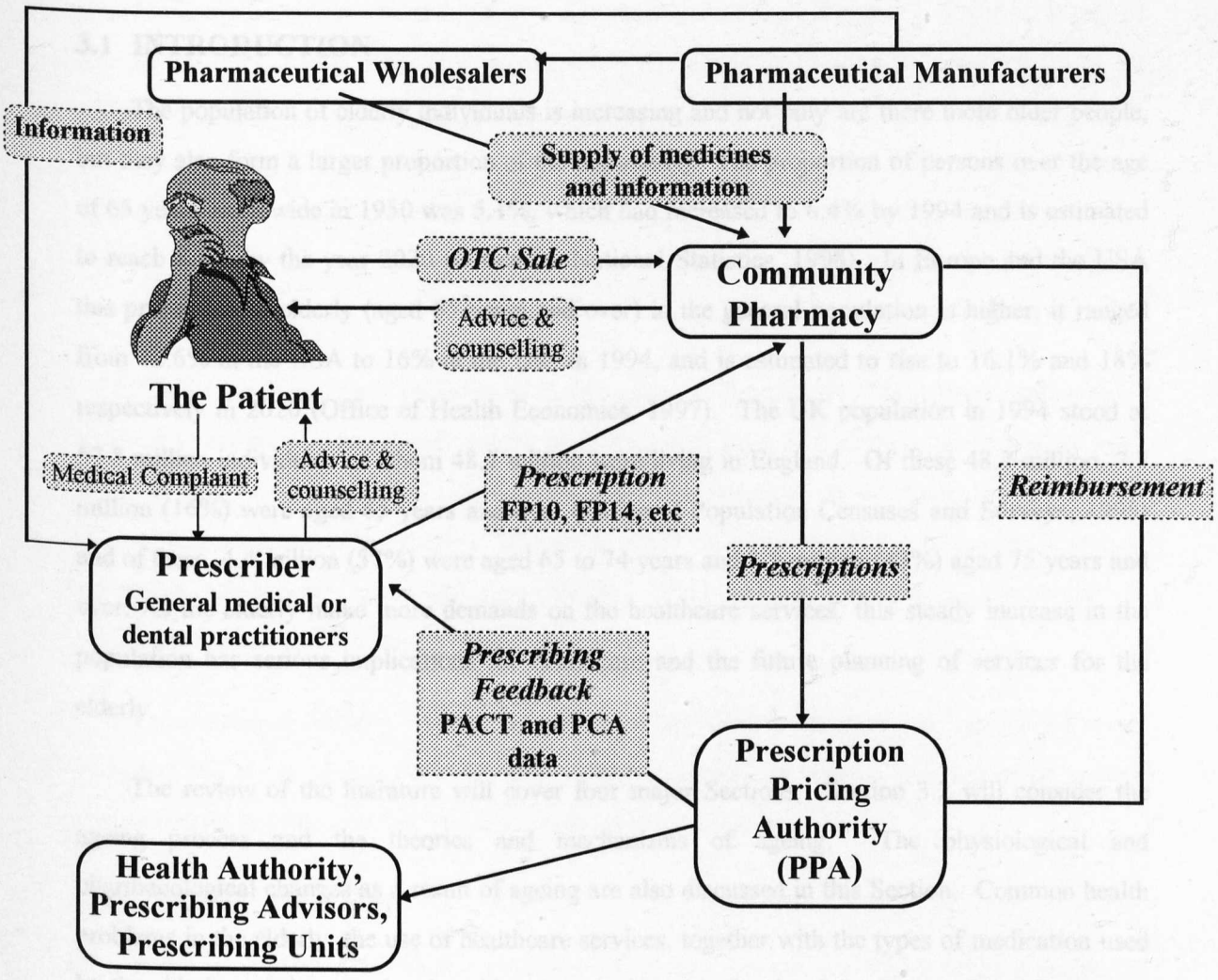


Figure 2.2 The prescribing and dispensing of medicines in primary care, in the UK



CHAPTER 3

REVIEW OF THE LITERATURE

3.1 INTRODUCTION

The population of elderly individuals is increasing and not only are there more older people, but they also form a larger proportion of the population. The proportion of persons over the age of 65 years worldwide in 1950 was 5.1%, which had increased to 6.4% by 1994 and is estimated to reach 8.8% by the year 2020 (Office for National Statistics, 1998). In Europe and the USA this proportion of elderly (aged 65 years and over) in the general population is higher; it ranged from 12.6% in the USA to 16% in the UK, in 1994, and is estimated to rise to 16.1% and 18% respectively in 2020 (Office of Health Economics, 1997). The UK population in 1994 stood at 57.8 million individuals of whom 48.7 million were living in England. Of these 48.7 million, 7.7 million (16%) were aged 65 years and over (Office of Population Censuses and Surveys, 1995) and of these, 4.4 million (57%) were aged 65 to 74 years and 3.3 million (43%) aged 75 years and over. As the elderly make more demands on the healthcare services, this steady increase in the population has serious implications for healthcare and the future planning of services for the elderly.

The review of the literature will cover four major Sections. Section 3.2 will consider the ageing process and the theories and mechanisms of ageing. The physiological and pharmacological changes as a result of ageing are also discussed in this Section. Common health problems in the elderly, the use of healthcare services, together with the types of medication used by the elderly and the associated problems are reviewed in Section 3.3. Section 3.4 will consider the oral health of the elderly, their nutritional status and, in particular, oral problems caused by medication. Section 3.5 discusses sugars, sugars-containing medicines and medicines with prolonged oral clearance and the impact of their use on oral health.

3.2 MECHANISMS AND PHYSIOLOGY OF AGEING

3.2.1 Introduction

"How old would you be if you didn't know how old you was" *Satchel Paige* (Cristofalo, 1990).

Why do we grow old? This question must be one of the most commonly addressed issues for mankind. It has been postulated that God or Evolution caused animals to age to make room for younger, fitter off-spring to inherit the earth (Comfort, 1965) suggesting that the older individuals are not required once they have fulfilled their role in producing off-spring. However, it can be argued that the old offer an indirect evolutionary advantage by offering their experience to the young. Examples of this include certain moths that are foul tasting to birds. The older moth offers itself to the bird, saving the lives of the young moths (Comfort, 1965). This theory of ageing suggests a pre-programmed mechanism, but what processes cause organisms to age? Do animals simply 'wear out' during their lives, or are there processes which control the ageing process?

There have been many attempts to define ageing. Bromley (1988) defined ageing as "a complex cumulative, time-related process of psycho-biological deterioration occupying the adult phase of life" (Bromley, 1988). Ageing has also been described as a "decline in fertility and vitality, with an increase in mortality" (Comfort, 1965), as a "process which brings about an ever increasing age-specific mortality" (Fairweather, 1991) and an "increasing vulnerability to environmental change" (Comfort, 1965).

These many definitions reflect the difficulties involved in research into ageing when one considers the many ageing scenarios that occur in nature, as well as the impact of various environmental and intrinsic mechanisms occurring independently.

3.2.2 Ageing Mechanisms

There are a number of theories regarding the ageing process, and many of these attempt to identify a single cause for senescence. However, it has been argued that ageing is unlikely to be the result of a single factor (Cristofalo, 1990). Ageing may be a result of environmental factors or it may be an intrinsic process, involving changes in the body over time that are independent of extrinsic interactions (Harman, 1998). The following theories look at possible intrinsic mechanisms for the process of senescence.

3.2.2.1 Intrinsic Ageing

Research into intrinsic ageing has focused on three major areas: (a) 'programmed' ageing, (b) stochastic theories which consider the concept of error accumulation and (c) reactive oxygen and free radicals theory.

3.2.2.1.1 Programmed Ageing

Programmed ageing involves the concept of a decaying biological clock, with each organism having a specified lifetime (Baillie & Woodhouse, 1988; Wilson, 1974). Like other lifetime events (e.g. puberty, menopause), it has been suggested that ageing is genetically determined within a species. Man has an approximate life-span of eighty five years. Other organisms such as the ocean quahog (Arctic islanica) may live for two hundred years, whilst certain bird species are thought to live for approximately forty years (Fairweather, 1991). This implies that individual species have been 'programmed' to live to a certain maximum age, after which they will die. It has been suggested that the development of maximum life-spans could be a part of the evolutionary process; senescence being required to provide 'space' for future generations (Fairweather, 1991).

Genetic control of senescence after menopause has been suggested (Wilson, 1974), and the possibility of a 'deleterious' gene or genes has also been considered, along with hypotheses that these genes may be associated with fertility, and in later life (post-reproduction) be involved in ageing (Cristofalo, 1990). This would suggest that ageing is the price we pay for successful reproduction and evolution, however these theories have yet to be scientifically proven.

3.2.2.1.2 Stochastic theories

The group of stochastic ageing theories are based upon the knowledge that within the internal environment, cell components are constantly being damaged. Over time this damage accumulates, until a threshold is reached when the cell can no longer function and a level of damage incompatible with life is reached (Cristofalo, 1990).

Error accumulation is the result of mutation, due to external factors such as radiation, in mitochondrial (mtDNA). As mitochondrial DNA, is used to produce mitochondrial RNA (mtRNA), these mutations produce incorrect sequences of mtDNA which is then incorrectly transcribed into incorrect mtRNA, thus producing faulty enzymes and proteins. Over time this will result in the gradual loss of efficiency of the mitochondrial energy production system, with pathological consequences (Linnane *et al.*, 1989).

Using DNA isolated from aged monkeys, it has been shown that mitochondrial DNA deletions do occur and the incidence of these increase with age (Lee *et al.*, 1993). Experiments involving skeletal muscle mitochondria have shown that there is a reduction in their function as a

result of ageing (Lee *et al.*, 1993). The central point of this theory is that the cumulative effect of these errors will build up over time, reducing the efficiency of the various organs and systems in the body.

3.2.2.1.3 Free radicals theory

Normal metabolic reactions in the body result in the formation of free radicals which are reactive molecular fragments. Normally these free radicals are destroyed by enzyme systems such as superoxide dismutase, however some free radicals escape destruction and cause damage to inter-cellular contents. Damage accumulates and can eventually interfere with the normal function of the cell. It has been postulated that these effects cause ageing (Cristofalo, 1990; Harman, 1998), and that advancing age is also associated with a reduced capacity to limit this damage, due to a reduced function of the cells' enzyme repair systems, resulting in more free radicals and more damage (Horan & Pendleton, 1995). Nohl (1993) reviewed the research into the production of free radicals and concluded that ageing is associated with an increase in free radical production, however it was unclear whether free radicals contributed to the initiation or propagation of ageing (Nohl, 1993).

A lower metabolic rate is associated with lower production of free radicals. In a species of mammals, the bigger the animal, the lower the metabolic rate. An inverse relationship has been shown between metabolic rate and life-span suggesting that the production of free radicals may be related to the life-span of a species (Harman, 1998). However, if the free radical theory was entirely correct it would mean that exercise resulting in an increased metabolic rate and greater caloric expenditure would produce more free radicals and reduce life-span (Dhahbi *et al.*, 1998). Experiments using antioxidants such as Vitamin E have failed to prove that reducing free radicals increases life expectancy (Cristofalo, 1990).

There is now a growing consensus, largely based on the results of measures to minimise more or less random endogenous free radicals, that such creations are a major cause of ageing (Harman, 1998).

3.2.2.1.4 Other intrinsic theories

The immune system forms the basis for another intrinsic theory of ageing (Cristofalo, 1990). This theory suggests that reduced T-cell numbers and function, which occur with age, lead to reduced resistance to infection, and the emergence of age-associated auto-immune disease. In

addition, as a result of mutation described by the stochastic theory of ageing (Section 3.2.2.1.2), the body's own cells may not be recognised and be attacked by auto-antibodies (Comfort, 1965; Harman, 1996).

3.2.2.2 Extrinsic ageing

There is great inter-species and intra-species variation in life-span. For example, humans have an average life-span of eighty five years, yet may live up to one hundred and twenty years or die at fifty years or younger. Intrinsic theories have tried to explain the mechanisms of ageing and the programmed ageing theory has suggested that we live up to a certain genetically predefined point. These theories cannot however explain the variation in life spans within the same species.

This intra-species variation is more likely to be due to exposure to environmental and lifestyle factors which vary from person to person. For example, twins separated at birth and brought up in different environments will show different physical characteristics and differing life expectancy. Environmental conditions such as early exposure to disease, accidents during childhood or geographical location can cause a person to age or die before others.

In summary, ageing appears to be multifactorial in aetiology, involving a complex interaction of many intrinsic and extrinsic factors which are still not fully understood, although the most recent literature on ageing theories suggest that free radicals are the major cause of ageing.

3.2.3 The effects of physiological changes due to ageing upon pharmacokinetics

3.2.3.1 Introduction

Age-associated changes can be found in most adult body systems. The possible causes of these ageing effects have been discussed in the previous section. The effects of age differ between those structures and systems which are rapidly replaced (e.g. the skin) and those which are non-renewable (e.g. teeth).

Pharmacokinetics is the study of the mechanisms by which drugs are absorbed, distributed, metabolised and excreted from the body. The pharmacological effects of drugs are usually dependent upon interactions between drugs and receptors. Over recent years research on the effects of age upon pharmacokinetics has focused on the three areas of absorption, distribution and excretion. This Section will review this research and discuss the major findings.

3.2.3.2 Drug absorption and the Gastrointestinal System

Ageing is associated with secretory and morphological changes in the gastrointestinal system. After the age of 50 years, about 80% of stomachs show muscular atrophy. This is due to a cumulative effect of surface injury and repair and is accompanied by reduction in mucus production (Lamy, 1991). Stomach function is further impaired by a reduction in splanchnic blood flow by as much as 50%, by the age of 65 years. To add to these effects, the influence of psychosomatic and behavioural factors such as fear of disease and death, depressive illness and anxiety have a negative effect on gastric motility and secretory function (Lamy, 1991). Ageing is associated with a decline in gastric secretions, especially acid secretions, with secretory volumes as low as 50% in some elderly patients, compared with younger individuals (Geokas & Haverback, 1969). In addition, the elderly may have a reduced splanchnic blood flow, increase in gastric pH, impaired intestinal motility and decreased gastric motility (Geokas & Haverback, 1969; Ouslander, 1981) and as a result of these effects, chronic gastritis, irritable colon, spastic colitis, heartburn, and nausea are frequent problems. As gastritis increases with age, there is a reduction the number of chief and parietal cells in the mucosa (Lamy, 1991), resulting in an ageing stomach which is vulnerable to insult by exogenous substances, especially drugs and in particular, non-steroidal anti-inflammatory and corticosteroid drugs.

Although one would expect an age-related change in the absorption of pharmacological agents, evidence from investigative studies has shown that few drugs have altered absorption in the elderly (Avorn & Gurwitz, 1990). Drugs that are affected include digoxin and chlordiazepoxide, where absorption is slightly delayed in the elderly.

3.2.3.3 Drug distribution

There is a decrease in total body water and lean body mass, with a proportionate increase in body fat, with age. With the decline in muscle mass and power, conditions such as arthritis and osteoporosis become common in the elderly (Lamy, 1991). A decreased bone turnover in the elderly leads to a lower bone density which accounts for the increased incidence of fractures in this population, particularly the hip and pelvis (Diggory *et al.*, 1991). Also as a result of the decrease in lean body mass, by the age of 65 years the average man will have lost 12kg, and the average woman 5kg in weight (Ouslander, 1981). These changes can either increase or decrease the volume of distribution of drugs, depending on the type of drug. For example water-soluble (polar) drugs (e.g. diazepam and nitrazepam) have a reduced volume of distribution and therefore increased initial concentrations in the blood. The main exceptions to this are the antibacterial

tobramycin and the muscle relaxant pancuronium (Williams & Lowenthal, 1992). Conversely the fat-soluble (non-polar) drugs (e.g. cimetidine and digoxin) have a greater volume of distribution and therefore a lower initial concentration, however the volume of distribution is not affected for some non-polar drugs, such as lorazepam and amobarbital (Williams & Lowenthal, 1992).

Drugs can only act if they are in the free, unbound form. Proteins such as serum albumin bind with certain drugs, reducing the drugs concentration in plasma. Lower serum albumin levels may be found in the elderly due to age, disease or malnutrition, causing lower drug protein binding (Avorn & Gurwitz, 1990; Williams & Lowenthal, 1992), allowing more free drug to circulate, leading to a larger pharmacological effect. As a result, drugs such as acetozolamide, diazepam, naproxen, phenytoin, tolbutamide and warfarin, which normally bind to serum albumin, have a more marked pharmacological response in the elderly (Piraino, 1995).

3.2.3.4 Excretion

The excretion of drugs from the body is through either the kidneys or the liver and age related changes in these systems can affect the breakdown of these drugs, potentiating side effects or resulting in sub-therapeutic plasma levels.

Age-related changes in hepatic function will affect the distribution of drugs as the liver is responsible for the breakdown of a number of drugs using a system of enzymes known as the P-450 system. Drugs such as cimetidine, propranolol, metoprolol and labetalol are primarily deactivated during first pass metabolism through the liver. With age, the efficiency of this process is reduced, resulting in increased circulating levels of these drugs (Piraino, 1995).

Age and disease are the major contributors to renal changes. The kidneys of elderly individual tend to be smaller in size, and have a reduced blood flow. The decrease in the renal blood flow and number of functional glomeruli results in a drop in the glomerular filtration rate which makes the kidneys to become less efficient at clearing metabolites and other waste products from the blood (Beck & Burkart, 1985). Glomerular filtration rate decreases by between 35 per cent and 50 per cent from the age of 70 to 90 years (Ouslander, 1981; Williams & Lowenthal, 1992). In addition, there is a fall in creatinine clearance by the kidneys, however the creatinine levels in plasma remain the same suggesting that creatinine production has also decreased.

This change in renal function and its impact on pharmacokinetics has been well documented (Beck & Burkart, 1985; Ouslander, 1981; Williams & Lowenthal, 1992). As a result of this

reduction in renal function, drugs eliminated by the kidneys (e.g. digoxin, ranitidine, atenolol) are retained at higher plasma levels, leading to potential toxicity and adverse drug reactions in the elderly.

3.2.4 Other physiological changes in the elderly

The skin is the largest human organ and shows the most visible changes during chronological ageing. The reduction in subcutaneous fat, increased collagen and fragmented inelastic elastin cause the skin to wrinkle (Diggory *et al.*, 1991). The cells of the stratum corneum tend to hold less moisture, making them more brittle (Balin, 1990). The decreased renewal rate of skin increases the time taken for wounds to heal. The number of melanocytes decrease with age, causing graying of the hair and more importantly, decreased protection from exposure to ultraviolet radiation.

Age-related changes in the cardiovascular system, include hypertrophy of smooth muscle cells, a decrease in connective tissue elasticity, as well as an increase in atherosclerosis; changes which may result in increasing blood pressure with age (Applegate, 1990; Horan & Pendleton, 1995). The function of the resting heart does not vary with increasing age (Lakatta & Gerstenblith, 1990), however changes in the peripheral circulation associated with age are compensated for by hypertrophy of the left ventricle.

Ageing is associated with several changes in pulmonary physiology. The diameters of the trachea and central airways increase, increasing the anatomical dead space. The lung weight decreases by 20%, and there is a loss of alveolar elastic recoil (Lamy, 1991). These changes to the airways result in a decrease in maximum expiratory flow and an increased risk of respiratory failure.

Age also affects the central nervous system. Although there is approximately a 2% decrease in the mass of the brain per decade after 50 years, the most important changes are observed at a microscopic level. There is neuron loss from all areas of the brain which may be related to the neurological conditions associated with ageing (Horvath & Davies, 1990).

3.2.5 Summary

The process of ageing has attracted extensive research and many theories have been postulated as to why we age. More important in the management of the health of the elderly is the effect of these changes on their physiology. In addition to the broad circulatory, respiratory and

gastrointestinal changes with ageing, there are changes in the distribution and excretion of drugs, which will affect the final plasma levels of these drugs. These effects must be accounted for in the prescribing and dispensing of medicines to the elderly and may require changes in dosage or dose form as a result. The following section will look at the general health of the elderly as a result of ageing and discuss the pharmacological treatment and control of any health problems.

3.3 GENERAL HEALTH OF THE ELDERLY

3.3.1 Introduction

Since the turn of the century there have been major improvements in the health of the UK population. With regard to life expectancy, only 332 males and 599 females per thousand were expected to reach the age of sixty five years in 1896, but by 1945 this number had increased to 398 males and 725 females per thousand (Stocks, 1950). The approach of the Second World War prompted major social and healthcare reforms and major scientific advances were made with introduction of the first drugs effective against life-threatening infections. Diseases such measles, rubella, whooping cough, smallpox, chicken-pox, syphilis and mumps were all major causes of death at the turn of the 19th Century (Stocks, 1950). However, Salvarsan for the treatment of syphilis and 'Sulfa Drugs' for the treatment of pneumonia were introduced in the late 1930s. Penicillin became available after 1941. Major healthcare reform during and following the second world war resulted in the publication of the Beveridge Report in 1942, which formed the basis for the foundation of the Labour Party's National Health Service in 1948 (Abel-Smith, 1978) providing comprehensive healthcare for all ages. The free NHS was not to remain so for long, with the introduction of prescription charges to try and reduce the burden on the Health Service.

In 1948, in the UK, life expectancy at birth was 66.4 and 71.2 years for males and females respectively and the life expectancy for a 65 year old male and female was 12.8 years and 15.3 years respectively. By 1994, life expectancy at birth had increased to 74.3 and 79.6 years and life expectancy for a 65 year old had increased to 14.6 and 18.2 years for males and females respectively (Office of Health Economics, 1997).

3.3.2 The elderly as health care users

Elderly persons have a higher morbidity than younger members of the population; chronic ill health being reported by 62% of persons aged sixty five years and over, compared with only 17% and 31% of persons aged under sixteen and sixteen to sixty four year olds, respectively, in 1994 (Office of Health Economics, 1997). In 1993, 15% of the UK population of all ages consulted a

NHS general medical practitioner. This proportion was greater in the elderly population, with 20% and 21% of 65-74 year olds and ≥75 year olds respectively consulting a doctor (Office of Health Economics, 1997). Of the 45.6 million consultations with a NHS general medical practitioner in 1994, 7.9 million (17%) were by persons 65 years and older, of which 3 million were for cardiovascular conditions, 2.6 million for musculoskeletal problems and 2.1 million for central nervous system disorders (Office of Health Economics, 1997).

Expenditure on health in the UK was £1 billion in 1960, and rose to £46 billion (£41.4 billion was for NHS expenditure) in 1994. Of the £41 billion NHS expenditure, 49% was for patients aged 65 years and over. The cost of this drug therapy in 1994 was £1.5 billion pounds, which represented 44% of the total drugs expenditure of £3.4 billion in England in 1994 (Prescription Pricing Authority, 1995).

In developed countries, the elderly use more health resources than younger members of the population. Studies in the United States (Williams & Lowenthal, 1992) have calculated that individuals aged sixty five years and over account for 25 per cent of the total drug expenditure, a figure which is estimated to reach 40 per cent by the year 2030 (Williams & Lowenthal, 1992). The elderly population also account for 25-30% of all healthcare expenditure (Ouslander, 1981).

3.3.3 Drug prescribing to the elderly

3.3.3.1 In the UK

Medical problems in the elderly are managed mostly by drug therapy prescribed by their general medical practitioner in primary care. Even those individuals referred for secondary care in hospitals as outpatients have their drug therapy prescribed by general medical practitioners under the guidance of a consultant.

Analysis of prescriptions dispensed shows that, in terms of number of drugs dispensed, the elderly require relatively more than a younger population. The elderly in the UK were dispensed a mean of 22.2 prescription items per head of population in 1997 (Department of Health, 1998). This amounted to 245 million prescriptions, 49 per cent of all prescription items in 1997, an increase of 4% from 1984 (Department of Health, 1998).

Other studies in the UK have looked at more specific areas of prescribing. Of 1003 patients aged 69 years and over taking part in a longitudinal study looking at prescribing trends in Nottingham, 71% were found to be taking at least one prescribed medication in 1985, with a mean

of 1.8 drugs per patient being taken. By 1989, this proportion of elderly taking at least one medication per patient had increased to 75.2%, with a mean of 2.1 drugs per patient (Rumble & Morgan, 1994). Of the 1003 patients, the proportion taking 2 or more medicines were 49.4% and 54.4% in 1985 and 1989 respectively. These results were consistent with a study by the Consumers Association (Consumers Association, 1990) which surveyed the medication of 805 elderly persons in ten parliamentary constituencies in England and showed that 70% were prescribed at least one medicine on a long-term basis, with an average of 2.8 medicines per person. The Rumble and Morgan study (1994) also showed that with increasing age the number of drugs taken also increased (Rumble & Morgan, 1994), with patients aged 69-72 years taking a mean of 1.3 medicines each, which increased to 3 medicines per person in the 89 years and over group, in 1989 (Rumble & Morgan, 1994). There was no data for patients under the age of 69.

3.3.3.2 Worldwide

Drug prescribing to the elderly in Germany has shown a higher level of utilisation. When the drugs of 300 elderly patients aged 75 years and over attending a geriatric clinic in Heidelberg, Germany from 1984 to 1989 were examined, 94% of patients were taking one or more medicine, with a mean of 4.3 medicines per patient (Kruse *et al.*, 1991). The study showed that institutionalised patients were on a significantly higher number of medicines than non-institutionalised patients (5 medicines per person compared with 4.1). Of the 300 patients, in the study 118 (43%) were prescribed five drugs or more.

Drug utilisation research in 324 elderly patients aged 55 years and over in four nursing homes and central hospitals in urban Harare, Central Africa showed that 210 (65%) were taking at least one medicine (Nhachi *et al.*, 1994). The group were taking 1117 different medicines, with each person taking a mean of 3.4 medicines.

3.3.4 Drugs commonly used in the elderly

3.3.4.1 Introduction

Increased morbidity in the elderly accounts for large numbers of drugs taken by this group of the population. Table 3.1 shows some of the common groups of drugs dispensed in England during a one year period (1994), the number of prescriptions written and the total cost for prescribing these drugs to elderly exempt patients.

Table 3.1 Prescription Cost Analysis data for Elderly Exempt Patients in England 1994 (Prescription Pricing Authority, 1995)

BNF Section[1]	Therapeutic Group	Items Dispensed		Cost[2]	
		Millions	%	£ millions	%
01	Gastrointestinal	19	10.5	234	12.0
02	Cardiovascular	51	27.6	343	25.8
03	Respiratory	14	7.5	145	10.9
04	Central Nervous System	36	19.5	133	10.0
05	Infections	10	5.6	48	3.6
06	Endocrine	10	5.5	60	4.5
09	Nutrition/Blood	5	2.9	35	2.6
10	Musculoskeletal	12	6.2	94	7.1
	Others	27	14.6	45	23.3
	Total	**184**	**100**	**1,544**	**100**

[1]**British National Formulary No. 34 (British Medical Association & Royal Pharmaceutical Society, 1997)**

[2]**Net Ingredient Cost (the cost of drugs, excluding any other charges such as dispensing and other fees)**

3.3.4.2 Cardiovascular drugs

Table 3.1 shows that in 1994, 27.6% of all drugs prescribed to the elderly (those exempt from prescription charges) in England were drugs used in cardiovascular conditions. Other studies have also confirmed that the most prevalent conditions in the elderly are those that affect the cardiovascular system. In a study of 300 patients in Germany (Kruse *et al.*, 1991), 276 were taking 782 drugs, with 28.5% of these drugs being cardiovascular medicines. In the study looking at medication use in the four nursing homes and central hospitals in urban Harare, Central Africa, over 20% of the drugs used were for cardiovascular medicines, of which hydrochlorothiazide and frusemide were the most common (Nhachi *et al.*, 1994). Of the 1409 drugs highlighted as being used by patients 65 years and over in a UK longitudinal study (Rumble & Morgan, 1994), 30.4% were for cardiovascular medicines.

Diuretics and beta-adrenoceptor blocking drugs (B-blockers) are commonly used as first line drugs in the treatment of hypertension (Beard *et al.*, 1992) and these groups of drugs along with vasodilators (nitrates, calcium channel blockers) were the three most commonly dispensed sub-groups of cardiovascular drugs dispensed to elderly exempt patients in 1994 (Prescription Pricing Authority, 1995).

3.3.4.3 Central nervous system (CNS) drugs

Central Nervous System drugs, particularly hypnotics, anxiolytics and analgesics, account for the second major area of drug use in the elderly, with 19.7 per cent of all drugs dispensed in

England, in 1994, having effects in this therapeutic area (Prescription Pricing Authority, 1995). The longitudinal study in Nottingham also highlighted Central Nervous System medicines as commonly used by the elderly, with 29.1% of 1409 drugs being for CNS medicines (Rumble & Morgan, 1994). CNS medicines were also widely used by the elderly in the study undertaken in urban Harare, Central Africa (Nhachi *et al.*, 1994).

Hypnotics, particularly benzodiazepines have formed a traditional drug therapy for insomnia, a clinical problem commonly found in the elderly as average sleep time decreases with age (Mulligan & Sobel, 1994). In 1971, a total of 41.7 million items were written for hypnotics for all ages (Conrad, 1982). However with concerns over physical and psychological drug dependency, there has been a decrease in hypnotic use over recent years. Hypnotics currently represent approximately 23% of all CNS drugs dispensed to the elderly in England 1994 (Prescription Pricing Authority, 1995).

Depression, a psychiatric disorder which is diagnosed fairly commonly in the elderly (World Health Organisation, 1985) is managed with antidepressants which represent approximately 12% of CNS prescription items dispensed to the elderly in the UK. Traditional treatments include tricyclic antidepressant drugs (e.g. amitriptyline, imipramine, nortriptyline and clomipramine). However their use in the elderly is limited to some extent by the large number of side effects associated with their use including xerostomia (Bertram *et al.*, 1979; Peters, 1989). Older antidepressants have now been replaced by newer, more selective drugs which have fewer side effects associated with them. These drugs are referred to as SSRIs and are now commonly used in the elderly (Mulligan & Sobel, 1994).

Analgesics were another area of common use by the elderly, with almost 45% (16 million items) being dispensed to the elderly in 1994, in England (Prescription Pricing Authority, 1995). The analgesics prescribed ranged from minor analgesics such as paracetamol, to stronger opoid pain killers such as morphine based products.

3.3.4.4 Drugs used in musculoskeletal and joint disorders

Musculoskeletal complaints are common in the elderly and were responsible for approximately one third of all GP consultations in patients over 65 years of age in the UK (Nuki, 1990). Non-steroidal anti-inflammatory drugs (NSAIDs) are the first line treatment for rheumatic and muscular pain. NSAIDs represent around 5% of all prescriptions written in the UK, with 50% of the patients using these drugs aged 60 years or over (Goorah & Wynne, 1995). Aspirin

was the original and most commonly used NSAID, but its use has been superseded by newer products such as ibuprofen and naproxen, which are associated with fewer side effects. Currently, there are approximately fourteen different NSAIDs on the market (British Medical Association & Royal Pharmaceutical Society, 1997). Major variations in the therapeutic response of these drugs between patients often necessitate medication with different types before the most suitable formulation is found (Lamy, 1988)

3.3.4.5 Respiratory drugs

Respiratory problems tend to increase during ageing and as Table 3.1 shows, respiratory medicines accounted for 7.5% of all prescription items dispensed to elderly exempt patients in 1994 (Prescription Pricing Authority, 1995). Drugs are a common adjunct to other therapies, such as oxygen and physiotherapy in the treatment of congestive obstructive airways disease such as bronchitis and emphysema. Bronchodilators such as salbutamol and terbutaline which are taken for wheezing and cough, are the most common respiratory drugs used, accounting for over 50% of all respiratory drugs (Prescription Pricing Authority, 1995). Steroidal products such as beclomethasone and budesonide (inhaled) and prednisolone (oral) are also used in moderate to severe respiratory disease.

Drug utilisation studies which have been carried out have concentrated on the analysis of a particular medicine or medicines within a particular therapeutic area or cohort of the population rather than considering the dose form used. With regard to medicines taken orally, no studies have analysed drug utilisation by dose form.

3.3.5 Problems with drug use in the elderly

3.3.5.1 Polypharmacy and adverse drug reactions (ADRs)

Elderly persons suffer from more medical conditions than younger and take a wide range of drugs to alleviate these problems (Stewart & Cooper, 1994). The term 'polypharmacy' describes the co-administration of two or more drugs. As the number of drugs taken by the patient increases, so do the possibility of drug-drug interactions, where one drug may modify the action of, or have its actions modified by, another drug. These modifications may result in toxicity or under-dosing and the outcome of such an interaction may result in an adverse drug reaction (ADR). Although drug-drug interactions can happen in any patient, they are of particular concern in the elderly as they take large numbers of medicines and may be frail. Stewart and Cooper (Stewart & Cooper, 1994) reviewed the results of several studies of multiple drug regimes, and

concluded that as the number of medications increased, the potential for interactions between drugs increased. They described studies where the use of combinations of prescribed and OTC medicines ranged from 3.1 to 7.9 drugs per person and showed that the use of these drugs was often inappropriate, with 72.8% of all drug reactions being caused by the use of drugs which were unnecessary for that patient in the first place.

In another review of adverse drug reactions in the elderly (Walker & Wynne, 1994), the authors estimated a prevalence of between 1.5% to 35% in hospitalised patients (Walker & Wynne, 1994). Williamson and Chopin (Williamson & Chopin, 1980) monitored 1998 patients admitted to 42 geriatric medical units in the UK and reported adverse drug reactions in 248 (12.4%) of them at the time of admission. In 209 of these elderly patients the ADR was thought to have contributed to the admission. The use of NSAIDs is common in the elderly, with over 50% of all NSAID users being 60 years and over (Goorah & Wynne, 1995). These drugs were responsible for 25% of all ADRs reported and were highlighted as a particular risk to elderly patients.

The problems of inappropriate prescribing have been further highlighted by practice pharmacists who have been employed primarily to reduce practice costs, but now have a role in rationalising prescribing.

3.3.5.2 Patient compliance problems in the elderly

Some 2500 years ago, Hippocrates said "patients often lie when they state they have taken a certain medicament". The problem of patients taking their medicines is one that has a number of implications, not only for their healthcare and financial costs to the NHS, but also to drug utilisation studies. Information on drug use obtained through prescription analysis relates to what is prescribed or dispensed to the patient. However what proportion of this quantity is actually consumed by the patient is less clear. A recent working party set up by the Royal Pharmaceutical Society of Great Britain has suggested that as many as 50% of patients identified in studies of compliance may not be taking their medication (Royal Pharmaceutical Society of Great Britain, 1997).

Other studies have determined non-compliance rates to be as high as 40% to 75%, with non-compliance being higher in females than males (Salzman, 1995). Salzman *et al* (1995) suggested that possible reasons for such high non-compliance could be the large number of medicines used

by the elderly, forgetfulness and confusion, and intentional non-compliance to avoid the side-effects resulting from the use of particular medicines (Salzman, 1995).

A review of non-compliance by Gillum *et al* (Gillum & Barsky, 1974) reported that a third of patients failed to comply with doctors orders, with 50% of patients reporting non-compliance. The proportion of patients who did not follow advice for six types of medicines, in 68 studies ranged from 37.5% to 54.6% (Stahelin, 1982). However, a study looking at 156 patients aged 70 years and over who were hospitalised with congestive heart failure, in Washington, USA, showed that intervention and patient counselling improved compliance in the elderly (Rich *et al.*, 1996).

A survey looking at prescriptions written over three months from a health centre in Tayside, Scotland found that 14% of the 4854 patients who were issued a prescription were not redeeming it at a pharmacy (Beardon *et al.*, 1993). Of the 1638 elderly patients in this study, 10% failed to redeem their prescription.

Compliance with a medication regime is an important issue as non-compliance will lead to under-dosing and possible ill health as the patient is not receiving effective medication. Other issues such as cost are also important as the patient may be 'hoarding' medicines. Non-compliance has been recognised as a major issue by the Royal Pharmaceutical Society of Great Britain, who recently published a report ('From compliance to concordance'), in which they recommended that medication taking should take a partnership approach between the general medical practitioner and the patient (Royal Pharmaceutical Society of Great Britain, 1997).

3.4 THE ORAL HEALTH OF THE ELDERLY

3.4.1 Introduction

Over fifty years ago it was common for an elderly person to have no natural teeth, however, with major improvements in dental care and preventative dental policies most aspects of the oral health of this group of the population have improved dramatically. A number of studies have observed a positive relationship between oral and general health amongst elderly people (Agerberg & Carlsson, 1981; Mattsson *et al.*, 1990; Osterberg *et al.*, 1984) and the maintenance of dental health in the elderly is important in the maintenance of good quality of life in the elderly population.

3.4.2 Dental caries

National adult dental health surveys have been carried out in the UK every 10 years since 1968 and have documented the improvements in dental health over the last 30 years (Todd & Lader, 1991; Todd & Walker, 1980; Todd *et al.*, 1982). This trend has been seen in all age groups. In the 1988 survey, the elderly had a mean of 0.7 decayed teeth, compared with a mean for all ages of 0.2. More recently, a study (Steele *et al.*, 1996) of 2280 subjects aged 60 to 64 years undertaken in three areas of England (Richmondshire, Darlington and Salisbury), showed that elderly in Richmondshire, Darlington and Salisbury had a mean of 0.8, 1.0 and 0.8 mean decayed teeth respectively.

3.4.3 Periodontal disease

Periodontal disease is a chronic disease characterised by gingival inflammation which can result in destruction of the periodontal connective tissue (Hugoson & Jordan, 1982). It is primarily a disease of adulthood; the 1988 national UK dental health survey (Todd & Lader, 1991) reported higher levels of periodontal disease in the older age groups with 16% of individuals aged 65 years having one or more periodontal deep pockets (>6mm). The proportion of elderly patients aged 55 and over with some periodontal disease was 96% in 1978 and had risen slightly to 97% in 1988 (Todd & Lader, 1991; Todd *et al.*, 1982). The 1968 dental health survey did not give information on periodontal disease (Todd & Walker, 1980).

In Sweden, 600 individuals were assessed for severity of periodontal disease in 1973, which was compared to a similar cohort of 597 persons in 1983 (Hugoson *et al.*, 1992). The study showed that in 1973 younger members of the group (20 to 50 years) had more mild to moderate periodontal disease than 60 year and 70 year olds, where only 12% and 4% respectively were affected. In 1973 moderately severe periodontal disease affected only 2% of the sample and 3% and 6% of those aged 60 years and 70 years respectively, which had increased to 26% and 38% of these age groups respectively, in 1983.

A US survey looking at a sample of 14,690 dentate Americans aged 15 to 74 years reported an increase in periodontal disease with age (Abdellatif & Burt, 1987). The highest percentage of persons with periodontitis was in the 55 to 59 year age group. Of those aged between 60 and 69 years, almost 17% had periodontitis, the prevalence in the 70 years and over, was lower at 13.4%,

which was due to a higher rate of edentulousness in the older group. The authors concluded that where oral hygiene was poor the incidence of the disease was higher.

3.4.4 Tooth wear

Tooth wear describes the three processes of attrition, abrasion and erosion (Nunn *et al.*, 1996). Attrition is the loss of tooth substance caused by contact between teeth which occurs during normal functions. Abrasion is the progressive loss of tissue caused by mechanical factors other than tooth-tooth interactions (e.g. tooth-brushing and chewing). Erosion is the chemical dissolution of tooth enamel and dentine. Its aetiology may be intrinsic (e.g. due to acid regurgitation) or extrinsic (e.g. due to dietary factors) (Donachie & Walls, 1996).

Dental erosion is common with acidic drinks, particularly carbonated soft drinks which are now very widely available, although their use tends to be more prevalent in the younger population (Milosevic, 1993). There has been an increase in the consumption of such drinks by 700% since the 1950s (Nunn *et al.*, 1996). There is very little literature on dental erosion associated with the use of acidic medicines, however, it would appear that such medicines could adversely affect tooth wear. A report on a case study linked dental erosion to the use of chewable vitamin C tablets (Giunta, 1983) and a study looking at 42 children with Juvenile Rheumatoid Arthritis (Sullivan & Kramer, 1983) which compared 25 children taking chewable aspirin with 12 children taking swallowed aspirin only found tooth erosion in those children that were taking the chewable tablets and concluded that the erosion was due to the topical effect of the medicine.

3.4.4.1 Tooth wear in the elderly

As tooth wear is an irreversible process and cumulative, older adults have more wear than younger members of the population. In the Adult Dental Health Survey of 1988 (Todd & Lader, 1991) an investigation of root surfaces showed that there were 0.8 worn teeth per person. However there were major age differences, with persons aged 65 years having an average of 2.4 worn teeth whilst the mean for the youngest group was only 0.1 worn teeth.

Hugoson et al (Hugoson *et al.*, 1992) studied a population of 20 to 80 year olds in 1983 and studied incisal and occlusal wear. They concluded that with increasing age there was an increase in the number of teeth with incisal or occlusal wear, with 77% of 60, 70 and 80 year olds affected, compared with 65% of 20 year olds. There was extensive occlusal wear in the group aged 60 years and over.

In a study of 148 subjects composed of three ethnic groups in Northern Borneo (Milosevic, 1993), with 32% each of Chinese and Malay and 36% of Kadazan groups, 95% of all subjects showed tooth wear, with 41% showing severe tooth wear. The rate of tooth wear in Kadazan was accounted for by a more frequent use of chewable tablets.

3.4.5 Edentulousness

3.4.5.1 In the UK

Edentulousness or the complete absence of teeth becomes more prevalent with ageing as natural teeth are lost due to dental caries or periodontal disease. The national dental surveys undertaken in the UK since 1968 have shown a steady decrease in the prevalence of edentulousness in the UK adult population, but with regional differences for both young and older adults.

The national dental health survey undertaken in the UK in 1978 reported that 30% of adults aged 16 years and over had no natural teeth (Todd *et al.*, 1982), with 28% of adults in England as a whole and 35% in the North and North East of England having no natural teeth. Of the elderly population (65 years and over) in the UK, England and the North and North East of England, 79%, 78% and 88% respectively were edentulous. The national survey also took into account the differences in rates of edentulousness between the North and South of England; 80% of the elderly (aged 65 years and over) in the North of England in 1988 were edentulous, compared with only 57% in the south.

The most recent national dental health survey in the UK, was undertaken in 1988. This showed a further reduction in the number of edentulous adults and especially edentulous elderly. From 1978 to 1988 the number of adults in the UK with no natural teeth fell from 30% to 21%. There was a significant decrease in the number of edentulous elderly (aged 65 years and over), with 67% having no natural teeth in 1988, compared with 79% in 1978 (Todd & Lader, 1991).

A more recent study under taken in three English communities of Richmondshire, Darlington and Salisbury showed that of the 2280 subjects aged 60 years and over sampled, 47% (1069) were edentulous (Steele *et al.*, 1998). The study also showed that edentulousness was higher in the North of England compared to the South, with 39%, 55% and 76% of the three elderly groups (aged 60-64y, 65-74y and ≥75y) in Darlington being edentulous compared with 15%, 32% and 47% in Salisbury.

3.4.5.2 Worldwide

Studies which have looked at the dental health of the elderly in terms of edentulousness have mainly been confined to developed countries. An oral health review of individuals aged 3 to 70 years in Jonkoping, Sweden in 1973 (n = 1000), 1983 (n = 1024) and 1993 (n = 1007) showed that only persons aged 40 years and over were edentulous in 1973, 50 years and over in 1983 and 60 years and over in 1993 (Hugoson *et al.*, 1995). Of the adults aged 60 years and 70 years in 1973 (n = 200), 1983 (n = 197) and 1993 (n = 192) 28%, 22% and 16% respectively, were edentulous.

Tooth loss and edentulousness was investigated in institutionalised elderly in four nursing homes in Naples, Italy (Angelillo *et al.*, 1990). Of the 234 individuals aged 65 years and over, in the study, 140 (60%) were edentulous.

Weintraub *et al* (Weintraub & Burt, 1985) reported on 7 studies conducted in the USA from 1957 to 1980 and showed that over time the proportion of edentulousness in the 65 to 74 year age group had fallen from 55.4% in 1957-58 to 33.8% in 1980. A more recent study which determined the prevalence of edentulousness in the elderly in the USA was the New England Elders Dental Study. This was undertaken to assess the dental health of non-institutionalised elders aged 70 years and over, living in six states of New England. Of the 1151 persons in the survey 433 (38%) were found to be edentulous (Douglass *et al.*, 1993).

Progressive diseases like periodontal disease and untreated dental and root caries result in irreversible dental damage, often leading to tooth loss. However in recent decades, as the national dental health survey in the UK and surveys in other developed countries, such as the USA, have shown, the dental health of the elderly has improved, the prevalence of edentulousness in the elderly has reduced and this trend continues.

A table of surveys showing the prevalence of edentulousness both in the UK and worldwide shows a range from 16% to 78% in the elderly (Table 3.2).

Table 3.2 Surveys showing the prevalence of edentulousness in the UK and worldwide

Area of Survey	n	Age group	no. edentulous (%)	Reference
United Kingdom	574	≥65y	574 (65%)	(Downer, 1991)
Richmondshire, Darlington & Salisbury, UK	2280	≥60y	1069 (47%)	(Steele *et al.*, 1996)
West Essex, UK	414	Male ≥65y & Female ≥60y	323 (78%)	(Tobias, 1988)
Oslo, Norway	371	≥67y	202 (55%)	(Ambjornsen, 1986)
Naples, Italy	234	≥65y	140 (60%)	(Angelillo *et al.*, 1990)
New England, USA	2057	≥70y	782 (38%)	(Douglass *et al.*, 1993)
Jonkoping, Sweden	192	60y to 79y	93 (16%)	(Hugoson *et al.*, 1995)

3.4.6 Nutrition and oral health in the elderly

Nutrition, amongst other biological factors may play a role in ageing. As well as having a role in health and fitness, nutrition may also contribute to the development and progression of degenerative diseases that are associated with ageing (Munro, 1981). As nutrition has such a major role in health, the appropriate management of health problems should take into account the links between health, nutrition and ageing (Watkins, 1978).

Nutritional status has a direct effect upon general and oral health in individuals of all ages. In addition, nutrition has an important and complex relationship with dental health. In particular, food consumed by the elderly may adversely affect their dental health or conversely oral health problems may force the elderly to adversely change their eating habits.

There is evidence that nutritional deficiency at an early stage in life may affect health later in life (Schlenker *et al.*, 1973). Screening for dietary deficiencies in the elderly in the USA has been taking place for many years (Kuczmarski *et al.*, 1994), with the US Department of Agriculture funding food composition records compiled in 1892 and the national dietary surveys of the 1930s. A number of studies have suggested that the elderly may have a poorer nutritional state than younger individuals (Beveridge *et al.*, 1965; Blass, 1980; Brown *et al.*, 1977; Grandjean *et al.*, 1981; Posner *et al.*, 1993; Stiedemann *et al.*, 1978). A number of dietary nutrients have been identified as being below the standard recommended levels in the elderly. These include vitamin A, thiamin, riboflavin, iron, calcium and pyridoxine, which are all associated with a lower mean caloric intake.

A survey carried out in Great Britain during 1994-95 on behalf of the Ministry of Agriculture, Fisheries and Food of diet and nutrition in the elderly aged 65 years and over (Finch *et al.*, 1998), studied two groups of elderly individuals, one free-living and one institutionalised. Intake of vitamins A, B6, B12, C and E were well above the reference levels for the majority of subjects, however lower levels of vitamin D were consumed. Analysis of the data from this study by Steele *et al* (Steele *et al.*, 1998) found that for the free-living sample there were differences between edentate and dentate groups, with fewer of the edentate eating certain foods such as apples, compared with the dentate group. The authors reported that there were more dietary restrictions for institutionalised elderly with some foods such as nuts and raw carrots not being eaten at all.

Factors that may influence nutritional state in the elderly include lower physiologic functions (Masoro, 1976), as well as alterations in olfactory and taste thresholds (Cohen & Gitman, 1967; Schlenker *et al.*, 1973), which may affect appetite. Oral problems such as xerostomia, sore gums, loose teeth, dental pain may also affect nutritional intake. Regional differences also have their impact upon diet and nutritional status in the elderly. The study by Finch *et al* (Finch *et al.*, 1998) on diet and nutrition showed the average intake of vitamins to be higher in London and the South East than in Scotland and the North of England.

Tooth loss may be of concern as it can interfere with foodstuffs the edentate elderly population may be consuming. Moynihan (Moynihan, 1995) reviewed the relationship between tooth loss, diet and nutritional status found that the elderly have a lower masticatory ability and as a result digestion was impaired. This problem was increased if the patient was edentate. The review highlighted edentate people as being unable to digest hard fibrous foods such as fruit, raw vegetables, meat and cheese, having instead to rely on soft foods such as porridge. Lack of high fibre foodstuffs has health implications; restriction of fibre in the diet may lead to constipation and possibly higher cholesterol levels.

Nutrition has a major role in the ageing process and is an important component of health care in the elderly, due to the important relationship between diet, ageing and health.

3.4.7 Saliva and oral health

3.4.7.1 Introduction

In the 16th century, salivary glands were thought to have a sieve-like role in straining of excrementous substances from the blood, such as 'emunctories' (bad spirits of the brain) (Garrett, 1975). It was common for physicians to administer substances such as mercurous chloride to increase saliva production and cleanse the system (Mandel, 1987). Ancient judicial systems also used saliva as a early version of the lie detector; the accused was given some rice and if they could not form a bolus as a result of inhibition of saliva secretion (due to fear or guilt?) then 'off with his head'. It was not until 1856 and the publication of 'Adenographia' by Thomas Wharton that the concept of salivary secretion was born. It is now understood that saliva has two basic roles: to digest food and protect the mouth (Mandel, 1987).

3.4.7.2 Formation and function of saliva

Saliva is produced from three major glands: the submandibular, sublingual and parotid, along with contributions from other minor glands (Levine, 1989). Its secretion is controlled by a complex supply of nerves to the glands (Whelton, 1996).

The protective function of saliva is the result of a number of mechanisms. Salivary mucins have low solubility, high viscosity, high elasticity and adhesiveness (Tabak *et al.*, 1982), which allows saliva to concentrate on the oral mucosal surfaces and offer protection against environmental insult. Mucin glycoproteins produce a high strength film which coats areas of the mouth (Mandel, 1987), however strong acids such as aspirin can destroy this layer and cause damage to the epithelial cells below (Levine, 1989). Salivary mucins are also involved in the control of the permeability of mucosal surfaces, limiting the penetration of potential irritants and toxins in foods and beverages (Tabak *et al.*, 1982).

Saliva exerts a direct bactericidal effect (Bowen, 1996), through salivary proteins such as lysozyme, lactoferrin, and lactoperoxidase which interfere with bacterial growth or kill the bacterial cells directly. The histidine-rich peptide of parotid saliva has been shown to have inhibitory and bactericidal effects (MacKay *et al.*, 1984). It also has been shown that hypothiocyanate ions produced from salivary thiocyanate by an oxidation process will inhibit plaque acid production (Tenovuo *et al.*, 1981).

Another major protective role of saliva is the maintenance of salivary pH at a normal resting level of between 6 and 7 (Edgar & Higham, 1996). This is important for the protection of the enamel and dentine of teeth from the demineralising effects of acid produced by the metabolism of fermentable carbohydrates by bacteria, which is achieved through a series of buffer systems. These are primarily bicarbonate, calcium and phosphate buffering systems. In stimulated saliva the bicarbonate ion is the most important buffer and is responsible for about 80% of saliva buffering capacity (Helm *et al.*, 1982). At rest, the levels of bicarbonate are low and the buffering action is mainly from histidine-rich peptides and phosphates (Edgar & Higham, 1996).

3.4.7.3 Saliva and oral clearance

"Clearance" in terms of pharmacokinetics describes the removal of drugs from the body, usually through the hepatic or renal systems. The term "oral clearance" is used to describe the removal of substances from the oral cavity following intake. This is important in terms of assessment of risk to the teeth from foods and drinks which may contain sugars and other substances detrimental to dental health. It also helps to explain some of the susceptibility to disease amongst individuals. A high salivary concentration of sucrose and long periods of retention in the oral cavity will increase the risk of dental caries therefore it is important that fermentable carbohydrates are removed or 'cleared' from the oral cavity as quickly as possible. Some studies comparing the prevalence of dental caries to rates of oral clearance of fermentable carbohydrates have produced equivocal results with both positive (Adorjan & Stack, 1976; Miura *et al.*, 1991) and negative (Keene *et al.*, 1966) correlations described. However, it is clear that a rapid salivary clearance of harmful substances such as sucrose or acids is beneficial for oral health (Dawes, 1996).

There are three main factors which determine oral clearance; firstly, oral sensory and motor function and co-ordination which is directly affected by the number of natural teeth in the mouth and the wearing of dentures. Secondly, the rate and efficiency of swallowing and thirdly, salivary secretion rates.

Oral clearance has been investigated in a number of *in vivo* studies in elderly individuals. The oral distribution of ingested sucrose was investigated in 10 subjects and it was found that the concentration of sucrose in saliva in different regions of the mouth varied (MacPherson & Dawes, 1993). The lowest concentration of sucrose was found to be on lingual surfaces where

submandibular saliva enters the mouth suggesting that a high salivary flow increases sucrose clearance, reducing contact time with plaque and reducing the risk of dental caries.

Dawes (Dawes, 1983) used a mathematical model to show that oral clearance was affected by unstimulated salivary flow rate and the volumes of saliva in the mouth immediately before and after swallowing. In a later study in 1987 Dawes (Dawes, 1987) suggested that lower volumes of saliva would result in faster clearance of sugar and a lower salivary flow rate would result in an increased clearance time. The paper also discussed results from several studies which looked at unstimulated flow rate and found that this ranged from 0.04ml/min to 0.39ml/min, and stimulated flow rate, which ranged from 0.52ml/min to 4.55ml/min. Results from these studies did not show any age-related change in flow rate, suggesting that the elderly have normal flow rates. However, a survey of secretion rates of saliva in 629 adults found an age related decrease in saliva secretion, but only in women, with females aged 64 to 74 years having the lowest unstimulated (0.2ml/min) and stimulated (1.2ml/min) salivary flow rates (Heintze *et al.*, 1983). The authors suggested that this may be due to post-menopausal changes in females (Heintze *et al.*, 1983). This finding was supported by Osterberg *et al* (1984), who reported a significantly lower unstimulated secretion of saliva in women aged 70 years of age (Osterberg *et al.*, 1984).

A study looking at glucose clearance in the elderly (Hase *et al.*, 1987), compared the clearance of glucose between hospitalised and non-hospitalised elderly. In total there were 54 persons, all aged over 75 years in the study, which showed all elderly had a slow salivary glucose clearance, but this was more pronounced in the hospitalised elderly. This was thought to be due to the reduced salivary flow rates found in the elderly, often due to consumption of xerogenic medicines (see Section 3.4.7.4) (Osterberg *et al.*, 1984), resulting in prolonged oral clearance times. The authors also found a relationship between edentulousness and flow rate, with the edentate having reduced flow rates, which could account for lower flow rates seen in some elderly.

Fermentable carbohydrates in liquids clear faster than solids (Edgar *et al.*, 1975), with carbohydrates from drinks, fresh fruit and vegetables being cleared quickly, compared with carbohydrates in wheat grain and bread products, with the slowest clearance being from sticky sweets, chewing gum and chocolate (Swenander, 1957). Clearance from plaque is dependent upon the velocity of the salivary film, with a reduced salivary film flow rate resulting in reduced clearance (Collins & Dawes, 1987). Also oral clearance is site specific with the slowest clearance being from the maxillary anterior spaces, intermediate clearance occurring from the maxillary

posterior region and the fastest clearance from the mandibular anterior spaces (Nevin & Walsh, 1951).

Individual factors may also affect the rate of oral clearance, with much variability between individuals shown for salivary flow rate (Volker & Pinkerton, 1947). There have been contradictory findings shown for the relationship between salivary flow rate and rate of sugar clearance; with one study showing a positive correlation (Britse & Lagerlof, 1987) and another showing no statistical difference (Swenander, 1957).

The literature on saliva and oral clearance has shown that the elderly generally have normal salivary flow, however due to the large number of elderly being medically compromised and potentially taking xerogenic medicines, they may have reduced salivary flow and a reduced rate of clearance, which can increase the risk of dental caries for the dentate elderly.

A reduced rate of oral clearance has implications for foodstuffs and medicines that remain in the oral cavity for longer periods of time. Examples of such medicines with prolonged oral clearance would include liquid oral medicines, pastilles, lozenges, chewable, buccal and sublingual tables. If, as some surveys have shown, the elderly have a reduced oral clearance of sucrose, then any sucrose-containing medicines taken by this group of individuals, which due to their dose form are retained in the mouth rather than immediately and completely swallowed, may increase their risk of dental caries. Medicines with prolonged oral clearance will be discussed in section 3.5.4.

3.4.7.4 Xerostomia

Absence of saliva is referred to as xerostomia which presents as a dryness of the mouth, sometimes associated with a burning sensation.

Many prescription and over-the-counter drugs can cause a reduction in saliva production by affecting the autonomic nervous systems and increasing sympathiomimetic tone leading to reduced saliva production. These drugs include analgesics, anti-cholinergic and anti-spasmodic agents, anti-diarrhoeals, anti-histamines, anti-hypertensives (Sreenby, 1996). The cholinergic nervous system is responsible for regulating the internal environment of the body during periods of rest and energy conservation, via pathways of the autonomic nervous system. This system is to some extent affected by the ageing process as a decrease in organ mass results in a decrease in the number of receptors. Age-related changes in the cholinergic system may contribute to functional

decline, with drugs that block the cholinergic system (anticholinergic drugs) producing further negative effects (Feinberg, 1993).

A review of anticholinergic effects of medications in the elderly reported that xerostomia was a common complaint (Peters, 1989). Lewis *et al* (Lewis *et al.*, 1993) showed of the 4163 subjects in their study, 56% were taking at least one type of medication that caused xerostomia.

Drugs with anticholinergic effects are used for a range of clinical disorders such as irritable bowel syndrome (Colofac), urinary incontinence (hyoscine hydrobromide), motion sickness (Stugeron) and Parkinson's disease (procyclidine). Some of these drugs with anticholinergic side effects are listed in Table 3.3 (Feinberg, 1993).

A group of 40 dentate elderly subjects aged between 61 and 98 years from nursing homes were divided into those taking medicines with anticholinergic effects and those not taking any medication (Perrson *et al.*, 1991). Of these 40 patients, two used no medications and 8 used no medication with xerostomic effects. The remaining 30 patients all used medicines which may cause xerostomic effects and there was significant decrease in the flow rate of stimulated whole saliva in this group compared with the controls (0.94ml/min vs 1.52ml/min).

Table 3.3 Common drugs with anticholinergic effects (Feinberg, 1993)

Therapeutic group	Example
Anti-parkinsonian	Benzatropine, procyclidine
Cycloplegics	Atropine, cyclopentolate, homatropine
Antidepressants	Amitriptyline, amoxapine, clomipramine, doxepin
Antihistamine	Brompheniramine, clemastine, hydroxyzine
Antiemetic	Cyclizine, scopoloamine, meclozine
Antispasmodic	Propantheline, dicycyclomine, oxybutynin
Antiarrhythmics	Disopyramide, quinidine, procainamide
Antidiarrhoeals	Diphenoxylate
Antipsychotics	Chlorpromazine, clozapine, haloperidol

Saliva secretion following therapy with other drugs known to cause xerostomia has been well documented. Bertram *et al* (1979) examined 8 patients undergoing antidepressant therapy with nortriptyline for 7 weeks, which included a 2 week blind placebo period (Bertram *et al.*, 1979). They concluded that the antidepressant caused a reversible reduction in saliva secretion. Long-term use of the antidepressant Maprotiline caused inhibition of salivary secretion rate, in a study of 10 healthy volunteers (Mornstad *et al.*, 1986).

The problem of xerostomia in the elderly appears to be extrinsic in aetiology, as most healthy elderly have normal saliva secretion rates, although there is some evidence that menopausal females may have a reduced rate of secretion. Osterberg *et al* (Osterberg *et al.*, 1984) reported that 30 per cent of women and 33 per cent of men had low unstimulated saliva secretion rates, and that a reduction in the number of teeth resulted in low stimulated saliva secretion. They noted that elderly people often complain of mouth dryness, however it was unclear whether this reduction in saliva was due to age or was a result of other medical conditions or certain drug therapy, such as the use of tricyclic antidepressants (Bertram *et al.*, 1979). A dry mouth, whether drug-induced, disease or age related, in combination with poor chewing function can lead to high levels of periodontal disease and a high incidence of dental caries when associated with a high intake of carbohydrate foods and medicines.

3.4.8 Attitudes to oral health in old age

Older people have difficulty in changing attitudes that have been forged over many years. For many elderly, especially those aged over 75 years, dental care as a child would have been a luxury and only sought due to reasons such as pain. In most cases a tooth would be removed rather than saved (Ettinger, 1992).

A survey in Belfast investigated the attitudes to dental health of 81 adults aged 30 years and over (Keogh & Linden, 1991). Adults from a higher socioeconomic class had better knowledge and a more positive attitude to dental health, than those in a lower socioeconomic group.

A survey of attitudes in Hong Kong of 398 middle aged (35-44 years) and 559 elderly (65-74 years) individuals was undertaken by Lo and Schwarz in 1991 (Lo & Schwarz, 1994) and of the 559 elderly in the study, 253 had not seen a dentist in the previous three years, and 80% said that they felt they had no dental problems. The majority (59%) said they would contact a dentist if they had toothache. This attitude was also found in a study by Steele *et al* (1996), who found in their survey of three areas of England, involving 2280 subjects aged 60 years and over, that between 19% and 28% were dental non-attenders (Steele *et al.*, 1996). Reasons for not attending included the belief that they did not need to attend (over 54% in all three areas), dislike or fear of treatment (22% to 37% in the three areas) and the feeling that they 'couldn't be bothered' (12% to 25% in the three areas).

A survey of dentists attitudes towards the elderly was undertaken in 332 dental practices in Washington, USA (Kiyak *et al.*, 1982). The authors reported that in general dentists have an

inaccurate perception of the elderly. The study also found that dentists who had been practicing longer had better attitudes towards the elderly. The attitudes of dental students in clinical and non-clinical years varied, with those in the clinical years having more positive attitudes than their non-clinical colleagues (Devlin *et al.*, 1994).

3.5 SUGARS AND MEDICINES WITH PROLONGED ORAL CLEARANCE

3.5.1 Introduction

It has been shown in previous studies that the elderly are prescribed large quantities of medicines. This section will consider the impact of sugars in the diet and the implications of this for those patients requiring long-term medication.

3.5.2 Sugars in the diet

3.5.2.1 Introduction

Sugar plays an important role in the western diet today, however its history can be traced back thousands of years, with early sources of sugar reported to have come from sugar cane which was thought to originate in Asia (Nevins, 1995). This was brought to the west via Africa and onto Europe, where there was a great demand. In the 18th Century sugar beet rather than cane was introduced in Germany as a source of sugar, which was beneficial for western countries as beet was able to thrive in more temperate climates, allowing European countries to reduce their dependency on the tropical countries for sugar (Nevins, 1995).

Carbohydrates are a source of energy required by humans and animals for metabolism, and they are found in certain food groups e.g. cereals, pasta and rice (Nevins, 1995). Sugar is a major source of refined carbohydrates and is easily broken down by plaque bacteria to acid, which will lower the plaque and salivary pH and predispose the tooth to dental caries (Thylstrup & Fejerskov, 1986). The drop in the pH is dependent upon factors such as frequency of intake of sugar, which is more important in terms of risk of dental caries than the amount of sugar ingested (Holloway & Ryan, 1983).

3.5.2.2 Sugars and dental caries

Sugar as an aetiological factor in dental caries prevalence has been extensively researched (Burt *et al.*, 1988; Catalanotto *et al.*, 1979; Rugg-Gunn & Edgar, 1984; Woodward & Walker, 1994). This review will briefly look at some of the evidence.

Comparisons of skulls from ancient burial sites in England with present day caries prevalence have shown fewer cavities due to dental caries in ancient skulls (Holloway & Edgar, 1983). Dental caries only became recognised as a disease process around the 17th century, which coincided with the establishment of the New World sugar industry. At this time the annual consumption of sugar had risen from nil to approximately 10lb per head of the English population per year (Holloway & Edgar, 1983).

More scientific evidence has come from reviews of the literature (Holloway & Drucker, 1983; Holloway & Edgar, 1983; Holloway & J.H.Shaw, 1983; Holloway & Moore, 1983; Holloway & Ryan, 1983; Rugg-Gunn & Edgar, 1984). These researchers have looked at evidence from world-wide epidemiological studies, war-time diet studies, human clinical trials, laboratory experiments and animal studies. They also looked at studies of groups of people on special diets, such as low sugar diets for diabetics and studies of people with high sugar diets (e.g. workers in the confectionery industry). Their conclusions were that sugar is the most important dietary item in caries aetiology, and as the availability of sugar increases in a country or community, its concentration in foodstuffs increases. However, the frequency of sugar intake is more important than the amount ingested overall. This has a number of implications in terms of dental health education and the dental health messages for maintenance of a healthy mouth and prevention of dental caries.

Many of the studies looking at sugars intake and dental health have been undertaken in children and there is little published literature on the elderly. In a three year longitudinal study (1982 to 1985) carried out in a group of school children aged 11 to 15 years from two American communities in Quincy and Michigan (Burt *et al.*, 1988), 499 children were interviewed and received baseline and three-year dental examinations. Of these children, 22.2% were caries free at the baseline examination. Comparison of the children whose sugar intake was low with those whose sugar intake was high showed that there was three-fold increase in the increment of approximal caries in the low sugar intake group compared with the high sugar intake group. The dmfs (decayed, missing and filled primary tooth surfaces) increment on approximal surfaces was 0.19 in the low sugar intake group compared with 0.65 in the high sugar intake group. In a survey of 328 12 year old English schoolchildren investigated in a cross sectional study in Northumberland, a positive correlation was found between sugar intake and caries experience (Beighton *et al.*, 1996). Woodward & Walker (1994) compared the DMFT (decayed, missing, filled permanent teeth) scores for 12 year old children with the mean annual sugar consumption in

the five years prior to the survey, in ninety countries (Woodward & Walker, 1994) and showed that for all countries DMFT scores rose with sugar consumption.

3.5.3 Alternative sweeteners and dental health

The concerns regarding the cariogenic potential of sugars has led to the development and use of sweeteners with low or no acidogenicity. Alternative sweeteners can be divided into two groups: bulk sweeteners and intense sweeteners (Table 3.4). Six new sweeteners were added to the list of those permitted for use in foods and drinks in the UK, in 1983, after new regulations came into force in England and Wales (Ministry of Agriculture, Fisheries and Food 1983), Northern Ireland (Department of Health and Social Services 1983) and Scotland (Scottish Home and Health Department 1983). Prior to 1983, sorbitol and mannitol were the only bulk sweetening agents permitted for use. The changes in regulations allowed xylitol, hydrogenated glucose syrup, isomalt, maltitol and lactitol to be used.

There are four intense sweeteners currently available for use in the UK. Prior to 1983, only saccharin was allowed, however changes to the regulations for artificial sweeteners introduced three new intense sweetening agents; acesulfame potassium, aspartame and thaumatin.

Table 3.4 Bulk and intense artificial sweeteners permitted for use in the UK (Ministry of Agriculture, Fisheries and Food 1983, Northern Ireland Department of Health and Social Services 1983 and Scottish Home and Health Department 1983)

Bulk Sweeteners	Intense Sweeteners
Sorbitol	Saccharin
Mannitol	Acesulfame potassium
Xylitol	Aspartame
Hydrogenated glucose syrup	Thaumatin
Isomalt	
Maltitol	
Lactitol	

3.5.3.1 Bulk sweeteners

Sorbitol has a relative sweetness of 0.5 compared with sucrose and has a negative heat of dissolution, providing a cool taste. It is fermented slowly by oral bacteria, however studies have shown that this is of little significance in terms of dental caries (Glass, 1983) and sorbitol also has low acidogenicity.

Xylitol is an intermediate product of glucose metabolism in man and as with sorbitol it also has a negative heat of dissolution causing and mouth-cooling effect. *In vivo* and *in vitro* studies reviewed by Rugg-Gunn and Edgar (Rugg-Gunn & Edgar, 1985) have shown that xylitol is non-cariogenic and may even promote remineralisation. In the Turku sugar studies (Scheinin & Makinen, 1976; Scheinin *et al.*, 1976) 125 subjects were divided into three groups; those continuing to consume sucrose and two groups where sucrose in the diet was completely replaced with xylitol or fructose. The results showed that the mean increment of decayed, missed and filled tooth surfaces was 0 in the xylitol and fructose groups compared with 7.2 in the sucrose group.

The only hydrogenated glucose syrup to be licensed for use in foods and drinks is Lycasin. Lycasin has a relative sweetness of 0.75 compared to sucrose and *in vivo* it is metabolised to glucose and sorbitol. Lycasin was found to have lower acid producing potential than glucose, with French Lycasin having a lower activity than the original Swedish Lycasin (Frostell & Birkhed, 1978). A *in vitro* study looking at the acidity and demineralising actions of lozenges containing sucrose, glucose or Lycasin, either on their own or in combination showed that the fermentability of the Lycasin formulation by plaque bacteria was lower as was acid production (Grenby, 1995).

3.5.3.2 Intense sweeteners

Intense sweeteners have no acidogenic properties, however they cannot directly be substituted for sucrose as they lack the bulking properties. Saccharin which was discovered in 1879 and has been used in foodstuffs for over 80 years (Rugg-Gunn, 1985). It is used extensively in diet soft drinks as well as pharmaceuticals. Another common intense sweetener is aspartame which is 200 times more sweeter than sucrose, with a similar taste to sucrose. A relatively new sweetening agent is acesulfame potassium which is 130 times sweeter that sucrose.

The intense group of sweeteners and their dental effects have not been studied as extensively as the bulk sweeteners, however evidence from all studies show that they are non-cariogenic. A study comparing sucrose and aspartame in six groups of 20 rats showed no caries in the rats that were fed aspartame, as well as a reduction in the number of carious lesions found in the rats fed aspartame and sucrose, compared with rats fed sucrose alone (Das *et al.*, 1997).

3.5.4 The use of medicines with prolonged oral clearance

Liquid oral medicines (syrups, linctuses, elixirs), chewable tablets, pastilles, lozenges, sublingual and buccal tablets all have a prolonged clearance from the oral cavity. These dose forms are not swallowed directly but they are designed to be chewed, sucked or dissolved slowly in the mouth. There are situations where it is advantageous to use medicines with prolonged oral clearance instead of solid oral doses, for example where the patient has problems swallowing, when such medicines are easier to administer and in the case of sublingual and buccal tablets, when absorption of the drug occurs quickly through the oral mucosa. Liquid oral medications, have a faster action compared with solid oral doses as the drug is immediately available for absorption in the stomach. Pastilles and lozenges are more effective in alleviating upper respiratory conditions such as cough and sore throat, having a direct soothing action during dissolution in the mouth.

There has been little research regarding the use of medicines with prolonged oral clearance in the UK and worldwide. The main area of research in this field has been on liquid oral medicines. Maguire and Rugg-Gunn (1994) showed that in 1987, 8.6% (581) of all drug preparations (6738) dispensed in Great Britain were for liquid oral medicines (Maguire & Rugg-Gunn, 1994) and 43.9 million items (10.9% of all items) were prescribed for liquid oral medicines, in 1987. This represented a volume of 10.3 million litres and a cost of £90.7 million. There was a similar pattern of prescribing of liquid oral medicines in the Northern Region of England, with 2.7 million prescription items and a volume of 0.7 million litres dispensed (Maguire & Rugg-Gunn, 1994). The medicines used were from a large number of therapeutic areas such as Gastrointestinal, Central Nervous System and Antibiotics, suggesting that liquid oral medicines as well as other medicines with prolonged oral clearance were not restricted to specific therapeutic categories but were available for use for a wide range of medical problems.

3.5.5 Sugars and medicines with prolonged oral clearance

3.5.5.1 Introduction

Many substances of medicinal value are associated with unpleasant bitter tastes which may make compliance with their use difficult. To overcome this pharmaceutical manufacturers have used low molecular weight carbohydrates to mask these tastes and make the medicine more organoleptically acceptable.

3.5.5.2 The use of sucrose

Sucrose is a colourless, odourless, white crystalline powder with a sweet taste (Royal Pharmaceutical Society of Great Britain, 1988). It is a very soluble substance and is stable over a pH range of 4-8. Sucrose is commonly used in the manufacture of pharmaceutical products, especially liquid oral medicines, as well as other products with prolonged oral clearance. It is effective at masking the bitter taste of some drugs as well as having a soothing effect on the membranes of the throat (Billany, 1998). As well as providing sweetness, sucrose has many other desirable properties, such as texture, bulk and stability, which also makes it ideal for the manufacture of pharmaceuticals (Rugg-Gunn, 1985). It is a good bulking and suspending agent in the manufacture of liquid oral medicines. Syrup BP is a commercial product containing 65%w/v sucrose. At this concentration it will retard the growth of micro-organisms, making it an ideal preservative.

3.5.5.3 Sugar-containing medicines and dental caries

In 1953 James and Parfitt suggested syrup based iron tonics were a risk factor in dental caries (James & Parfitt, 1953). Roberts and Roberts (1979) undertook a dental survey of 91 children, aged under six years of age (Roberts & Roberts, 1979). Forty four children were on sugar containing liquid oral medicines were compared with 47 children, who acted as the control group. The sweetening agent for all the medicines was sucrose. It was found that the children on long-term sucrose-based medicines had significantly higher level of dental caries (mean def 5.6) than the control group (mean def 1.3).

The dental health of school children aged 2 to 17 years taking only sugar-containing oral medicines for one year or more was compared with their siblings and with other school children (of similar age) taking only sugar-free liquid oral medicines for one year or more (Maguire *et al.*, 1996). Children taking long-term sugar-containing liquid oral medicines were found to have a significantly higher level of dental caries than their siblings ($p=0.046$). There was no difference in the prevalence of dental caries between the children on sugar-free medicines and those on sugar-containing medicines. The authors suggested that this may have been due the sugars-free group being on sugar-containing medicines for prolonged periods in the past.

A study of 158 preschool children in Reykjavik (Holbrook *et al.*, 1989), showed that the 49 children on paediatric medicines (especially antibiotics and medicines for the treatment of asthma)

had a higher prevalence of dental caries (dmft=3) compared with those not taking medicines (dmft=2.1)($p<0.05$). The mean dmft was 3.3 for all the children in the group.

The pH changes after consuming liquid oral medicines containing sucrose were assessed for 7 dental students (Rekola, 1989). The results showed that when the syrupy medicine was sweetened with sucrose, the pH dropped from normal saliva pH to a low pH, predisposing the patient to dental caries.

These studies that have been carried out on sugar-containing medicines and the prevalence of dental caries in children have shown that long-term use of such medicines is a risk factor in the aetiology of dental caries. In view of this there is some concern that liquid oral medicines as well as other medicines with prolonged oral clearance, containing sucrose could adversely affect the dental health of the elderly.

3.5.5.4 Formulation of medicines

The use of sugars in medicines formulation, in particular liquid paediatric medicines has been comprehensively researched with many surveys linking dental caries in children with sugars-containing medicines (Duxbury *et al.*, 1988; Feigal & Jensen, 1982; James & Parfitt, 1953; Roberts & Roberts, 1979). This has put pressure on pharmaceutical manufacturers of remanufacture their products as sugars-free (Hobson, 1985; Hobson & Fuller, 1987).

The switch to sugars-free from sugars-containing is not a simple process as the sugar provides the medicine with a number of properties which are difficult to replace with a sugars-free sweetening agent. The sugar used in the formulation of a medicine also has preservation, viscosity and bulking properties, and in the case of sucrose is cheaply available. To replace the sugar the sugars-free sweetening agent would have to replace the properties of sucrose as completely as possible.

The bulk sweeteners often have side effects such as flatulence and diarrhea. Their other disadvantage is the relative cost, which is greater than sucrose. Intense sweeteners may also be used in the formulation of sugars-free medicines however they lack the bulking and preservative properties of sucrose and saccharin has a bitter aftertaste which can restrict its suitability for use.

3.5.5.5 Sugar-free medicines with prolonged oral clearance

The well documented link between sugar-containing medicines and dental caries has led to pharmaceutical manufacturers formulating medicines with alternative sweeteners. Currently the industry have recognised this problem in children and responded by reformulating many paediatric medicines as sugars-free, however they have failed to recognise the implications of the use of sugars-containing medicines in adults and the elderly and many of these medicines remain as sugars-containing products. There have been no studies on the use of medicines with prolonged oral clearance in the elderly, so it has not been possible to assess the extent of the problem.

The availability of sugar-free medicines and the awareness of the dental risks of taking sugar-containing medicines has led to more sugar-free products becoming available. In a two year study involving pharmaceutical manufacturers of liquid oral medicines for which Syrup BP was the recommended diluent (Jenkins *et al.*, 1989), only 30% of pharmaceutical companies, representing 34 from 115 products said that they would be able to suggest an alternative sugar-free diluent to Syrup BP. At the time of the study in 1988, 23.3% of the manufacturers had already reformulated one or more of their products and 34.4% were currently involved in a reformulation process. However, the majority of the products that were being reformulated were for paediatric medicines.

Journal articles have listed sugar-free medicines (Dangor & Veltman, 1986; Sadler & Brandon, 1989) and other booklets have produced lists of medicines with their type and content of sweeteners (Bosso & Pearson, 1973; Greenwood, 1989; Jin & Naylor, 1984; Taylor, 1981). Analysis of these publications has shown that the majority of sugars-free medicines with prolonged oral clearance are for paediatric use and adult medication with prolonged oral clearance tends generally to be sugars-containing.

The use of generic medicines has been previously highlighted as a potential problem in that the specificity of the drug name used by the prescriber may influence whether a sugars-free or sugars-containing medicine is dispensed (Maguire & Rugg-Gunn, 1994).

Work has also been undertaken with 'over the counter' medicines (Mackie *et al.*, 1993). During a one year period during which pharmacists in a test group were sent dental health education leaflets, it was found that the mean number of sugar-containing liquid oral medicines stocked by the test group pharmacists fell from 7.7 to 7.1 ($p<0.05$). However 70% of the pharmacists still recommended sugar-containing medicines more than sugar-free. In a study

evaluating a sugars-free medicines campaign in North East England, the authors concluded that the campaign was most effective at changing prescribing habits of general medical practitioners and had less of an impact on OTC medicines (Maguire *et al.*, 1999).

In a study to determine the factors influencing general medical practitioners' decisions to prescribe sugars-free medicines, 55% of general medical practitioners supported the principle of sugars-free medicines prescribing, but only 30% felt their knowledge of sugars-free medicines was up to date (Bradley & Kinirons, 1996). The main sources of information on sugars-free medicines was from medical representatives and professional journals.

3.6 SUMMARY OF THE LITERATURE REVIEW

This literature review has focused on a number different areas which together affect the health of the elderly. The main points for consideration are:

- The elderly population is increasing and they currently represent 16% of the population of England (48.7 million).
- Research into ageing has highlighted the role of free radicals as well as the effects of the environment such as diet and exposure to infection.
- Ageing is associated with a number of physiological changes which affect all the major systems of the body and in turn affect the processes of drug absorption, distribution and excretion.
- The elderly have higher a morbidity than younger members of the population, with 62% of all elderly in 1994 in the UK reporting a medical problem
- As a result of ill-health, the elderly use more of healthcare resources than younger members of the population. They were dispensed almost 50% of all drugs in England in 1994.
- Prescribing in the elderly is also high in other westernised countries such as the USA and drugs for the cardiovascular, central nervous system and gastrointestinal medicines are commonly used.

- The concomitant use of many drugs is common in the elderly, which may result in adverse drug reactions.

- Compliance with drugs in the elderly is poor and this has a number of implications including ineffective treatment, possibly leading to hospitalisation and the cost of medicines not being used.

- The dental health of the elderly is improving, with more elderly retaining their natural teeth into old age.

- The elderly in general have poorer nutrition, and consume less fibrous food than younger individuals, which may have health implications.

- Saliva is an important defence mechanism against dental disease and the oral clearance of carbohydrates from the mouth is linked to dental caries.

- Oral clearance is affected by sensory and motor functions, the rate and efficiency of swallowing and salivary secretion rate of stimulated and unstimulated saliva.

- A lack of saliva (xerostomia) will predispose patients to dental caries and although the elderly have normal saliva secretion rates, the side-effects of their drug therapy may cause dry mouth.

- Sugars such as sucrose have been implicated in the aetiology of dental caries and the frequency, rather than the amount of sugar is important.

- Bulk and intense sweetening agents as alternatives to sugars are non-acidogenic or have less acidogenic effects and are available for use in foods, drinks and medicines.

- There is an established link between medicines with prolonged oral clearance containing sucrose and dental caries

- Sugars in liquid oral medicines (especially in paediatrics) have been extensively studied, but there has been little research carried out into the use of other medicines with prolonged oral clearance, and their use by other age groups.

CHAPTER 4

AIMS OF THE STUDY

4.1 INTRODUCTION

Most medical problems are managed by medication which may require short-term or long-term use. This medication may be formulated as one with prolonged oral clearance, i.e. one that lingers in the mouth after administration. Such medicines, if sugars-containing may be a threat to dental health. Medicines with prolonged oral clearance may be obtained through numerous routes of supply; by a prescription from a general medical practitioner, general dental practitioner or by purchasing a OTC medicine, within the primary healthcare sector or from hospital pharmacy services in the secondary healthcare sector. The methods to determine the prevalence and volume of use of these medicines had to be designed specifically for this purpose.

4.2 MAIN AIM

To assess the prevalence of use of medicines (prescribed and 'over the counter') with prolonged oral clearance used regularly (once daily or alternate day) and long-term (three months or longer) by the elderly (aged sixty years and over).

4.3 SUBSIDIARY AIMS

4.1. To determine the age and gender profiles of elderly patients taking medicines with prolonged oral clearance (prescribed and 'over the counter') regularly and long-term.

4.2. To determine the medical problems of the elderly patients taking medicines with prolonged oral clearance regularly and long-term.

4.3. To determine the sugar content of medicines with prolonged oral clearance used regularly and long-term by the elderly

4.4. To assess the volume of all medicines (prescribed and 'over the counter') with prolonged oral clearance and those used long-term by the elderly, used in England, the Northern Region and Newcastle, during a one year period.

4.5. To determine the effect of generic prescribing on the use of medicines with prolonged oral clearance.

The main and subsidiary aims relate to the whole study; aims specific to each survey will be given at the beginning of the chapter corresponding to that survey.

CHAPTER 5

PRESCRIBED MEDICINES PREVALENCE SURVEY

5.1 INTRODUCTION

As a result of improving health and socioeconomic conditions, nationally and internationally the number of elderly citizens is increasing. In 1997 the population of the UK was 59 million individuals, of which 10.7 million (18%) were of a pensionable age, that is, aged 60 and over (Office of Population Censuses and Surveys, 1998). The elderly population of the Northern Region of England in 1995 was 0.62 million (21% of the overall Northern Region population), which had increased from 0.44 million in 1979, when the elderly represented 14.2% of the population. Appendix 5.1 show a map of the Northern Region and 1995 population data (Office for National Statistics, 1995).

The dental health of the elderly has improved over recent decades - the proportion of all adults in the UK with some or all of their own teeth increased from 21% in 1978 to 33% in 1988 (Todd & Lader, 1991). The proportion of adults aged 55 to 64 years with some natural teeth increased from 36% in 1968 to 64% in 1988 (Todd & Lader, 1991). Over the same period the proportion of persons aged 65 to 74 years with some natural teeth increased from 21% to 44%, and for those aged over 75 years from 12% to 20% (Todd & Lader, 1991).

Medical problems are common in the elderly (Diggory *et al.*, 1991; Iliffe *et al.*, 1991). In 1997, 49.3% of all prescriptions dispensed in the general medical services were to patients over a pensionable age, accounting for 247 million prescription items (Department of Health, 1998). Most medical problems in the elderly are treated with oral medication, most commonly solid oral doses, that is, tablets and capsules. This dose form is not always appropriate due to formulation or compliance difficulties, and other oral dose forms such as liquids, syrups, chewable tablets, pastilles, lozenges, sublingual and buccal tablets may be used. These other dose forms all have prolonged clearance from the oral cavity however, there is no information on the use of these medicines in the elderly and this was the purpose of the prevalence survey.

5.2 AIMS

5.2.1 Main aim

- To determine the prevalence of regular (daily or alternate day) and long-term (three months or longer) use of prescribed oral medication with prolonged oral clearance in the elderly (60 years

and older), in five districts of the Northern Region (Newcastle, North Tyneside, South Tyneside, Gateshead and Northumberland).

5.2.2 Subsidiary aims

- To determine the age and gender profile of elderly patients taking long-term prescribed oral medication with prolonged oral clearance.
- To determine the medical problems for which prescribed oral medicines with prolonged oral clearance are taken by the elderly.
- To determine the types of prescribed medicines with prolonged oral clearance used regularly and long-term by the elderly.
- To determine the sugars content of prescribed medicines with prolonged oral clearance used regularly and long-term by the elderly

5.3 METHODS

5.3.1 Introduction

The main aim of this study was to assess the prevalence of use, by elderly patients in the Northern Region, of medicines with prolonged oral clearance. It was not practical to examine the medication of all 0.62 million elderly persons in the Northern Region. Instead, it was decided to select five representative districts in the Northern Region (Appendix 5.1) and within them choose ten general medical practices from which the number of elderly patients taking medicines with prolonged oral clearance regularly and long-term would be determined.

5.3.2 Sources of data

To assess the overall use of medication in the elderly would involve collecting data from a number of sources. Preparation for this required all potential sources of data to be identified and assessed to see if they could provide accurate information. In recent years the government has required NHS services to be audited in a bid to improve patient care and reduce running costs and as a result, most aspects of healthcare are carefully recorded. This record keeping has been extended to provide useful information for both auditing and research purposes. This section reviews the various types of data which were available and how the data source was selected for the Prevalence Survey. Figure 5.1 shows the interactions between the patient and the providers of

primary health care; the general medical practice and the pharmacy, and the further interactions with other organisations that may be potential sources of data.

5.3.2.1 The patient

The patient who requires healthcare has four main options: to do nothing, to visit a community pharmacy, to visit their general medical practitioner or go to hospital. The latter three options may result in the provision of medication to relieve their symptoms or treat their condition, making the patient a valuable source of research data for this and other surveys.

5.3.2.2 General medical practices

5.3.2.2.1 Computers in general practice

General medical practices in recent years have been encouraged by local health authorities to use computers for the management of their patient records and other practice business. The main types of computer software systems on the market currently are EMIS[1], Meditel[2], Vamp[3] and Genisyst[4]. Although other medical computer systems are available, these four are the most commonly used in practices in the Northern Region, as shown by surveying lists of computer systems obtained from computer facilitators for general medical practices in five districts of the Northern Region. EMIS and Meditel systems provide fast and accurate sorting, printing and down-loading of demographic and medical information about the patients registered. EMIS uses a series of databases to store patient demographic details, medical patient histories, medication records and other notes. Access to medication records involves a number of key-strokes and is time consuming however it allows searches to be undertaken by age, doctor, medication and other variables.

In contrast, Meditel offers easier access to medication records than the EMIS system, however it is a lot more difficult to use for searches as it requires the input of a complicated set of instructions. Downloading information from the Meditel system is not an easy menu-driven process and requires advanced knowledge about the software, unlike EMIS where searches are easily saved onto floppy disk for further analysis.

[1] Egerton Medical Information System
[2] Meditel, AAH Meditel, Rigby Hall, Rigby Lane, Bromsgrove, B602EW Phone 01527 579414.
[3] VAMP, Inpractice Systems, Delta Park, Smugglers Way, London, SW18 1EG.
[4] Genisyst, Aremissost, Theobald Business Centre, Knowl Piece, Wilbury Way, Hitchin, SG4 0TY.

5.3.2.2.2 Patient medication records (PMRs)

General medical practices have traditionally kept detailed written records of all patient consultations on cards stored in folders. With advances in computing and software availability, many practices have started storing all medical information on computers. A recent survey in four general medical practices in the Trent Region of England showed that in 1000 patient consultations, 696 patients were issued an prescription. Only 87.2% of these prescriptions were recorded on manual records compared with 100% in computer records (Pringle *et al.*, 1995), indicating that prescribing information obtained from general medical practice computer systems can often provide a more accurate estimate of medicine use than manual records.

Storing information on computers has the additional advantage of allowing the general medical practitioners quick access to a patient's medical history and facilitating a search for a group of patients taking a specific medicine within certain set criteria; for example, all patients within a specific age range can be identified. With these factors in mind, it was felt that it would be most appropriate to undertake a survey of the prevalence of use of medicines by the elderly, using computerised patient medication records.

5.3.3 The Sample

Mid-year population data showed that there were 0.62 million elderly individuals aged 60 years and over living in the Northern Region in 1995 (Office for National Statistics, 1995). After discussions with two statisticians, it was decided that a cluster sampling technique would be the best approach to data collection with each cluster comprising all the elderly patients aged sixty years and over in a single general medical practice.

The survey was undertaken in five of the fourteen districts of the Northern Region of England which collectively were representative of rural, inner city and urban areas. These districts were Newcastle, North Tyneside, South Tyneside, Gateshead and Northumberland (Appendix 5.1).

To ensure that the practices were representative of the whole population, it was decided that only practices meeting the following inclusion criteria would be included in the survey:

- A large list size (5000 patients or greater)
- A good socioeconomic mix
- Computerised patient medication records (PMRs)

The Family Health Authority for each of the five districts was asked for a list of general medical practices with computing facilities. From these lists, practices with comprehensive computing facilities, (i.e. those using either EMIS, Genisyst, Meditel or VAMP) were highlighted. Of these, ten general medical practices, two from each district, were chosen at random. If the selected practice had a list size of less than 5000 then another was randomly selected. Once selected, the practice was contacted by letter (Appendix 5.2) explaining the purpose of the survey and asking for permission to use the patient medication records at the practice.

5.3.4 Ethical committee approval

The study involved access to confidential patient information, and required permission from the ethical committees from the five districts. Applications for approval were sent to the five district ethical committees and to the Newcastle and North Tyneside joint ethical committee in June 1995. Once ethical committee approvals had been obtained, the senior partner in each of the ten practices was contacted by a letter (Appendix 5.2) which outlined the aims of the study and how the study would be carried out. The letter was followed up by a telephone call, when a meeting was arranged with either the senior partner or a colleague and the practice manager to discuss the survey further and arrange access to practice computer records, if the practice was willing to participate in the survey.

5.3.5 Data collection and preparation

5.3.5.1 The database

A database was constructed using Microsoft (MS) Access to collect, store and collate all data collected in this and related surveys (Chapters 6 and 7). A plan was made of all the types of data that would be collected from the survey and from this, 'tables' were constructed in MS Access. A table is a part of the overall database and each table held a number of fields which contained information. The database consisted of a series of these tables (Figure 5.2) linked

together using common fields. The tables could be searched according to specific criteria, individually or linked using 'queries'.

For the purposes of the Prevalence Survey, two tables were created to facilitate data collection and subsequent analysis. The **PATIENT DATA** table (Figure 5.2) was designed to hold demographic information about the patients in the survey. This table contained fields for the following information:

- Patient code
- Practice
- Gender
- Date of birth

The **PATIENT MEDICATION** table (Figure 5.2) was created to hold the following data from this survey:

- Patient code
- Medication problem code
- Drug code
- Dose
- Frequency of administration
- Date treatment started
- Date data collected

A **DRUGS** table (Figure 5.2) was designed to hold information on all medicines with prolonged oral clearance. This table was derived from a database supplied by John Richardson Computers plc.[1], which contained over 20,000 'prescription only' (POM) and 'over the counter' (OTC) medicines and surgical items, and included all dose forms of medicines, including oral medicines with and without prolonged clearance. By undertaking searches by dose form, medicines with prolonged oral clearance were separated from all other preparations. The resulting list was then checked against the British National Formulary (British Medical Association & Royal Pharmaceutical Society, 1995) and Data Sheet Compendium (Association of British Pharmaceutical Industry, 1995) to ensure that all medicines with prolonged oral clearance were identified.

[1]John Richardson Computers, NDC, 57 Benedicts House, Brown Lane, Bamber Bridge, Preston, PR5 6ZB.

For each preparation with prolonged oral clearance the following information was entered:

- BNF Section
- Unique medicine code to identify each individual preparation
- Dose form (e.g. liquid, solid or powder)
- Manufacturer
- How the medicine was prescribed (i.e. generic or proprietary name)

BNF Sections categorised the medicine in terms of its therapeutic area of use. Dose form identified the nature of the medicine and its unit of measurement was recorded as follows:

- liquid oral medicines in millilitres
- solids with prolonged oral clearance (e.g. effervescent tablets) in number of tablets
- loose powders and oral gels in grams
- powders in sachets in number of sachets

In the UK, medicines are available as either generic or proprietary brands. Generic preparations are often manufactured by many different pharmaceutical manufacturers to produce many formulations of the same preparation. To account for these multiple formulations in the analysis of the data from this survey, the table, **GENERIC FORMULATIONS** was created to contain information on all the generic formulations of the generic medicines and was linked to the **DRUGS** table.

5.3.5.2 Management of the data

Once the database was constructed, 'Data Entry Forms' were designed in MS Access which provided an interface to allow the data to be entered into the relevant fields in the various tables. The forms consisted of boxes into which the data were typed. The 'boxes' were programmed to only accept certain types of data and maximise accuracy in data entry, for example, they were programmed to accept a number only or a range of data such as a date of birth which would reject any entry for patients under sixty.

The three tables in the database, described above and shown in Figure 5.2 were linked by common fields in each table. For example the **DRUGS** table was linked to the **PATIENT MEDICATION** table by the *drug code* and in turn the **PATIENT MEDICATION** table was linked to the **PATIENT DATA** table by the *patient code*. The other tables shown in Figure 5.2

are discussed in the relevant chapters. Data were also entered into these linked tables via the forms. For example, the table which held demographic information about patients in the survey was linked by a unique patient identifier code to a table into which information from a questionnaire was entered.

5.3.5.3 Patient medication information

Patient medication data were collected in three phases for all ten practices, each phase being completed for each of the ten practices before the next phase was started. Each practice was visited at least once every two weeks during the period of data collection. The three phases of the data collection are summarised in Table 5.1.

Table 5.1 Summary of data collection phases

Phase One	Computer records of all elderly patients examined; those taking medicines with prolonged oral clearance highlighted.
Phase Two	Prescribing details of highlighted patients examined further; those taking medicines with prolonged oral clearance regularly and long-term identified.
Phase Three	Medication and prescribing details for identified patients entered into a relational database

5.3.5.3.1 Phase One

For each practice an initial search was undertaken on the practice computer for all patients aged sixty years and over, and details of name, gender, date of birth and patient registration number within that practice (a unique identification number given to all patients registered on the practice computer) collected on a printout.

Using patient registration numbers, the medication record for each of these patients was then examined using the practice computer. Any patient currently taking a medicine with prolonged oral clearance was highlighted and their medication details printed (Appendix 5.3).

5.3.5.3.2 Phase Two

In the second phase, the computer records for those patients taking medicines with prolonged oral clearance were examined further. Each medication with prolonged oral clearance taken

regularly (daily or alternate day) and long-term (3 months or longer at the time of the survey) by the patient was identified and the start date, dose and schedule of prescribing recorded.

5.3.5.3.3 Phase Three

In the third phase, details of the patients identified as taking medicines with prolonged oral clearance regularly and long-term were coded and entered into the **PATIENT DATA** table of the database. Medication details for each individual patient were also coded and entered into the linked **PATIENT MEDICATION** table (Figure 5.2).

5.3.5.4 Sugars content of medicines

Using the British National Formulary and ABPI Data Sheet Compendium (1995-96) (Association of British Pharmaceutical Industry, 1995; British Medical Association & Royal Pharmaceutical Society, 1995), information on the sugars content of each proprietary medication with prolonged oral clearance was collected and entered into the **DRUGS** table of the database. When these sources could not supply this information, the pharmaceutical manufacturers were contacted. A preparation was considered to be sugars-free if it did not contain an acidogenic sweetening agent. The British National Formulary advises that oral liquid preparations that do not contain fructose, glucose or sucrose can be labelled as 'sugars-free' (British Medical Association & Royal Pharmaceutical Society, 1997), and these guidelines were followed when the medicines with prolonged oral clearance were classified according to their sugars content. However, medicines containing milk sugars such as lactose, that are identified in the BNF as being cariogenic but has low acidogenicity, were classified as sugars-containing.

All generic pharmaceutical manufacturers for each of the generic preparations were approached for written information on the type and amount of sweetening agent for each medicine, which was then entered into the **GENERIC FORMULATIONS** table of the database. Where the pharmaceutical manufacturers did not respond they were contacted by telephone and verbally asked for the information. Generic preparations which were available as both sugars-free and sugars-containing formulations, were classified as variable.

5.3.6 Validation

To maximise the accuracy of the data collection process, the records of 100 patients (20 patients from each of the five practices) were randomly chosen and checked for errors in collection, coding and entry of data.

5.3.7 Population data

Regional and national demographic data for England, the Northern Region and the five districts (Newcastle, North Tyneside, Gateshead, South Tyneside and Northumberland) were collected using information from the Office of Population Censuses and Survey (OPCS 1996). These mid-year data for 1995 included national, regional and local population sizes, by age and gender (Office for National Statistics, 1995).

5.3.8 Data analysis

The data, once entered into the database tables was analysed using a series of queries. A query is a question about data stored in tables. Once the data was entered into the database, 'queries' were designed and run to retrieve certain information, for example, all patients of a specific age or all those taking a specific drug.

Once the query had been undertaken the results were viewed and printed in a number ways. Results could be exported into a spreadsheet for further analysis or into a word processor. MS Access also was used to produce and summarise reports, such as a list of medicines, sorted by therapeutic category.

Statistical analysis was undertaken using a chi-squared test adjusted for age to look at differences between age and gender of the patients taking medicines with prolonged oral clearance regularly and long-term.

5.4 RESULTS

5.4.1 Contact with practices

The computing departments of each FHSA confirmed that all 199 practices in the five districts were computerised. From this list of 199 practices, 125 (63%), were identified as operating one of the four comprehensive computer systems (EMIS, Genisyst, Meditel and VAMP) chosen to facilitate data collection. From these 125 practices, 10 (8%) were randomly selected to provide ten clusters in which the survey was carried out.

Approval from the ethics committees in all five districts took 3 months to obtain and had been granted by September 1995. The ten randomly selected practices were contacted by November 1995, however three of these practices were unable to take part; two practices in Newcastle were too busy to help and a third in Northumberland was already committed to another research project. Therefore, three more practices were randomly sampled using the same process of cluster sampling as discussed in section 5.3.3 and all three agreed to take part in the study.

5.4.2 Data collection and analysis

Data collection commenced in March 1996 and each of the ten practices were visited at least once every two weeks, until November 1996. Three practices (practices 1, 5 and 6, in North Tyneside, Gateshead and South Tyneside) had larger numbers of elderly patients and were visited once a week. The manual examination of all computer records of all elderly patients (Phase 1) was complete by June 1996 for all ten practices. The second phase in which patients taking medicines with prolonged oral clearance regularly and long-term were identified and their prescribing details, collected was started in July 1996 and completed by November 1996. Phase 3, where medication information was coded and entered into the database, was completed by March 1997.

The validation exercise used a random sample of 100 patient records after Phase 3 and checked these against the database and found that there were some minor errors such as wrongly coded drugs and codes entered wrongly, however there were no data collection errors. This exercise also highlighted minor problems with the structure of the database which is discussed in section 5.5.3.

5.4.3 The sample

The ten practices surveyed employed 48 full time equivalent (FTE) general medical practitioners (GMPs), who provided medical services to a total of 92570 registered patients (Table 5.2). Of these registered patients, 48.9% were male and 51.1% were female, with the mean male:female ratio being 1:1.04, ranging from 1:1.23 in Practice 10 (Newcastle) to 1:0.93 in Practice 3 (Newcastle).

The mean number of registered patients per practice was 9257 with a range from 4920 in Practice 9 (Northumberland), to 14020 patients in Practice 1 (North Tyneside). The two Northumberland practices had the smallest list sizes, the practices with the three largest list sizes being in North Tyneside, South Tyneside and Gateshead. The mean number of patients per general medical practitioner ranged from 1589 in Practice 9 (Northumberland), with three FTE general medical practitioners to 2660 in Practice 7 (South Tyneside), also with three FTE general medical practitioners. The mean number of patients per GMP for the ten practices was 1928 (SDev = 340.9).

Table 5.2 Practice profiles for the ten practices in the Prevalence Survey

Practice	District	Total no. of patients registered	Male		Female		FTE[1] GMPs	Patients /GP
			No.	%	No.	%	No.	
1	North Tyneside	14020	6766	48.3	7254	51.7	6.5	2157
2	North Tyneside	7369	3495	47.4	3874	52.6	4.0	1842
3	Newcastle	9567	4966	51.9	4601	48.1	6.0	1594
4	Gateshead	9932	4866	49.0	5066	51.0	5.5	1806
5	Gateshead	11159	5657	50.7	5502	49.3	6.0	1860
6	South Tyneside	13654	6764	49.5	6890	50.5	6.0	2276
7	South Tyneside	7980	3947	49.5	4033	50.5	3.0	2660
8	Northumberland	6357	3062	48.2	3295	51.8	4.0	1589
9	Northumberland	4920	2356	47.9	2564	52.1	3.0	1640
10	Newcastle	7612	3409	44.8	4203	55.2	4.0	1903
Total	-	**92570**	**45288**	**48.9**	**47282**	**51.1**	**48.0**	-
Mean	-	**9257.0**	**4528.8**	-	**4728.2**	-	**4.8**	**1928**
SDev	-	**3003.7**	**1531.6**	-	**1491.0**	-	**1.3**	**340.9**

[1]**Full Time Equivalent**

5.4.4 Elderly patients in the sample

Of the 92570 patients registered with the ten practices, 20371 (22%) were elderly patients aged sixty years and over (Table 5.3). Of these elderly people, 8757 (42.9%) were male and

11614 (57.1%) were female, with the male:female ratio being approximately 1:1.3, 13458 (66%) were aged 60 to 74 years ('young' elderly), and 6919 (34%) aged 75 years and over ('old' elderly). Of the elderly aged 60 to 74 years, 6467 (48%) were male and 6991 (52%) were female, with male:female ratio of 1:1.1. The male:female ratio of elderly patients aged 75 years and over was 1:2.0, with 2290 (33.1%) being male and 4623 (66.9%) female.

The number of elderly aged sixty years and over at each of the ten practices ranged from 1388 to 3051 patients, with a mean of 2037 patients per practice. The mean number of males and females aged sixty years and over was 876 (SDev = 235.7) and 1161.4 (SDev = 348.5) respectively. Elderly patients as a proportion of the total number of patients registered in each practice ranged from 17.5% in Practice 5 (Gateshead) to 28.2% in Practice 9 (Northumberland), with a mean of 22%. The number of elderly patients per general medical practitioner ranged from 281 in Practice 3 (Gateshead) to 626 in Practice 7 (South Tyneside), with a mean of 424 patients per GMP.

Table 5.3 Elderly profiles for each of the ten practices in the survey

Practice	District	Total elderly (No.) (≥60y)	Elderly male (No.) (≥60y)	Elderly female (No.) (≥60y)	No. elderly by age (years)		Elderly as a % of all patients	No. Elderly per GMP
					60-74	≥75		
1	N. Tyneside	3051	1248	1803	1964	1087	21.8	469
2	N. Tyneside	1681	691	990	1073	608	22.8	423
3	Newcastle	1689	923	766	1198	491	17.7	281
4	Gateshead	2298	945	1353	1513	785	23.1	418
5	Gateshead	1959	857	1102	1441	518	17.5	327
6	S. Tyneside	2976	1294	1682	2072	904	21.8	496
7	S. Tyneside	1879	808	1071	1318	561	23.5	626
8	Northumberland	1740	720	1020	1004	736	27.3	435
9	Northumberland	1388	604	784	791	597	28.2	463
10	Newcastle	1710	667	1043	1084	626	22.5	427
Total	-	**20371**	**8757**	**11614**	**13458**	**6913**	-	-
Mean	-	**2037.0**	**876.0**	**1161.4**	**1345.8**	**691.3**	**22.0**	**424**
SDev	-	**565.0**	**235.7**	**348.5**	**413.2**	**188.5**	-	-

5.4.5 Comparison with regional and national data

As Table 5.4 shows, the total population of the ten practices (92570) represented 8.1% of the 1.14 million population of the five districts in which the study was undertaken, 3.2% of the 2.9

million population in the Northern Region and 0.2% of the 48.9 million population in England in 1993 (Office for National Statistics, 1995).

The 20371 elderly patients registered at the ten practices aged sixty years and over represented 22% of the total number of patients registered at these practices. Regional and national data (Office for National Statistics, 1995) show that individuals aged sixty years and over represented 21% of the population for both the Northern Region and England and the male:female ratio for all 92570 patients registered in the ten practices was 1:1.04, which was similar to the ratio for the Northern Region and England. Overall, the proportion of elderly males and females in the ten practices was 43% and 57% respectively, which was similar to the Northern Region and England (Table 5.4).

Table 5.4 Population data for England and the Northern Region (mid-year 1995) (Office for National Statistics, 1995)

	Population All Ages			Elderly ≥60 years		
	Total ($x10^3$)	Male ($x10^3$)	Female ($x10^3$)	Total ($x10^3$)	Male ($x10^3$)	Female ($x10^3$)
Ten practices in the prevalence survey	92.6	45.3 (49%)	47.3 (51%)	20.4 (22%)[2]	8.8 (43%)	11.6 (57%)
5 districts in North-East England[1]	1142.4	556.4 (49%)	586.0 (51%)	250.9 (22%)[2]	105.3 (42%)	145.6 (58%)
Northern Region	2923.2	1429.0 (49%)	1494.2 (51%)	617.8 (21%)[2]	262.1 (42%)	355.1 (58%)
England	48903.4	24007.6 (49%)	24895.8 (51%)	10041.0 (21%)[2]	4275.8 (43%)	5765.2 (57%)

[1] **Newcastle, North Tyneside, Gateshead, South Tyneside and Northumberland**
[2] **% of the total population of all ages**

5.4.6 Identification of medicines with prolonged oral clearance

5.4.6.1 Therapeutic classification

The **DRUGS** table of the database contained information on 613 medicines with prolonged oral clearance. These 613 preparations were found in 11 of the 15 therapeutic sections identified in the British National Formulary and as Table 5.5 shows, 65.9% (404 preparations) of these had actions on the three BNF sections of Infections (167 preparations), the Central Nervous System (126 preparations) and the Gastrointestinal System (111 preparations).

Of the 167 medicines with prolonged oral clearance in the Infections section of the BNF, 144 (86 %) were antibiotics, 131 (78%) were formulated as liquid oral medicines and of these 115 (69%) were antibiotic liquid oral medicines. These medicines are mainly formulated for paediatric use, although some are used by adults who have difficulty in swallowing solid dose forms. Of the 126 Central Nervous System medicines with prolonged oral clearance, 90 (71%) were liquid oral medicines, with the three main therapeutic areas of use being minor analgesics (36 medicines), anti-psychotics (27 medicines) and anti-epileptics (21 medicines).

Table 5.5 Preparations with prolonged oral clearance by BNF section and dose type.

BNF Section	LOMs[1]	Solids with POC	Powders & Oral Gels	Sachets	Total no. of preps
01 Gastrointestinal System	60	26	7	18	111
02 Cardiovascular System	15	10	0	5	30
03 Respiratory System	60	0	0	0	60
04 Central Nervous System	96	20	1	9	126
05 Infections	131	17	0	19	167
06 Endocrine System	0	1	0	2	3
07 Obstetrics and Gynaecology	3	2	0	0	5
08 Malignant Disease	1	0	0	0	1
09 Nutrition and Blood	19	15	0	17	51
10 Musculoskeletal and Joint Disease	9	9	0	5	23
11 Eye	0	0	0	0	0
12 Ear, Nose and Oropharynx	13	16	6	1	36
Total	**407**	**116**	**14**	**76**	**613**
(%)	**(66.4%)**	**(18.9%)**	**(2.3%)**	**(12.4%)**	**(100.0%)**

[1] Liquid oral medicines

5.4.6.2 Dose form

When analysed by dose form, 66% (407 preparations) of all medicines with prolonged oral clearance were liquid oral medicines, with 19% (116 preparations) being solids. Loose powders and oral gels and powders in sachets only accounted for 2% (14 preparations) and 13% (76 preparations) respectively of all 613 preparations with prolonged oral clearance.

5.4.7 Prevalence of the use of medicines with prolonged oral clearance

Of the 20371 elderly (aged ≥60y) registered at the ten practices, 3777 (18.5%) patients were taking medicines with prolonged oral clearance, both on a 'when required' basis and regularly. Of these patients, 1752 (46.4%) were male and 2025 (53.6%) were female, showing a male:female ratio of 1:1.2, compared with the male:female ratio of 1:1.33 for the elderly registered at the ten

general medical practice in the survey. Of the 3777 patients, 61% (2304) were aged 60 to 74 years and 39% (1473) aged 75 years or older, compared with 66% and 34% respectively for all elderly patients in the sample.

5.4.8 Prevalence of long-term and regular use of medicines with prolonged oral clearance in the elderly

When long-term (>3 months) and regular (once daily or alternate day) use of medicines with prolonged oral clearance was determined, of the 3777 patients taking medicines with prolonged oral clearance, 2002 (53%) patients (≥60 years) were taking at least one medicine with prolonged clearance regularly and long-term. As Table 5.6 shows, this represented a mean prevalence of 9.8% of the 20371 elderly patients in the ten practices, with a range of prevalence from 5.9% in a North Tyneside practice (Practice 2) to 13.3% in a Gateshead practice (Practice 5). For the 1070 patients aged 60 to 74 years the prevalence of long-term and regular use of medicines with prolonged oral clearance was 7.9% and for the patients aged 75 years and over the prevalence was 13.5%.

Table 5.6 Elderly (aged ≥60y) taking medicines with prolonged oral clearance regularly and long-term by practice and district

Practice	District	No. elderly registered	Elderly patients taking medicines with POC long-term & regularly					
			Total no.	%	Male	Female	60-74y	≥75y
1	North Tyneside	3051	342	11.2	108	235	193	149
2	North Tyneside	1681	100	5.9	17	83	54	46
3	Newcastle	1689	188	11.1	61	127	109	79
4	Gateshead	2298	191	8.3	61	130	88	103
5	Gateshead	1959	261	13.3	95	165	169	92
6	South Tyneside	2976	294	9.9	108	186	158	136
7	South Tyneside	1879	137	7.3	49	88	77	60
8	Northumberland	1740	156	9.0	37	119	56	100
9	Northumberland	1388	150	10.8	51	99	75	75
10	Newcastle	1710	183	10.7	51	132	91	92
Total	-	**20371**	**2002**	-	**638**	**1364**	**1070**	**932**
Mean	-	**2037.1**	**200.2**	**9.8**	**63.8**	**136.4**	**107.0**	**93.2**
SDev	-	**565.0**	**75.8**	-	**30.5**	**47.2**	**49.2**	**31.5**

5.4.8.1 Age and gender profiles

As Table 5.6 describes, of the 2002 patients taking medicines with prolonged oral clearance regularly and long-term at the time of the survey, 1070 (54%) were aged 60 to 74 years and 932

(46%) aged 75 years and over. When compared with the age distribution of the 3777 patients taking medicines with prolonged oral clearance overall, the long-term medication group had a larger proportion of individuals in the ≥75y group. When the male and female ratio was considered, 638 patients (32%) were male and 1364 (68%) were female; representing a male:female ratio of 1:2.1, suggesting that patients taking medicines with prolonged oral clearance regularly and long-term are also more likely to be female. Statistical analysis showed that females aged ≥75y were more likely to take medicines with prolonged oral clearance than other age and gender groups ($p<0.0001$).

5.4.9 Medical problems of patients taking medicines with prolonged oral clearance regularly and long-term

Analysis of the medical problems of patients taking medicines with prolonged oral clearance regularly and long-term showed that the 2002 patients taking medicines with prolonged oral clearance regularly and long-term reported 2956 medical problems, with a mean of 1.47 medical problems per person, with a range of 1 to 8 (Table 5.7). Of the 2002 patients, 860 (43%) only reported one medical problem. The major problems suffered by the elderly were cardiovascular disease (37.7%) and musculoskeletal problems (23.7%). A full list of medical problems is shown in Appendix 5.4.

Table 5.7 Medical problems by BNF (1995) Therapeutic Section

BNF Therapeutic Section	Number of patients	%
01 Gastrointestinal System	238	8.1
02 Cardiovascular System	1115	37.7
03 Respiratory System	268	9.1
04 Central Nervous System	192	6.5
05 Infections	7	0.2
06 Endocrine System	221	7.5
07 Obstetrics and Gynaecology	29	1.0
08 Malignant Disease	32	1.1
09 Nutrition and Blood	26	0.9
10 Musculoskeletal and Joint Disease	700	23.7
11 Eye	57	1.9
12 Ear, Nose and Oropharynx	38	1.3
13 Skin	33	1.1
Total	**2956[1]**	**100.0**

[1]1142 patients reported more than one medical problem (range 1 to 8)

5.4.10 Medicines with prolonged oral clearance used by the elderly

5.4.10.1 Total number of medicines used by the elderly taking medicines with prolonged oral clearance regularly and long-term

At the time of the survey, the 2002 elderly patients identified as taking medicines with prolonged oral clearance regularly and long-term were taking a total of 11751 medicines of all types, each of which represented a prescribing instance (PI). The medicines used were divided into four medication categories shown in Table 5.8.

- oral medicines without prolonged oral clearance (e.g. solid oral doses such as tablets and capsules)
- non-oral medicines (e.g. creams, injections, inhalers)
- medicines with prolonged oral clearance, used either on a 'when required' basis (e.g. minor analgesics used for occasional pains) or used long-term and regularly
- medicines with prolonged oral clearance used regularly and long-term by the elderly

The most common medication category prescribed was for medicines formulated as solid oral doses, with 53.5% of the 11751 prescribing instances being for either tablets or capsules. Non-oral formulations accounted for 1831 (15.6%) of prescribing instances. Formulations with prolonged oral clearance represented 30.9% (3625) of all the prescribing instances. Of these 7.1% (829) were for 'when required' use and 23.8% (2796) for regular and long-term use of 143 different preparations with prolonged oral clearance (Table 5.8). Overall there were 5.8 prescribing instances per head (range: 1-18), with medicines with prolonged oral clearance used regularly and long-term accounting for 1.4 prescribing instances per head (range: 1-5).

Table 5.8 Number of Prescribing Instances (PIs) for 2002 elderly patients taking medicines with prolonged oral clearance, by medication category

Medication category	No. of Prescribing Instances (PIs)	% of total	No. PIs/head
Oral medicines without POC (tablets or capsules)	6295	53.6	3.1
Non-oral medicines (creams, inhalers, injections)	1831	15.6	0.9
Medicines with POC used 'when required'	829	7.0	0.4
Medicines with POC used long-term	2796	23.8	1.4
Total	**11751**	**100.0**	**5.8**

5.4.10.2 Medicines with prolonged oral clearance taken regularly and long-term by the elderly

5.4.10.2.1 Number of preparations and prescribing instances by BNF therapeutic sections

The 2796 prescribing instances for medicines with prolonged oral clearance taken regularly and long-term at the time of the study were for 143 medicines.

As Table 5.9 shows, Gastrointestinal medicines accounted for 36% (52 preparations) of the 143 preparations but represented 53.4% (1494) of the 2796 prescribing instances.

Central Nervous System and Cardiovascular medicines were also commonly prescribed and accounted for 31 (21.7%) and 18 (12.6%) of the 143 preparations respectively. However these two sections of the BNF accounted for 543 (19.4%) and 537 (19.2%) prescribing instances respectively. Overall, these three BNF sections (Gastrointestinal System, Central Nervous System and Cardiovascular System) accounted for 92% of the prescribing instances to the elderly, whilst representing 70.7% of the preparations used regularly and long-term.

5.4.10.2.2 Number of preparations and prescribing instances by dose form

Of the 143 medicines used regularly and long-term by the elderly, 85 (59%) were liquid oral medicines, 41 (29%) were solids with prolonged oral clearance, 4 (3%) loose powders and oral gels, and 13 (9%) powders or granules packaged in sachets. Liquid oral medicines together with solids with prolonged oral clearance accounted for 89% (2478) of the 2796 prescribing instances (Table 5.9). Although accounting for fewer preparations, solids with prolonged oral clearance accounted for more of the prescribing instances; 1251 (45%), compared with 1227 (44%) for liquid oral medicines.

Of the 85 liquid oral medicine preparations, 62 (73%) were Gastrointestinal (31%), Central Nervous System (24%) or Respiratory (19%) medicines, however of the 1227 prescribing instances for these liquid oral medicines, 84% (1028) were for Gastrointestinal medicines, with Central Nervous System and Respiratory medicines only accounting for 6.4% (79) and 5.5% (68) of the prescribing instances. Closer examination of the 1028 prescribing instances for Gastrointestinal medicines showed that 58% (596) were for antacids and 41% (417) for laxatives.

Table 5.9 Number of preparations and Prescribing Instances (PIs) by BNF category and dose type, for medicines with POC used long-term and regularly by 2002 elderly patients in 10 practices

BNF Section	Liquid oral medicines		Solids with prolonged oral clearance		Loose powders and oral gels		Powders and granules in sachets		Totals	
	No of preps	No. of PIs	No of preps	No. of PIs	No of preps	No. of PIs	No of preps	No. of PIs	No. of preps	No. of PIs
01 Gastrointestinal System	26	1028	15	163	4	19	7	289	**52**	**1499**
02 Cardiovascular System	10	18	5	516	0	0	3	7	**18**	**541**
03 Respiratory System	16	79	0	0	0	0	0	0	**16**	**79**
04 Central Nervous System	20	68	9	467	0	0	2	2	**31**	**537**
05 Infections	1	1	0	0	0	0	1	1	**2**	**2**
06 Endocrine System	0	0	0	0	0	0	0	0	**0**	**0**
07 Obstetrics, Gynae. and Urinary Tract	1	1	1	1	0	0	0	0	**2**	**2**
08 Malignant Disease and Immunosupp.	0	0	0	0	0	0	0	0	**0**	**0**
09 Nutrition and Blood	5	12	6	86	0	0	0	0	**11**	**98**
10 Musculoskeletal and Joint Disorders	5	19	4	16	0	0	0	0	**9**	**35**
11 Eye	0	0	0	0	0	0	0	0	**0**	**0**
12 Ear, Nose and Oropharynx	1	1	1	2	0	0	0	0	**2**	**3**
Total	**85**	**1227**	**41**	**1251**	**4**	**19**	**13**	**299**	**143**	**2796**

Of the 41 solid dose preparations with prolonged oral clearance, 37% (15 preparations) were Gastrointestinal and 30% (9 preparations) Central Nervous System medicines. This distribution by therapeutic section was very different when the 1251 prescribing instances for this dose form were considered, with Cardiovascular and Central Nervous System medicines accounting for 41% (516) and 37% (467) of the 1251 prescribing instances respectively. Only 13% of the prescribing instances were for Gastrointestinal medicines.

Of the 516 prescribing instances for Cardiovascular medicines, 460 (89%) were for only one preparation (aspirin 75mg effervescent tablets) and 406 (87%) of the 467 prescribing instances for Central Nervous System medicines were for two different strengths of the analgesic co-codamol effervescent tablets.

Solids with prolonged oral clearance can be split into distinct sub-dose forms; effervescent and soluble tablets, chewable tablets, pastilles and lozenges and sublingual and buccal tablets. Effervescent tablets contain a weak acid and base, which interact when added to water producing the gas carbon dioxide, which causes the tablet to explode and disperse the drug in the solution. There is usually excess acid in the formulation so that the resulting solution is acidic in nature and more palatable. Of the 1251 prescribing instances for solid preparations with prolonged oral clearance used regularly and long-term, 937 (75%) were for effervescent tablets.

5.4.10.3 Use of generic and proprietary medicines with prolonged oral clearance

5.4.10.3.1 Number of preparations, formulations and prescribing instances by therapeutic section

The 143 medicines with prolonged oral clearance used regularly and long-term by the elderly were classified according to whether they were available generically or as a proprietary brand. Table 5.10 shows this distribution by therapeutic section. Of the 143 preparations, 101 (70.6%) were proprietary preparations and 42 (29.4%) generic preparations. The 42 generic preparations were produced by one or more different pharmaceutical manufacturer and accounted for a total of 144 generic formulations, manufactured by 27 companies.

Generic and proprietary preparations from the Gastrointestinal, Cardiovascular, Respiratory and Central Nervous System Sections of the BNF accounted for 83% of the 42 generic preparations, 85% of the 144 generic formulations and 81% of the 101 proprietary preparations. Generic medicines were found fairly evenly across all four sections of the BNF, with 16.7% in the

Cardiovascular and Respiratory Sections, and 21% and 29% in the Gastrointestinal and Central Nervous System Sections, whereas 43% of the 101 proprietary medicines were for Gastrointestinal medicines.

Table 5.10 Number of generic and proprietary medicines with prolonged oral clearance (POC) used regularly and long-term in the elderly

BNF Section[1]	Generic Medicines with POC						Proprietary Medicines with POC			
	Preparations		Formulations		Prescribing instances		Preparations		Prescribing instances	
	No.	%	No.	%	No.	%	No.	%	No.	%
01	9	21.4	30	20.8	448	30.9	43	42.6	1051	78.2
02	7	16.7	19	13.2	471	32.4	11	10.9	70	5.2
03	7	16.7	40	27.8	55	3.8	9	8.9	24	1.8
04	12	28.6	33	22.9	454	31.3	19	18.8	83	6.2
Others	7	16.7	22	15.3	24	1.7	19	18.8	116	8.6
Total	**42**	**100.0**	**144**	**100.0**	**1452**	**100.0**	**101**	**100.0**	**1344**	**100.0**

[1] **01 = Gastrointestinal System 02 = Cardiovascular System**
03 = Respiratory System 04 = Central Nervous System

Of the 43 proprietary Gastrointestinal medicines, 19 (44%) were antacids and 12 (28%) laxatives. The antacids were complex combinations of acid neutralising chemicals which act locally in the stomach to reduce excess acidity. Although many have been on the UK market for a number years and no longer have patents, generic companies have not produced direct equivalents. Due to the large number of active ingredients in each preparation general medical practitioners and other prescribers tend to use the simpler proprietary name when prescribing these medicines.

Of the 42 generic preparations with prolonged oral clearance, the 7 respiratory medicines had the highest number generic formulations associated with them. These 40 formulations were mainly three medicines; salbutamol syrup, pholcodeine linctus and simple linctus.

As Table 5.10 shows, the 42 generic preparations accounted for 1452 (52%) of the 2796 prescribing instances for medicines with prolonged oral clearance used regularly and long-term at the time of the study, with proprietary medicines accounting for 1344 (48%) prescribing instances. Prescribing instances (PIs) for Cardiovascular (471 PIs), Central Nervous System (454 PIs) and Gastrointestinal (448 PIs) medicines accounted for 94% of all 1452 prescribing instances for generics with prolonged oral clearance (Table 5.10). The distribution of proprietary medicines with prolonged oral clearance was considerably different, with 1051 (78%) of the 1344 prescribing instances being for Gastrointestinal medicines.

Of the 471 prescribing instances for generic Cardiovascular medicines, 460 (98%) were for aspirin 75mg effervescent tablets. The 454 prescribing instances for generic Central Nervous System medicines were mainly analgesics (423 (93%) prescribing instances) and of the 448 generic Gastrointestinal medicines, 404 (90%) were laxatives, of which lactulose liquid accounted for 350 prescribing instances. Of the 1051 prescribing instances for proprietary Gastrointestinal medicines, 706 (67%) were antacids and 321 (31%) laxatives.

5.4.10.3.2 Dose form

As Table 5.11 describes, of the 42 generic preparations used regularly and long-term by the elderly in the survey, 31 (73.8%) were liquid oral medicines accounting for 542 prescribing instances (37% of the total of 1452 prescribing instances for generic preparations), and 10 were solids with prolonged oral clearance representing 909 prescribing instances (63% of the total). In contrast, of the 101 proprietary preparations 54 (54%) were liquid oral medicines which accounted for 685 prescribing instances (50% of the 1344 prescribing instances for proprietary preparations), and 31 (31%) were solids with prolonged oral clearance accounting for 342 prescribing instances (26% of the 1344 prescribing instances). Of the 1344 prescribing instances, 298 (22%) were for proprietary medicines formulated in sachets as powders or granules (Table 5.11).

Table 5.11 Numbers of preparations and prescribing instances for generic and proprietary medicines with prolonged oral clearance used regularly and long-term, by dose type

	Generic		Proprietary		Total	
	No of preps	No. of PIs	No of preps	No. of PIs	No of preps	No. of PIs
Liquid oral medicines	31	542	54	685	**85**	**1227**
Solids with prolonged oral clearance	10	909	31	342	**41**	**1251**
Powders and Oral Gels	0	0	4	19	**4**	**19**
Sachets	1	1	12	298	**13**	**299**
Total	**42**	**1452**	**101**	**1344**	**143**	**2796**

5.4.10.4 Top ten medicines with prolonged oral clearance used by the elderly

Of the 143 preparations with prolonged oral clearance taken regularly and long-term by the elderly, the ten most commonly prescribed, representing 75.7% (2116) of the 2796 prescribing instances are shown in Table 5.12. Seven of these top 10 preparations were Gastrointestinal medicines, with two Central Nervous System and one a Cardiovascular medicine. Of the 7

Gastrointestinal preparations which accounted for 1257 (45%) prescribing instances, 4 preparations were antacids, accounting for 603 prescribing instances and 3 preparations were laxatives, accounting for 654 prescribing instances.

As Table 5.12 shows the most commonly used preparation (long-term and regularly) with prolonged oral clearance in the elderly was aspirin 75mg effervescent tablets. This preparation was prescribed 460 times in the 2002 elderly patients identified as taking medicines with prolonged oral clearance regularly and long-term at the time of the survey and represented 16.5% of the total of 2796 prescribing instances.

The ten medicines in Table 5.12, are shown by their generic names. Of these, 4 were available as both generic and proprietary formulations, however all four were prescribed generically in all prescribing instances. The remaining six preparations were only available as proprietary brands although one (Ispaghula Husk) was prescribed by generic name in 33% of the 255 instances of long-term prescribing.

5.4.11 Duration of use of long-term medicines with prolonged oral clearance

When the duration of use by patients for medicines with prolonged oral clearance was determined, it was found that 48% of all prescribing instances were from three months to two years, with 27% of the prescribing instances being for medicines prescribed for one to two years. Overall, 78.6% of the prescribing instances were for medicines with prolonged oral clearance used for one year or longer (Table 5.13).

Prescribing of Gastrointestinal medicines was found in all periods of use; the greatest number of prescribing instances being for medicines prescribed for 1 to 2 years at the time of the survey (Table 5.13). Cardiovascular medicines were mainly prescribed for a period of 3 months to 2 years at the time of the study, accounting for 62.3% of the prescribing instances. Central Nervous System medicines were prescribed predominantly in two time periods; 1 to 2 years (26.1%) and over 5 years (19.7%).

Table 5.12 Number of prescribing instances (PIs) for the top 10 medicines with prolonged oral clearance used long-term in the elderly by generic (G) and proprietary (P) name

Preparation	BNF Section[1]	No. of PIs	% of total	Avail-ability as G or P	% generically prescribed
Aspirin 75mg dispersible tablets	CVS	460	16.5	G & P	100
Sodium alginate 250mg/ sodium bicarbonate 133.5mg/ calcium carbonate 80mg /5ml liquid	GIT	423	15.1	P	0
Co-codamol 500mg/ 8mg effervescent tablets	CNS	363	13.0	G & P	100
Lactulose liquid	GIT	350	12.5	G & P	100
Ispaghula husk 3.5g sachets	GIT	255	9.1	P	33
Alginic acid 200mg/ aluminium hydroxide 80mg/ magnesium trisilicate 40mg/ sodium bicarbonate 70mg/ chewable tablets	GIT	64	2.3	P	0
Alginic acid 500mg/ aluminium hydroxide 100mg/ magnesium trisilicate 25mg/ sodium bicarbonate 170mg / chewable tablets	GIT	62	2.2	P	0
Aluminium hydroxide 420mg/ activated dimethicone 135mg/ light magnesium oxide 70mg /5ml suspension	GIT	54	1.9	P	0
Co-danthramer suspension	GIT	49	1.8	G & P	100
Co-codamol 500mg/ 30mg effervescent tablets	CNS	36	1.3	P	0
Other POC medicines used long-term and regularly	-	680	24.3	-	-
Total	-	**2796**	**100.0**	-	-

[1] **BNF Section: GIT = Gastrointestinal System (BNF Section 1)**
CVS = Cardiovascular System (BNF Section 2)
CNS = Central Nervous System (BNF Section 3)

Table 5.13 Duration of time over which medicines with prolonged oral clearance were prescribed

Duration of use	Total no. of PIs	%	Prescribing Instances									
			Section 01[1]		Section 02[1]		Section 03[1]		Section 04[1]		Other[2]	
			No. of PIs	%	No. of PIs	%	No. of PIs	%	No. of PIs	%	No. of PIs	%
< 1 year	582	20.8	287	19.1	160	29.6	16	20.3	78	14.5	41	29.3
≥1 to <2 y	752	26.9	377	25.2	177	32.7	19	24.1	140	26.1	39	27.9
≥2 to <3 y	352	12.6	216	14.4	53	9.8	4	5.1	59	11.0	20	14.3
≥3 to <4 y	433	15.5	251	16.7	68	12.6	6	7.6	90	16.8	18	12.9
≥4 to <5 y	289	10.3	166	11.1	38	7.0	14	17.7	62	11.5	9	6.4
≥ 5 years	376	13.4	196	13.1	43	7.9	20	25.3	106	19.7	11	7.9
No Info.	12	0.4	6	0.4	2	0.4	0	0.0	2	0.4	2	1.4
Total	**2796**	**100.0**	**1499**	**100.0**	**541**	**100.0**	**79**	**100.0**	**537**	**100.0**	**140**	**100.0**

[1] 01 = Gastrointestinal 02 = Cardiovascular
03 = Respiratory System 04 = Central Nervous System
[2] Other BNF Sections

5.4.12 Frequency of administration of medicines with prolonged oral clearance used regularly and long-term

The frequency of administration of the 143 medicines with prolonged oral clearance used regularly and long-term was classified into four categories: once daily (including morning and night), twice daily, three times a day and four times a day (Table 5.14). A large proportion (67%) of the prescribing instances were for dosing frequencies of 'four times a day' (36.9%) or 'once daily' (30.1%), where 'once daily' included single instances of morning and night use (Table 5.14).

When the frequency of administration was analysed by dose form, liquid oral medicines used 'four times a day' accounted for 519 (42%) of the 1227 prescribing instances and 'twice daily' use accounting for 305 (25%) prescribing instances (Table 5.14). Medicines used 'four times' a day were generally antacids and the those used 'twice daily' were laxatives (Table 5.15). In contrast, medicines formulated as solids with prolonged oral clearance were used 'once daily' as well as 'four times a day'. The solid medicines with prolonged oral clearance used 'once daily' were mainly Cardiovascular medicines (414 prescribing instances), with those used 'four times a day' being effervescent analgesics (Central Nervous System) and antacid chewable tablets (Gastrointestinal Section). Medicines used at night accounted for 212 prescribing instances, of which 194 (92%) were liquid oral medicines and 158 (75%) of these were Gastrointestinal medicines (Table 5.15). Of the 299 prescribing instances for sachets, 231 were for medicines prescribed 'twice daily', and these were all Gastrointestinal medicines (laxatives).

Table 5.14 Number of prescribing instances for each frequency of administration by dose form

Frequency	LOM[1]	%	Solid	%	Pwd[2]	%	Sach[3]	%	Total	%
Once daily[4]	50	4.1	484	38.7	3	15.8	44	14.7	**581**	**20.8**
In the morning	4	0.3	49	3.9	0	0.0	1	0.3	**54**	**1.9**
At night	194	15.8	8	0.6	2	10.5	8	2.7	**212**	**7.6**
Twice daily	305	24.9	64	5.1	13	68.4	231	77.3	**613**	**21.9**
Three times each day	155	12.6	134	10.7	1	5.3	12	4.0	**302**	**10.8**
Four times each day	519	42.3	512	40.9	0	0.0	3	1.0	**1034**	**37.0**
Total	**1227**	**100.0**	**1251**	**100.0**	**19**	**100.0**	**299**	**100.0**	**2796**	**100.0**

[1] **Liquid oral medicines** [2] **Powder or oral gels**
[3] **Powders or granules in sachets** [4] **Once daily use where specification of morning or night use was not made**

Table 5.15 Number of prescribing instances for each frequency of administration by BNF Section

Frequency	GIT[1]	%	CVS[2]	%	Resp[3]	%	CNS[4]	%	Other[5]	%	Total	%
Once daily[6]	74	4.9	414	76.5	1	1.3	39	7.3	53	37.9	**581**	**20.8**
In the morning	2	0.1	46	8.5	0	0.0	2	0.4	4	2.9	**54**	**1.9**
At night	158	10.5	0	0.0	8	10.1	39	7.3	7	5.0	**212**	**7.6**
Twice daily	526	35.1	16	3.0	3	3.8	19	3.5	49	35.0	**613**	**21.9**
Three times each day	123	8.2	45	8.3	47	59.5	66	12.3	21	15.0	**302**	**10.8**
Four times each day	616	41.1	20	3.7	20	25.3	372	69.3	6	4.3	**1034**	**37.0**
Total	**1499**	**100.0**	**541**	**100.0**	**79**	**100.0**	**537**	**100.0**	**140**	**100.0**	**2796**	**100.0**

[1] **Gastrointestinal Section of the BNF**
[2] **Cardiovascular Section of the BNF**
[3] **Respiratory Section of the BNF**
[4] **Central Nervous System**
[5] **Other sections of the BNF**
[6] **Once daily use where specification of morning or night use was not made**

Night time use of medicines with prolonged oral clearance is important in terms of dental health as salivary flow is reduced at night and this increases the time taken for the medicine to clear from the oral cavity. Of the 212 prescribing instances for night time use, 194 (92%) were liquid oral medicines and of these 158 (81%) prescribing instances were for Gastrointestinal medicines, the majority (147 prescribing instances) being laxatives.

When the dosing frequencies for the top 10 medicines with prolonged oral clearance used regularly and long-term by the elderly were analysed (Table 5.16), it was clear that the majority of the prescribing instances were for the standard dose frequency recommended by the manufacturer, however there was a range of prescribing at other doses. For example, lactulose liquid is recommended to be used 'twice daily', however the survey recorded its use over all dosing frequencies. Similarly, ispaghula husk has a recommended dose frequency of 'twice daily', but in the survey it was used at all other dose frequencies recorded.

5.4.13 Prescription only medicines (POM) versus 'over the counter' (OTC) medicines prescribed regularly and long-term

Many medicines which are prescribed can also be bought 'over the counter' from community pharmacies. Of the 143 preparations with prolonged oral clearance used regularly and long-term in the elderly, 81 (57%) were 'prescription only medicines' (POM), the other 62 (43%) being 'over the counter' (OTC) medicines, of which 29 (47%) were available as 'pharmacy only', that is, only available from a pharmacist, and the remaining 33 (53%) were 'general sales list' (GSL) medicines, available from all retail outlets.

Over 80% of both the POM and OTC medicines were from the four BNF Sections of Gastrointestinal, Cardiovascular, Respiratory and Central Nervous System, with 17 (21%) POM preparations being Cardiovascular and Central Nervous System medicines accounting for 27 (33%) preparations, and 58% of OTC medicines being Gastrointestinal (36 preparations).

Only two of the top ten medicines with prolonged oral clearance and used long-term and regularly by the elderly were POM medicines. These were the laxative, co-danthramer suspension and the minor analgesic, co-codamol 500mg/30mg effervescent tablets. The other eight preparations were OTC medicines; four 'general sales list' and four 'pharmacy only'.

Table 5.16 Prescribing Instances for the top ten preparations by dosing frequency

Preparation (Generic Name)	Number of Prescribing Instances						
	Daily			Twice Daily	Three times a day	Four times a day	Total
	Morning	Night	Unspecified				
Aspirin 75mg dispersible tablets	44[1]	0	403[1]	8	1	4	**460**
Sodium alginate 250mg/ sodium bicarbonate 133.5mg/ calcium carbonate 80mg /5ml liquid	0	7	4	14	43	355[1]	**423**
Co-codamol 500mg/ 8mg effervescent tablets	0	2	1	5	43	312[1]	**363**
Lactulose liquid	1	84	13	238[1]	9	5	**350**
Ispaghula husk 3.5g sachets	1	7	33	204[1]	7	3	**255**
Alginic acid 200mg/ aluminium hydroxide 80mg/ magnesium trisilicate 40mg/ sodium bicarbonate 70mg chewable tablets	0	0	0	2	4	58[1]	**64**
Alginic acid 500mg/ aluminium hydroxide 100mg/ magnesium trisilicate 25mg/ sodium bicarbonate 170mg /5ml chewable tablets	0	0	2	2	6	52[1]	**62**
Aluminium hydroxide 420mg/ activated dimethicone 135mg/ light magnesium oxide 70mg /5ml suspension	0	2	3	8	9	32[1]	**54**
Co-danthramer suspension	0	38[1]	4	4	2	1	**49**
Co-codamol 500mg/ 30mg effervescent tablets	0	2	0	1	8	25[1]	**36**
Other POC medicines used long-term and regularly	8	69	114	126	177	186	**680**
Total Number	**54**	**211**	**577**	**612**	**309**	**1033**	**2796**
%	**1.9**	**7.6**	**20.6**	**21.9**	**11.1**	**36.9**	**100.0**

[1] **Recommended dose frequency (BNF 1995)**

Of the 2796 prescribing instances for the 143 preparations with prolonged oral clearance only 400 (14.3%) were for POM medicines. The remaining 2404 (85.7%) prescribing instances were for medicines which could be prescribed on a NHS prescription, but may also be bought from a pharmacy as a 'pharmacy only' (P) medicine (1314 prescribing instances) or from any retail outlet as 'general sales list' (GSL) medicine (1082 prescribing instances).

5.4.14 Sugar content of medicines with prolonged oral clearance used regularly and long-term by the elderly

5.4.14.1 Number of preparations that were sugars-free and sugars-containing

The quality of current information from the literature on which preparations were sugars-free and sugars-containing was variable and in most cases the type of sweetening agent was not given. Therefore, after the initial search of sources of literature for sugars content of medicines with prolonged oral clearance, (Association of British Pharmaceutical Industry, 1995; British Medical Association & Royal Pharmaceutical Society, 1995), it was decided to seek information on the sugars content of all preparations directly from the manufacturers of these medicines.

The information received varied in quality, from those manufacturers that gave the type and quantity of sweetening agent in each medicine to those who just supplied information as to whether it was sugars-free or sugars-containing. The manufacturers of proprietary preparations were more responsive in that the majority of companies posted or faxed information after the first request. In contrast, of the 27 manufacturers of the 144 generic formulations, only 6 responded after the first written request, the remainder were contacted by letter and fax, but even then only a further 5 responded. The remaining 16 companies were then contacted by telephone for the information, and all responded. The quality of information was poorer from the generic manufacturers compared with the proprietary preparations, in that for 78 of the 144 formulations the sweetening agent were not given, with the only information offered being whether the formulation was sugars-free or sugars-containing.

Using this information from the pharmaceutical manufacturers, the preparations were classified as sugars-free or sugars-containing. Generic medicines that were manufactured both as sugars-free and sugars-containing formulations were classified as variable.

5.4.14.1.1 Proprietary medicines

As Table 5.17 describes, 52.5% (53 preparations) of the 101 proprietary preparations with prolonged oral clearance used regularly and long-term by the elderly were sugars-free, 39 (38.6%) were sugars-containing and no information could be obtained for the remaining nine preparations.

Fifty-four of the 101 proprietary preparations were liquid oral medicines and of these 32 (59.3%) were sugars-free and 18 (33.3%) sugars-containing (Table 5.17). Of the 31 solid proprietary preparations with prolonged oral clearance only 12 (38.7%) were sugars-free. Seventeen solid preparations (54.8%) were sugars-containing and no information was obtained for the remaining two. Of the 12 sugars-free solids with prolonged oral clearance, 7 were effervescent tablets, the remainder being chewable tablets. Of the 17 sugars-containing preparations, 13 were chewable or buccal and sublingual tablets.

Table 5.17 Number of proprietary sugars-free and sugars-containing preparations with prolonged oral clearance by dose form

	Liquid oral medicines		Solids with prolonged oral clearance		Powders/ oral gels		Powders in sachets		Total	
	No. of preps	%	No. of preps	%	No. of preps	%	No. of preps	%	No. of preps	%
Sugars-free	32	59.3	12	38.7	1	25.0	8	66.7	**53**	**52.5**
Sugars-containing	18	33.3	17	54.8	3	75.0	1	8.3	**39**	**38.6**
No Information	4	7.4	2	6.5	0	0.0	3	25.0	**9**	**8.9**
Total	**54**	**100.0**	**31**	**100.0**	**4**	**100.0**	**12**	**100.0**	**101**	**100.0**

5.4.14.1.2 Generic medicines

Of the 42 generic preparations used regularly and long-term by the elderly, 14 (33.3%) were sugars-free and 23 (54.8%) were sugars-containing (Table 5.18), with no information available for 1 (2.4%) preparation. The remaining 4 (9.5%) generic preparations with prolonged oral clearance were available as both sugars-free and sugars-containing and were classified as variable.

Thirty-one (73.8%) of the generic preparations were liquid oral medicines and of these 10 (32.3%) were sugars-free, 18 (58.1%) sugars-containing, with 3 liquid oral medicines available as both sugars-free and sugars-containing and classed as variable. Of the 10 solid preparations with

prolonged oral clearance 4 (40%) were sugars-free, 4 (40%) sugars-containing, 1 (10%) variable and for 1 (10%) no information was available.

Of the 10 sugars-free liquid oral medicines, 4 were Gastrointestinal preparations, mainly laxatives and 3 were Cardiovascular medicines. Of the 18 sugars-containing liquid oral medicines, 8 were Central Nervous System preparations.

Table 5.18 Number of generic sugars-free and sugars-containing medicines with prolonged oral clearance by dose form

	Liquid oral medicines		Solids with prolonged oral clearance		Powders/ oral gels		Powders in sachets		Total	
	No. of preps	%	No. of preps	%	No. of preps	%	No. of preps	%	No. of preps	%
Sugars-free	10	32.3	4	40.0	0	-	0	0.0	**14**	**33.3**
Sugars-containing	18	58.1	4	40.0	0	-	1	100.0	**23**	**54.8**
Variable	3	9.7	1	10.0	0	-	0	0.0	**4**	**9.5**
No information	0	0.0	1	10.0	0	-	0	0.0	**1**	**2.4**
Total	**31**	**100.0**	**10**	**100.0**	**0**	**0**	**1**	**100.0**	**42**	**100.0**

5.4.14.2 Number of prescribing instances for sugars-free and sugars-containing medicines with prolonged oral clearance

Overall, when the 2796 prescribing instances for medicines with prolonged oral clearance used regularly and long-term by the elderly were analysed according to sugar content, 1986 (71%) were sugars-free, 715 (25.6%) were sugars-containing, 41 (1.5%) were variable and there was no information for 54 (1.9%) prescribing instances (Table 5.19). Of the 1452 prescribing instances for generic preparations 947 (65.2%) were sugars-free and 461 (31.7%) were sugars-containing, with 41 (2.8%) being for generic preparations where the sugar content was variable (Table 5.19).

Of the 1344 prescribing instances for proprietary medicines, 1039 (77.3%) were sugars-free and 254 (18.9%) were sugars-containing, with no information available for 51 (3.8%) prescribing instances (Table 5.19).

Table 5.19 Number of prescribing instances for sugars-free and sugars-containing medicines with prolonged oral clearance used regularly and long-term in the elderly

	Generic		Proprietary		Total	
	No. of PIs	%	No. of PIs	%	No. of PIs	%
Sugars-free	947	65.2	1039	77.3	1986	71.0
Sugars-containing	461	31.7	254	18.9	715	25.6
Variable	41	2.8	0	0.0	41	1.5
No information	3	0.2	51	3.8	54	1.9
Total	**1452**	**100.0**	**1344**	**100.0**	**2796**	**100.0**

5.4.14.2.1 Proprietary medicines

As Table 5.19 shows, there were 1344 prescribing instances for proprietary preparations with prolonged oral clearance of which 1039 (77.3%) were sugars-free and 254 (18.9%) sugars-containing. Proprietary liquid oral medicines accounted for 685 (51%) of the total of 1344 prescribing instances for proprietary medicines (Table 5.20) and of these 625 (91.2%) were sugars-free. Of the 342 prescribing instances for solid proprietary preparations, 149 (43.6%) were for sugars-free preparations and 52.6% were sugars-containing. Of the 298 prescribing instances for powders and granules in sachets, 263 (88.3%) were sugars-free (Table 5.20).

Of the 625 prescribing instances for sugars-free proprietary liquid oral medicines, 569 (91%) were for Gastrointestinal medicines of which antacids accounted for 561 prescribing instances. Of the 159 prescribing instances for sugars-free proprietary solids with prolonged oral clearance 99% were accounted for within the three BNF Sections of Gastrointestinal (45%), Nutrition and Blood (28%) and Central Nervous System (26%), with 92 (62%) of the 159 prescribing instances being for chewable tablets and 57 (38%) for effervescent tablets. Of the 180 prescribing instances for proprietary sugars-containing preparations, 89% (161) were from the Gastrointestinal (41%), Cardiovascular (31%) or Nutrition and Blood (17%) Sections of the BNF, 93 (53%) being for chewable tablets and 59 (33%) for buccal or sublingual tablets.

Table 5.20 Number of prescribing instances (PIs) for proprietary medicines with prolonged oral clearance by dose form

	Liquid oral medicines		Solids with prolonged oral clearance		Powders & oral gels		Powders in sachets		Total	
	No. of PIs	%	No. of PIs	%	No. of PIs	%	No. of PIs	%	No. of PIs	%
Sugars-free	625	91.2	149	43.6	2	10.5	263	88.3	**1039**	**77.3**
Sugars-containing	52	7.6	180	52.6	17	89.5	5	1.7	**254**	**18.9**
Variable	0	0.0	0	0.0	0	0.0	0	0.0	**0**	**0.0**
No Information	8	1.2	13	3.8	0	0.0	30	10.1	**51**	**3.8**
Total	**685**	**100.0**	**342**	**100.0**	**19**	**100.0**	**298**	**100.0**	**1344**	**100.0**

5.4.14.2.2 Generic medicines

In contrast to proprietary medicines, liquid oral medicines only accounted for 37% (542) of the 1452 prescribing instances for all generic medicines (Table 5.21) and of these 437 (80.6%) were sugars-containing, 90 (16.6%) sugars-free, with 15 (2.8%) prescribing instances being for variable preparations. Solid preparations with prolonged oral clearance accounted for 62% of the prescribing instances, of which 94.3% were sugars-free, 2.5% (23) sugars-containing and 2.9% (26) variable (Table 5.21).

Table 5.21 Number of prescribing instances (PIs) for generic medicines with prolonged oral clearance by dose form

	Liquid oral medicines		Solids with prolonged oral clearance		Powders & oral gels		Powders in sachets		Total	
	No. of PIs	%	No. of PIs	%	No. of PIs	%	No. of PIs	%	No. of PIs	%
Sugars-free	90	16.6	857	94.3	0	-	0	0.0	**947**	**65.2**
Sugars-containing	437	80.6	23	2.5	0	-	1	100.0	**461**	**31.7**
Variable	15	2.8	26	2.9	0	-	0	0.0	**41**	**2.8**
No information	0	0.0	3	0.3	0	-	0	0.0	**3**	**0.2**
Total	**542**	**100.0**	**909**	**100.0**	**0**	-	**1**	**100.0**	**1452**	**100.0**

Of the 437 prescribing instances for sugars-containing generic liquid oral medicines, 359 (82%) were for Gastrointestinal medicines, of which 350 (98%) were for the laxative lactulose. Of the 857 prescribing instances for sugars-free generic solids with prolonged oral clearance, 460

(54%) were for the Cardiovascular medicine, aspirin 75mg effervescent tablets and 397 (46%) for Central Nervous System medicines, of which 363 (91%) were for the analgesic, co-codamol effervescent tablets.

5.4.14.3 Types of sweetening agents used in sugars-free and sugars-containing medicines with prolonged oral clearance

Each manufacturer of the 144 generic formulations and 101 proprietary formulations was contacted separately. All information on whether the formulation was sugars-free or sugars-containing was obtained for all of the 144 generic preparations, however it was not possible to obtain information on the type of sweetening agents used in 78 formulations. In contrast, manufacturers of all but 9 proprietary preparations provided detailed information on the types of sweetening agents in their preparations.

The 245 preparations (101 proprietary and 144 generic) contained 18 different sweetening agents either singly or in combination. Seven of these were classified as sugars-containing, the remaining 11 were classed as sugars-free.

5.4.14.3.1 Proprietary Preparations

For proprietary preparations, information was obtained for 92 of the 101 preparations. Of these 92 preparations 53 (58%) were sugars-free and 39 (40%) were sugars-containing (Table 5.22).

Of the 53 sugars-free preparations, eight preparations contained no sweetening agent, 28 contained saccharin (singly in 14 preparations and in combination with other sugars in 14 preparations). Saccharin was also found in three sugars-containing preparations.

Of the 39 sugars-containing preparations the most common sugar was sucrose which was either the sole sugar (23 preparations) or in combination with other sweetening agents (6 preparations).

5.4.14.3.2 Generic preparations

For the 42 generic medicines there were 144 different formulations, manufactured by 27 pharmaceutical companies (Table 5.23). Information on whether the product was sugars-free or sugars-containing was obtained for all but 1 of the 144 formulations, however the manufacturers of 78 formulations (33 sugars-free, 44 sugars-containing and 1 for which no information was

available) declined to provide information on the type of sweetener used in the formulation. From the remaining 66 formulations, 36 contained sugars-free sweetening agents and 30 sugars-containing sweetening. Four formulations contained no sweetening agents and were classed as sugars-free.

Of the 36 sugars-free formulations for which information was obtained, saccharin was the most common sweetening agent, being used in 18 formulations as the only sweetening agent and in 7 preparations in combination with other sweeteners. The majority of saccharin containing formulations (16 formulations) were solid doses with prolonged oral clearance.

Of the 30 sugars-containing generic formulations for which information was obtained, 25 (83%) were liquid oral medicines, 4 formulations were solids with prolonged oral clearance and one was a sachet. Sucrose was the main sweetening agent found in sugars-containing generic formulations accounting for 19 formulations, with 16 containing only sucrose and 3 formulations using sucrose in combination with other sugars.

Table 5.22 Sweetening agents found in 101 proprietary preparations with prolonged oral clearance

	Proprietary Medicines				
	Liquids	**Solid**	**Powder/ gels**	**Sachets**	**Total**
Sugars-free					
No Sugar	3	2	1	2	**8**
Saccharin	10	4	0	0	**14**
Aspartame	0	2	0	5	**7**
Sorbitol	6	0	0	0	**6**
Xylitol	0	0	0	1	**1**
Saccharin + Sorbitol	6	1	0	0	**7**
Saccharin + Mannitol	0	1	0	0	**1**
Saccharin + Cyclamate	0	1	0	0	**1**
Sorbitol + Lycasin + Aspartame	0	1	0	0	**1**
Glycerol + Sorbitol	1	0	0	0	**1**
Saccharin + Glycerol	2	0	0	0	**2**
Saccharin + Sorbitol + Glycerol	3	0	0	0	**3**
Sorbitol + Saccharin + Glycerol + Lycasin	1	0	0	0	**1**
Total	**32**	**12**	**1**	**8**	**53**
Sugars-containing					
Sucrose	14	5	3	1	**23**
Lactose	1	7	0	0	**8**
Sucrose + Saccharin	0	1	0	0	**1**
Sucrose + Glucose + Sorbitol	1	0	0	0	**1**
Sucrose + Sorbitol + Saccharin	2	0	0	0	**2**
Sucrose + Glucose + Dextrose	0	1	0	0	**1**
Mannitol + Saccharin + Lactose	0	1	0	0	**1**
Sucrose + Sorbitol+ Lycasin + Aspartame	0	1	0	0	**1**
Lactose + Sorbitol + Saccharin + Aspartame	0	1	0	0	**1**
Total	**18**	**17**	**3**	**1**	**39**
Overall Total					
Sugars-free	32	12	1	8	**53**
Sugars-containing	18	17	3	1	**39**
No information	4	2	0	3	**9**
Total	**54**	**31**	**4**	**12**	**101**

Table 5.23 Sweetening agents found in 144 generic formulations with prolonged oral clearance

	Generic Medicines				
	Liquids	**Solid**	**Powder/ gels**	**Sachets**	**Total**
Sugars-free					
No Sugar	4	0	0	0	**4**
Saccharin	4	14	0	0	**18**
Sorbitol	3	0	0	0	**3**
Lycasin	3	0	0	0	**3**
Saccharin + Sorbitol	5	2	0	0	**7**
Sorbitol + Lycasin	1	0	0	0	**1**
Total	**20**	**16**	**0**	**0**	**36**
Sugars-containing					
Sucrose	14	1	0	1	**16**
Lactose	0	1	0	0	**1**
Lactulose	7	0	0	0	**7**
Sucrose + Sorbitol	1	0	0	0	**1**
Sucrose + Lactose	0	1	0	0	**1**
Sucrose + Lactose + Starch	0	1	0	0	**1**
Lactose + Lactulose + Galactose	2	0	0	0	**2**
Fructose + Tagatose + Galactose + Lactose + Epifructose	1	0	0	0	**1**
Total	**25**	**4**	**0**	**1**	**30**
Overall Total					
Sugars-free	20	16	0	0	**36**
Sugars-containing	25	4	0	1	**30**
No information	49	29	0	0	**78**
Total	**94**	**49**	**0**	**1**	**144**

5.5 DISCUSSION

5.5.1 The sample

To estimate the prevalence of use of medicines with prolonged oral clearance prescribed and taken regularly and long-term by the elderly (aged sixty years and over) the sample had to be representative of the total elderly population. In general, the larger the practice list size, the better the socioeconomic mix of subjects would be, however, the location of a practice would also determine its population and therefore it was important that a representative sample of all socioeconomic classes was included in the survey. With this in mind, practices from five districts representing urban (North Tyneside and South Tyneside), inner city (Newcastle and Gateshead) and rural (Northumberland) settings were included in the sampling frame. In general, the North East of England is more deprived than other areas in England; unemployment in the North East was 9.8% in 1997 compared with the 6.9% for the whole of England (Office for National Statistics, 1998) and studies have shown that social deprivation is linked to morbidity. In view of this some caution is needed in extrapolating the results of this study in the Northern Region, nationally.

Other criteria for inclusion in the study for the medical practices included a large list size and the use of computerised patient medication record systems. It was important that these computer systems allowed easy searching of records and provided clear information on repeat prescribing. During the planning of this study advice was taken on the feasibility of using general practice computing systems for undertaking a prevalence survey and a number of computer systems were considered. The ease of printing information and conducting of searches using different variables was discussed and it became apparent that two systems: EMIS and MEDITEL offered these facilities. Of the ten practices that were finally included in the survey, nine used the EMIS system and one used MEDITEL. Both systems allowed easy searching and printing of patient records and offered on-screen information about current repeat prescribing along with information on start dates for each medication, which was vital for easy and accurate data collection. In addition, both systems allowed the connection of an additional external printer to the terminal, to output patient medication data, which was important as it did not interfere with the running of the medical practices and the printing of prescriptions by practice staff. The technical help lines which both systems offered were used initially to gain information on the use of the computer where practice staff could not help and provided data on practice demographics at the time of the study.

The 10 general medical practices were selected at random, using a cluster sampling process, from a list of all practices that had comprehensive computing facilities. All practices had list sizes of approximately 5,000 and over and complied with the inclusion criteria. Three practices of the 10 initially selected were unable to help; one was already involved in another research project and the other two were too busy. With changes in primary health care, the role of the general medical practitioner in recent years has evolved to include more management and audit work as well as clinical duties. The practices that agreed to help were highly organised and employed practice and fund-holding managers. These practices also were highly computerised, using the practice computer for not only for patient records but also for general practice management and audit. It may be that due to the highly organised structure of these practices that their prescribing may vary from smaller and less structured practices and place a selection bias in this study; for example, all these practices had adopted practice formularies, devised with the help of health authority and community pharmacists, to optimise cost-effective prescribing. The use of a practice formulary may lead to some variation in prescribing compared with those practices that don't use one, however in the Northern Region, the district health authority, in a bid to cut prescribing costs, has introduced practice formularies in the majority of general medical practices. The use of formularies tends to result in the prescribing of a narrower range of drugs both overall and for particular medical problems and increased use of cheaper generic formulations (Consumers Association, 1997).

The aim of a cross-sectional study of this design was to estimate prevalence at a single point in time: ideally one day in which all the elderly patients registered with the 10 practices taking medicines with prolonged oral clearance regularly and long-term would be identified. This however was unrealistic since there were 20371 elderly patients registered at the ten practices. It was estimated during the planning of the study that data collection would take approximately 12 months for all ten practices but the majority of the elderly tend to take the same medication over long periods of time. In this survey 78.8% of the prescribing instances for medicines with prolonged oral clearance used regularly and long-term were being prescribed for over a year with prevalence of use remaining fairly constant over relatively long periods of time and it was felt that this time span for data collection was acceptable. The fact that the data were collected over 12 months also helped to eliminate any seasonal variations in prescribing. The manual aspect of the data collection was main reason for this long time span and this discussed further in Section 5.5.3.

The 20371 elderly patients in the sample represented 22% of the total population of the practices, which was very similar to the proportion of elderly in the five districts of the study (22%), the Northern Region (21%) and England (21%). Also the proportion of male (43%) and female (57%) elderly patients in the sample was similar to the proportion of elderly males and females in the five districts (42% and 58% respectively), the Northern Region (42% and 58% respectively) and England (43% and 57% respectively) (Office for National Statistics, 1995). This was also true of age distribution and showed that the sample was suitably representative and any extrapolation on a local and regional level could be made with reasonable confidence.

5.5.2 The data collection process

During the period of data collection each of the ten practices were visited at least once every two weeks and all ten practices were at the same stage throughout the data collection process. An alternative way to collect the data would have been to collect the data from one practice at a time, reducing the time taken to collect the data from each practice. However the data would then have been collected at different times during the year, and seasonal variations in prescribing would influence the results. On balance, collection of information from the ten practices using the methodology chosen was felt to have been the most appropriate method.

The data collection process was very time-consuming; in Phase 2 the records of over 20000 patients had to be examined manually on the computer screen, to extract demographic and medical data which then had to be coded and entered into a database. This process could have been facilitated by downloading the data straight from a practice computer to a disk and then importing these data into a database, however this would have involved copying large amounts of data (approximately 4 Megabytes) onto computer disks. At the time of the survey computer disks capable of holding large amounts of data (>1.4 Megabytes) were not commercially available and this did prolong the time taken to complete this part of the survey. Although this method would provide a more accurate point prevalence survey than the method used in this study, the technology was not available at the time.

5.5.3 Accuracy of the data

As all the data in the Prevalence Survey were taken directly from practice computer systems, the accuracy of the data relied on how accurate the general medical practice computer records were. It has been demonstrated that prescribing information is very accurate in general medical

practice, with one survey showing 100% of all consultations where a prescription was issued being logged onto the computer (Pringle *et al.*, 1995).

With the large amounts of data which had to be manually collected, coded and entered into the database it was important to ensure that all data collection and coding was accurate. Data entry into the database was controlled by programming the fields to only accept certain types of data. For example, when entering the date of birth of a patient, the field was programmed to accept a series of 8 digits only, for example in the form 01011997. In addition the database would reject any month over 12 and it would not allow entry of a date of birth for a patient aged under sixty years of age. A 5% random sample of the data from the 2002 patients taking medicines with prolonged oral clearance regularly and long-term was randomly taken from five of the ten practices and checked for collection, coding and entry errors. No errors were discovered due to collection, coding and entry of the data, however the validation exercise did highlight problems with the construction of the database. To analyse data from different tables, there had to be similar fields in the tables and the data in these fields had to match, for example the medicine code had to be the same for the tables holding information on patients medicines (**PATIENT MEDICATION**) and medicines information (**DRUGS**). In practice this information was entered separately for each table, however during the course of the study it became apparent that this process could have been automated by the database.

The process of collecting and entering data manually is no longer necessary as advances in computing technology have allowed computers to be connected directly to practice computers and allowed information to be down-loaded directly into a database. The whole process, which took over a year for this survey could be done in much less time in any future work of this nature.

Further advances in the use of information technology in general medical practice, include the release of the PRODIGY project in 1998 (Purves, 1998). This system provides the general medical practitioner with a software program helping him decide which drugs to prescribe, based on evidence of efficacy and cost The Royal Pharmaceutical Society is also setting up a working party looking at the use of computer technology in primary care with view to standardise all general medical practice and pharmacy systems. This will allow interchange of data between pharmacies, general medical practices and the Prescription Pricing Authority, perhaps even eliminating the paper based prescription form. The implications of this technology for future

studies of this nature, i.e. prevalence surveys are that the data may be directly downloaded from computer systems, eliminating the time-consuming process of data collection and entry.

5.5.4 The estimate of prevalence of use of medicines with prolonged oral clearance used regularly and long-term in the elderly

The survey of 92570 patient records in ten practices identified 20371 elderly patients of whom 3777 (18.5%) were taking at least one medicine with prolonged oral clearance. Of these elderly patients 9.8% (2002) of all elderly patients sampled were taking medicines with prolonged oral clearance regularly (daily or alternate day) and long-term (>3 months). This prevalence rate varied between the practices, from 5.3% of the elderly population of a North Tyneside practice compared with 13.3% of a South Tyneside practice and regular and long-term use of similar practices, for example, two urban practices from North Tyneside also varied dramatically (5.9% and 11.2%) in the prevalence rate. These results would suggest that the prevalence of use of medicines with prolonged oral clearance regularly and long-term by the elderly is not dependent on the area (i.e. rural, inner city or urban) or the district, as two different areas such as rural Northumberland and urban South Tyneside had similar rates. It is more likely that medical and other factors such as age influence the prescribing of medicines with prolonged oral clearance.

The 10 practices surveyed provided a representative sample of the five districts in the Northern Region of England in terms of the male:female ratio as well as the proportion of elderly individuals. Extrapolation of the prevalence rates of 7.9% in the 60y to 74y group and 13.5% in the 75y and over group to the five districts with an elderly population of 0.25 million (Office for National Statistics, 1995) would mean that 24588 elderly in these five districts (19821 aged 60y to 74y, 33872 aged ≥75y) may be taking medicines with prolonged oral clearance regularly and long-term. Further extrapolation to the whole of the Northern Region with an elderly population of 0.62 million in 1995 (Office for National Statistics, 1995) would mean that 60544 elderly (48806 aged 60y to 74y, 83403 aged ≥75y) may be taking medicines with prolonged oral clearance regularly and long-term. In view of the socioeconomic differences between the Northern Region and the rest of the country and the impact of these differences on health, the extrapolation for England should be treated with some caution, however, with an elderly population of 10 million in England (Office for National Statistics, 1995), over 2 million elderly (790000 aged 60y to 74y, 1.35 million aged ≥75y) may be potentially taking medicines with prolonged oral clearance regularly and long-term. Since there are sugars-containing medicines with prolonged

oral clearance and the elderly are retaining their natural teeth, then these elderly are at risk from these medicines in terms of dental health.

5.5.5 Age and gender profiles of the elderly taking medicines with prolonged oral clearance regularly and long-term

Of the total population of all ages in all ten practices in the survey (92,570 patients), 51.1% were female, with 57% aged 60 years and over being female, reflecting demographic trends in England which show that females have greater life expectancy (Office for National Statistics, 1998). This proportion was very similar to that found in the Northern Region and England where the elderly females (aged 60 years and over) represented 58% of all elderly patients (Table 5.4). However, the results of the Prevalence Survey showed that of the 2002 elderly patients on regular long-term medication with prolonged oral clearance, 68.1% were female (60y to 74y - 63% female, ≥75y - 74% female). In the population identified there were more female than male elderly patients and the proportion of elderly male to females was consistent throughout the five districts, the Northern Region and England. The patients on long-term medicines with prolonged oral clearance were more likely to be female ($p<0.0001$) and as the patients aged, the proportion of females increased; 74% of the patients aged ≥75y being female. This is important in terms of targeting population groups for health education, with regard to medicine use.

5.5.6 Medical problems of patients

All 2002 patients identified in the Prevalence Survey suffered from at least one medical problem, with a range of 1 to 8 medicines with prolonged oral clearance used regularly and long-term. The major medical problems of patients taking medicines with prolonged oral clearance were cardiovascular (38%) and musculoskeletal (24%), with most cardiovascular problems being hypertension and angina, and the main musculoskeletal problem being arthritis. Prescribing data for all medicines dispensed to elderly patients (those exempt from prescription charges) in 1994 show that 27.6% of all 184.2 million prescriptions dispensed were for cardiovascular medicines (Prescription Pricing Authority, 1995), which was lower than the prevalence of the disease in the study population. This could be due to a higher rate of cardiovascular disease in the North; 40.7 males and 27.2 females per 1000 patients of all ages in 1996 was diagnosed with Coronary Heart Disease (Office of Health Economics, 1997). One of the risk factors for cardiovascular disease is hypertension and in a study of 1948 patients from 13 general medical practices in England, looking at cardiovascular risk factors, 53.3% were on treatment for raised blood pressure

(Poulter *et al.*, 1996). The authors also reported that all risk factors for cardiovascular disease were higher in the Northern practices.

5.5.7 Types of medicines with prolonged oral clearance used regularly and long-term by the elderly

5.5.7.1 Preparations

The 2002 patients identified as taking at least one medicine with prolonged oral clearance were taking 11,751 medicines in total (mean = 5.9 medicines per person, range = 1 to 18). Of these instances of prescribing, 53.5% (6295) were for oral medicines without prolonged oral clearance (i.e. solid oral doses). In the UK the solid oral dose is the most common dosage form as it is convenient for the patients in that it is easy to administer a specific dose without taste problems and is not bulky to store. It is also cheaper than liquids to produce because it is stable and does not have the high storage and transport costs incurred by bulky liquid oral medicines, making it a popular choice. However the patients taking medicines with prolonged oral clearance regularly and long-term were also taking other medicines in the form of tablets and capsules. This would indicate that either the formulation of the medicine with prolonged oral clearance was contributing to the therapeutic effect, that medicines with prolonged oral clearance taken regularly and long-term were not available as a solid oral dose or that the prescriber (for some reason) preferred to prescribe medicines with prolonged oral clearance. Prescribers may choose to use medicines with prolonged oral clearance for reasons such as swallowing difficulties, in a bid to improve compliance. Medicine factors could be a faster onset of action by prolonged oral clearance medicines and less local side effects.

There is no evidence in the literature to suggest that prescribers prefer medicines with prolonged oral clearance to solid dose forms and it is more likely that the medicine with prolonged oral clearance was being used for either its local effect in the oral cavity (such as lozenges or cough syrups) or in the stomach, such as antacids or laxatives. This is confirmed by the results of the Prevalence Survey, which have shown that of the 143 medicines used regularly and long-term by the elderly, 36.3% (52 medicines) were from the Gastrointestinal Section of the BNF and 23 of these were antacids. Antacids are normally alkaline substances which neutralise the acid produced in the stomach and alleviate the symptoms of excess acid such as indigestion. Antacids are more effective as liquids or chewable tablets, since a large volume is required to produce an antacid effect, and this could not be achieved by solid oral doses such as capsules and tablets.

The liquid or chewable tablet dose forms have a faster action as there is a greater surface area of drug to have the neutralising effect required in the stomach.

Laxatives were the other main medicines used in the gastrointestinal section; there were 17 preparations with prolonged oral clearance in this therapeutic sub-section, used regularly and long-term by the elderly. The smooth muscle of the bowel becomes less efficient with age and this problem is compounded by the large number of medicines used in the elderly, many of which can cause chronic constipation (e.g. anticholinergic medicines). The bowel function is further compromised by the poor diet of the elderly, who consume less fibre than younger members of the population (Finch *et al.*, 1998). The laxatives commonly used were ispaghula husk, a bulk-forming powder which is reconstituted with water prior to use, and lactulose, a liquid laxative which is mainly composed of the disaccharide lactulose and other sugars which produce an osmotic effect drawing water into the gut to soften the faeces. Both these types of laxatives rely on dose form for effect and are not available as solid oral doses.

Central nervous system medicines with prolonged oral clearance were also commonly used regularly and long-term by the elderly. Most of these were anti-psychotics, minor analgesics and anti-depressants in liquid oral form, since anti-psychotics and antidepressants are often tailored to the individual patient and require the dose to be changed, often by small increments. By using a liquid preparation the prescriber can accurately administer the correct dose and also change this if required by altering the volume. The majority of minor analgesics identified as being used regularly and long-term by the elderly in this study were co-codamol effervescent tablets taken on a regular basis to control pain in chronic arthritic conditions. The physical size of the solid oral dose tablet is fairly large making it difficult for frail elderly individuals to swallow the tablets. Effervescent tablets offer an easier dose form, being dissolved in water before oral administration which will also increase the surface area of the drug, providing a faster reaction. Effervescent tablets work on the basis of a acid base reaction when placed in contact with water which causes the tablet to explode and disperses the drug in the water. There is usually an excess of weak acid resulting in an acidic solution which as well as producing a palatable solution, may also have dental health implications as this solution may cause dental erosion on contact with teeth. This is an area of increasing concern, previously highlighted in children (Nunn *et al.*, 1996), where the main cases appear to be the increasing consumption of carbonated drinks, many of which are acidic or liberate acid on contact with teeth. Although there is little literature on the use of solid

doses with prolonged oral clearance and dental erosion, recent studies have reported dental erosion associated with chewable tablets (Giunta, 1983; Sullivan & Kramer, 1983).

One group of medicines with prolonged oral clearance used regularly and long-term by the elderly was respiratory system medicines (16%) which were mainly syrups and linctuses to alleviate cough. Cardiovascular preparations with prolonged oral clearance accounted for 12.6% of the preparations used regularly and long-term and most of these were diuretics such as frusemide, and the four different strengths of the anti-angina preparation glyceryl trinitrate in a buccal formulation. In both cases other more commonly used dose forms are available, such as frusemide oral tablets and isosorbide mononitrate (a nitrate similar to glyceryl trinitrate), suggesting that the reason for giving a prolonged oral clearance medicine was for the patient reasons. The patient may have problems swallowing solid oral doses and in a bid to improve compliance the doctor may have prescribed a liquid oral medicine, as compliance is a problem in the elderly (Salzman, 1995), where poor compliance was estimated to be as much as 40% to 75%. Compliance with medication tends to decrease in the elderly as they generally take more medicines than younger members of the population. The Royal Pharmaceutical Society of Great Britain has recently launched an initiative ('From compliance to concordance') to assess the reasons for poor compliance and to look at ways of improving it (Royal Pharmaceutical Society of Great Britain, 1997).

5.5.7.2 Prescribing instances

The number of prescribing instances for medicines used, rather than the number of preparations gave a more accurate indication of what medicines were commonly being used by the elderly. The results showed that 75.7% of all prescribing instances for medicines with prolonged oral clearance used regularly and long-term were for only ten preparations. Analysis by BNF Section showed that 53.4% of prescribing instances were for Gastrointestinal medicines and 87% of these were for ten preparations. This illustrates the narrow range of these medicines for the elderly. The elderly do suffer from gastric problems and ageing is associated with a decline in gastric secretions, especially acid secretions, with secretory volumes as low as 50% in some elderly patients, compared with younger individuals (Geokas & Haverback, 1969). This often leads to gastritis increasing with age, with a reduction the number of chief and parietal cells in the mucosa (Lamy, 1991), resulting in an ageing stomach which is vulnerable to insult from exogenous substances, especially drugs, and in particular, non-steroidal anti-inflammatory and

corticosteroid drugs. This would explain why the elderly are commonly prescribed antacids which have optimal efficacy when formulated as chewable tablets or liquid oral medicines.

Of the 541 prescribing instances for the Cardiovascular Section, 506 (75%) were for one medicine: aspirin 75mg effervescent tablets, used as prophylaxis against blood clotting. There has been an increase in the use of oral aspirin in patients who are at risk from cardiovascular disease, with one study showing that 9.5% of men used aspirin daily for coronary heart disease prevention (McCallum *et al.*, 1997). The overall number of prescribing instances for aspirin may not accurately reflect its use as this medicine may be bought from pharmacies due to its low cost and patients may prefer to purchase this rather than have it prescribed.

The Central Nervous System represented the third most prescribed area of regularly and long-term use of medicines with prolonged oral clearance. Two differing strengths of the minor analgesic co-codamol effervescent tablets represented 86% of all 537 prescribing instances for Central Nervous System medicines, again showing that prescribing was centered round a small range of medicines. The dose form used reflected the benefit gained from using aspirin in this effervescent form, allowing a greater surface area of the stomach to contact the drug preventing high concentrations of the drug coming into contact with the stomach lining, which may cause ulceration. This is a particular problem with aspirin, however there is no pharmacological reason for using co-codamol effervescent tablets as they do not cause local irritation from high concentrations in the stomach. The decision to choose this dose form may relate to swallowing difficulties or patient preference.

5.5.7.3 Dose form

Of the 143 medicines with prolonged oral clearance, used regularly and long-term in the elderly, liquid oral medicines were the most commonly used dose form and accounted for 85 preparations. Liquid oral medicines are the traditional alternative dose form to solid doses. This is especially true in children, however oral liquids also have an important role in the elderly where swallowing problems and general ill health may prevent them from using solid oral doses. Other newer dose forms with prolonged oral clearance include solids such as chewable, effervescent, buccal and sublingual tablets and lozenges and pastilles, all of which are retained for prolonged periods in the mouth. They are less bulky and more stable than liquid oral medicines, with a longer shelf life and offer a convenient method of administration. The other two dose forms which only accounted for 17 preparations were sachets and loose powders and oral gels. Loose powders

are rarely used as they do not offer an accurate means of measuring doses and in this study their use was restricted to laxatives. Powders and granules in sachets are becoming more common as they have the advantage of being dispersed to be administered as an oral liquid but unlike liquid oral medicines they are not bulky to transport. However they are expensive alternatives.

Of the 41 solid preparations with prolonged oral clearance, 67% were Gastrointestinal or Central Nervous System medicines, although only 13% of the prescribing instances were for Gastrointestinal medicines, with 79% being for Cardiovascular and Central Nervous System medicines. Aspirin 75mg effervescent tablets accounted for 99% of the prescribing instances for solid Cardiovascular medicines with prolonged oral clearance and co-codamol effervescent tablets for 89% of the prescribing instances for solid Central Nervous System medicines with prolonged oral clearance. Unlike dose forms such as inhalers and injection devices there is no literature on the use of solid doses with prolonged oral clearance and the analysis in this study could not be compared with any published data.

Although there was a wide range of preparations with prolonged oral clearance used in the Prevalence Survey, the majority of prescribing for these medicines to the elderly was across a narrow range of preparations in a few therapeutic areas.

5.5.8 Frequency of administration of medicines with prolonged oral clearance

Each pharmaceutical preparation has a recommended dose and dosing frequency, which is found in the drug data sheet (Association of British Pharmaceutical Industry, 1995). The frequency at which a medicine is prescribed is at the discretion of the prescriber, and most follow the prescribing guidelines set out in the British National Formulary and data-sheets, set following the result of stringent testing by manufacturers. However this survey showed a variation in the frequency at which a medicine was administered. Although most of the prescribing instances were for the standard frequency, there was a variation especially with the laxatives lactulose and ispaghula husk. For many drugs a range of dose frequencies is not a cause for concern, however a pharmacist must ensure that a prescribed dose is safe as well as effective and it would seem that there is a need for a closer working relationship between the general medical practitioner and the pharmacist, to ensure rational prescribing.

Antacids generally have no standard dosing regime and instead are administered on a 'when required' basis. However the antacids used regularly and long-term in the elderly were nearly all

prescribed for administration four times a day, highlighting the high level of use of gastrointestinal medicines in the elderly. Many of the conditions causing gastric problems such as excess acidity and chronic constipation may be due to poor health education by the professionals and improvements in diet and fluid intake may reduce the need for these medicines. Laxatives and antacids are also often used as an adjunct to treatment where the where another drug such as a laxative is prescribed to supplement the medication schedule, if the original prescribed medicine is causes constipation, rather than review and change the original medication. Although no medicines in this survey were used in a manner that would cause harm to the elderly patient, this was not an ideal situation and perhaps the introduction of practice protocols on the use of laxatives may reduce the level of such prescribing.

5.5.9 Generic and proprietary with prolonged oral clearance

The importance of generic prescribing in government efforts to reduce the national drugs bill, which was over £1.3 billion in 1994 in England (Prescription Pricing Authority, 1995), was highlighted as far back as 1982 with the publication of the Greenfield report to the secretary of state for health and social security on the findings of an informal working group on effective prescribing (Greenfield, 1982). The respective proportions of medicines prescribed generically and dispensed generically currently are 60.3% and 48.9%, respectively and rising (Department of Health, 1998). The current rate of generic prescribing in the Northern Region is 67% and locally in Newcastle it is even higher, at 71% (Department of Health, 1998). With pressure on practices to reduce prescribing costs, the level of generic prescribing will continue to increase.

In this survey, generic medicines with prolonged oral clearance prescribed to the elderly on a regularly and long-term basis accounted for 144 different formulations manufactured by 27 pharmaceutical companies. Those elderly on repeat medication prescribed generically could receive one of a number of formulations which may change each time a repeat prescription is issued depending on which pharmacy the patient attended. Pharmacies tend to stock the generic which is the cheapest available and this may change regularly depending on promotions and special offers from the pharmaceutical companies and pharmaceutical wholesalers, so that patients attending the same pharmacy may even receive different formulations on different occasions. Regardless of which generic formulation the pharmacist chooses to dispense, a set price decided by the government and referred in the Drug Tariff (Department of Health, 1995) is paid to the pharmacist. For proprietary preparations the prescribed brand would be the same each time it is dispensed, since this is a requirement of the 1968 Medicines Act (HMSO, 1969). The

increase in generic prescribing poses problems for the elderly as they are a vulnerable group of the population who become easily confused. Changes in packs, colour of medicine and taste may cause them concern and this could lead to a reduction in compliance, which is already a problem in the elderly (Salzman, 1995).

Of the top ten medicines with prolonged oral clearance used regularly and long-term by the elderly, six preparations were only available as proprietary preparations and 4 preparations were available as both generic and proprietary brands from a number of manufacturers. For the latter four preparations the final preparation received by the patient would depend on where the prescription was dispensed. Even when there is no generic equivalent available, general medical practitioners are encouraged to prescribe generically in anticipation of a generic becoming available. This has led to more and more medicines being dispensed with their chemical name, which may also have implications for prescribing in the elderly, with confusion over medicines names leading to poorer compliance. During a changeover period from proprietary to generic prescribing the patient may mistakenly use both, believing they are different medicines although there is no evidence in the literature to suggest that currently this is a significant problem.

5.5.10 Prescription only and 'over the counter' (OTC) medicines

The Prescribed Medicines Prevalence Survey looked at whether the prescribed medicines with prolonged oral clearance were available as prescription only medicine (POM) or if they could be purchased 'over the counter (OTC) from a pharmacy. Of the 143 preparations, 43% could be purchased OTC, however 85.7% of the 2796 prescribing instances were for medicines available for purchase over the counter (OTC). That medicines with prolonged oral clearance used regularly and long-term by the elderly could be bought without prescription and that many elderly may be buying these medicines reinforced the need for a prevalence survey of OTC medicines use by the elderly to provide an overall view of medicine use in the elderly. This aspect is covered later in the Over the Counter Medicines Survey (Chapter 6).

5.5.11 Duration of use of medicines with prolonged oral clearance used

Of all 2796 prescribing instances, in the 2002 elderly patients identified as taking medicines with prolonged oral clearance regularly and long-term, 78.8% were for medicines with prolonged oral clearance were used for one year or more. Their use appeared to be stable over long periods, which could be cause for concern in the case of laxatives and antacids which may be being used long-term unnecessarily. Computer generated repeat prescriptions were used by all practices in

the survey. Although efficient in terms of time saved compared with manually written prescriptions this system does have a number of disadvantages, including the difficulty in checking and reviewing each prescription, to monitor repeat prescribing. Many medicines such as antacids and laxatives may be initially prescribed short term but once on the practice computer there may be a tendency for regular repetition. Repeat prescribing monitoring is encouraged and software for computers can highlight repeats for patients who have not seen their doctor for a number of weeks to enable a review appointment to be made with the patient.

5.5.12 Sugar content of medicines with prolonged oral clearance taken regularly and long-term by the elderly

Medicines with prolonged oral clearance linger in the mouth after administration, and they are in contact with teeth much longer than other medicines such as tablets and capsules. A review a number of studies, mostly with children, have shown that sugars-containing liquid oral medicines taken regularly and long-term increased the risk of dental caries (Feigal & Jensen, 1982; Kenny & Somaya, 1989; Roberts, 1988; Roberts & Roberts, 1979). Although many of these sugars-containing medicines are also available sugars-free, the specificity of prescribing determines the sugar content since both sugars-free and sugars-containing preparations now exist.

In the Prevalence Survey, information from pharmaceutical manufacturers of the 143 preparations was used to classify each preparation used as sugars-free or sugars-containing. In general, information from the manufacturers of proprietary medicines was obtained promptly and was detailed. In contrast, the response from the 27 pharmaceutical companies that manufactured the 144 generic formulations was very poor. The poor response from the generic manufacturers is regrettable as health professionals will rely increasingly on information from generic companies as prescribing moves from to proprietary to generic. This information will need to be accurate and comprehensive to ensure that patients receive the most appropriate medication for which the prescriber and pharmacist has all the necessary therapeutic data readily available. This should include information on sugars content.

Overall, there were more sugars-free than sugars-containing proprietary preparations and the number of prescribing instances for sugars-free preparations medicines were three times that for sugars-containing medicines. Analysis by dose type showed that proprietary liquid oral medicines prescribed to the elderly were more likely to be sugars-free (59.3% of preparations and 91.2% of the prescribing instances) than sugars-containing, whereas solid doses with prolonged oral

clearance were more likely to be sugars-containing, (54.8% of preparations, 52.6% of prescribing instances).

In contrast, the generic medicines showed a very different distribution in terms of sugars content. Of the 42 generic preparations used, 54.8% were sugars-containing and only 33.3% sugars-free. Although, overall the majority of the prescribing instances for generic medicines were for sugars-free medicines, the majority of the prescribing instances for liquid oral medicines were sugars-containing (80.6%) and majority of prescribing instances for solid doses were sugars-free (94.3%).

Both in terms of number of preparations and number of prescribing instances, sugars-free medicines were more commonly used regularly and long-term, however, the Prevalence Survey showed that generic liquid oral medicines were an area for concern due to the large proportion which were sugars-containing. There has been considerable work done in the field of liquid oral medicines and children's dental health (Hobson, 1985; Mackie & Bentley, 1994; Maguire & Rugg-Gunn, 1994; Maguire & Rugg-Gunn, 1994). As a result many manufacturers have reformulated paediatric liquid oral medicines as sugars-free formulations. This has occurred mainly with proprietary formulations and with OTC preparations (Maguire & Rugg-Gunn, 1994). It would appear that there is a need for generics to be targeted, particularly the liquid oral medicines, and the advances made with paediatric formulation changes to sugars-free alternatives should progress into adult formulations.

Another area of some concern was solid doses with prolonged oral clearance that were chewable tablets as these were more likely to be sugars-containing, however they were mainly available as proprietary brands. The survey has identified that chewable tablets are used long-term and may be sugars-containing, and it is important manufacturers are aware of this in view of recommendations made by Hobson and Fuller (1987) that "the pharmaceutical industry should provide a greater range of sugars-free preparations, particularly those which are commonly used by children on a long-term basis" (Hobson, 1985). In a progress report, two years later, Hobson 1987 (Hobson & Fuller, 1987) reported that The Industrial Pharmacists Group Committee of the Royal Pharmaceutical Society had said that sugar was being removed from medicines gradually, however this was a costly process. Over ten years later, this survey has shown that sugar is still being used in medicines with prolonged oral clearance, although paediatric liquid oral medicines were generally sugars-free. The pharmaceutical manufacturers must be aware of the risk of dental

caries in adults and the elderly and be informed of the medicines with prolonged oral clearance that are used regularly and long-term.

Of the 39 sugars-containing proprietary preparations and 30 sugars-containing generic formulations, sucrose was found in 74% of the preparations and 63% of the formulations. The main sweetening agent in sugars-free medicines was the non-acidogenic intense sweetener saccharin found in 29 of the proprietary preparations and 25 generic formulations, and commonly used in the formulation of effervescent tablets. It was difficult to obtain an accurate overview of the types of sweetening agent in generic medicines due to the lack of information available.

This survey used information from general medical practices on the use of medicines with prolonged oral clearance used regularly and long-term in the elderly. The practices could not provide information on medicines that were not prescribed, i.e. purchased from community pharmacies or other retail outlets. In order to assess overall use of medicines with prolonged oral clearance used in the elderly, another survey, looking at the use of 'over the counter' (OTC) medicines use in the elderly was undertaken (Chapter 6).

5.6 CONCLUSIONS

The main findings from this survey of assessing the prevalence of use of prescribed medicines with prolonged oral clearance are summarised below.

- The prevalence of use of medicines with prolonged oral clearance, used regularly and long-term, in ten pratices in the Northern Region was 9.8% (2002 elderly patients).

- Of these 2002 patients, 32% were male and 54% were aged 60 to 74 years, with females aged ≥75 years more likely to take medicines with prolonged oral clearance regularly and long-term ($P<0.0001$).

- The main medical problems for patients taking medicines with prolonged oral clearance regularly and long-term were cardiovascular (37.7%) and musculoskeletal (23.7%).

- The 2002 patients were taking 143 medicines with prolonged oral clearance regularly and long-term, 2796 times.

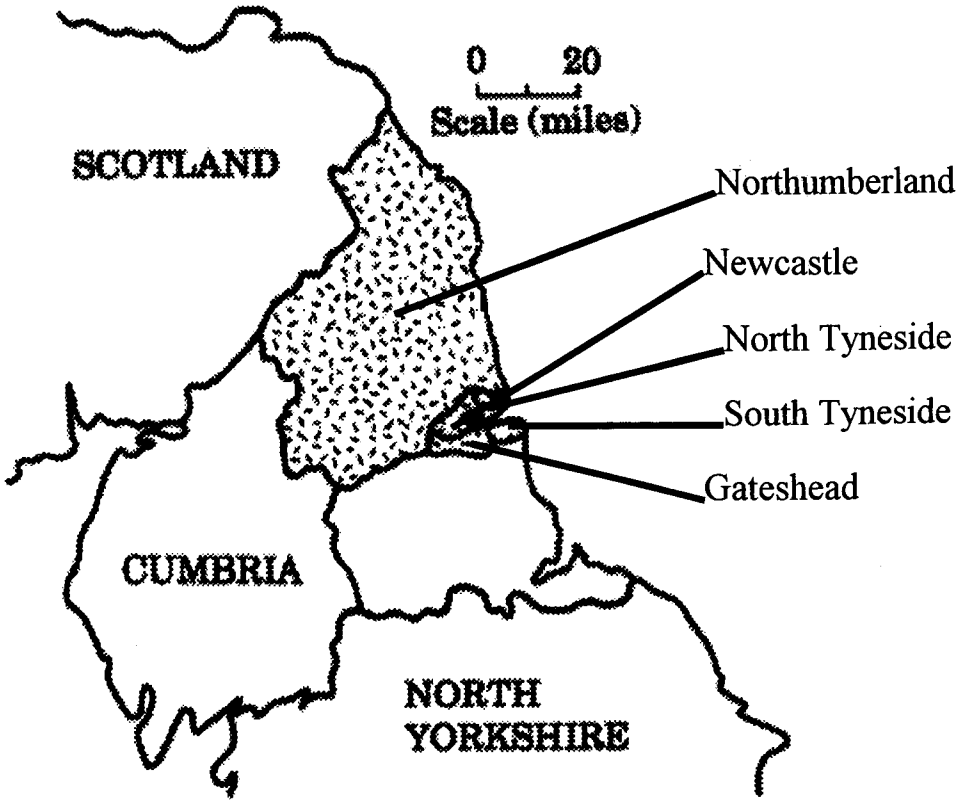
- Of these 2976 prescribing instances, 54% were for gastrointestinal medicines and 44% and 45% were liquid oral medicines and solids with prolonged oral clearance respectively.

- Generic formulations accounted for 42 preparations, 144 formulations and 52% of the prescribing instances.

- In terms of sugar-content, 39 (39%) of the 101 proprietary and 23 (55%) of the 42 generic were sugars-containing.

- Of the prescribing instances for proprietary liquid oral medicines, 8% were sugars-containing compared with 81% of the prescribing instances for generic liquid oral medicines.

APPENDIX 5.1
Map showing the five districts in the Northern Region, in which the study was undertaken.



Mid -1995 Population Data
(Office for National Statistics, 1995)

	No. all ages (x1000)	No. aged ≥60 years (x1000)	% aged ≥60 years (x1000)
10 practices in the 5 districts	92.6	20.4	22.0
Newcastle	201.8	44.3	22.0
North Tyneside	193.9	45.0	23.2
Gateshead	201.8	44.3	22.0
South Tyneside	156.3	36.0	23.0
Northumberland	307.3	68.5	22.3
Northern Region	2923.2	617.2	21.1
England	48903.4	10041.0	20.5

APPENDIX 5.2
Letter to general medical practices

11 September, 1995.

«GP»
«ADDRESS»
«PHONE»

Dear «GP»,

I write to ask for your help in a research project, currently being undertaken in the Dental School at the University of Newcastle upon Tyne.

The local effects of sugared medicines with prolonged oral clearance, e.g. pastilles, syrups, liquids, lozenges, buccal and sublingual tablets, upon dental health have been recognised for a number of years by the medical and dental professions. Increasing numbers of individuals in the community are retaining their natural teeth into old age - however, the number of elderly individuals taking such medication is unknown. I am currently carrying out a survey in order to determine this, together with Wasim Baqir (Pharmacist and Research Student) and Dr Anne Maguire (Clinical Lecturer).

We would like to carry out a prevalence survey which would consist of a General Medical Practice Survey of ten practices (randomly sampled from the five Districts of Newcastle, North Tyneside, South Tyneside, Gateshead and Northumberland) which would aim to search practice computer records of all patients over the age of 60 years, to identify the numbers and medication regime of those patients on regular (daily or alternate day) long-term (3 months or longer) medication with prolonged oral clearance. The study has been approved by the Research Ethics Committees of the five Districts.

We have taken advice from the Department of Medical Statistics and Dr Ian Purves in the Department of Primary Health Care with regard to the sampling of practices with comprehensive computing facilities, and I understand that your practice would be a good candidate for sampling since I believe that you have a flourishing practice with a broad age and socio-economic mix of patients in your care.

The survey has been registered with the Data Protection Registrar of the University of Newcastle upon Tyne, and information collected would be treated with the strictest confidence, and individual patients would only be identified by a code and not their name, under the terms of the Data Protection Act 1984. I enclose a copy of the information sheet which would be used to collect patient information.

We would like to collect data in a manner that would cause minimal disruption to the day to day running of the practice and I am writing to you in the first instance so that you might have a chance to discuss this matter with your partners. Then perhaps it would be possible for Mr Baqir to meet with you or one of your colleagues to discuss the matter further? If this is acceptable, Mr Baqir will contact your secretary within the next two weeks to arrange a convenient appointment to see you.

With many thanks.

Yours sincerely,

Professor Andrew J. Rugg-Gunn
Professor of Preventive Dentistry

APPENDIX 5.3
Example of a patient medication record from a general medical practice computer record

No:1234 Mrs A. Smith 123 Any Road, Anytown, A12 12A
12/03/28 (Age 70) 19/04/98

Current (Acute) Prescribing		*Issued*
Amoxycillin 250mg caps	tds	15/12/97

Repeat Prescribing		*Start*	*Last*
Lactulose Liquid	bd	13/05/93	4/04/98
Frusemide 40mg tabs	od	19/08/96	4/04/98
Senna Syrup 7.5mg/5ml	nocte	24/11/97	4/04/98
Gaviscon Liquid	qds	12/09/96	4/04/98
Paracetamol 500mg tabs	qds prn	09/01/94	9/03/98
Atenolol 50mg tabs	od	22/09/96	4/04/98

APPENDIX 5.4
Medical problems of patients taking medicines with prolonged oral clearance regularly and long-term

CODE	CONDITION	Number of patients	%
01	**GASTROINTESTINAL**		
01.01	HEARTBURN	16	0.6
01.02	INDIGESTION	41	1.4
01.03	GASTRIC REFLUX	10	0.4
01.04	CONSTIPATION	15	0.5
01.05	GASTRIC SPASMS	3	0.1
01.06	GASTRIC/ DUODENAL ULCER	41	1.4
01.07	ULCERATIVE COLITIS/ CROHN'S DISEASE	4	0.2
01.08	HIATUS HERNIA	65	2.2
01.09	IRRITABLE BOWEL SYNDROME	24	0.8
01.10	DIVERTICULAR DISEASE	18	0.6
	Sub-total	**238**	**8.1**
02	**CARDIOVASCULAR**		
02.00	GENERAL HEART DISORDERS	95	3.2
02.01	HEART FAILURE	10	0.4
02.02	HYPERTENSION	428	14.5
02.03	BLOOD COAGULATION DISORDERS	4	0.2
02.04	HYPERLIPAEMIA	4	0.2
02.05	ANGINA	311	10.5
02.06	CARDIOVASCULAR ACCIDENT	75	2.6
02.07	ARRYTHMIAS	25	0.9
02.08	HEART ATTACK	19	0.7
02.09	CIRCULATION PROBLEMS	22	0.8
02.10	HIGH CHOLESTEROL	34	1.2
02.11	OEDEMA	38	1.3
02.12	ARTERY DISEASE	19	0.7
02.13	CORONARY HEART DISEASE	3	0.1
02.14	VARICOSE VEINS	16	0.6
02.15	ISCHAEMIC HEART DISEASE	7	0.3
02.16	MYOCARDIAL INFARCTION	1	0.1
	Sub-total	**1115**	**37.7**
03	**RESPIRATORY SYSTEM**		
03.01	ASTHMA	133	4.5
03.02	PERSISTANT COUGH	3	0.1
03.03	NASAL CONGESTION	7	0.3
03.04	CORONARY OBSTRUCTIVE AIRWAYS DISEASE	12	0.4
03.05	ALLERGIC RHINITIS	12	0.4
03.06	HAYFEVER	10	0.4
03.07	BRONCHITIS	64	2.2
03.08	EMPHYSEMA	13	0.5
03.09	TUBERCULOSIS	3	0.1
03.10	SINUSITIS	10	0.4
	Sub-total	**268**	9.1

APPENDIX 5.4 (continued)

CODE	CONDITION	Number of patients	%
04	**CENTRAL NERVOUS SYSTEM**		
04.01	INSOMNIA	7	0.3
04.02	PSYCHOSIS	7	0.3
04	**CENTRAL NERVOUS SYSTEM (Continued)**		
04.03	DEPRESSION	38	1.3
04.04	NAUSEA & VOMITTING/ VERTIGO	31	1.1
04.05	CHRONIC PAIN	0	0.0
04.06	EPILEPSY	15	0.5
04.07	PARKINSONISM	24	0.8
04.08	TRIGEMINAL NEURALGIA	12	0.4
04.09	ANXIETY	16	0.6
04.10	DEMENTIA/ALZHEIMERS	19	0.6
04.11	MIGRAINE	19	0.7
04.12	HEADACHE	3	0.1
	Sub-total	**192**	**6.5**
05	**INFECTIONS**		
05.01	INFECTION PROPHYLAXIS	1	0.0
05.02	RECURRENT INFECTIONS	6	0.2
	Sub-total	**7**	**0.2**
06	**ENDOCRINE SYSTEM**		
06.01	DIABETES MELLITUS	120	4.1
06.02	THYROID DISEASE	101	3.4
	Sub-total	**221**	**7.5**
07	**OBSTETRICS, GYNAECOLOGY AND URINARY TRACT**		
07.01	UROLOGICAL PAIN	2	0.1
07.02	URINARY INCONTINENCE	12	0.4
07.03	BLADDER CANCER	3	0.1
07.04	PROSTATE ENLARGEMENT	12	0.4
	Sub-total	**29**	**1.0**
08	**MALIGNANT DISEASE AND IMMUNOSUPPRESSION**		
08.01	PROSTATE CANCER	7	0.3
08.02	GENERAL MALIGNANT DISEASE	15	0.5
08.03	BREAST CANCER	7	0.3
08.04	LEUKEAMIA	2	0.1
	Sub-total	**32**	**1.1**
09	**NUTRITION AND BLOOD**		
09.00	ANAEMIAS (GENERAL)	19	0.6
09.01	ANAEMIA - PERNICIOUS	7	0.3
	Sub-total	**26**	**0.9**
	MUSCULOSKELETAL AND JOINT DISORDERS		
10.01	JOINT PAINS/ RHEUMATIC DISEASE	16	0.5
10.02	GOUT	30	1.0
10.03	OSTEOARTHRITIS/ OSTEOPOROSIS	111	3.8
10.04	ARTHRITIS	478	16.2
10.05	BACK PAIN/ PROBLEMS	65	2.2
	Sub-total	**700**	**23.7**

APPENDIX 5.4 (continued)

CODE	CONDITION	Number of patients	%
11	**EYE**		
11.00	EYE PROBLEMS	12	0.4
11.01	GLAUCOMA	35	1.2
11.02	CATARACT	10	0.4
	Sub-total	**57**	**1.9**
12	**EAR, NOSE AND OROPHARYNX**		
12.01	TINNITIS	23	0.8
12.02	DEAFNESS	15	0.5
	Sub-total	**38**	1.3
13	**SKIN**		
13.01	ECZEMA	19	0.6
13.02	DERMATITIS	4	0.2
13.03	ROSACEA	2	0.1
13.04	PSORIASIS	8	0.3
	Sub-total	**33**	**1.1**
	TOTAL	**2956**	**100.0**

Figure 5.1 The potential sources of data available to determine the prevalence of use of medicines

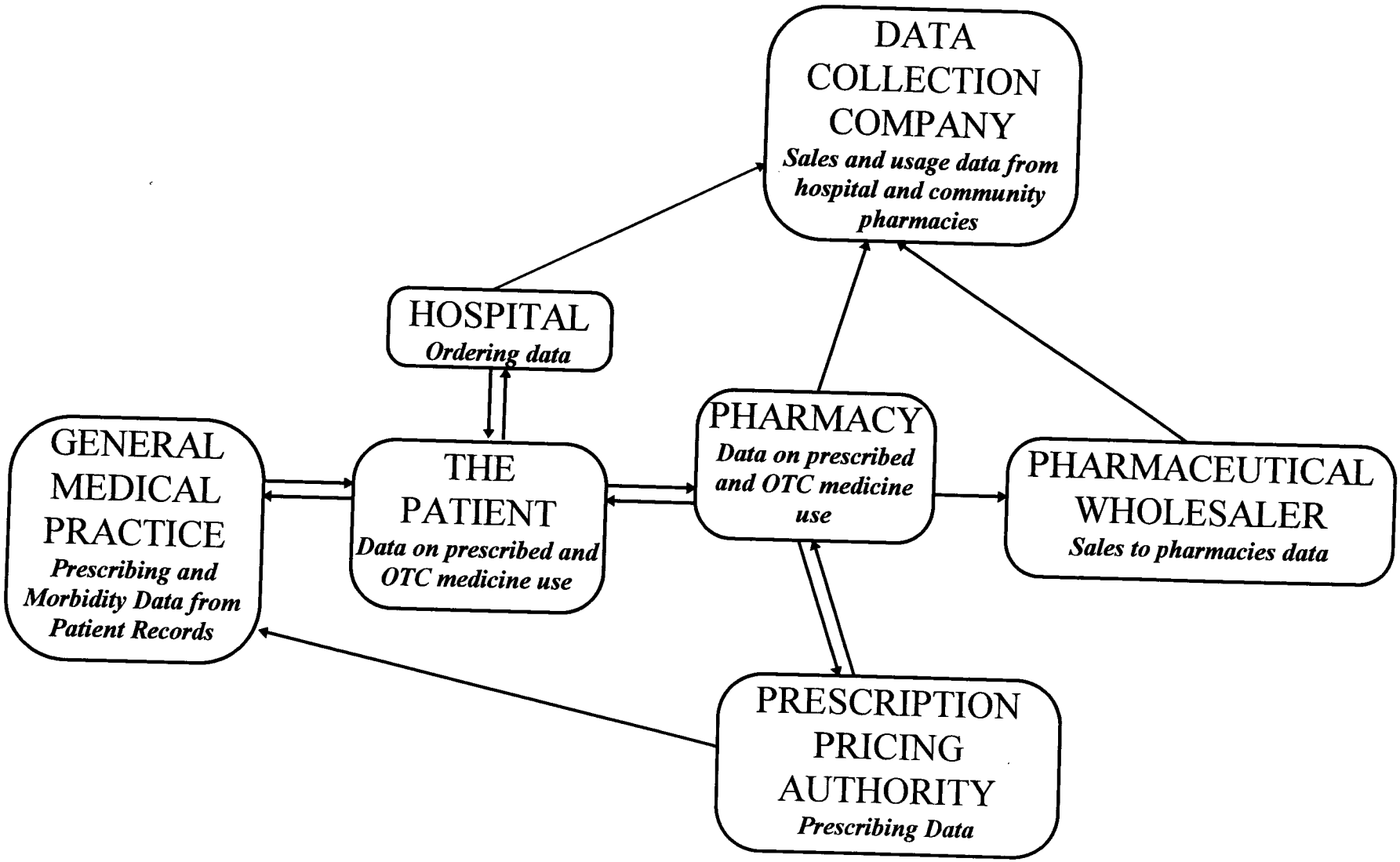
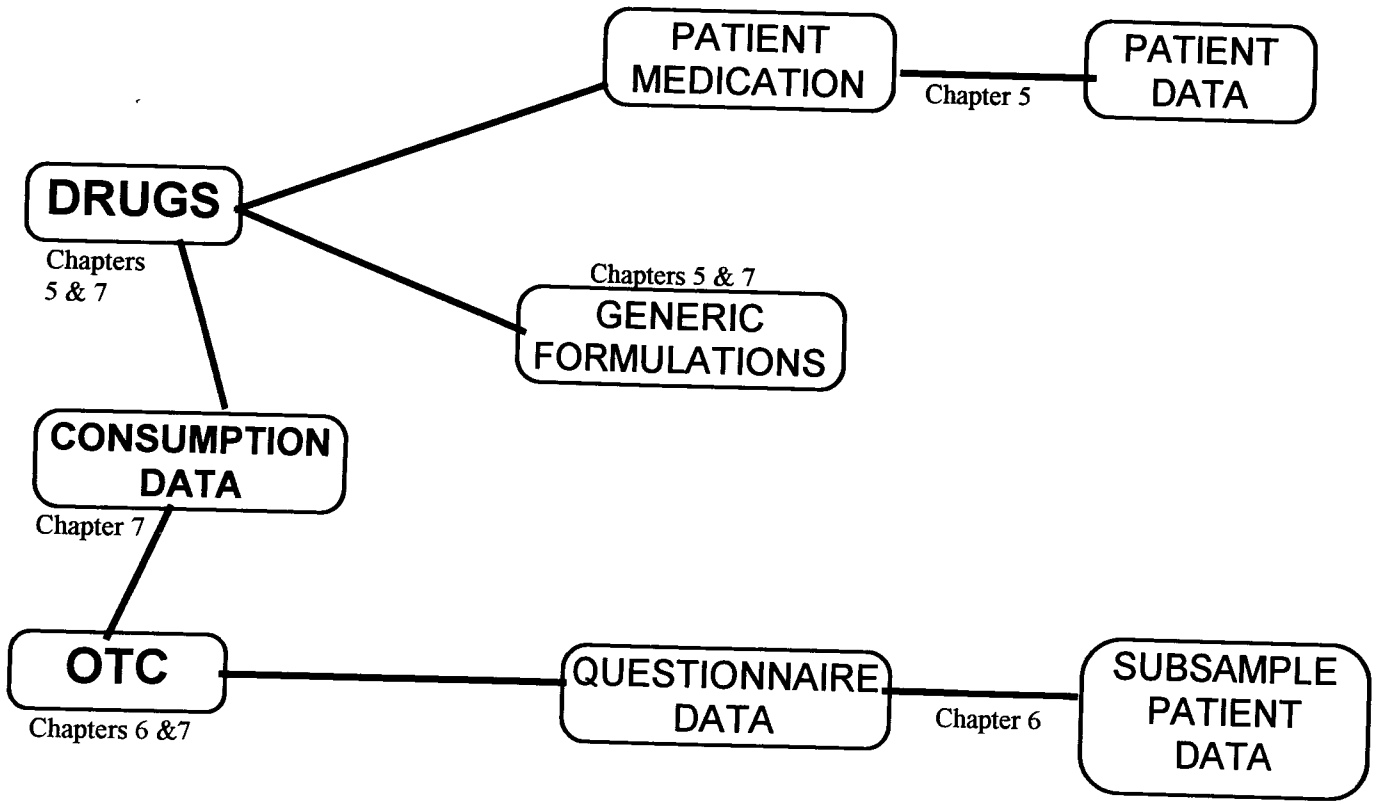


Figure 5.2: Relationships between database tables



CHAPTER 6

OVER THE COUNTER (OTC) MEDICINES PREVALENCE SURVEY

6.1 INTRODUCTION

'Over the counter' (OTC) medication is available from community pharmacies for purchase for a large number of minor medical conditions. However, it was unclear how many of these medicines have a prolonged oral clearance, what proportion contain sucrose, and which medicines are taken regularly and long-term by the elderly. The information from the practices in the Prescribed Medicines Prevalence Survey did not contain details of medication that an elderly patient may have bought from community pharmacies. Therefore it was necessary to investigate this aspect of medication use further and this was undertaken using a survey of OTC medicines use in a sub-sample of the elderly surveyed in the Prescribed Medicines Prevalence Survey.

6.2 AIMS

6.2.1 Main aim

- To determine the prevalence of use of OTC medicines with prolonged oral clearance used regularly (daily or alternate day) and long-term (for three months or longer) in the elderly.

6.2.2 Subsidiary aims

- To assess the age and gender profiles of patients taking OTC medicines with prolonged oral clearance regularly and long-term.
- To identify the medical problems for which OTC medicines with prolonged oral clearance are used regularly and long-term by the elderly.
- To assess the sugar content of OTC medicines used by the elderly, regularly and long-term.

6.3 METHODS

6.3.1 Ethical committee approval

Once Ethical Committee approval in the five districts used in the Prescribed Medicines Prevalence Survey (Newcastle, Northumberland, North Tyneside, South Tyneside and Gateshead) had been given, preparation for the OTC Medicines Survey commenced.

6.3.2 Pilot study

Information on over the counter (OTC) medicines used by the elderly was required for this survey. However, as OTC medicine use information is not recorded for patients registered in general medical practices, other data collection methods were needed to provide a source of information on OTC medicine use.

Collecting data directly from pharmacies was considered and ten pharmacies were randomly chosen from the Newcastle area for a pilot study. For a period of 4 weeks pharmacists and pharmacy staff were asked to note every sale of an OTC medicine with prolonged oral clearance and determine the age of the person purchasing the product. This project relied entirely on the participants enthusiasm and them remembering to note each sale. The initial results showed that this form of data collection would not produce accurate results as feedback from the pharmacies showed that many purchases were not recorded and many staff admitted later to 'guessing' the number of purchases. Another drawback was the difficulty in determining the age of the patient for whom an OTC medicine was being purchased, requiring the pharmacist or pharmacy staff to explain the aims of the study when making an inquiry about age.

An alternative approach to a survey of OTC medicines use was to collect data directly from an elderly population already identified in the Prescribed Medicines Prevalence Survey. This was considered to be the most appropriate way to collect these data and was the method used.

6.3.3 The sample

After consultation with statisticians it was decided that a sub-sample of the patients aged 60 years and over from the ten general medical practices selected in the Prescribed Medicines Prevalence Survey, would be used.

Ten general medical practitioners were selected at random from a list of all 48 general medical practitioners at the ten practices surveyed previously in the Prescribed Medicines

Prevalence Survey and contacted by a letter (Appendix 6.1) which explained details of the survey and requested access to a list of their registered patients aged 60 years and over.

Once permission had been given, a computer search was undertaken for all patients aged 60 years and over registered to each randomly chosen practitioner, and fifty percent of these patients were randomly selected, to form the sample. The name and address, date of birth, gender and patient identification code for each patient was obtained from the practice computer, and saved to a floppy computer disk as a text file.

Before this information could be used the text file had to be modified. Using a text editor, 'commas' were placed in the text so that the database recognised where one field stopped and another started. For example placing the 'comma' between the first name and surname allowed the database to enter these data into separate fields. This modified text file was imported into the **SUBSAMPLE PATIENT DATA** table of the relational database described below (6.3.4).

6.3.4 The database

A database of all 'over the counter' (OTC) medicines with prolonged oral clearance was constructed using the OTC Directory 1994/1995 (Proprietary Association for Great Britain, 1995) to identify all OTC medicines with prolonged oral clearance on the market in 1995. This database was incorporated into the main study database as a table called **OTC** (Chapter 5, Figure 5.1). Each OTC medicine identified was given an individual code and the following information was obtained and entered into the database:

- BNF Section
- Dose form (e.g. liquids, solids etc.)
- Manufacturer
- Active ingredients
- Pack sizes
- The type and amount of sweetening agent used in the medicine

Another table, **SUBSAMPLE PATIENT DATA** (Chapter 5, Figure 5.1) was designed and created to hold demographic information and contained the following fields:

- Patients name and postal address
- Date of birth
- Gender
- Practice number
- Patient identification code (PIC)

The patient identification code was a unique number to identify each patient in the database. It was formed by prefixing each patients 'patient medication record' (PMR) number with a practice code, identifying the practice at which the patient was registered.

6.3.5 Postal Questionnaire

A questionnaire (Appendix 6.2) was designed with advice from the Centre for Health Services Research (University of Newcastle upon Tyne). Close attention was paid to the questionnaire's construction and the accompanying letter (Appendix 6.3) to ensure clarity and avoid confusion. The letter provided details of the study, requested participation in the study and was signed by the researcher's head of department and the patient's general medical practitioner.

This questionnaire was piloted with 196 persons aged 60 years and over randomly sampled from a practice in Corbridge, Northumberland. Each questionnaire was sent along with an evaluation form asking the patients for their comments about the layout, ease of reading and any possible ambiguities in the questionnaire.

From the 196 questionnaires distributed, 120 (61%) were returned. All questionnaires were accurately completed indicating that the individual had understood the questions and did not find the questionnaire confusing or difficult. From these results and the evaluation forms returned it was clear that the format of the questionnaire was appropriate and it was decided that a postal questionnaire would be the method of choice for collecting data from the elderly for this survey.

The questionnaire consisted of two parts (Appendix 6.2). The first section asked the patient to note their current medical problems, number of natural teeth, how often they bought medicines from a pharmacy, the type of medicine they preferred to buy and whether they asked for sugar-free medicines. The second section asked patients to list all their current medication, both prescribed and bought 'over the counter' (OTC) and include details of the start date and frequency of administration of each medicine listed. A commercial printing company was used to print 3,000 copies of the questionnaire for distribution.

6.3.6 Mailing schedule

The **SUBSAMPLE PATIENT DATA** table of the database, created from the modified text files from the general medical practices, was used to produce mailing labels with each patient's name and address for questionnaire distribution. For each patient a corresponding self-addressed label for the return of the questionnaire was printed. This self-addressed label also held a patient

identity number which was used to identify the original questionnaire upon its return and protect patient confidentiality, since the questionnaire itself did not carry any form of patient identification.

Just prior to postal distribution an inquiry was made to each participating practice to ensure that none of the patients had de-registered or died. If this was the case then this was noted in the database. The questionnaires were posted by district, with the sampled patients from the same district being posted together. The initial mailing of the questionnaires was made in four batches, followed by two reminders for all non-respondents.

Once returned, the patient's identity code on the self-addressed label was transferred to the completed questionnaire and a '*Returned Questionnaire*' field in the main patient database was completed for each patient. After a two week interval to allow patients to return the questionnaires, using the '*Returned Questionnaire*' field of the database, non-respondents were identified and were sent two reminders, approximately two weeks apart.

6.3.7 Data entry and analysis

A table called **QUESTIONNAIRE DATA** was created to hold information from the returned questionnaires using the following fields:

- Medical condition
- Medicine code
- Start date
- Frequency of use
- OTC medicine (Yes or No)

All information collected from the returned questionnaire was coded to prior to entry into the **QUESTINNAIRE DATA** table of the database. Each medical problem identified was allocated a code using a specially designed coding frame (Appendix 6.4). The medical condition code was derived from the relevant British National Formulary (BNF) Section together with a unique number for each condition. For example, 'angina' was allocated the code 02.04, where the '02' was the BNF Section (cardiovascular system) and '04' was the unique code for this condition. Each medicine used was coded according to whether it was, firstly, a medicine with prolonged oral clearance, and then whether it was a prescribed or purchased OTC medicine. Each coded medicine was then entered into the database along with the date when it was started and the

frequency of administration. The coding frames used were based on the **OTC** table of the database (Section 6.3.4) allowing links to be established between this table and the **QUESTIONNAIRE DATA** table, for data analysis.

Queries were run to link information from the **SUBSAMPLE PATIENT DATA**, **QUESTIONNAIRE DATA** and **OTC** tables of the database, to determine the prevalence of use of OTC medicines with prolonged oral clearance and identify the types of OTC medicines used and the medical problems for which these medicines were commonly used.

6.4 RESULTS

6.4.1 The sample size and response rate

The ten general medical practitioners randomly selected were from eight of the ten practices used in the Prescribed Medicines Prevalence Survey. One of the sampled general medical practitioners who agreed to help had to be withdrawn from the survey and another practitioner sampled in his place as it was difficult to download the names and addresses of his sampled patients onto floppy disks using the practice computer system (MEDITEL). The sub-sample survey of OTC medicines use was started in July 1997. Mailing to the patients was staggered due to the large number of questionnaires involved. Preparation and mailing for each practice took three weeks, with all questionnaires being posted by mid-September and the last returned questionnaire received by mid-December 1997. A total of 2322 questionnaires were sent out to the patients of the ten practitioners and the response to the survey is shown in Table 6.1.

Overall, of the 2322 questionnaires sent out, 1661 (71.5%) responses were received, however after the initial posting only 1029 (44.3%) questionnaires had been returned (Table 6.1). The first reminder resulted in a further 308 questionnaires being returned, increasing the response rate to 57.6%. The final reminder took the response rate to 71.5%.

The responses from 129 (7.8%) of the 1661 respondents could not be used in the survey. Of these 42 (2.5%) were unopened questionnaires returned as the patient no longer lived at the address, 55 (3.3%) were returned questionnaires where the patient had refused to take part in the study, 22 (1.3%) gave medical reasons for not completing the questionnaire, and despite efforts to eliminate this problem, questionnaires were sent to 10 (0.7%) patients who had died. The number of questionnaires which could be used in the survey was 1532, giving an overall response rate of 66%.

Table 6.1 Response rate to postal questionnaire by practice

Practice Number	No. of GPs	District	Total no. of questionnaires sent	% of total no. sent	No. Returned after Initial Posting		No. returned after first reminder		No. returned after second reminder		Total Returned	
					No.	% of total sent to patients of practice	No.	% of total sent to patients of practice	No.	% of total sent to patients of practice	No.	% of total sent to patients of practice
1	2	North Tyneside	488	21.0	230	47.1	69	14.1	65	13.3	**364**	**74.6**
3	1	Newcastle	188	8.1	83	44.1	27	14.4	16	8.5	**126**	**67.0**
4	1	Gateshead	176	7.6	83	47.2	13	7.4	21	11.9	**117**	**66.5**
5	1	Gateshead	102	4.4	35	34.3	9	8.8	16	15.7	**60**	**58.8**
6	1	South Tyneside	419	18.0	165	39.4	51	12.2	67	16.0	**283**	**67.5**
7	2	South Tyneside	600	25.8	249	41.5	85	14.2	97	16.2	**431**	**71.8**
9	1	Northumberland	211	9.1	125	59.2	23	10.9	20	9.5	**168**	**79.6**
10	1	Newcastle	138	6.0	59	42.8	31	22.5	22	15.9	**112**	**81.2**
Total	**10**		**2322**	**100.0**	**1029**	**44.3**	**308**	**13.3**	**324**	**14.0**	**1661**	**71.5**

Table 6.2 Age and gender profiles of the respondents

	Males		Female		Total	
	No.	%	No.	%	No.	%
60-74 years	486	74.1	553	63.1	**1039**	**67.8**
≥75 years	170	25.9	323	36.9	**493**	**32.2**
Total	**656**	**100.0**	**876**	**100.0**	**1532**	**100.0**

A telephone number was provided on the covering letter to enable patients to request further information about the questionnaire and the aims of the study and 141 patients made use of this service, after which 131 took part in the study.

The response from patients at individual practices varied from 58.8% of the 102 sampled from Practice 5 in Gateshead to 81.2% of the 138 sampled from Practice 10 in Newcastle.

6.4.2 Age and gender profiles of respondents

As Table 6.2 describes, of the 1532 patients who completed the questionnaire, 656 (42.8%) were male and 876 (57.2%) were female, 1039 (67.8%) were aged 60 to 74 years and 493 (32.2%) were aged 75 years and over. This compares well with the 2322 patients in the sample, of which 42.5% (987) were male, 57.5% (1335) female, 65.2% (1513) were aged 60 to 74 years and 34.8% (809) aged 75 years and over.

When compared with the elderly population at the ten practices (Table 5.3, Chapter 5) there were similar proportions of elderly males and females in the ten practices (43% and 57% respectively) and the sample of respondents (42.8% and 57.2% respectively). The proportion of young (60 to 74 years) and old (75 years and over) elderly at the ten practices was 66.1% and 33.9% respectively, which compared well with the respondents in this survey (67.8% and 32.2%) respectively.

Of the 1513 patients aged 60 to 74 years, 1039 responded (68.7%) compared with 493 responses from the 809 patients aged 75 years and over (60.9%). Of the 719 males aged 60 to 74 years sent a questionnaire, 67.6% (486) responded, compared with 59.4% of males aged 75 years and over (170 responses from 286 questionnaires). The response from females aged 60 to 74 years was 69.6% (553 responses from 794 questionnaires) compared with only 59.7% (323 responses from 541 questionnaires) from females aged 75 years and over. In summary, the response suggested that 'young elderly' females were more likely to respond than the other groups.

6.4.3 Number of natural teeth

Of the 1532 respondents, 45.6% were dentate, (13.9% with ≤12, 31.7% with >12 natural teeth), 52.2% were edentate and 2.2% gave no information (Table 6.3).

When all ages were considered together, of the 656 male respondents, 41% (269) were edentate and 56.3% (369) had some or all natural teeth and of the 876 females who responded, 60.6% (530) were edentate and 37.6% (330) were dentate (Table 6.3).

Table 6.3 Number of edentate and dentate elderly in the OTC Medicines Survey by gender

No. of natural teeth	Male		Female		Total	
	No.	%	No.	%	No.	%
0	269	41.0	530	60.6	**799**	**52.2**
≤12	112	17.1	102	11.6	**214**	**13.9**
>12	257	39.2	228	26.0	**485**	**31.7**
No information	18	2.7	16	1.8	**34**	**2.2**
Total	**656**	**100.0**	**876**	**100.0**	**1532**	**100.0**

When analysed by age, the 60 to 74 year old group contained more dentate (53.5%) than edentate individuals (44.7%). Conversely, in the ≥75 year old group there were fewer dentate respondents (29%) than edentate (68%) (Table 6.4). Of the 556 dentate respondents aged 60 to 74 years, 38.8% had more than 12 natural teeth, compared with 16.6% of the ≥75 year old dentate respondents.

Table 6.4 Number of edentate and dentate elderly in the OTC Medicines Survey by age

No. of natural teeth	60-74y		≥75y	
	No.	%	No.	%
0	464	44.7	335	68.0
1 to 12	153	14.7	61	12.4
>12	403	38.8	82	16.6
No information	19	1.8	15	3.0
Total	**1039**	**100.0**	**493**	**100.0**

6.4.4 Medical problems

The questionnaire also collected information on the current medical problems of the respondents (Table 6.5). In total, of the 1532 respondents, 1308 (85%) suffered from 2095 medical problems with a mean of 1.36 medical problems per patient (range = 0 to 8). The majority of medical problems suffered by the elderly respondents were cardiovascular (36.5%) and musculoskeletal (23.6%) in nature, with most cardiovascular problems being hypertension

and angina, and the main musculoskeletal problem being arthritis (Table 6.5 and Appendix 6.4). Appendix 6.4 provides a full distribution of all medical problems reported in the survey.

Table 6.5 Medical problems suffered by 1532 elderly patients in the OTC Medicines Survey

BNF Section	Number of Patients	%
01 - Gastrointestinal System	170	8.1
02 - Cardiovascular System	764	36.5
03 - Respiratory System	183	8.7
04 - Central Nervous System	133	6.3
05 - Infections	4	0.2
06 - Endocrine System	171	8.2
07 - Obstetrics, Gynaecology and Urinary Tract	20	1.0
08 - Malignant Disease	24	1.1
09 - Nutrition and Blood	23	1.1
10 - Musculoskeletal and Joint Disorders	495	23.6
11 - Eye	42	2.0
12 - Ear, Nose and Oropharynx	27	1.3
13 - Skin	39	1.9
Total	**2095[1]**	**100.0**

[1]224 patients had no medical problems and 1308 suffered from more than one medical problem

6.4.5 Prevalence of use of OTC medicines

Of the 1532 respondents, 13% were currently taking OTC medicines and overall there were 258 instances of use for a total of 88 OTC preparations. This included OTC medicines with and without prolonged oral clearance.

The number of instances of use of OTC medicines with prolonged oral clearance was 88, with 44 OTC medicines taken by 79 patients. These OTC medicines with prolonged oral clearance were taken on a 'when required' basis as well as those taken long-term (Table 6.6). Over 58% of these OTC preparations were for gastrointestinal and respiratory medicines.

Only 13 OTC medicines with prolonged oral clearance were taken regularly and long-term by 17 patients representing a prevalence rate of 1.1%. Of these patients, 53% were male, 47% female, 77% aged 60 to 74 years.

Although the prevalence rate of 1.1% was low, when extrapolated for the elderly population of the five districts and the Northern Region of England, which was 0.25 million and 0.62 million

respectively, in 1995 (Office for National Statistics, 1995), approximately 2760 and 6796 elderly persons over the age of 60 years might be expected to be taking OTC medicines with prolonged oral clearance regularly and long-term, in the five districts and the Northern Region, respectively.

Of the 17 patients identified as taking OTC medicines with prolonged oral clearance regularly and long-term, only three reported a medical problem: with each reporting one problem - angina, migraine or diabetes.

6.4.6 OTC medicines with prolonged oral clearance used by the elderly

Table 6.6 shows the number of OTC medicines and instances of use for all OTC medicines with prolonged oral clearance and OTC medicines with prolonged oral clearance used regularly and long-term by the elderly, by BNF Section.

The main areas of use of all OTC medicines with prolonged oral clearance used by the elderly were the Respiratory System, Gastrointestinal System, Central Nervous System and Nutrition and Blood, which together accounted for 84% of the 44 OTC medicines, respectively (Table 6.6). In terms of instances of use, 63.6% were for OTC medicines in Gastrointestinal (29.5%) and Respiratory Sections (34.1%) of the BNF.

Of the 13 OTC medicines with prolonged oral clearance used regularly and long-term, 8 (61.6%) were Gastrointestinal (30.8%) or Nutrition and Blood (30.8%) medicines (Table 6.6). In terms of instances of regular and long-term use, Nutrition and Blood accounted for 29.4% and the Gastrointestinal System, 23.5% of the total.

Table 6.7 shows the OTC medicines with prolonged oral clearance used regularly and long-term by the elderly in this survey. Of the four Nutrition and Blood preparations, 3 were cod liver oil preparations and one was a health tonic (*Metatone*). Three of the four Gastrointestinal preparations were antacids and one a laxative. Of the 13 OTC medicines, 7 were liquid oral medicines and 6 were solid doses with prolonged oral clearance (5 tablets, 1 lozenge).

Table 6.6 Number of preparations and instances of use for all OTC medicines with prolonged oral clearance and those used regularly and long-term.

BNF Section	All OTC medicines with POC				OTC medicines with POC used regularly and long-term			
	Preparations		Instances of use		Preparations		Instances of use	
	No.	%	No.	%	No.	%	No.	%
01 - Gastrointestinal System	12	27.3	26	29.5	4	30.8	4	23.5
02 - Cardiovascular System	1	2.3	4	4.5	1	7.7	2	11.8
03 - Respiratory System	13	29.5	30	34.1	1	7.7	2	11.8
04 - Central Nervous System	7	15.9	12	13.6	2	15.4	3	17.6
05 - Infections	0	0.0	0	0.0	0	0.0	0	0.0
06 - Endocrine System	0	0.0	0	0.0	0	0.0	0	0.0
07 - Obstetrics, Gynaecology and Urinary Tract	0	0.0	0	0.0	0	0.0	0	0.0
08 - Malignant Disease	0	0.0	0	0.0	0	0.0	0	0.0
09 - Nutrition and Blood	5	11.4	8	9.1	4	30.8	5	29.4
10 - Musculoskeletal and Joint Disorders	0	0.0	0	0.0	0	0.0	0	0.0
11 - Eye	0	0.0	0	0.0	0	0.0	0	0.0
12 - Ear, Nose and Oropharynx	6	13.6	8	9.1	1	7.7	1	5.9
Total	**44**	**100.0**	**88[1]**	**100.0**	**13**	**100.0**	**17[2]**	**100.0**

[1]taken by 79 patients
[2]taken by 17 patients

Table 6.7 Number of instances of use for the 13 OTC preparations with POC used regularly and long-term in the elderly

BNF Section	Medicine	Instances of use	%	Sugars-free?
09 - Nutrition and Blood	Seven Seas cod liver oil	2	11.8	Yes
09 - Nutrition and Blood	Seven Seas cod liver oil lemon	1	5.9	Yes
09 - Nutrition and Blood	Sanatogen cod liver oil	1	5.9	Yes
09 - Nutrition and Blood	Metatone Liquid	1	5.9	No
01 - Gastrointestinal System	Regulose Solution	1	5.9	No
01 - Gastrointestinal System	Setlers Tablets	1	5.9	No
01 - Gastrointestinal System	Mil-par liquid	1	5.9	Yes
01 - Gastrointestinal System	Bisodol Antacid tablets	1	5.9	No
04 - Central Nervous System	Aspro Clear eff. Tablets	2	11.8	Yes
04 - Central Nervous System	Solpadeine Eff Tablets	1	5.9	Yes
03 - Respiratory System	Covonia Cough Mixture	2	11.8	No
02 - Cardiovascular System	Beecham Aspirin tablets	2	11.8	Yes
12 - Ear, Nose and Oropharynx	Merocet Lozenges	1	5.9	No
	Total	**17**	**100.0**	-

6.4.7 Duration of use of OTC medicines with prolonged oral clearance used regularly and long-term

Of the 17 instances of regular and long-term use, 8 were for medicines taken for two years or longer at the time of the survey, 3 for medicines taken for 1 to 2 years and 2 for medicines taken for 3 months to 1 year (Table 6.8). For the remainder no information was given on duration of use.

The 8 instances of medicines used for 2 years and longer were for 6 OTC medicine preparations, four of which were Nutrition and Blood preparations, the remaining two being a minor analgesic (*AsproClear* effervescent tablets) and aspirin 75mg effervescent tablets used in the prevention of cardiovascular disease (Table 6.8).

Of the three patients taking OTC medicines with prolonged oral clearance regularly and long-term who reported a medical problem, the patient with diabetes had been taking an antacid for 1 to 2 years at the time of the study, the patient with angina had been taking aspirin 75mg effervescent tablets for 1 to 2 years and the patient with migraine had been taking a cough suppressant for over 2 years.

Table 6.8 Duration of use of the 13 OTC medicines with prolonged oral clearance used regularly and long-term by the 17 elderly patients identified in the OTC Medicines Survey

OTC Medicine	Number of instances of use			
	3 months to 1 years	1 to 2 years	> 2years	No information
Seven Seas cod liver oil	0	0	1	1
Seven Seas cod liver oil lemon	0	0	1	0
Sanatogen cod liver oil	0	0	1	0
Metatone Liquid	0	0	1	0
Regulose Solution	0	1	0	0
Setlers Tablets	0	0	0	1
Mil-par liquid	1	0	0	0
Bisodol Antacid tablets	0	1	0	0
Aspro Clear eff. Tablets	0	0	2	0
Solpadeine Eff Tablets	0	0	0	1
Covonia Cough Mixture	0	1	0	1
Beecham Aspirin tablets	0	0	2	0
Merocet Lozenges	1	0	0	0
Total	**2**	**3**	**8**	**4**

6.4.8 The sweetening agents used in OTC medicines with prolonged oral clearance used regularly and long-term by the elderly

Seven of the thirteen OTC medicines with prolonged oral clearance used regularly and long-term by the elderly contained sweetening agents with no acidogenic properties and were classified as sugars-free (Table 6.7); the remainder were sugars-containing.

Of the sugars-containing OTC medicines, sucrose was the most common sweetening agent, being found in five of the six preparations (Table 6.9). Of the 7 sugars-free OTC medicines, 4 contained no sweetening agents and the intense sweetening agent, saccharin was found in the other three preparations, in one preparation in combination with the bulk sweetening agent, sorbitol.

Table 6.9 Type of sweetening agents in OTC medicines with prolonged oral clearance used regularly and long-term in the elderly

Sweetening agent	Liquids	Solids with POC	Total preps
Sugar-containing			
Sucrose	1	1	2
Sucrose and glucose	1	1	2
Sucrose and saccharin	0	1	1
Lactose + galactose +lactulose	1	0	1
Sub-total	**3**	**3**	**6**
Sugar-free			
No sugar	4	0	4
Saccharin	0	2	2
Saccharin and sorbitol	0	1	1
Sub-total	**4**	**3**	**7**
Total	**7**	**6**	**13**

6.5 DISCUSSION

Data obtained from the Prescribed Medicines Prevalence Survey (Chapter 5) provided information on the use of prescribed medicines with prolonged oral clearance used regularly and long-term by the elderly. However as the medical practices did not record information on medicines which a patient may have purchased from community pharmacies it was unclear whether OTC medicines formed a large part of regularly and long-term medication use in the elderly. There is evidence to suggest that OTC medicine use is increasing overall (Baines & Whynes, 1997; Batty *et al.*, 1997; Bradley & Blenkinsopp, 1996), and government is encouraging patients to visit the pharmacist before seeking advice of a general medical practitioner (Baines & Whynes, 1997). Therefore it was important that a prevalence survey of OTC medicine use was conducted to enable an overall estimate of prevalence of use of medicines with prolonged oral clearance to be made in terms of both prescribed and OTC medicines.

6.5.1 The data collection process

As there is no national or local data on OTC medicine purchase by elderly patients, information on the use of OTC medicines with prolonged oral clearance in the elderly could only be obtained from either the pharmacy that sold the medication or by asking the patient directly. International Medical Statistics (IMS), a data management company, collect quantity and cost data for orders of OTC medicines to pharmacies but this is not patient related. After pre-study information gathering with pharmacists in Newcastle it was clear that OTC sales data in the elderly could not be collected accurately from a pharmacy without causing administrative and operational problems. It was decided that the most efficient and accurate way to estimate the prevalence of use of OTC medicines with prolonged oral clearance would be by collecting data from patients.

The use of a patient questionnaire has inherent problems in relying on the patient to provide information on medicine use. The reliability of this information will vary between patients and be affected by a number of factors such as health, literacy, understanding of their health and willingness to help. For instance, they may feel that a certain medication is not important enough to be included because they bought it from a supermarket, or may not offer other information on frequency and length of use if they have forgotten. However information from the pilot study indicated that a patient completed questionnaire could provide sufficient information to enable an estimate of prevalence of use of OTC medicines and it was decided that this method of data collection would be the most appropriate. However, the medical problems question was

commonly not completed by patients and it was difficult to know whether this was because they had no medical problems or because they had refused to answer the question. In retrospect this aspect of the questionnaire could have been worded more accurately to allow patients to record if they had no medical problems.

6.5.2 The sample

This study was undertaken immediately after the Prescribed Medicines Prevalence Survey had been carried out and where a good working relationship with general medical practices involved had developed. It was decided that the use of a sub-sample of the patients used in the Prescribed Medicines Prevalence Survey where the use of prescribed medicines had been determined, would be appropriate and useful. The collection of name and addresses from practice computers was relatively straight forward since the practices all allowed full access to computers for transfer of data files to floppy disks. This allowed the names and addresses to be imported directly into a database to produce names and addresses after modification of the text file using a text editor.

Of the two types of computing systems used, the MEDITEL system proved to be problematic. Several attempts were made to download the names and addresses of the patients to a floppy disk and after a number of trips to the practice and many telephone calls to MEDITEL it became necessary withdraw the general medical practitioner from the study and randomly select another doctor.

The name and address data were collected three to four days prior to sending the questionnaire out to reduce the chances of sending a questionnaire to a deceased patient. In addition, the practice was phoned on the day of the mailing to check that none of the sampled patients had died, however from the 2322 questionnaires posted ten were to patients who had died. This was regrettable but had occurred because notification to the general medical practice had not been made by the local Family Health Services Authority.

6.5.3 The response rate

To maximise the response rate the covering letter was signed by the patients doctor as well as the researcher's head of department. In the letter the patient was reassured about confidentiality and told that their care in the practice would not be affected if they refused take part in the study. A telephone number on the cover letter allowed patients to phone for advice on filling the

questionnaire, which was used by 141 respondents. The telephone calls were mainly from people with no medical problems and no medication, who were not clear as to whether they should complete and return the form. As well as reassuring the patient that this questionnaire did not directly affect their medical treatment, it was also possible to advice the patient verbally on how to complete the form and improve the quality of information received. It was felt that the telephone helpline was useful.

The overall response rate was 71.5% (1661 respondents) after two reminders which compared favourably with other epidemiological studies involving the use of questionnaires in an elderly population (Table 6.10). The response rate may have been increased by telephoning the patient or actually visiting the patient at home and helping them with the questionnaire, however with large number of questionnaires involved, this was not felt to be practical.

Table 6.10 Response rates in questionnaire studies in older adults

Authors	Type of study	Reference	Response Rate (%)
Trenkwalder C. *et al*	Door to door survey of patients aged 65 years and over	Archives of Neurology. **52** (10):1017-22, 1995	82.5
Noro A. and Aro S.	Health-related quality of life among the least dependent institutional elderly compared with the non-institutional elderly population.	Quality of Life Research. **5** (3):355-66, 1996	83.0
Calder S.J. *et al*	A subjective health indicator for follow-up. A randomised trial after treatment of displaced intracapsular hip fractures.	Journal of Bone & Joint Surgery - British Volume. 77 (3):494-6, 1995	67.4
O'Keefe E.A. *et al*	Bowel disorders impair functional status and quality of life in the elderly: a population-based study.	Journals of Gerontology. Series A, Biological Sciences & Medical Sciences. **50** (4):M184-9, 1995	75.0

Of the 1532 questionnaires included in the OTC Medicines Survey, 51.2% were from females and 67.8% from patients aged 60 to 74 years. This was similar to the age and gender profiles of the elderly patients of the 10 general medical practices where 51.1% were female and 66.1% were aged 60 to 74 years (see Chapter 5) suggesting that patients responding were representative of the practices where they were registered.

6.5.4 The prevalence rate

The survey identified 79 patients taking OTC medicines with prolonged oral clearance. Of these, only 17 were taking these medicines regularly and long-term, representing a prevalence rate of 1.1% of the 1532 patients who returned the questionnaire. Extrapolation of this prevalence rate would mean that as many as 6796 patients in the Northern Region (mid-1995 population of 0.62 million (Office for National Statistics, 1995) may potentially be taking OTC medicines with prolonged oral clearance regularly and long-term. In comparison with prescribed medicines this was a significantly lower prevalence of long-term use, however, with 45.6% the patients who responded having some or all of their natural teeth (53.5% of respondents aged 60 to 74 years and 29% of respondents ≥75 years), the long-term use of these OTC medicines, if sugars-containing, could pose a threat to their dental health.

6.5.5 Medical problems

The medical problems of the 1532 respondents were mainly cardiovascular (36.5%) and musculoskeletal (23.6%) which were very similar to the medical problems identified in patients in the Prescribed Medicines Prevalence Survey taking prescribed medicines with prolonged oral clearance regularly and long-term. Prescribing data for all medicines dispensed to elderly patients (those exempt from prescription charges) in 1994 showed that 27.6% of all 184.2 million prescriptions dispensed were for cardiovascular medicines (Prescription Pricing Authority, 1995), which was lower than the prevalence of the disease in the study population (36.5%). This could be due to a higher rate of cardiovascular disease in the North; 40.7 males and 27.2 females per 1000 patients of all ages in 1996 were diagnosed with coronary heart disease (Office of Health Economics, 1997).

A survey looking at 1409 elderly patients in Nottingham, England reported that 30.4% were taking cardiovascular medicines (Rumble & Morgan, 1994), however the use of musculoskeletal medicines (9.3%) is lower than the prevalence of the disease in the practice population (23.6%).

6.5.6 Types of OTC medicines used regularly and long-term

The 17 patients taking OTC medicines with prolonged oral clearance regularly and long-term were taking 13 different preparations 17 times overall. These 13 preparations were mainly Gastrointestinal (4 preparations) and Nutrition and Blood (4 preparations) medicines.

The pharmacists role is to decide whether the medical complaint of an individual purchasing a medicine over the counter is minor and treat it appropriately or whether to refer the patient to his doctor or a hospital. Over the counter medicines are generally used to treat minor ailments and are indicated for short term use. Pharmacists are trained to discourage patients from using them regularly and long-term. However this survey showed that some OTC medicines are purchased and used long-term. Other OTC medicines are indicated for long-term use and these include vitamin supplements and mineral replacement products such as cod liver oil.

Aspirin has traditionally been used as a analgesic for minor aches and pains, however, more recently its association with Reyes Syndrome has stopped its use in children. Aspirin 75mg dispersible tablets are now the mainstay of prophylactic treatment for cardiovascular disease. A review of aspirin use in cardiovascular concluded that aspirin therapy was associated with a reduction in risk of subsequent myocardial infarction (MI) in patients with pre-existing cardiovascular disease (Hennekens, 1997). This review also reported that there is clear reduction of risk of MI when used in primary prevention. McCallum *et al* concluded from their study of 5751 British men aged 57 to 73 years, in 1992, that despite the strong evidence for the benefits of aspirin in cardiovascular disease, many patients were not receiving aspirin (McCallum *et al.*, 1997). However the study may have underestimated aspirin use as many patients may be buying it OTC. This was shown in a study of six general medical practices in Eating, Hammersmith and Houslow where patients with MI were surveyed using a questionnaire. Regular aspirin was used by 80% of the sample, of which 22% was OTC aspirin (Hoper & Pierce, 1998). It may be that the patients general medical practitioner is aware of them buying this medicine OTC and they are being monitored, however there is some anecdotal evidence to suggest that some patients may buy this medicines as a result of reading about its health benefits in the national press.

Five of the 13 OTC medicines used regularly and long-term by the elderly were Nutrition and Blood and Cardiovascular System preparations, and were appropriate for long-term use. These were three cod liver oil preparations, a health tonic and dispersible aspirin 75mg. However, 8 of the 13 OTC medicines used long-term were not indicated for long-term use. These were antacids, laxatives, cough medicines and pain killers which should be used on a 'when required' basis. This was of some concern since the use of OTC preparations may mask more serious conditions which present as dyspepsia, constipation, cough and general pain. For example, long-term dyspepsia may be a symptom of a gastric ulcer, which if not treated may become perforated and life threatening.

6.5.7 Duration of use

Of the 17 instances of use of OTC medicines with prolonged oral clearance used regularly and long-term, 8 were for medicines used for two years or longer. All these were medicines that were appropriate for long-term use as discussed above. Medicines not generally indicated for long-term use (antacids and cough preparations) were being used for periods of between 3 months and 2 years. Currently, the pharmacist and pharmacy staff can only monitor regular use of these medicines if the patients buys them from the same pharmacy and this may not be the case as the patient can purchase from any pharmacy of their choice. Even when a pharmacist has highlighted a potential problem of overuse, determined patients will only go to another pharmacy if they are refused a sale. Improving patient knowledge about the dangers of OTC medicines is required to ensure that these medicines are used appropriately and the introduction of patient records of OTC medicines, perhaps linked to existing pharmacy systems would highlight those at risk.

6.5.8 Sweetener content of OTC medicines used regularly and long-term

There were almost equal numbers of sugar-containing (6 preparations) and sugar-free (7 preparations) preparations. Of the six sugar-containing preparations, three were liquid oral medicines and three were solids. These sugars-containing medicines with prolonged oral clearance will increase the risk of dental caries if they are being used regularly and long-term in patients with natural teeth, many of whom may have salivary flow compromised by other medications (Bertram *et al.*, 1979; Mornstad *et al.*, 1986; Perrson *et al.*, 1991) or age associated morbidity (Gandara *et al.*, 1985). Patients should be encouraged to use sugars-free alternatives or change to another similar product if a direct equivalent is not available. The pharmacist is ideally placed to advise patients to purchase sugars-free OTC medicines where available, however there may be lack of understanding of the dangers of sugars-containing medicines used regularly and long-term and there is a need to ensure that pharmacists are educated about this issue. In an evaluation of a sugars-free medicines campaign in the North East of England it is reported that greatest impact of the event was with prescribed medicines with the effect on OTC medicines being less (Maguire *et al.*, 1999).

6.5.9 Supply of OTC medicines

Currently over the counter medicines can be bought without the general medical practitioner knowing and if a GSL product is bought from a non-pharmacy retail outlet then there will be no

involvement from a healthcare professional. This survey has shown that, although only a small number of patients were involved, OTC medicines were being used regularly.

The role of the pharmacist is to regulate the safe supply of all medicines and it is their job to ensure that patients buying OTC medicines are using them effectively and safely. However this survey has shown that OTC medicines not intended for long-term use are being used regularly and long-term. Pharmacy monitoring of OTC medicines purchases is difficult: without computing technology the patient would have to buy all their medicines from one pharmacy and the same pharmacist should be on duty. Pharmacies are increasingly opening for longer periods which involves a large turnover of pharmacists on duty. In addition patients visit city and town centre pharmacies as a 'one off' when they are 'passing by'. Pharmacy computer systems are now well developed for dispensing and keeping records of prescribed medicines, and although most new systems will allow recording of OTC sales this is rarely done, since there are obstacles to recording these data. The OTC medicine buyer may not have a record necessitating the creation of a new record as well as entering the sale which would be time-consuming and may cause delays. However, the advantage of such a system include the retention of records of the sale to allow a check to be made against any future medicines for interactions and possible interactions with prescribed medicines. With further advances in computing, future innovations in information technology may allow easy entry of OTC purchases using a bar code or a PMR system linked to the cash register.

6.6 CONCLUSIONS

The main findings from this survey of OTC medicines with prolonged oral clearance used regularly and long-term by the elderly are summarised as follows:

- Of the 2322 elderly persons (≥60 years), 1532 (66%) returned a questionnaire and were included in the survey.
- Of the 1532 respondents, 42.8% were male and 67.8% were aged 60 to 74 years.
- 45.6% of the respondents were dentate.
- The prevalence of use of OTC medicines with prolonged oral clearance used regularly and long-term was 1.1% (17 patients).

- Only three of these 17 patients reported a medical problem.

- The 17 patients were taking 13 OTC medicines with prolonged oral clearance regularly and long-term, 17 times.

- Of the 13 medicines, 7 were sugars-free and 6 sugars-containing accounting for 10 and 7 instances of use, respectively.

- Sucrose was the most common sweetening agent, found in 5 of the 6 sugars-containing OTC medicines, with saccharin being the most common sweetening agent for sugars-free medicines.

APPENDIX 6.1
Letter to general medical practitioners

14 March, 1997

Dear Dr

RE: USE OF MEDICINES WITH PROLONGED ORAL CLEARANCE IN THE ELDERLY

Wasim Baqir (Pharmacist and Research Student), under the supervision of Dr Anne Maguire, has been, over the last year, collecting data from your practice as part of a survey to assess the prevalence of the use of prescribed medicines with prolonged oral clearance in the elderly.

This survey is now complete and Wasim is now ready to start the final phase of the project. A sample of patients will be surveyed using a postal questionnaire, to collect information regarding the use of 'over the counter medicines' (OTC) with prolonged oral clearance. The project has received approval from the Local Ethics Committee of your district.

A random sample of 10 out of 47 general medical practitioners surveyed in the prevalence survey has selected you for the sub-sample survey if you are agreeable. I write to ask if you would consider allowing us to survey a sample of your elderly patients using the enclosed questionnaire. The questionnaire has been designed with the help of the Centre for Health Services Research (University of Newcastle upon Tyne) and has been piloted in one practice already.

If you are happy for this survey to take place we would like to ask you to sign a covering letter (enclosed) with myself as a co-signatory. We feel this would reassure these patients and minimise any concerns they might have. The responses from the patients would remain confidential, with no reference being made to individual responses.
If you would kindly agree to help, Wasim would be happy to contact yourself and arrange a time for a short meeting to discuss the project further.

Please do not hesitate to contact me or Wasim (0191 222 7017), if you require any further information.

Yours sincerely

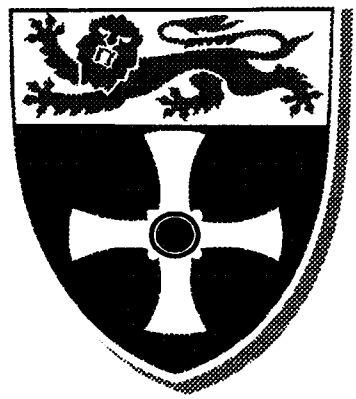
Professor Rugg-Gunn
Professor of Preventive Dentistry

APPENDIX 6.2
Questionnaire sent to patients in OTC Medicines Prevalence Survey

For Official Use

School of Dentistry

UNIVERSITY OF
NEWCASTLE UPON TYNE



CONFIDENTIAL

USE OF MEDICINES QUESTIONNAIRE

Please answer the questions on page 1 and then complete the table on page 2 (continuing on page 3 if necessary).

The information you give us will be treated with the strictest confidence.

Thank you for taking part in this study. Please return the completed questionnaire in the enclosed 'freepost' envelope (no stamp required) to Wasim Baqir, Medicine Use Survey, Child Dental Health, FREEPOST NEA902, Newcastle upon Tyne, NE2 1BR.

APPENDIX 6.2 (continued)
Questionnaire sent to patients in OTC Medicines Prevalence Survey

USE OF MEDICINES QUESTIONNAIRE

Please answer the following questions:

1. What Medical Conditions do you have (e.g. angina, diabetes, etc.)?

List all current medical problems

2. How many natural teeth do you have?

Please tick one box

None ☐ **Up to 12** ☐ **More than 12** ☐

3. How often do you buy medicines from a pharmacy?

Please tick one box

Hardly ever ☐
At least once a month ☐
At least once a week ☐
Every two to three days ☐

4. Which type of medicines do you prefer to buy from pharmacies?

Please tick one box

Tablets and capsules ☐
Liquids (e.g. syrups) ☐
Either (no preference) ☐
Depends on what the medicine is for ☐

5. When buying a liquid medicine do you ask for a sugar-free version?

Please tick one box

Yes ☐
No ☐
Sometimes ☐

APPENDIX 6.2 (continued)
Questionnaire sent to patients in OTC Medicines Prevalence Survey

In the following table please list all the medicines you take on a regular basis. This list should include **ALL** medicines **prescribed by your doctor** as well as medicines **bought from a pharmacy (chemist)**. For each medicine please give the approximate date you started and how often you take that medicine.

What is the name of your Medicine(s)?	Approximately when did you start taking this medicine?	How often do you take this medicine?
1	Month_____ Year____	
2	Month_____ Year____	
3	Month_____ Year____	
4	Month_____ Year____	
5	Month_____ Year____	
6	Month_____ Year____	
7	Month_____ Year____	

APPENDIX 6.3
Cover letter to patient

Dear Sir/Madam,

A SURVEY OF MEDICINE USE

Professor Andrew Rugg-Gunn and Dr Anne Maguire of The Dental School, University of Newcastle Upon Tyne would like your assistance in a research project they are carrrying out. They are interested in looking at the use of medicines in older adults. This medical practice is one of a number of practices they have chosen in this region.

I hope that you will agree to help in this survey but we emphasise that the choice of whether to take part is entirely yours and will not affect your care in this practice in any way.

If you are willing to help, I would be grateful if you or someone on your behalf could fill in the short questionnaire enclosed. On it please list **all** the medication you are currently taking. **This includes any medicines bought from a pharmacy**. Please then return it in the enclosed freepost envelope (no stamp required).

If you have any queries or require help in completing the questionnaire, then please do not hesitate to contact Wasim Baqir (Pharmacist and Research Student) on 0191 222 7017.

With many thanks for your help in this project.

Yours faithfully,

Dr
Health Centre Name

Professor A.J. Rugg-Gunn
Professor of Preventive Dentistry

APPENDIX 6.4
Coding frame to identify medical problems in OTC Medicines Prevalence Survey

CODE	MEDICAL CONDITION
01.01	HEARTBURN
01.02	INDIGESTION
01.03	GASTRIC REFLUX
01.04	CONSTIPATION
01.05	GASTRIC SPASMS
01.06	GASTRIC/ DUODENAL ULCER
01.07	ULCERATIVE COLITIS/ CROHN'S DISEASE
01.08	HIATUS HERNIA
01.09	IRRITABLE BOWEL SYNDROME
01.10	DIVERTICULAR DISEASE
02.00	GENERAL HEART DISORDERS
02.01	HEART FAILURE
02.02	HYPERTENSION
02.03	BLOOD COAGULATION DISORDERS
02.04	HYPERLIPAEMIA
02.05	ANGINA
02.06	CARDIOVASCULAR DISEASE
02.07	ARRYTHMIAS
02.08	HEART ATTACK
02.09	CIRCULATION PROBLEMS
02.10	HIGH CHOLESTEROL
02.11	OEDEMA
02.12	ARTERY DISEASE
02.13	CORONARY HEART DISEASE
02.14	VARICOSE VEINS
02.15	ISCHAEMIC HEART DISEASE
02.16	MYOCARDIAL INFARCTION
03.01	ASTHMA
03.02	PERSISTANT COUGH
03.03	NASAL CONGESTION
03.04	CHRONIC OBSTRUCTIVE AIRWAYS DISEASE
03.05	ALLERGIC RHINITIS
03.06	HAYFEVER
03.07	BRONCHITIS
03.08	EMPHYSEMA
03.09	TUBERCULOSIS
03.10	SINUSITIS
04.01	INSOMNIA
04.02	PSYCHOSIS
04.03	DEPRESSION
04.04	NAUSEA & VOMITTING/ VERTIGO
04.05	CHRONIC PAIN
04.06	EPILEPSY
04.07	PARKINSONISM

APPENDIX 6.4 (continued)

CODE	MEDICAL CONDITION
04.08	TRIGEMINAL NEURALGIA
04.09	ANXIETY
04.10	DEMENTIA/ALZHEIMERS
04.11	MIGRAINE/ HEADACHE
05.01	INFECTION PROPHYLAXIS
05.02	RECURRENT INFECTIONS
06.01	DIABETES MELLITUS
06.02	THYROID DISEASE
07.01	UROLOGICAL PAIN
07.02	URINARY INCONTINENCE
07.03	BLADDER CANCER
07.04	PROSTATE ENLARGEMENT
08.01	PROSTATE CANCER
08.02	GENERAL MALIGNANT DISEASE
08.03	BREAST CANCER
08.04	LEUKEAMIA
09.00	ANAEMIAS (GENERAL)
09.01	ANAEMIA - PERNICIOUS
10.01	JOINT PAINS/ RHEUMATIC DISEASE
10.02	GOUT
10.03	OSTEOARTHRITIS/ OSTEOPOROSIS
10.04	ARTHRITIS
10.05	BACK PAIN/ PROBLEMS
11.00	EYE PROBLEMS
11.01	GLAUCOMA
11.02	CATARACT
12.01	TINNITIS
12.02	DEAFNESS
13.01	ECZEMA
13.02	DERMATITIS
13.03	ROSACEA
13.04	PSORIASIS

CHAPTER 7

OVERALL CONSUMPTION OF MEDICINES WITH PROLONGED ORAL CLEARANCE

7.1 INTRODUCTION

In the UK, dispensing of the majority of medicines used by the population is carried out by pharmacists. Pharmacy practice occurs mainly within the three areas of hospital, community and industrial pharmacy with most dispensing of medicines in the general medical services being by NHS contracted community pharmacists for prescriptions prescribed by general medical practitioners. General dental practitioners as prescribers and 'over the counter' (OTC) medicines sold by pharmacists account for a smaller volume of use, although as a result of recent changes in primary health care, both financial and organisational, and the changing role of community pharmacy, more emphasis has been placed on the role of pharmacists as the first port of call for healthcare and advice (McElnay & Dickinson, 1994; Moore & Johnson, 1993). This, together with the increasing range of 'over the counter' (OTC) medicines available as more 'prescription only medicines' (POMs) become 'pharmacy' (P) medicines, has increased the use of such medicines. OTC medicines are classified as pharmacy only (P) medicines or general sales list (GSL) medicines. P medicines are only available from pharmacies and must be sold under the supervision of a qualified pharmacist, whereas GSL medicines may be sold from any retail outlet, such as a supermarket or petrol station. Medicines used by the hospital service are dispensed by hospital pharmacy departments and there is normally little use of OTC medicines in hospitals. Unlike prescribed medicines dispensed within primary health care services in the community, hospital medicine usage is not collated at a national, regional or local level, but information on medicines dispensed is collected by some hospitals for audit purposes. However medicine ordering information is available and this was used to estimate the quantity of medicines with prolonged oral clearance dispensed through hospital pharmacies.

To assess the overall consumption of medicines with prolonged oral clearance, quantity data for these prescribed and OTC medicines used in the primary health care and hospital services were required. These data were collected using three surveys: A Prescription Analysis Survey, a Hospital Drug Ordering Survey and an 'Over the Counter' (OTC) Medicines Survey.

7.2 PRESCRIPTION ANALYSIS SURVEY

7.2.1 Introduction

At the end of each month community pharmacists in England and Wales send all dispensed prescription scripts to the Prescription Pricing Authority (PPA), a special health authority based in Newcastle upon Tyne. The PPA is responsible for reimbursing the pharmacist the cost of the medicines as well as other professional fees based on the information from each prescription form entered into a computer database at the PPA. Raw prescribing data are also collated to analyse national, regional and local dispensing.

7.2.2 Aims

- To determine the number of prescription items and the quantities of all medicines with prolonged oral clearance and those used regularly and long-term by the elderly, dispensed from prescriptions issued in primary health services, during a one year period (1994) in England, the Northern Region and one district within the Northern Region (Newcastle).

- To determine the sugars content of prescription items and quantities for medicines with prolonged oral clearance used regularly and long-term by the elderly, dispensed during a one year period (1994) in the Northern Region of England.

- To determine the proportion of generically prescribed medicines with prolonged oral clearance dispensed during a one year period (1994) in the Northern Region of England.

7.2.3 Methods

7.2.3.1 Sources of data

The PPA produce two types of reports, published by Her Majesty's Stationary Office (London): Prescribing Analysis and Cost (PACT) reports, which provide prescribing data by the area in which the prescription was prescribed and Prescription Cost Analysis (PCA) reports which provide dispensing information by the area where the prescription was dispensed.

PACT and PCA data provide information on the number of prescription items and quantities of medicines dispensed as well as their net ingredient cost before dispensing fees are added. These data offer an accurate breakdown of dispensing, being compiled from all prescriptions dispensed, from a

general practitioner level to a national level. However the two types for prescribing data vary in that PCA data are based on the health authority in which the prescription was dispensed and give the total number of prescription items and quantity for each preparation dispensed, whereas PACT data are based on the health authority where the prescription was prescribed and give the number of prescription items dispensed by quantity prescribed for each preparation. PCA data are only available at a regional and national level, whereas PACT data are available at general medical practitioner, practice, district, regional and national level.

7.2.3.2 The database

As Figure 5.2 in Chapter 5 describes a number of different tables were used to construct the database that was used in all five surveys in the study. The **DRUGS** table was the main database table and held information on all 613 medicines with prolonged oral clearance that were identified from a database of all medical and surgical products supplied by John Richardson Computers plc. In the case of generic medicines, where there could be one or more manufacturer, this field in the **DRUGS** table, was allocated the code 999 which identified the medicine as a generic medicine. The **DRUGS** table was linked to two other tables: **PATIENT MEDICATION** and **CONSUMPTION DATA** which held data collected from the Prescribed Medicines Prevalence Survey (Chapter 5) and Prescription Analysis Survey, respectively. As described in Chapter 5, using the Generics Supplement 1995 (Chemist and Druggist, 1995), the **GENERIC FORMULATIONS** table was created to hold information for each generic formulation and this was also linked to the **DRUGS** table.

In addition a field in the **DRUGS** table of the database recorded whether the 613 medicines with prolonged oral clearance were sugars-free or sugars-containing and collected information on the type of sweetening agent used in their formulation. A similar set of fields in the **GENERIC FORMULATIONS** table recorded the sugar content and type of sweetening agent used in the generic formulations.

7.2.3.3 Retrieval of dispensing data

The Prescription Pricing Authority was contacted by letter and permission obtained to retrieve PACT and PCA data for Newcastle, the Northern Region and England for a one year period (1994). The pharmaceutical advisor for Newcastle was also informed about the study. Since the PACT and PCA data required were also held at the Northern Region Health Authority Regional Drug

Information Unit, Newcastle upon Tyne, permission was sought, in writing, from the unit for access to these data.

Data from the Prescription Analysis Survey were entered into the **CONSUMPTION DATA** table of the database (Figure 5.1, Chapter 5). A field was used to record dose form and identified the medicine as a:

- liquid oral medicine
- solid dose with prolonged oral clearance (e.g. effervescent or chewable tablets)
- oral gel, loose powder or granule for reconstitution with a liquid (usually water)
- powder or granules packaged in a sachet for reconstitution with a liquid (usually water)

It was necessary to separate the medicines by dose types as they all had different units of measurement. Quantities for liquid oral medicines were measured in litres, solid doses with prolonged oral clearance as single units as were sachets containing powders or granules. Quantities for loose powders, granules and oral gels were both measured in grams. The number of prescription items and quantities dispensed were determined for:

- all medicines with prolonged oral clearance (613 medicines)
- prescribed medicines with prolonged oral clearance used regularly and long-term by the elderly identified in the Prescribed Medicines Prevalence Survey (143 medicines)

7.2.3.4 Data entry

Prescribing Cost Analysis (PCA) dispensing data for England for a one year period (1994) were examined manually and the number of prescription items and quantity dispensed for each medicine with prolonged oral clearance was retrieved and entered into the relevant fields of the **CONSUMPTION DATA** table of the database. For the Northern Region and Newcastle, PACT prescribing data for a one year period (1994) were manually examined and individual quantities for each quantity prescribed were added to give a total quantity prescribed for each medicine before entering into the **CONSUMPTION DATA** table of the database.

7.2.3.5 Data analysis

After entering all the data into the **CONSUMPTION DATA** table of the database, analysis was undertaken to assess the number of prescription items and quantities prescribed and dispensed for all

medicines with prolonged oral clearance and medicines with prolonged oral clearance taken regularly and long-term by the elderly. A closer analysis was made of the use of medicines with prolonged oral clearance in the Northern Region by generic prescribing and sugar content.

PACT data provided information on all generic prescribing, including those medicines where no generic equivalent was available. The numbers of prescription items and quantities for generically prescribed medicines where there was no generic available were added to the numbers of prescription items and quantities for the proprietary preparation that was dispensed.

A link was established between the **MEDICATION DATA** table in the Prescribed Medicines Prevalence Survey and the **CONSUMPTION DATA** table which held information on number of prescription items and volume of medicines used in this survey. Using these linked tables the number of prescription items and quantities of medicines prescribed and dispensed for preparations used long-term and regularly by the elderly in the Prescribed Medicines Prevalence Survey was calculated for England, the Northern Region and Newcastle.

7.2.4 Results and Discussion

7.2.4.1 Data retrieval and sources of data

The data, although produced by the Prescription Pricing Authority (PPA) were held at the Regional Drug Information Unit in Newcastle who kindly allowed access to the unit for data retrieval. Access to the unit was initially restricted to two afternoons per week, but later increased to every afternoon. The retrieval of PCA data for England began in June 1996, and was completed by August 1996. Collection of PACT data for Newcastle was started December 1996 and completed in February 1997, with information from the Northern Region PACT data commencing in April 1997 and being complete two months later in June 1997.

To assess the overall use of medicines with prolonged oral clearance the most accurate data available were PCA and PACT as these data were based on 100% of all dispensed prescriptions. However, these data only record what was prescribed and subsequently dispensed to the patient and an estimate of what may have been consumed. Poor compliance is a common problem (Royal Pharmaceutical Society of Great Britain, 1997), especially in the elderly (Salzman, 1995), and had to be considered when analysing the data. The two forms of data used, PCA and PACT, varied slightly in that PCA was a record of what was dispensed and PACT recorded what was prescribed. In

reality there is little difference between these two sources, however the use of PCA for England reduced the time spent calculating total quantities for individual medicines.

PCA data already contained information on quantities dispensed allowing dispensing information to be entered directly into the database. However, PCA data were not available for the Northern Region or Newcastle and for these areas PACT data had to be used. Although the difference between data from the two reports related only to the area where the prescription was prescribed (PACT) compared to the area where dispensed (PCA), the collection of PACT data was time consuming as it involved entering information into a spreadsheet to calculate the total quantities for each preparation, followed by entry of this information into the **CONSUMPTION DATA** table of the database.

Data entry forms were created in MS Access to facilitate data entry and were linked to the **CONSUMPTION DATA** table of the database. The forms were programmed to accept only numeric values and to reject any wrong numbers (e.g. more than one decimal point or negative numbers). This helped eliminate errors from the data entry process and allowed a number of entries to be rejected during the data entry process, for example, entering two values in the same field.

Since this study, the PPA have released a new version of PACT data called ePACT (electronic PACT), which is a modified version of current electronic systems (PACTLINE, HAEPACT and EXEPACT) and will eventually replace these and the paper based data. The PPA are currently introducing this service into all general medical practices (PPA Web Site: http://www.ppa.org.uk/). The impact of this is that any future prescribing analysis studies of this nature could be simplified, allowing data to be downloaded straight into a database for analysis.

7.2.4.2 Number of different preparations dispensed (Table 7.1 and Appendix 7.1)

The database of all medicines with prolonged oral clearance identified 613 preparations (Table 7.1). From Table 7.1 it can be seen that overall, medicines with prolonged oral clearance covered a wide range of BNF Sections. However, of the 613 preparations, 404 preparations (65.9%) had actions on only three BNF Sections: Infections (27.2%, 167 preparations), the Central Nervous System (20.6%, 126 preparations) and the Gastrointestinal System (18.1%, 111 preparations).

Table 7.1 Number of preparations for all medicines with prolonged oral clearance dispensed in England, Northern Region, and Newcastle in 1994 by British National Formulary Section

BNF Section	Total no. of preps.		England			Northern Region			Newcastle		
	No. listed in BNF	%	No. of preps dispensed	%	% of all preps with POC	No. of preps dispensed	%	% of all preps with POC	No. of preps dispensed	%	% of all preps with POC
01 Gastrointestinal System	111	18.1	102	17.8	91.9	96	18.4	86.5	82	21.0	73.9
02 Cardiovascular System	30	4.9	30	5.2	100.0	28	5.4	93.3	24	6.2	80.0
03 Respiratory System	60	9.8	59	10.3	98.3	49	9.4	81.7	41	10.5	68.3
04 Central Nervous System	126	20.6	122	21.3	96.8	113	21.6	89.7	77	19.7	61.1
05 Infections	167	27.2	151	26.4	90.4	133	25.5	79.6	102	26.2	61.1
06 Endocrine System	3	0.5	3	0.5	100.0	3	0.6	100.0	2	0.5	66.7
07 Obstetrics and Gynaecology	5	0.8	4	0.7	80.0	4	0.8	80.0	4	1.0	80.0
08 Malignant Disease	1	0.2	1	0.2	100.0	1	0.2	100.0	1	0.3	100.0
09 Nutrition and Blood	51	8.3	47	8.2	92.2	43	8.2	84.3	37	9.5	72.5
10 Musculoskeletal and Joint Disease	23	3.7	22	3.8	95.7	21	4.0	91.3	16	4.1	69.6
11 Eye	0	0.0	0	0.0	-	0	0.0	-	0	0.0	-
12 Ear, Nose and Oropharynx	36	5.9	31	5.4	86.1	31	5.9	86.1	4	1.0	11.1
Totals	**613**	**100.0**	**572**	**100.0**	**93.3**	**522**	**100.0**	**85.2**	**390**	**100.0**	**63.6**

Of these 613 preparations with prolonged oral clearance, 93.3% (572) were dispensed in England, and 84.6% (522) prescribed in the Northern Region and 63.6% (390) in Newcastle, in 1994 (Table 7.1). The proportion of medicines with prolonged oral clearance prescribed in the Northern Region compared with all medicines with prolonged oral clearance available varied from 79.6% (Infections) to 100%. In Newcastle the range was wider, 11% (Ear, Nose and Oropharynx) to 100% (Table 7.1).

The lower numbers of medicines used in Newcastle compared to the Northern Region and nationally was mainly due to the lower number of general medical practitioners involved with a smaller prescribing range. It may also have been due to prescribing initiatives aimed at cutting drug costs and the use of local drug formularies. General medical practitioners from similar local, medical and educational backgrounds, in Newcastle, compared with the Northern Region and nationally, would also contribute to the smaller range of medicines prescribed locally. Medicine use between the BNF Sections for all three areas was fairly consistent apart from the Ear, Nose and Oropharynx Section, where only 11.1% of the 36 preparations with prolonged oral clearance available were used in Newcastle compared with 86.1% in both England and the Northern Region. This may also have been due local formularies limiting the number of medicines to choose from, although a number of medicines with prolonged oral clearance in this section are antiseptic lozenges and oral sprays, which general medical practitioners may be encouraged not to prescribe as well as advice from the BNF states that "there is no convincing evidence that antiseptic lozenges and sprays have a beneficial action and they sometimes irritate and cause sore tongue and sore lips. Some of these preparations contain local anaesthetics which relieve pain but may cause sensitisation." (British Medical Association & Royal Pharmaceutical Society, 1997). The 143 medicines with prolonged oral clearance that were used regularly and long-term by the elderly in ten general medical practices in five districts of the North East of England are discussed in detail in Section 5.4.10 of Chapter 5.

7.2.4.3 Number of prescription items dispensed in England, the Northern Region and Newcastle

7.2.4.3.1 For all medicines with and without prolonged oral clearance

In England, during 1994, 457 million prescription items were dispensed for all medicines with and without prolonged oral clearance (Table 7.2). For the Northern Region and Newcastle, the total number of prescription items prescribed during 1994 were 32 million and 2.97 million, representing 7% and 0.7% of the total for England respectively. There was slight variation in

prescribing within the BNF Sections for these three areas with the proportion of prescription items for the Central Nervous System being higher in Newcastle (22.2%) and the Northern Region (20.6%) than England (18%). The higher use of these medicines could be due to patients visiting their general medical practitioners rather than buying minor analgesics from pharmacies. In the Northern Region (including Newcastle) there are more lower income households (especially elderly householders) than the national average. There are higher levels of long-term unemployed person the north compared with the rest of the country (Office for National Statistics, 1998), who are entitled to free prescriptions and who may see a general medical practitioner for minor ailments rather than purchase an over the counter treatment from their pharmacist.

Table 7.2 Number of prescription items (millions) dispensed for all medicines in England, the Northern Region and Newcastle in 1994 by BNF Section (Source of data: PACT, Prescription Pricing Authority, 1995)

BNF Section	Prescription items					
	England		Northern Region		Newcastle	
	No. (millions)	% of total	No. (millions)	% of total	No. (millions)	% of total
01 Gastrointestinal System	37.5	8.2	2.8	8.6	0.27	9.1
02 Cardiovascular System	82.2	18.0	6.0	18.4	0.57	19.2
03 Respiratory System	46.0	10.1	3.1	9.5	0.31	10.4
04 Central Nervous System	82.2	18.0	6.7	20.6	0.66	22.2
05 Infections	48.9	10.7	3.3	10.1	0.32	10.8
06 Endocrine System	26.5	5.8	1.7	5.2	0.16	5.4
07 Obstetrics and Gynaecology	11.7	2.6	0.8	2.5	0.07	2.4
08 Malignant Disease	2.3	0.5	0.2	0.6	0.01	0.3
09 Nutrition and Blood	14.0	3.1	0.8	2.5	0.08	2.7
10 Musculoskeletal and Joint Disease	25.5	5.6	1.8	5.5	0.14	4.7
11 Eye	11.3	2.5	0.7	2.1	0.06	2.0
12 Ear, Nose and Oropharynx	8.8	1.9	0.5	1.5	0.05	1.7
Others	60.1	13.2	4.2	12.9	0.27	9.1
Totals	**457.0**	**100.0**	**32.6**	**100.0**	**2.97**	**100.0**

7.2.4.3.2 For medicines with prolonged oral clearance (Table 7.3 and Appendix 7.1)

As Table 7.3 shows, in England in 1994, 61.4 million prescription items were dispensed for medicines with prolonged oral clearance which represented 13% of the total number of prescriptions items dispensed for all medicines. Of these prescriptions, 65% were from three BNF Sections: Gastrointestinal System (27.2%), Infections (21.4%) and Central Nervous System (16.7%), and represented similar proportions to the number of preparations in these Sections.

Of the 37.5 million items dispensed in England for all gastrointestinal medicines (Table 7.2), 44.5% (16.7 million prescription items) were for medicines with prolonged oral clearance (Table 7.3). Prolonged oral clearance medicines represented a smaller percentage of the number of prescription items by therapeutic section for Infections, Nutrition and Blood and the Central Nervous System, with 27% (13.2 million), 17.8% (2.5 million) and 12.4% (10.2 million) being for medicines with prolonged oral clearance, respectively. Overall, gastrointestinal medicines were more likely to have a prolonged oral clearance from the oral cavity, since most gastrointestinal medicines act locally to achieve their effect, for example, antacids interact with acid in the stomach to neutralise it and a liquid oral medicine provides a larger surface area available for interaction with the stomach acid. Of the 16.7 million prescriptions items dispensed for gastrointestinal medicines, 8.1 million (48.5%) were for antacids and 7.9 million (47.3%) for laxatives.

The medicines with prolonged oral clearance for infections accounted for 13.2 million prescriptions items of which 12 million (91%) were for antibiotics, and of the 10.2 million prescriptions items dispensed for central nervous system medicines (Section 04), 8.1 million (79%) were for minor analgesics.

In the Northern Region, 4.5 million prescription items were prescribed for medicines with prolonged oral clearance (Table 7.3) which represented 14% of all prescription items prescribed in the Northern Region in 1994 (Table 7.2). Prescribing in the Northern Region followed a similar pattern to that of dispensing in England, in that gastrointestinal and central nervous system medicines together with those for infections accounted for 71.8% of the total number of prescription items for medicines with prolonged oral clearance dispensed in 1994. However the proportion of prescription items for central nervous system medicines was higher in the Northern Region (26%) compared to England (16.7%).

Table 7.3 Number of prescription items ($x10^3$) dispensed for all POC medicines and long-term POC medicines in England, Northern Region and Newcastle in 1994

BNF Section[1]	England					Northern Region					Newcastle				
	All POC medicines		Long-term POC medicines		% of All used long-term	All POC medicines		Long-term POC medicines		% of All used long-term	All POC medicines		Long-term POC medicines		% of All used long-term
	No. ($x10^3$)	%	No. ($x10^3$)	%		No. ($x10^3$)	%	No. ($x10^3$)	%		No. ($x10^3$)	%	No. ($x10^3$)	%	
01	16715.0	27.3	15273.9	50.2	91.4	1204.0	26.9	1079.8	42.7	89.7	121.4	27.3	107.8	45.3	88.8
02	7575.1	12.3	6184.4	20.3	81.6	603.1	13.5	470.8	18.6	78.1	66.3	14.9	46.5	19.5	70.1
03	8486.7	13.8	3323.4	10.9	39.2	425.0	9.5	193.1	7.6	45.4	40.5	9.1	17.8	7.5	44.0
04	10242.9	16.7	4413.2	14.5	43.1	1164.6	26.0	708.9	28.0	60.9	112.2	25.2	61.0	25.6	54.4
05	13157.3	21.4	84.5	0.3	0.6	820.4	18.3	3.6	0.1	0.4	83.7	18.8	0.3	0.1	0.4
06	265.8	0.4	0.0	0.0	0.0	17.3	0.4	0.0	0.0	0.0	1.2	0.3	0.0	0.0	0.0
07	75.8	0.1	56.1	0.2	74.0	3.4	0.1	2.4	0.1	70.6	0.5	0.1	0.2	0.1	40.0
08	26.3	0.0	0.0	0.0	0.0	1.0	0.0	0.0	0.0	0.0	0.1	0.0	0.0	0.0	0.0
09	2532.2	4.1	541.5	1.8	21.4	127.7	2.9	38.7	1.6	30.8	13.7	3.1	2.3	1.0	16.8
10	706.0	1.2	338.9	1.1	48.0	35.9	0.8	16.9	0.7	47.1	3.2	0.7	1.7	0.7	53.1
11	0.0	0.0	0.0	0.0	-	0.0	0.0	0.0	0.0	-	0.0	0.0	0.0	0.0	-
12	1563.6	2.5	208.0	0.7	13.3	71.3	1.6	16.0	0.6	22.4	2.7	0.6	0.4	0.2	14.8
Total	**61346.7**	**100.0**	**30424.0**	**100.0**	**49.6**	**4473.6**	**100.0**	**2530.3**	**100.0**	**56.6**	**445.4**	**100.0**	**238.1**	**100.0**	**53.5**

[1]Key to BNF Sections:

01 Gastrointestinal System
02 Cardiovascular System
03 Respiratory System
04 Central Nervous System
05 Infections
06 Endocrine System
07 Obstetrics and Gynaecology
08 Malignant Disease
09 Nutrition and Blood
10 Musculoskeletal and Joint Disease
11 Eye
12 Ear, Nose and Oropharynx

Over 91% of the prescription items prescribed for Central Nervous System medicines in the Northern Region were for minor analgesics (Appendix 7.1), and in comparison with other health authority areas, the Northern Region overall has a lower socioeconomic status, with 9.6% of the population of the North of England being unemployed compared with an unemployment rate in the UK of 8.3%, in 1996, as well as the average earnings being considerably lower in the North East, compared with the averages for England and the UK (Office for National Statistics, 1998). A higher proportion of patients in the Northern Region may be entitled to exemption from prescription charges and this may be why patients are being prescribed these analgesics rather than buying them from pharmacies.

In contrast to minor analgesics, there was a lower proportion of prescription items for medicines for Infections dispensed in the Northern Region (18.3%) compared to England (21.4%). This may be due to local prescribing initiatives to reduce antibiotic prescribing and the use of formularies.

Of the 2.8 million prescription items prescribed in the Northern Region for all Gastrointestinal medicines (Table 7.2), 42.9% (1.2 million) were for medicines with prolonged oral clearance (Table 7.3). For Infections and Central Nervous System medicines the proportions were lower with 24.2% and 17.9% being for medicines with prolonged oral clearance, respectively (Table 7.2 and Table 7.3). This reflected the finding in England, that Gastrointestinal medicines were more likely to have prolonged oral clearance.

In Newcastle, 0.45 million prescription items were prescribed for medicines with prolonged oral clearance, representing 14.4% of all prescription items prescribed in Newcastle in 1994 (Table 7.3). The pattern of prescribing in Newcastle was very similar to that of the Northern Region with the Gastrointestinal System (27.3%), Central Nervous System (25.2%) and Infections (18.8%) Sections of the BNF accounting for 71.3% of prescriptions dispensed for medicines with prolonged oral clearance.

Of the 0.27 million items prescribed in Newcastle for all gastrointestinal medicines (Table 7.2), 44% (0.12 million items) were for medicines with prolonged oral clearance (Table 7.3). Similarly, of the 0.32 million prescription items for infections and the 0.66 million prescription items for the central nervous system, 25% and 17% were for medicines with prolonged oral clearance, respectively.

In summary, in all three areas of the Survey (England, the Northern Region and Newcastle) approximately 14% of prescription items dispensed or prescribed in 1994 were for medicines with prolonged oral clearance. Overall prescription data for all medicines dispensed to patients of all ages in 1994 (Table 7.2) showed that the Gastrointestinal, Cardiovascular, Respiratory, Central Nervous System and Infections Sections of the BNF were the main areas of medicines use. However, prescription data for all medicines dispensed to the elderly (Prescription Pricing Authority, 1995) have shown that the main therapeutic areas of prescribing to the elderly are the Central Nervous System and the Cardiovascular system. When all medicines with prolonged oral clearance were considered this pattern of prescribing differed, in that medicines for the Gastrointestinal System, Infections and the Central Nervous System were the most commonly prescribed or dispensed, accounting for over 65% of the prescriptions in all areas studied (England, the Northern Region and Newcastle).

The proportion of prescription items prescribed or dispensed for gastrointestinal medicines was similar in Newcastle, the Northern Region and England. However, in Newcastle and the Northern Region the Central Nervous System medicines accounted for a larger proportion and Infections medicines a smaller proportion, compared with England. Analgesics accounted for 79% and 92% of all CNS medicines in England and the Northern Region respectively. Over 91% (Appendix 7.1) of these were minor analgesics which can be bought over the counter from pharmacies, however the prescribing pattern suggested these were more likely to be prescribed in the Northern Region and Newcastle.

7.2.4.3.3 Number of prescription items dispensed for medicines with prolonged oral clearance used regularly and long-term by the elderly

The 143 medicines with prolonged oral clearance that were used regularly and long-term by the elderly identified in the Prescribed Medicines Prevalence Survey, accounted for 49.6% (30.4 million prescription items) of the 61.3 million prescription items dispensed for medicines with prolonged oral clearance in England, in 1994 (Table 7.3). The top three Sections dispensed were Gastrointestinal, Cardiovascular and Central Nervous System medicines, accounting for 15.3 million items (50.2%), 6.2 million items (20.3%) and 4.4 million items (14.5%) respectively, and 85% of the total number of prescription items for medicines with prolonged oral clearance used regularly and long-term by the elderly.

The 15.3 million prescriptions for Gastrointestinal medicines with prolonged oral clearance potentially used long-term by the elderly accounted for 40.8% of the 37.5 million items for all

Gastrointestinal medicines dispensed in England (Table 7.2 and Table 7.3). In contrast, prescriptions dispensed for Cardiovascular and Central Nervous System medicines only accounted for 7.5% and 5.4% of all prescriptions dispensed for these medicines in England, in 1994. In addition, less than 1% of all prescriptions dispensed for medicines in the Infections Section of the BNF were for medicines used regularly and long-term by the elderly.

The Gastrointestinal medicines were mainly antacids (7.5 million items) or laxatives (7.3 million items) which acted locally. Of the 5.4 million items for Cardiovascular medicines, 79% were for aspirin 75mg effervescent tablets used in the prevention of cardiovascular disease, and of the 5.4 million items for Central Nervous System medicines, 69% were for minor analgesics. Antibiotics are normally used for a short duration (5 to 28 days depending on severity of the infection) and uncommonly used long-term. Only two preparations, cefixime and erythromycin, were being used regularly and long-term by the elderly.

In the Northern Region during 1994, 2.5 million prescription items were prescribed for medicines with prolonged oral clearance used regularly and long-term by the elderly. This represented 56.6% of the 4.47 million prescription items prescribed overall (Table 7.3). Of these 2.5 million items, 89.3% were for Gastrointestinal, Central Nervous System and Cardiovascular medicines, with these Sections accounting for 1.08 million (42.7%), 0.71 million (28%) and 0.47 million (18.6%) prescription items, respectively (Table 7.3).

In Newcastle, 53.5% of the 0.45 million prescription items for all medicines with prolonged oral clearance prescribed in 1994, were for medicines used regularly and long-term by the elderly. The prescribing pattern for Newcastle was similar to the Northern Region with Gastrointestinal, Central Nervous Systems and Cardiovascular medicines accounting for 90.4% of prescriptions prescribed for these long-term medicines, with 0.11 million (45.3%), 0.06 million (19.5%) and 0.05 million (25.6%) prescription items prescribed respectively during a one year period (1994).

In summary, the three most common therapeutic areas for medicines with prolonged oral clearance equivalent to those used regularly and long-term in the elderly, in terms of the number of prescription items dispensed in 1994 in England, were the Gastrointestinal System, Cardiovascular System and the Central Nervous System in that order. However in the Northern Region and Newcastle, Central Nervous System medicines were prescribed more commonly than Cardiovascular medicines. As for all medicines with prolonged oral clearance there was increased use of Central Nervous System medication in the Northern Region and Newcastle and most of

these Central Nervous System medicines were minor analgesics which could have been bought over the counter from pharmacies.

When comparing the prescribing and dispensing of all medicines with prolonged oral clearance with medicines with those used regularly and long-term, the major differences were that very few Infections medicines were used long-term, there was increased use of Gastrointestinal medicines long-term and Central Nervous System medicines use was similar.

Of the medicines with prolonged oral clearance equivalent to those used regularly and long-term, antacids and laxatives were most commonly prescribed. Antacids were used to treat excess acidity leading to heartburn or indigestion; conditions which are common in this age group (Geokas & Haverback, 1969; Nelson & Castell, 1990). Ageing can reduce the motility of the gastrointestinal tract and the elderly may often have a diet lacking in fibre which, along with reduced fluid intake may cause chronic constipation for which laxatives are commonly prescribed. The elderly also often take medicines such as non-steroidal anti-inflammatory drugs and anticholinergic medicines which can cause gastric problems or constipation as side-effects and for which they are often prescribed antacids and laxatives (Finch *et al.*, 1998).

Cardiovascular medicines were also commonly prescribed, representing approximately 20% of the prescriptions prescribed and dispensed nationally, regionally and locally. The elderly suffer from more cardiovascular problems than the general population in the UK (Lakatta, 1993; Williams, 1991), which would account for a large proportion of the Cardiovascular medicines dispensed. In particular, aspirin 75mg effervescent tablets accounted for 95% of all the prescription items dispensed in this Section, in all three areas. This drug is now used prophylactically by the elderly as well as younger individuals suffering from cardiovascular problems such as angina and hypertension.

7.2.4.4 Dose form of medicines with prolonged oral clearance used regularly and long-term by the elderly

When the prescription items were analysed by dose form, liquid oral medicines and solids with prolonged oral clearance were most popular dose types, accounting for over 90% of the prescription items dispensed in each of the three areas of England, the Northern Region and Newcastle (Table 7.4).

Table 7.4 Number of prescription items (Rx) dispensed in 1994, for medicines with prolonged oral clearance used regularly and long-term by the elderly, by dose type

Dose Type	England		N. Region		Newcastle	
	Rx Items (x1000)	%	Rx Items (x1000)	%	Rx Items (x1000)	%
Liquid oral medicine	15363.5	50.5	1037.2	41.0	102.2	42.9
Solid doses	12170.1	40.0	1304.3	51.5	118.1	49.6
Powders and oral gels	471.1	1.5	33.4	1.3	3.2	1.3
Sachets	2419.3	8.0	155.4	6.2	14.6	6.2
Totals	**30424.0**	**100.0**	**2530.3**	**100.0**	**238.1**	**100.0**

In England, liquid oral medicines were the most common dose form, accounting for 50.5% (15.4 million) of the prescription items. This was in contrast to medicines dispensed in the Northern Region and Newcastle, where the solid dose form with prolonged oral clearance accounted for approximately 50% of the prescription items, compared with approximately 42% for liquid oral medicines.

Liquid oral medicines are the traditional alternatives to solid oral doses. There are more preparations with prolonged oral clearance formulated as liquid oral medicines and they are well established as a suitable dose form especially in children and patients with swallowing problems. They are also the cheapest dose form with prolonged oral clearance and pressure on prescribers to cut drug costs may increase their use. Liquid oral medicines, as well as other medicines with prolonged oral clearance offer the patient a convenient form of administration of medicines where swallowing is a problem. However, the solid oral dose with prolonged oral clearance offers advantages over liquid oral medicines in that these dose forms are less bulky and more convenient for patients, at the same time having the advantages of liquid oral medicines in that they do not have to be swallowed whole and can offer faster onset of action (e.g. soluble and effervescent tablets), offer more control over dosing (e.g. buccal and sublingual tablets that may be removed at any time) and have local effects (e.g. lozenges and pastilles).

The other dose forms, which were not as commonly prescribed as liquid oral medicines and solid doses, were oral gels and loose powders and powders packaged in sachets. Oral gels and loose powders, although very different dose forms were analysed in the same category as they were both measured in grams, the significance of which discussed later (Section 7.2.4.5). In England, the Northern Region and Newcastle the number of prescription items dispensed for medicines formulated as loose powders or oral gels was only 471,000 (1.5%), 33,400 (1.3%) and 1,300 (1.3%) items respectively, reflecting the small range prescribed regularly. In fact, these

prescription items were for just four preparations, three of which were different brands of ispaghula husk, a bulk forming laxative and one was a brand of senna granules, also used for chronic constipation.

Prescriptions for powders packaged as sachets represented between 6.2% (in Newcastle and the Northern Region) and 8% (in England) of all prescription items for medicines with prolonged oral clearance used regularly and long-term, dispensed in 1994. Sachets are more expensive than liquid oral medicines and loose powders and as a result prescribers are encouraged to reduce their use, which may be a reason why they are not commonly prescribed.

7.2.4.5 Quantities dispensed during a one year period for all medicines with prolonged oral clearance (Appendix 7.2, 7.3 and 7.4)

To assess the total quantity of medicines dispensed, the four different dose forms of medicines with prolonged oral clearance, liquid oral medicines, solids, loose powders and oral gels and sachets, were considered separately according to their units of measurement. Quantities for liquid oral medicines were measured in litres, and solids and sachets as the number of tablets and sachets. Loose powders and oral gels were placed in the same category as their units of measurement were grams (Table 7.5).

As Table 7.5 shows, in England in 1994, 10.6 million litres, 1122.9 million tablets, 191.2 million grams and 307 million sachets for liquid oral medicines, solid doses, loose powders and oral gels, and sachets (containing powders for reconstitution) respectively, were dispensed.

Table 7.5 Quantities for all medicines with prolonged oral clearance dispensed in England, the Northern Region and Newcastle during 1994, by dose type

Dose Type	Unit	Quantity		
		England ($x10^3$)	N. Region ($x10^3$)	Newcastle ($x10^3$)
Liquid oral medicine	litres	10569.6	716.4	78.1
Solid doses with prolonged oral clearance	number	1122908.4	134152.3	14070.4
Powders and oral gel	grams	191234.5	12214.1	1091.2
Sachet (containing powders)	number	307022.1	20179.1	1877.2

Of the 10.6 million litres of liquid oral medicines dispensed, 5.9 million litres (56%) were for Gastrointestinal medicines, with 1.7 million (16.4%), 1.3 million (12.8%) and 1.2 million (11.5%) litres dispensed for medicines in the Respiratory, Central Nervous System and Infections Sections respectively (Table 7.6). These four BNF Sections accounted for 97% of the quantity of all liquid

oral medicines dispensed in England in 1994. As with prescriptions, the majority of the quantity of Gastrointestinal medicines were antacids (3.5 million litres) and laxatives (2.3 million litres), accounting for 98% of the total volume dispensed.

The solid doses with prolonged oral clearance (~~for example~~ effervescent and chewable tablets) used in England accounted for 1122.9 million tablets with prolonged oral clearance, with 92.8% of the total quantity being for Cardiovascular (44.7%), Central Nervous System (31.8%) and Gastrointestinal (16.3%) medicines (Table 7.5 and Table 7.6). Of the 502.5 million cardiovascular tablets with prolonged oral clearance, 349.4 million (70%) were aspirin 75mg effervescent tablets. There were 338.1 million solid doses dispensed for analgesics, accounting for 95% of all Central Nervous System medicines formulated as solid doses with prolonged oral clearance. As with liquid oral medicines, most solid Gastrointestinal medicines with prolonged oral clearance were antacids (89%).

Liquid oral medicines prescribed in the Northern Region accounted for 0.7 million litres, of which 61% were gastrointestinal medicines (Table 7.5 and Table 7.7). These were mainly antacids (52%) and antacids (36%).

Of the 134.2 million solid doses for all medicines with prolonged oral clearance prescribed in the Northern Region in 1994, 54% were for Central Nervous System medicines, with 72.5 million tablets prescribed (Table 7.7). The other main areas of use of solids with prolonged oral clearance were the Cardiovascular System and the Gastrointestinal System where 42.4 million (31.6%) and 13.5 million (10.1%) tablets with prolonged oral clearance were dispensed, respectively. Of the Central Nervous System medicines prescribed, analgesics accounted for 71.2 million tablets (98%). Aspirin 75mg effervescent tables accounted for 61% (25.9 million tablets) of all Cardiovascular medicines prescribed in 1994.

Newcastle followed a pattern similar to regional and national dispensing, with 77,400 litres of liquid oral medicines being prescribed in 1994 (Table 7.8), of which 65.8% (50,900 litres) were for Gastrointestinal medicines. Central Nervous System, Infections and the Cardiovascular medicines accounted for 9,100 (11.8%), 8,300 (10.7%) 8,000 (10.3%) litres of liquid oral medicines being prescribed, respectively (Table 7.8). The main Gastrointestinal medicines used were antacids (68%) and laxatives (30%).

Table 7.6 Quantities of all medicines with prolonged oral clearance and medicines with prolonged oral clearance used regularly and long-term in the elderly, dispensed in England in 1994

BNF[1]	Liquid oral medicines				Tablets with prolonged oral clearance				Powders and oral gels				Sachets			
	All POC meds		Long-term		All POC meds		Long-term		All POC meds		Long-term		All POC meds		Long-term	
	litres ($x10^3$)	%	litres ($x10^3$)	%	No. ($x10^3$)	%	No. ($x10^3$)	%	grams ($x10^3$)	%	grams ($x10^3$)	%	No. ($x10^3$)	%	No. ($x10^3$)	%
01	5919.1	56.0	5593.8	83.1	182861.1	16.3	171957.6	18.6	184458.9	96.5	178165.0	100.0	154245.5	50.2	131402.5	91.4
02	21.8	0.2	11.2	0.2	502488.8	44.7	361596.4	39.0	0.0	0.0	0.0	0.0	13822.7	4.5	10206.8	7.1
03	1737.3	16.4	778.7	11.6	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
04	1348.4	12.8	181.0	2.7	356787.8	31.8	346235.2	37.4	0.0	0.0	0.0	0.0	5462.9	1.8	2052.6	1.4
05	1210.8	11.5	4.1	0.1	5970.3	0.5	0.0	0.0	0.0	0.0	0.0	0.0	108929.0	35.5	100.3	0.1
06	0.0	0.0	0.0	0.0	9256.5	0.8	0.0	0.0	0.0	0.0	0.0	0.0	436.8	0.1	0.0	0.0
07	18.5	0.2	17.0	0.3	685.8	0.1	5.3	0.0	0.0	0.0	0.0	0.0	6.6	0.0	0.0	0.0
08	2.8	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
09	90.1	0.9	39.5	0.6	42226.3	3.8	36022.1	3.9	0.0	0.0	0.0	0.0	17998.7	5.9	0.0	0.0
10	134.2	1.3	107.0	1.6	8134.7	0.7	5445.8	0.6	0.0	0.0	0.0	0.0	6060.4	2.0	0.0	0.0
11	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
12	86.5	0.8	0.1	0.0	14497.1	1.3	5431.9	0.6	6775.6	3.5	0.0	0.0	59.5	0.0	0.0	0.0
Total	**10569.5**	**100.0**	**6732.4**	**100.0**	**1122908.4**	**100.0**	**926694.3**	**100.0**	**191234.5**	**100.0**	**178165.0**	**100.0**	**307022.1**	**100.0**	**143762.2**	**100.0**

[1]Key to BNF sections:

01 Gastrointestinal System
02 Cardiovascular System
03 Respiratory System
04 Central Nervous System
05 Infections
06 Endocrine System
07 Obstetrics and Gynaecology
08 Malignant Disease
09 Nutrition and Blood
10 Musculoskeletal and Joint Disease
11 Eye
12 Ear, Nose and Oropharynx

Table 7.7 Quantities of all medicines with prolonged oral clearance and medicines with prolonged oral clearance used regularly and long-term in the elderly, dispensed in Northern Region in 1994

BNF[1]	Liquid oral medicines				Tablets with prolonged oral clearance				Powders and oral gels				Sachets			
	All POC meds		Long-term		All POC meds		Long-term		All POC meds		Long-term		All POC meds		Long-term	
	litres ($x10^3$)	%	litres ($x10^3$)	%	No. ($x10^3$)	%	No. ($x10^3$)	%	grams ($x10^3$)	%	grams ($x10^3$)	%	No. ($x10^3$)	%	No. ($x10^3$)	%
01	436.7	61.0	412.3	86.7	13530.0	10.1	12287.9	10.6	11603.3	95.0	11069.9	100.0	11444.6	56.7	8963.2	92.7
02	1.2	0.2	0.6	0.1	42356.9	31.6	29007.7	25.0	30.6	0.3	0.0	0.0	722.0	3.6	596.9	6.2
03	88.9	12.4	45.7	9.6	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0	0	0.0
04	89.0	12.4	10.2	2.1	72589.7	54.1	71254.9	61.5	3.1	0.0	0.0	0.0	440.2	2.2	108.4	1.1
05	80.5	11.2	0.2	0.0	379.7	0.3	0.0	0.0	0.0	0.0	0.0	0.0	6588.0	32.6	4	0.0
06	0.0	0.0	0.0	0.0	538.9	0.4	0.0	0.0	0.0	0.0	0.0	0.0	9.5	0.0	0	0.0
07	0.9	0.1	0.7	0.1	26.7	0.0	2.6	0.0	0.0	0.0	0.0	0.0	0.6	0.0	0	0.0
08	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0	0.0
09	3.7	0.5	1.6	0.3	2936.5	2.2	2568.7	2.2	30.6	0.3	0.0	0.0	907.4	4.5	0	0.0
10	7.3	1.0	4.3	0.9	872.2	0.7	395.7	0.3	0.0	0.0	0.0	0.0	62.6	0.3	0	0.0
11	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0	0.0
12	8.1	1.1	0.01	0.0	921.7	0.7	391.1	0.3	546.5	4.5	0.0	0.0	2.9	0.0	0	0.0
Total	**716.4**	**100.0**	**475.6**	**100.0**	**134152.3**	**100.0**	**115908.6**	**100.0**	**12214.1**	**100.0**	**11069.9**	**100.0**	**20178.8**	**100.0**	**9672.5**	**100.0**

[1]Key to BNF Section:

01 Gastrointestinal System
02 Cardiovascular System
03 Respiratory System
04 Central Nervous System
05 Infections
06 Endocrine System
07 Obstetrics and Gynaecology
08 Malignant Disease
09 Nutrition and Blood
10 Musculoskeletal and Joint Disease
11 Eye
12 Ear, Nose and Oropharynx

Table 7.8 Quantities of all medicines with prolonged oral clearance and medicines with prolonged oral clearance used regularly and long-term in the elderly, dispensed in Newcastle in 1994

BNF[1]	Liquid oral medicines				Tablets with prolonged oral clearance				Powders and oral gels				Sachets			
	All POC meds		Long-term		All POC meds		Long-term		All POC meds		Long-term		All POC meds		Long-term	
	litres ($x10^3$)	%	litres ($x10^3$)	%	No. ($x10^3$)	%	No. ($x10^3$)	%	grams ($x10^3$)	%	grams ($x10^3$)	%	No. ($x10^3$)	%	No. ($x10^3$)	%
01	50.9	65.8	46.4	89.5	2544.0	18.1	1847.2	16.6	1063.2	97.4	1028.9	100.0	1089.9	58.1	815.4	93.6
02	0.09	0.1	0.02	0.0	4565.8	32.4	2533.3	22.8	1.0	0.1	0.0	0.0	61.7	3.3	52.3	6.0
03	8.0	10.3	4.0	7.7	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
04	9.1	11.8	0.9	1.7	6510.8	46.3	6498.4	58.5	0.0	0.0	0.0	0.0	22.1	1.2	2.2	0.3
05	8.3	10.7	0.01	0.0	42.3	0.3	0.0	0.0	0.1	0.0	0.0	0.0	587.7	31.3	1.6	0.2
06	0.0	0.0	0.0	0.0	37.9	0.3	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.0	0.0
07	0.1	0.1	0.1	0.2	0.5	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.03	0.0	0.0	0.0
08	0.01	0.0	0.0	0.0	0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
09	0.3	0.4	0.1	0.2	226.6	1.6	177.3	1.6	0.0	0.0	0.0	0.0	112.7	6.0	0.0	0.0
10	0.6	0.8	0.3	0.6	83.9	0.6	41.3	0.4	0.0	0.0	0.0	0.0	2.8	0.1	0.0	0.0
11	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
12	0.0	0.0	0.0	0.0	58.5	0.4	15.9	0.1	26.9	2.5	0.0	0.0	0.0	0.0	0.0	0.0
Total	**77.4**	**100.0**	**51.8**	**100.0**	**14070.3**	**100.0**	**11113.4**	**100.0**	**1091.2**	**100.0**	**1028.9**	**100.0**	**1877.0**	**100.0**	**871.5**	**100.0**

[1]Key to BNF Sections:

01 Gastrointestinal System
02 Cardiovascular System
03 Respiratory System
04 Central Nervous System
05 Infections
06 Endocrine System
07 Obstetrics and Gynaecology
08 Malignant Disease
09 Nutrition and Blood
10 Musculoskeletal and Joint Disease
11 Eye
12 Ear, Nose and Oropharynx

There were 14.1 million solid doses with prolonged oral clearance prescribed in Newcastle in 1994, of which 46.3% (6.5 million tablets) were for the Central Nervous System. The Cardiovascular and Gastrointestinal medicines accounted for 4.6 million (32.4%) and 2.5 million (18.1%) tablets, respectively (Table 7.8). As with numbers of prescriptions prescribed the main area of prescribing for Central Nervous System medicines was analgesics (99.6%). Aspirin 75mg effervescent tablets were the main cardiovascular medicine prescribed.

In summary, of the quantity of liquid oral medicines dispensed in the three areas, a large proportion was for Gastrointestinal medicines, with the proportion in the Northern Region and Newcastle (61% and 66% respectively) being slightly higher than England (56%). The proportion of liquid oral medicines dispensed for Central Nervous System (12%) and Infections (11%) was similar for England, the Northern Region and Newcastle.

Solid doses with prolonged oral clearance were mainly Gastrointestinal, Cardiovascular and Central Nervous System medicines and were mainly effervescent or soluble tablets which are dissolved in water before administration or chewable tablets which are sucked and chewed before swallowing.

Other solid doses were sublingual and buccal tablets which are placed under the tongue or in the buccal surface, and the medicine absorbed from the oral cavity. These were mainly found in the Cardiovascular Section and used for the prevention and relief of angina attacks and for nausea. Central Nervous System and Cardiovascular tablets with prolonged oral clearance tended to be effervescent tablets and Gastrointestinal medicines, chewable tablets. The proportion of use of this dose form varied between England, where 45% of solid doses with prolonged oral clearance were Cardiovascular medicines and the Northern Region, where approximately 50% of the quantity of solids with prolonged oral clearance were Central Nervous System Medicines.

7.2.4.6 Quantities of medicines with prolonged oral clearance used regularly and long-term by the elderly (Appendix 7.2, 7.3 and 7.4)

The quantity of liquid oral medicines dispensed in England in 1994, equivalent to the 143 medicines identified in the Prescribed Medicines Prevalence Survey was 6.7 million litres (63.7% of all liquid oral medicines) (Table 7.6). Of these, Gastrointestinal medicines accounted for 83.1% (5.6 million litres) of this volume, with the only other main area of use being the Respiratory System , which accounted for 0.7 million litres (11.6%).

In England in 1994, solid doses with prolonged oral clearance equivalent to those used regularly and long-term in the elderly represented 82.5% (926.7 million tablets) of all solids with prolonged oral clearance (Table 7.6), of which 361.6 million (39%) and 346.2 million (37.4%) were Cardiovascular system and Central Nervous System medicines, respectively, with the Gastrointestinal system accounting for 16.3% (172 million tablets). The Cardiovascular medicines were mainly aspirin 75mg effervescent tablets (97%), the Central Nervous System medicines mainly analgesics (94%) and the Gastrointestinal tablets mainly antacids (92%).

When the Northern Region was considered, of the 0.7 million litres of liquid oral medicines prescribed in 1994, 66% (0.48 million litres) were for the 143 medicines equivalent to those used regularly and long-term by the elderly (Prescribed Medicines Prevalence Survey). Of these, 0.41 million litres (87%) were Gastrointestinal medicines, of which 61% were antacids and 37% laxatives.

In the Northern Region, solid doses with prolonged oral clearance equivalent to those used regularly and long-term by the elderly accounted for 86.4% (115.9 tablets) of all medicines formulated in this way. The majority of these tablets were for Central Nervous System and Cardiovascular medicines which accounted for 71.3 million (61.5%) and 29 million (25%) tablets, respectively. Of the Central Nervous System medicines, 99% were for analgesics and 89% of the cardiovascular medicines were for aspirin 75mg effervescent tablets.

In Newcastle, 67% (51,800 litres) of the 77,400 litres of liquid oral medicines were used regularly and long-term by the elderly. Gastrointestinal medicines accounted for 89.5% (46,400 litres) of these medicines. As with the England and Northern Region these medicines were mainly antacids (61%) and laxatives (30%).

Solid doses with prolonged oral clearance used regularly and long-term by the elderly, dispensed in Newcastle, accounted for 79% (11.1 million tablets) of the 14.1 million of these tablets with prolonged oral clearance dispensed in Newcastle in 1994. The Central Nervous System, Cardiovascular and Gastrointestinal Sections of the BNF accounted for 58.5% (6.5 million tablets), 22.8% (2.5 million tablets) and 16.6% (1.9 million tablets) of these tablets respectively. Central Nervous System medicines were mainly analgesics (99.7%), Cardiovascular solid doses were mainly aspirin 75mg effervescent tablets (84%) and Gastrointestinal solid doses were mainly antacids (97%).

In summary, in all three areas (England, the Northern Region and Newcastle), the 143 medicines used regularly and long-term, identified by the Prescribed Medicines Prevalence Survey, were primarily liquid oral medicines and solid doses with prolonged oral clearance. Of the liquid oral medicines over 80% of the quantities dispensed were for Gastrointestinal medicines in all three areas studied. Central Nervous System solid doses with prolonged oral clearance represented a greater proportion of the total quantity of this dose form dispensed regularly and long-term, in the Northern Region (61.5%) and Newcastle (58.5%), compared with England (37%).

7.2.4.7 Sugar content of medicines with prolonged oral clearance and the impact of generic prescribing on the sugar content of dispensed medicines

Earlier sections have discussed the number of prescription items and quantities prescribed and dispensed for medicines with prolonged oral clearance. Further analysis determined the numbers of medicines, prescription items and quantities dispensed that were sugars-free, sugars-containing and variable. Variable medicines were classified as those generic formulations where the dispensed medicine was sugars-free or sugars-containing depending on which formulation was being used by the pharmacy.

7.2.4.7.1 Generic and proprietary medicines with prolonged oral clearance

Of the 613 medicines with prolonged oral clearance, 131 were generic and 482 proprietary preparations. The generic medicines were manufactured by 37 different manufacturers producing a total of 424 formulations. Each manufacturer produced between 1 and 57 different formulations and each medicine was manufactured by between 1 and 14 pharmaceutical manufacturers. Of the 143 medicines with prolonged oral clearance used regularly and long-term, 42 were generic and 101 were proprietary formulations. The 42 generic formulations with prolonged oral clearance used regularly and long-term were manufactured by 27 pharmaceutical companies producing 144 formulations.

In terms of prescribing in the Northern Region, of the 2.5 million prescription items dispensed for the 143 medicines with prolonged oral clearance used regularly and long-term by the elderly, 1 million (40%) were for proprietary medicines and 1.5 million (60%) were for generic medicines. This was consistent with the current rate of generic prescribing in England, which in 1997 was 60% of all prescriptions written, but lower than the rate of generic prescribing in the Northern Region, which was 66.6% (Department of Health, 1998).

7.2.4.7.2 Numbers of preparations for all medicines with prolonged oral clearance identified as sugars-free and sugars-containing

Of the 613 medicines which represented all medicines with prolonged oral clearance, 46% were sugars-free, 34% sugars-containing, 1% variable with no information for 19% of the medicines. Of the 482 proprietary medicines, 51% were sugars-free and 29.5% sugars-containing with no information obtained for the remaining 19.5% of the medicines. Of the 131 generic medicines, 27.5% were sugars-free, 50.4% were sugars-containing, 3% variable, with no information available for 19.1% of the medicines.

The 131 generic medicines were available as 424 generic formulations, 28.5% of which were sugars-free, 44.8% sugars-containing with no information available for 26.7% of the generic formulations. The numbers of generic and proprietary medicines with prolonged oral clearance used regularly and long-term by sugar content has been previously discussed in Chapter 5 (Section 5.4.15.1), where a similar distribution of sugars-free, sugars-containing and variable medicines was found.

The proprietary manufacturers were able to offer more comprehensive information on sugar content with information being received from 43 manufacturers for 388 (81%) of the proprietary preparations. Most proprietary manufacturers were major businesses with medical information departments dedicated to providing information on their product, whereas generic manufacturers appeared to have more problems in disseminating relevant information to inquiries from healthcare professionals and researchers.

Although over recent years there has been increased awareness of the threat to dental health from sugars-containing medicines (Hobson, 1985; Mackie & Bentley, 1994; Maguire *et al.*, 1996), there still are a large number of preparations that are being manufactured with acidogenic sugars. This has been particularly true of generic medicines; in a study of liquid oral medicines used long-term in paediatrics, in the Northern Region of England, of the 160 generically prescribed medicines, 39% were sugars-containing and 41% were variable (sugars-free or sugars-containing may be dispensed) (Maguire & Rugg-Gunn, 1994). In the present survey the lack of information from the pharmaceutical manufacturers was of particular concern, with the 15 of the 37 generic manufacturers not providing any information on their products, accounting for 89 (21%) of the 424 generic formulations, with manufacturers for a further 118 (28%) only providing partial information.

7.2.4.7.3 Number of prescription items dispensed in the Northern Region, during 1994, for medicines with prolonged oral clearance, used regularly and long-term by the elderly, by sugar content and dose form

Of the 4.5 million prescription items dispensed for all medicines with prolonged oral clearance in the Northern Region, 2.53 million (56%) were for medicines with prolonged oral clearance used regularly and long-term by the elderly. Of these, 73.1% (1.85 million prescription items) were for sugars-free medicines, 20.6% (0.52 million) for sugars-containing medicines, 5.3% (0.13 million) for variable medicines and 1% (0.02 million) for medicines with no information on sugar content.

Table 7.9 shows the number of prescriptions dispensed for the 101 proprietary medicines with prolonged oral clearance used regularly and long-term by the elderly in the Northern Region, by sugar content of these medicines. Of the 1.02 million prescriptions for proprietary medicines, 0.83 million (81%) were sugars-free, 0.17 million (17%) sugars-containing and there was no information for the remaining 0.02 million (2%) (Table 7.9). Over 90% of the prescriptions were for the first four BNF Sections, the main section being Gastrointestinal medicines which accounted for 73.4% (0.75 million items) of the prescription items, of which sugars-free accounted for 0.67 million items (89%).

The number of prescriptions dispensed for generic medicines with prolonged oral clearance used regularly and long-term by the elderly is shown in Table 7.10. Of the 1.52 million prescription items, 1.02 million (67%) were sugars-free, 0.36 million (24%), 0.13 million (8.6%) variable and the remaining 0.02 million (0.4%) prescription items were for medicines where the sugar content was not known (Table 7.10). Of the 0.34 million prescription items for Gastrointestinal medicines, only 0.04 million (13%) were sugars-free, with 0.29 million (87%) items being for sugars-containing medicines (Table 7.10). The majority of the prescriptions for Cardiovascular medicines (99.5%) were for sugars-free medicines. Of the 0.63 million prescription items for Central Nervous System medicines, 88% (0.55 million items) were for sugars-free medicines, with only 9% being for sugars-containing medicines (Table 7.10).

Table 7.11 and Table 7.12 show the number of prescriptions for proprietary and generic medicines by dose form and sugar content. Of the 1.02 million prescription items for proprietary medicines with prolonged oral clearance, liquid oral medicines accounted for 56% (0.57 million items) with 29% (0.26 million) being for solids with prolonged oral clearance.

Table 7.9 Number of prescriptions dispensed for proprietary medicines used regularly and long-term by the elderly in the Northern Region during 1994, by BNF Section and sugar content

BNF Section[1]	Sugars-free		Sugars-containing		No information		Total	
	No. (10^3)	%	No. (10^3)	%	No. (10^3)	%	No. (10^3)	%
01	669.6	81.0	67.3	40.7	8.0	33.7	**744.8**	**73.4**
02	2.3	0.3	38.0	23.0	0.0	0.0	**40.3**	**4.0**
03	62.8	7.6	0.6	0.3	14.6	61.5	**77.9**	**7.7**
04	53.5	6.5	27.1	16.4	0.9	3.7	**81.5**	**8.0**
Others	38.4	4.6	32.1	19.6	0.2	1.1	**70.9**	**6.9**
Total	**826.6**	**100.0**	**165.1**	**100.0**	**23.7**	**100.0**	**1015.4**	**100.0**

Table 7.10 Number of prescriptions dispensed for generic medicines used regularly and long-term by the elderly in the Northern Region during 1994, by BNF Section and sugar content

BNF Section[1]	Sugars-free		Sugars-containing		Variable		No information		Total	
	No. (10^3)	%	No. (10^3)	%	No. (10^3)	%	No. (10^3)	%	No. (10^3)	%
01	43.1	4.2	291.8	81.8	0.0	0.0	0.0	0.0	**335.0**	**22.1**
02	428.4	41.9	2.2	0.6	0.0	0.0	0.0	0.0	**430.6**	**28.4**
03	1.9	0.2	35.7	10.0	77.6	58.1	0.0	0.0	**115.2**	**7.6**
04	549.6	53.7	21.8	6.1	56.0	41.9	0.0	0.0	**627.4**	**41.4**
Others	0.1	0	5.1	1.5	0	0	1.6	100	**6.7**	**0.5**
Total	**1023.1**	**100.0**	**356.6**	**100.0**	**133.6**	**100.0**	**1.6**	**100.0**	**1514.9**	**100.0**

[1]**Key to BNF Sections:**

01 - Gastrointestinal System **03 - Respiratory**
02 - Cardiovascular System **04 - Central Nervous System**
Others - Infections, Endocrine System, Obstetrics and Gynaecology, Malignant Disease and Immunosuppression, Nutrition and Blood, Musculoskeletal and Joint Disease, Eye, Ear, Nose and Oropharynx

Of the 0.57 million prescription items for proprietary liquid oral medicines, 0.53 million (93.7%) were for sugars-free medicines, whereas 55.4% of the 0.26 million items for solid doses with prolonged oral clearance were sugars-free (Table 7.11). The proprietary sugars-containing solids with prolonged oral clearance were mainly chewable tablets, the sugars-free solids being effervescent tablets.

Effervescent tablets are formulated with intense sweeteners rather than bulk sweeteners to prevent bulking during manufacture (Rubinstein, 1988). They have a well established formulation and are often available generically. In contrast, chewable tablets are a relatively new dose form and all chewable tablets identified in this study were proprietary brands.. It is of some concern that new dose forms, like chewable tablets should be formulated with acidogenic sweetening agents, especially when being used regularly and long-term. In 1987, Hobson and Fuller (Hobson & Fuller, 1987) reported on the progress of eight recommendations they had made with regard to sugar based medicines and dental disease in an earlier paper (Hobson, 1985). One of these recommendations had been that "The pharmaceutical industry should provide a greater range of sugars-free preparations, particularly those which are commonly used by children on a long-term basis". The progress report showed that although a number of sugars-free medicines were being manufactured, there were still many formulations, especially for adults that were sugars-containing. In addition their paper reported that The British Pharmacopeia Commission had decided to move towards an open formula so that manufacturers were able to use alternatives to acidogenic sugars. It is then regrettable that even though the pharmaceutical industry is aware of the potential problems of sugar in medicines, they are still manufacturing new medicines as sugars-containing.

Generic medicines with prolonged oral clearance accounted for 60.1% of the 4.5 million prescription items dispensed for all medicines with prolonged oral clearance, in the Northern Region in 1994. Generic medicines with prolonged oral clearance used regularly and long-term accounted for 1.52 million items, of which 67.5% (1.02 million prescription items) were for sugars-free medicines and 23.5% (0.36 million) were for sugars-containing medicines, with 8.8% (0.13 million prescription items) being for variable medicines (Table 7.12). Of these 1.52 million prescription items dispensed generically, 0.47 million were for generic medicines liquid oral medicines, of which 9.7% (0.04 million) were for sugars-free medicines and 73.8% (0.35 million) were for sugars-containing medicines (Table 7.12).

Table 7.11 Number of prescriptions dispensed in the Northern Region in 1994 for sugars-free and sugars-containing proprietary medicines, potentially used regularly and long-term, by dose type

		Sugars-free		Sugars-containing		Variable		Total	
		No. (10^3)	%	No. (10^3)	%	No. (10^3)	%	No. (10^3)	%
LOM[1]	Prescriptions	531.5	64.3	20.1	12.2	15.6	65.8	**567.2**	**55.9**
	(% of total)	(93.7)		(3.6)		(2.7)		**(100.0)**	
Solids	Prescriptions	145.0	17.5	112.1	67.9	4.5	19.1	**261.6**	**25.8**
	(% of total)	(55.4)		(42.8)		(1.7)		**(100.0)**	
Powders	Prescriptions	3.6	0.4	29.8	18.0	0	0.0	**33.4**	**3.3**
	(% of total)	(10.8)		(89.2)		(0.0)		**(100.0)**	
Sachets	Prescriptions	146.5	17.7	3.1	1.9	3.6	15.1	**153.3**	**15.1**
	(% of total)	(95.6)		(2.0)		(2.4)		**(100.0)**	
Total	**Prescriptions**	**826.6**	**100.0**	**165.1**	**100.0**	**23.7**	**100.0**	**1015.4**	**100.0**
	(% of total)	**(81.4)**		**(16.3)**		**(2.3)**		**(100.0)**	

Table 7.12 Number of prescriptions dispensed in the Northern Region in 1994 for sugars-free and sugars-containing generic medicines potentially used regularly and long-term by dose type

		Sugars-free		Sugars-containing		Variable		No information		Total	
		No. (10^3)	%	No. (10^3)	%	No. (10^3)	%	No. (10^3)	%	No. (10^3)	%
LOM[1]	Prescriptions	45.4	4.4	347.0	97.3	77.6	58.1	0.0	0.0	**470.0**	**31.0**
	(% of total)	(9.7)		(73.8)		(16.5)		(0.0)		**(100.0)**	
Solids	Prescriptions	977.7	95.6	7.5	2.1	56.0	41.9	1.6	100.0	**1042.8**	**68.8**
	(% of total)	(93.8)		(0.7)		(5.4)		(0.2)		**(100.0)**	
Powders	Prescriptions	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	**0.0**	**0.0**
	(% of total)	(-)		(-)		(-)		(-)		(-)	
Sachets	Prescriptions	0.0	0.0	2.1	0.6	0.0	0.0	0.0	0.0	**2.1**	**0.1**
	(% of total)	(0.0)		(100.0)		(0.0)		(0.0)		**(100.0)**	
Total	**Prescriptions**	**1023.1**	**100.0**	**356.6**	**100.0**	**133.6**	**100.0**	**1.6**	**100.0**	**1514.9**	**100.0**
	(% of total)	**(67.5)**		**(23.5)**		**(8.8)**		**(0.1)**		**(100.0)**	

[1]**Liquid oral medicines**

Generic medicines are manufactured by a number of pharmaceutical manufacturers and the regulations for their manufacture do not extend to the type of sweetening agents used as long as they are inert agents and the bioavailability of the drug is correct. Since sweetening agents are classed as 'inert', manufacturers can choose to use cheaper sweetening agents such as sucrose.

In contrast, the majority (94%) of generic solid doses with prolonged oral clearance, used regularly and long-term by the elderly were sugars-free. All these were effervescent tablets which are routinely formulated with intense sweetening agents such as saccharin, as bulk sweetening agents such as sucrose and polyols are not suitable for this dose form (Rubinstein, 1988).

Overall, although more prescriptions dispensed for medicines with prolonged oral clearance used regularly and long-term in the elderly were sugars-free, there was a lot of variation between the sugar content of preparations depending upon whether a generic or proprietary medicine was prescribed and between different dose forms. There was a higher proportion of sugars-free prescription items for proprietary liquid oral medicines compared with generic liquid oral medicines, which were more likely to be sugars-containing, however, the majority of solids with prolonged oral clearance used regularly and long-term were sugars-free.

7.2.4.7.4 Quantity of medicines with prolonged oral clearance used regularly and long-term in the elderly, dispensed in the Northern Region in 1994 by sugar content and dose form

In the Northern Region in 1994 the overall quantity of medicines with prolonged oral clearance used regularly and long-term by the elderly was 0.48 million litres of liquid oral medicines, 115.9 million solid doses with prolonged oral clearance, 11.1 grams of loose powders and oral gels and 9.7 million sachets containing powders or granules (Table 7.7).

Of the 0.48 million litres dispensed for liquid oral medicines, 0.29 million (60%) were sugars-free and 0.18 million (40%) sugars-containing. Proprietary liquid oral medicines used regularly and long-term by the elderly, accounted for 279,900 litres dispensed in the Northern Region in 1994, of which, 96.3% (269,400 litres) were sugars-free, with sugars-containing proprietary liquids accounting for 2.5% (7,000 litres) (Table 7.13). In contrast, of the generic liquid oral medicines potentially used by the elderly regularly and long-term, dispensed only 8.9% (17,400 litres) were for sugars-free liquids, with 82.6% (161,600 litres) for sugars-containing liquids (Table 7.14).

Table 7.13 Quantity of sugars-free and sugars-containing proprietary medicines with prolonged oral clearance by dose type

	Quantity Dispensed ($x10^3$)							
	LOM[1] (litres)	%	Solids (tablets)	%	Powders & oral gels (grams)	%	Sachets (number)	%
Sugars-free	269.4	96.3	15162.0	59.9	1090.4	9.8	8940.2	94.6
Sugars-containing	7.0	2.5	9677.0	38.3	9979.5	90.2	340.1	3.6
No information	3.5	1.2	454.2	1.8	0.0	0.0	173.7	1.8
Totals	**279.9**	**100.0**	**25293.2**	**100.0**	**11069.9**	**100.0**	**9454.0**	**100.0**

[1]**Liquid oral medicine**

Table 7.14 Quantity of sugars-free and sugars-containing generic medicines with prolonged oral clearance by dose type

	Quantity Dispensed ($x10^3$)							
	LOM (litres)	%	Solids (tablets)	%	Powders & oral gels (grams)	%	Sachets (number)	%
Sugars-free	17.4	8.9	87032.1	96.0	0.0	-	0.0	0.0
Sugars-containing	161.6	82.6	868.7	1.0	0.0	-	218.5	100.0
Variable	16.7	8.5	2652.2	2.9	0.0	-	0.0	0.0
No information	0.0	0.0	62.5	0.1			0.0	0.0
Totals	**195.7**	**100.0**	**90615.5**	**100.0**	**0.0**	-	**218.5**	**100.0**

[1]Liquid oral medicine

Proprietary solid doses with prolonged oral clearance accounted for 25.3 million tablets dispensed, of which 59.9% (15.2 million) were sugars-free and 38.3 % (9.7 million) were sugars-containing (Table 7.13). Nearly all (96%) generic solid doses with prolonged oral clearance were sugars-free and all were effervescent tablets (Table 7.14).

The quantities of proprietary and generic liquid oral medicines dispensed showed a similar pattern to the number of prescriptions prescribed and dispensed in terms of sugar content. The proportion of volume of proprietary liquid oral medicines that was sugars-free was vastly greater than the proportion of generic sugars-free liquid oral medicines (Tables 7.13 and 7.14).

7.2.5 Overall summary of Prescribing Analysis Survey

The Prescribing Analysis Survey analysed the prescribing and dispensing of 613 medicines with prolonged oral clearance in England, the Northern Region and Newcastle. The main findings of the study were:

- In England, 10.6 million litres of liquid oral medicines and 1122.9 million solid doses with prolonged oral clearance were dispensed in 1994, of which 6.7 million litres of liquid oral medicines and 926.7 million solid doses with prolonged oral clearance were for the 143 medicines used regularly and long-term as identified in Chapter 5 (The Prescribed Medicines Prevalence Survey)
- In Newcastle, 0.08 million litres and 0.05 million litres of liquid oral medicines, and 14.1 million and 11.1 million solid doses with prolonged oral clearance, of all POC medicines and those used regularly and long-term, respectively were dispensed in 1994.
- In the Northern Region:
  - The 143 medicines with prolonged oral clearance used regularly and long-term accounted for 2.5 million prescription items, which represented 0.5 million litres of liquid oral medicines and 115.9 million solid doses with prolonged oral clearance.
  - The proprietary medicines represented 0.3 million litres of liquid oral medicines and 0.26 million items were for 25.3 million solid doses with prolonged oral clearance and the generic medicines represented 0.2 million litres and 90.6 million solid doses with prolonged oral clearance.
  - Of the generic liquid oral medicines, 83% of the 0.2 million litres were sugars-containing compared with proprietary liquid oral medicines, where only 2.5% of the 0.3 million litres were sugars-containing.
  - Of the generic solid doses with prolonged oral clearance, only 1% of the 90.6 million solid doses were sugars-containing, compared with 38% of the 25.3 million solid dose units being sugars-containing.

Generic prescribing of liquid oral medicines was more likely to be sugars-containing, whereas proprietary prescribing of liquid oral medicines more likely to be sugars-free. Generic prescribing accounted for more sugars-free solids with prolonged oral clearance compared with proprietary solids, where almost half the prescription items and volume for solids with prolonged

oral clearance were sugars-containing. Sugars-containing solids were mainly chewable tablets and buccal tablets, whilst all effervescent tablets were sugars-free.

7.3 'OVER THE COUNTER' (OTC) MEDICINES ORDERING SURVEY

7.3.1 Introduction

There is evidence that that OTC medicine use is increasing and, in particular, more OTC medicines are being used by the elderly (McElnay & Dickinson, 1994). However, there is currently no information on the overall volume of use of OTC medicines with prolonged oral clearance and what proportion of these medicines are sugars-containing.

7.3.2 Aim

- To estimate the quantity of OTC products with prolonged oral clearance used over a one year period (1994) in the Northern Region of England by dose form and sugar content.

7.3.3 Methods

7.3.3.1 Sources of data

Records of sales of OTC medicines from community pharmacies are rarely kept, although increasingly, some pharmacies operate patient medication record (PMR) systems to record the purchase of OTC medicines. This allows the pharmacist to monitor what the patient has bought previously and check any prescribed medication they may be taking.

The pharmaceutical wholesalers who operated in the Northern Region, Unichem plc and AAH Pharmaceuticals, were approached for this information. The area covered by these wholesalers, who provided services to the majority of independent and multiple pharmacies in this Region, is shown Appendix 7.5. The only two pharmacy groups that did not use these wholesalers were Boots the Chemists and Lloyds. At an early stage in the study Boots the Chemists and Lloyds Chemists declined to take part in this survey and therefore another method of collecting quantity data for 'over the counter' medicines for the Northern Region was required.

International Medical Statistics (IMS) is a company that collects medical statistics worldwide. It collects OTC data from pharmaceutical wholesalers and multiple pharmacy groups who do not use commercial wholesalers, such as Boots the Chemists and collates this information according to postal codes and television coverage areas. Appendix 7.6 shows the coverage area

for Channel 3 North East (Tyne Tees Television), in the Northern Region of England. Since this area covered most of the Northern Region, it was decided that data from this area could be used for this survey.

IMS was approached for OTC sales data for a one year period (1994) by letter in July 1997. Following a favourable response from IMS, they were sent a list of OTC drugs with prolonged oral clearance compiled from the **OTC** table of the database (Chapter 5, Figure 5.1), together with the corresponding pack sizes, and information on quantities of medicines with prolonged oral clearance sold within the Channel 3 North East television coverage area was requested.

IMS were able to run a search on their computer for the number of packs sold for each pack size for each OTC medicine. The results of this search were provided on a floppy disk as a spreadsheet file. The spreadsheet was used to calculate the total quantity of each OTC medicine sold by multiplying the pack volume by the number of packs sold.

7.3.3.2 The OTC database

Using the Proprietary Association of Great Britain's OTC directory 94/95 (Proprietary Association for Great Britain, 1995), the following information was obtained for all OTC medicines with prolonged oral clearance and entered into the **OTC** table (Chapter 5, Figure 5.1):

- BNF category
- Dose type (e.g. liquids, solids etc.)
- Manufacturer
- Active ingredients
- Pack sizes available

The quantity data derived from the information supplied by IMS was entered into this database table, and a series of queries were run to establish the total quantities of 'over the counter' medicines with prolonged oral clearance sold in the coverage area for Channel 3 North East.

7.3.3.3 Sugar content of OTC medicines with prolonged oral clearance

The British National Formulary 1995 (British Medical Association & Royal Pharmaceutical Society, 1995), Data Sheet Compendium (Association of British Pharmaceutical Industry, 1995) and the OTC directory (Proprietary Association for Great Britain, 1995) were used to obtain information on the sugar content of OTC medicines. In addition, where necessary, the

manufacturers of these OTC preparations were contacted and information on the sugar content of their medicines requested. A list of OTC preparations by manufacturer, along with a cover letter outlining the study was faxed to the medical information department of each pharmaceutical company. The company was asked to list the quantity of all sugar and non-sugar sweeteners in the OTC medicines. They were invited to reply by fax or email.

The information obtained was used to classify each OTC medicine as sugars-free, sugars-containing or a medicine for which no information was available.

7.3.4 Results and Discussion

7.3.4.1 Sources of data

Sales of medicines bought over the counter (OTC) are rarely recorded by community pharmacies and no other method of recording OTC medicine use currently existed. However, pharmaceutical wholesalers recorded their sales to pharmacies, and were felt to be the most useful potential source of information to allow an estimate of the quantity of OTC medicines used in the Northern Region. This estimate needed to be interpreted with caution as not all OTC preparations bought by community pharmacies from wholesalers may have been subsequently sold to the public, not all pharmacies may have used these wholesalers, and wholesalers may not have been the pharmacies only source of supply of OTC medicines, as in some instances they may buy directly from the manufacturer. However, as an estimate of medicine purchases, quantities of medicines ordered from wholesalers provided a useful estimate. Pharmacies are commercial institutions and it would not have been in the business interests of a pharmacy to have stock lying on its shelves for extended periods and perhaps even going out of date before it was sold. This is why most pharmacies have a strict stock rotation system, only ordering what they expect to sell, resulting in a rapid turnover of stock.

The two largest pharmaceutical wholesalers in England, Unichem and AAH, were approached in the study and were very helpful in providing data, however the two pharmacy chains (Boots the Chemists and Lloyds Chemists), who did not use pharmaceutical wholesalers declined to offer any OTC sales or ordering data. Since data purely from the two pharmaceutical wholesalers would not have given an accurate estimate of the total quantities of OTC products ordered by pharmacies, another method of obtaining these data was required. Through discussions with Boots the Chemists it became clear that one of the main reasons that they could not give OTC sales data for this survey was that they already had a contract with a company

(IMS) that collected prescribing, hospital ordering and OTC ordering data. These data, collated by IMS, are sorted by postal codes and television area. Through discussions with Tyne Tees Television it became clear that their television coverage area for Channel 3 North East was sufficiently similar to that of the Northern Region and the information provided by IMS on the ordering of OTC medicines by pharmacies from pharmaceutical wholesalers and pharmaceutical companies, would cover a similar area to the prescribing and hospital data collected. The television coverage area and the Northern Region were not exactly the same (Appendix 7.5 and 7.6), but this was the best available estimate to provide an overall view of OTC medicine use on a regional basis.

7.3.4.2 OTC medicines with prolonged oral clearance

7.3.4.2.1 Number of preparations by BNF Section

There were 323 OTC preparations with prolonged oral clearance identified from the OTC directory and these are classified according to BNF Sections in Table 7.15. The OTC products with prolonged oral clearance occupied seven different BNF Sections with 76.8% of the total number of preparations being Respiratory (35.9%), Gastrointestinal (22.9%) or Ear, Nose and Oropharynx (18%) preparations.

The OTC preparations in the Respiratory and Ear, Nose and Oropharynx Sections of the BNF were mainly liquid oral medicines and used for the treatment of minor cold and flu symptoms. The 74 preparations in the gastrointestinal system were virtually all antacids and laxative medicines.

The other main BNF sections where OTC preparations were found were the Central Nervous System (39 preparations) and Nutrition And Blood (30 preparations). The Central Nervous System preparations were mainly minor analgesics, and preparations in the Nutrition And Blood section were mainly mineral and nutrient supplements.

The majority of medical complaints which present to a pharmacist are minor aliments such as upset stomach (e.g. indigestion and heartburn), diarrhoea or cold and flu symptoms. The range of OTC medicines with prolonged oral clearance available reflected these minor medical complaints, with concentration in therapeutic areas where the dose form of the medicine is important for therapeutic efficacy. Pharmaceutical manufacturers are continually changing dose forms and presentations of OTC medicines to compete with other products in the market place. This has led

to a number of preparations with similar ingredients but different dose forms being marketed, usually backed up with television advertising. This, so the manufacturers claim, is to improve patient compliance and ensure proper use of the medicine, however it may lead to inappropriate use such as long-term use for medicines that are indicated for short-term use only. It is the role of the pharmacist to ensure that the OTC medicines are used appropriately and that is why a large number of such medicines are classed as 'pharmacy' (P) only medicines.

7.3.4.2.2 Number of preparations by dose form

Of the 323 OTC preparations, 183 preparations (57%) were liquid oral medicines, with the remainder being solid doses with prolonged oral clearance (26%), powders and oral gels (9%) and sachets containing powders and granules (8%) (Table 7.15). As for prescribed medicines with prolonged oral clearance, liquid oral medicines and solid doses with prolonged oral clearance were the most commonly available dose form.

Of the 116 preparations in the Respiratory Section of the BNF, 105 (91%) were liquid oral medicines. As well as a systemic effect, liquid oral medicines offer a local soothing effect on the mucous membranes of a sore throat, improving their efficacy and making them a popular choice for cold and flu medicines. This was also true of the Ear, Nose and Oropharynx preparations, where the dose form was also of primary therapeutic importance: 25 of the 58 solids with prolonged oral clearance, were pastilles or lozenges. These exert a local soothing effect on the mucosa of the throat as their primary action. These preparations are sucked and remain in the mouth for prolonged periods.

As Table 7.15 shows, solid tablets with prolonged oral clearance accounted for 83 OTC preparations. These were mainly Gastrointestinal (38.6%), Ear, Nose and Oropharynx (30.1%) and Central Nervous System (24.1%) preparations. The Gastrointestinal medicines were mainly antacid tablets, which offer quick relief from excess acid symptoms and are a popular alternative to antacid liquids which are bulky and more difficult to transport. The 20 preparations in the Central Nervous System section were all minor analgesics, the majority (75%) of which were formulated as effervescent tablets.

Table 7.15 Distribution of 323 OTC preparations with prolonged oral clearance (POC) by dose type and by BNF Section

BNF Section	Liquid oral medicines		Solids with POC		Powders & Oral Gels		Sachets		Total no. of preps with POC	
	No. of preps	%	No. of preps	%	No. of preps	%	No. of preps	%	No. of preps	%
01 Gastrointestinal System	30	16.4	32	38.6	8	27.6	4	14.3	**74**	**22.9**
02 Cardiovascular System	0	0.0	0	0.0	0	0.0	0	0.0	**0**	**0.0**
03 Respiratory System	105	57.4	2	2.4	0	0.0	9	32.1	**116**	**35.9**
04 Central Nervous System	14	7.7	20	24.1	0	0.0	5	17.9	**39**	**12.1**
05 Infections	2	1.1	0	0.0	0	0.0	1	3.6	**3**	**0.9**
06 Endocrine System	0	0.0	0	0.0	0	0.0	0	0.0	**0**	**0.0**
07 Obstetrics and Gynaecology	0	0.0	0	0.0	0	0.0	3	10.7	**3**	**0.9**
08 Malignant Disease	0	0.0	0	0.0	0	0.0	0	0.0	**0**	**0.0**
09 Nutrition and Blood	20	10.9	4	4.8	0	0.0	6	21.4	**30**	**9.3**
10 Musculoskeletal and Joint Disease	0	0.0	0	0.0	0	0.0	0	0.0	**0**	**0.0**
11 Eye	0	0.0	0	0.0	0	0.0	0	0.0	**0**	**0.0**
12 Ear, Nose and Oropharynx	12	6.6	25	30.1	21	72.4	0	0.0	**58**	**18.0**
Total	**183**	**100.0**	**83**	**100.0**	**29**	**100.0**	**28**	**100.0**	**323**	**100.0**

7.3.4.3 Quantities of OTC medicines used in the television coverage area for Tyne Tees Television (Channel 3 North East)

As Table 7.16 shows, of the 106,700 litres of OTC liquid oral preparations ordered by community pharmacies in 1994, 47300 litres (44.3%) and 23800 litres (22.3%) were for Respiratory and Gastrointestinal medicines, respectively. The other two main sections were Ear, Nose and Oropharynx (16700 litres) and the Central Nervous System (15000 litres). Gastrointestinal and respiratory medicines are both efficacious when in a liquid form and for the majority of these medicines a direct non-liquid equivalent is neither appropriate nor available.

Overall, 16.9 million solid tablets with prolonged oral clearance were ordered in the area covered by Channel 3 North East television in 1994. The three main therapeutic areas of use were Central Nervous System, Gastrointestinal medicines and Ear, Nose and Oropharynx medicines, accounting for 7.2 million (42.6%), 5.8 million (34.3%) and 3.5 million (20.7%) solid doses with prolonged oral clearance, respectively. A large number of OTC solid doses with prolonged oral clearance tend to be analgesics in the form of effervescent tablets, which are dissolved in a small volume of water prior to administration. The effervescent solution offers faster pain relief as the drug is in solution and can readily absorb into the system. Solid formulations have many advantages; they are chemically more stable than liquid oral medicines as well as easier to transport and store. This reduces production costs and is more convenient for the pharmacist in terms of storage and shelf life of the product.

OTC products with prolonged oral clearance formulated as loose powders, granules or oral gels accounted for 4.9 million grams being ordered by pharmacies, with Gastrointestinal medicines (antacids and laxatives) accounting for 4.3 million grams (77%). Ear, Nose and Oropharynx medicines accounted for 0.7 million grams and these were mainly oral gels used for local application. The main areas of use for the powders packed as sachets (1.1 million) were the Respiratory System (779,700 sachets) and Central Nervous System (286,000 sachets), which accounted for the 95% of the total quantity ordered. Sachets are a relatively new form of dosage, with each sachet containing a powder or granules which are dissolved in water before administration. All the sachets in the Respiratory section were cold and flu medicines usually containing a combination of paracetamol and a decongestant. They have similar advantages to solid doses with prolonged oral clearance in that they are relatively easy to store and are stable. In comparison with loose powders, they offer consistent dosing each time, taking away the guess

work involved in measuring such powders. The cold and flu sachets usually make up pleasant tasting lemon or blackcurrant drinks preferred by patients.

Table 7.16 Quantities of OTC medicines ordered in the Channel 3 North East coverage area, in 1994

BNF Section	Quantity of OTC Medicines			
	Liquid Oral Medicines (litres) ($x10^3$)	Solids with POC (no.) ($x10^3$)	Powders & oral gels (grams) ($x10^3$)	Sachets (no.) ($x10^3$)
01 Gastrointestinal System	23.8	5576.2	4248.4	8.5
02 Cardiovascular System	0.0	0.0	0.0	0.0
03 Respiratory System	47.3	5.4	0.0	779.7
04 Central Nervous System	15.4	6784.5	18.3	286.0
05 Infections	0.1	0.0	0.0	0.0
06 Endocrine System	0.0	0.0	0.0	0.0
07 Obstetrics and Gynaecology	0.0	0.0	0.0	13.0
08 Malignant Disease	0.0	0.0	0.0	0.0
09 Nutrition and Blood	16.7	393.0	0.0	35.9
10 Musculoskeletal and Joint Disease	0.0	0.0	0.0	0.0
11 Eye	0.0	0.0	0.0	0.0
12 Ear, Nose and Oropharynx	3.8	4029.5	656.5	0.0
Total	**107.1**	**16788.6**	**4923.2**	**1123.1**

7.3.5 Sugar content of OTC medicines with prolonged oral clearance

7.3.5.1 Number of sugars-free and sugars-containing OTC preparations

Overall, of the 323 OTC medicines with prolonged oral clearance identified, 126 (39%) were sugars-free and 162 (50.2%) preparations were sugars-containing. There was no information available for the remaining 35 (10.8%) preparations (Table 7.17). The sugar content of preparations in different therapeutic sections varied considerably; of the 74 Gastrointestinal medicines, 47% were sugars-free and 47% sugars-containing, whereas of the 116 Respiratory medicines, only 27.5% were sugars-free and 63.8% were sugars-containing. This related to their dose form, in that of the Gastrointestinal medicines, 30 were liquid oral medicines (of which 77% were sugars-free) and 32 solids with prolonged oral clearance (of which only 6% were sugars-free), whereas 105 of the 116 Respiratory medicines were liquid oral medicines, of which only 30% were sugars-free. In general, the Gastrointestinal liquid oral medicines were sugars-free and the solids with prolonged oral clearance were sugars-containing. All the sugars-containing Gastrointestinal medicines formulated as solids with prolonged oral clearance (26 preparations)

were chewable tablets, which is a relatively new dose form. As mentioned earlier, it is of some cause for concern that this dose form would appear to be a new source of sugars-containing medicines. Pharmaceutical manufacturers have been requested to formulate new products as sugars-free, especially when the product may be used long-term (Hobson & Fuller, 1987).

A similar pattern was seen for Central Nervous System OTC medicines where 74% of the 39 preparations were sugars-free, and 20 were effervescent tablets, a dose form commonly formulated with artificial intense sweeteners (Rubinstein, 1988). Of the liquid oral medicines in the Central Nervous System section, all were minor analgesics, with 13 preparations being formulated for children, of which 10 preparations were sugars-free. This reflected the impact of pressure for sugars-free medicines for children as a result of research which has linked sugars-containing medicines with dental caries (Mackie & Bentley, 1994; Mackie *et al.*, 1993; Maguire *et al.*, 1996; Roberts & Roberts, 1979), and which have persuaded manufacturers to produce sugars-free paediatric and children's medicines (Maguire & Rugg-Gunn, 1994). Although paediatric OTC medicines have increasingly become available as sugars-free formulations, a similar pattern has not been seen by OTC medicines primarily used by adults. This survey has shown that large numbers of sugars-containing OTC medicines with prolonged oral clearance are available and being used. The products formulated for adults that have become available sugars-free have been mainly in response to pressure from diabetic societies and consumer groups, and probably not in a bid to improve dental health.

Sugar content information could not be obtained for 16 of the 58 Ear, Nose and Oropharynx medicines. Of the remaining 42 preparations, 23 (39.7%) were sugars-containing and 19 (32.7%) sugars-free. Of the 30 Nutrition and Blood medicines, 63.3% (19 preparations) were sugars-containing, and these were mainly vitamins and health tonics.

Analysis of the number of OTC medicines with prolonged oral clearance by dose type (Table 7.18) showed that of the 184 liquid oral medicines, 42.4% were sugars-free and 48.9% were sugars-containing. Of the solid OTC preparations with prolonged oral clearance 57.5% were sugars-containing and only 30% were sugars-free. In general, paediatric liquid oral medicines tended to be sugars-free and those not indicated for children, sugars-containing. Sugars-free solids with prolonged oral clearance were mainly effervescent tablets; chewable tablets, pastilles and lozenges were usually sugars-containing.

Table 7.17 Number of sugars-free and sugars-containing OTC preparations by BNF section

BNF Section	Sugars-free		Sugars-containing		No information		Total	
	No.	%	No.	%	No.	%	No.	%
01 Gastrointestinal System	35	27.8	35	21.6	4	11.4	74	22.9
02 Cardiovascular System	0	0.0	0	0.0	0	0.0	0	0.0
03 Respiratory System	32	25.4	74	45.7	10	28.6	116	35.9
04 Central Nervous System	29	23.0	7	4.3	3	8.6	39	12.1
05 Infections	1	0.8	2	1.2	0	0.0	3	0.9
06 Endocrine System	0	0.0	0	0.0	0	0.0	0	0.0
07 Obstetrics and Gynaecology	1	0.8	2	1.2	0	0.0	3	0.9
08 Malignant Disease	0	0.0	0	0.0	0	0.0	0	0.0
09 Nutrition and Blood	9	7.1	19	11.7	2	5.7	30	9.3
10 Musculoskeletal and Joint Disease	0	0.0	0	0.0	0	0.0	0	0.0
11 Eye	0	0.0	0	0.0	0	0.0	0	0.0
12 Ear, Nose and Oropharynx	19	15.1	23	14.2	16	45.7	58	18.0
Total	**126**	**100.0**	**162**	**100.0**	**35**	**100.0**	**323**	**100.0**

Table 7.18 Number of sugars-free and sugars-containing OTC preparations with prolonged oral clearance by dose type (total number of preps=323)

Dose Form	Preparations with prolonged oral clearance							
	Liquid oral medicines		Solids with POC		Powders and oral gels		Sachets	
	No.	%	No.	%	No.	%	No.	%
Sugars-free	78	42.4	24	30.0	14	46.7	10	34.5
Sugars-containing	90	48.9	46	57.5	9	30.0	17	58.6
No information	16	8.7	10	12.5	7	23.3	2	6.9
Totals	**184**	**100.0**	**80**	**100.0**	**30**	**100.0**	**29**	**100.0**

7.3.5.2 Quantity of OTC medicines with prolonged oral clearance ordered by community pharmacies, by sugar content and dose type

Of the 107,100 litres of OTC liquid oral medicines ordered, approximately equal volumes were sugars-free (52,400 litres) and sugars-containing (53,000 litres). However, there were differences between sugars-free and sugars-containing quantities within BNF Sections, with 94% of the quantity of all Gastrointestinal medicines sold being sugars-free, whereas 87% of the quantity of Respiratory liquid oral medicines was sugars-containing. Overall, of the solid doses, 58.7% were sugars-free, 38.4% sugars-containing, with more Central Nervous System solids with prolonged oral clearance being sugars-free than sugars-containing, but almost equal quantities of sugars-free (2.7 million) and sugars-containing (2.8 million) solid doses of Gastrointestinal medicines being sold during 1994.

Table 7.19 Quantity of sugars-free and sugars-containing OTC preparations ordered in 1994 in the Channel 3 North East area, by dose type

	Quantity ($x10^3$)							
	Liquids		Solids with POC		Powders & oral gels		Sachets	
	Litres	%	No.	%	Grams	%	No.	%
Sugars-free	52.4	48.9	9863.3	58.7	1205.7	24.5	270.4	24.1
Sugars-containing	53.0	49.5	6451.7	38.4	3534.4	71.8	832.6	74.1
No information	1.7	1.6	473.6	2.8	183.2	3.7	20.0	1.8
Total	**107.1**	**100.0**	**16788.6**	**100.0**	**4923.2**	**100.0**	**1123.1**	**100.0**

7.3.5.3 Type of sweeteners used in OTC medicines with prolonged oral clearance

Of the 126 sugars-free preparations, 26 (21%) did not contain any sugar, and of these 17 were liquid oral medicines (Table 7.20). The most common sweetening agent for sugars-free OTC medicines was the intense sweetener saccharin on its own, and this accounted for 41 (33%) of the 126 sugars-free preparations. Saccharin and sorbitol in combination accounted for 13 of the 126 sugars-free preparations.

Table 7.20 Types of common sweetening agents found in OTC preparations with prolonged oral clearance

	LOM[1]	Solids	Powders & oral gels	Sachets	Total
Sugars-free					
No Sugar	17	0	7	2	**26**
Saccharin	19	15	4	3	**41**
Saccharin + Sorbitol	10	3	0	0	**13**
Others	32	6	3	5	**46**
Total	**78**	**24**	**14**	**10**	**126**
Sugars-containing					
Sucrose	34	18	5	5	**62**
Sucrose + Glucose	7	7	3	0	**17**
Sucrose + Saccharin	5	8	0	4	**17**
Sucrose + Glucose + Saccharin	9	0	0	0	**9**
Sucrose + Sorbitol	12	2	0	0	**14**
Others	23	11	2	3	**48**
Totals	**90**	**46**	**9**	**12**	**162**

[1]**Liquid oral medicines**

Of the 162 sugars-containing OTC preparations with prolonged oral clearance, the most common sweetening agent was sucrose used on its own or in combination with other preparations.

Sucrose was the sole sugar in 62 (38%) preparations. It was found in combination with glucose (17 preparations), saccharin (17 preparations), glucose and sorbitol (9 preparations) and sorbitol (14 preparations). Appendix 7.7 lists all sweetening agents used in all OTC preparations.

In summary, in terms of availability, there were more sugars-containing (50.2%) than sugars-free (39%) OTC medicines with prolonged oral clearance. In terms of preparations, the sugar content varied according to dose form with liquid oral medicines, solid doses (with prolonged oral clearance) and loose powders or oral gels being more likely to be sugars-containing. A similar pattern followed for quantities ordered, except that in terms of quantities, more sugars-free (58.7%) than sugars-containing (38.4%) solids with prolonged oral clearance were ordered. Effervescent tablets tended to contain artificial intense sweeteners which have better formulation properties (Rubinstein, 1988) and a high proportion of these were analgesics.

In terms of quantities, more sugars-containing than sugars-free OTC medicines with prolonged oral clearance were ordered by community pharmacies; the sugars-free medicines ordered were mainly paediatric formulations. There were also more sugars-containing than sugars-free solid OTC medicines with prolonged oral clearance available, however, greater quantities of sugars-free medicines were sold to pharmacies. The sugars-containing solids with prolonged oral clearance were mainly Gastrointestinal medicines in a chewable tablet form and used to much lesser extent than minor analgesics.

7.4 HOSPITAL PHARMACY MEDICINES ORDERING SURVEY

7.4.1 Introduction

To provide an overall estimate of the use of medicines with prolonged oral clearance in the North East of England a survey was necessary to determine the consumption of these medicines in the secondary healthcare services.

7.4.2 Aims

- To determine the quantity of medicines with prolonged oral clearance used by hospital pharmacy departments over a one year period (1994), in the Northern Region of England, by dose form and sugar content.

7.4.3 Methods

7.4.3.1 Data collection

The hospital services do not collect data equivalent to primary care prescribing data (PACT and PCA), although individual hospitals sometimes collect data on drug dispensing for audit purposes. However, in the UK International Medical Statistics (IMS) collects information on drugs ordered by NHS hospitals from the invoices of all drugs ordered by their pharmacy departments. The raw data from these invoices are entered into a computer for analysis, and are collated into regional and national statistics.

In order to maintain consistency with the Prescription Analysis Survey and the OTC Survey, data for 1994 were required for this survey. IMS data for hospital pharmacies in the Northern Region are purchased by the Regional Prescribing Unit, Newcastle upon Tyne. The unit kindly gave access to these data for 1994, and provided them as a spreadsheet (MS Excel) file on computer disk. This file contained pack size, name of formulation and the number of packs of all medicines ordered during the one year period (1994). As only information for medicines with prolonged oral clearance was required, the data from the disk were imported into a relational database (MS Access) and queries were run, using the dose form, to identify all medicines with prolonged oral clearance. All other products in the database were deleted. This list of medicines was then checked against the **DRUGS** table of the database to ensure that all medicines with prolonged oral clearance used in hospital were accounted for, and imported into MS Excel, where the number of packs ordered were multiplied by the pack size to give the total quantity of

medicines with prolonged oral clearance ordered by NHS hospitals in the Northern Region. This information was entered into the **CONSUMPTION DATA** table of the database (Chapter 5, Figure 5.1) to allow further analysis.

7.4.3.2 Sugar content of medicines with prolonged oral clearance used in hospitals

The **DRUGS** table of the database contained information on the sweetening agent of all drugs with prolonged oral clearance, collected during the Prescribed Medicines Prevalence Survey, and this was linked to the **CONSUMPTION DATA** table. Queries using MS Access were undertaken to determine the proportion of medicines that were sugars-free and sugars-containing, as well as the sugar content of the medicines with prolonged oral clearance ordered by hospital pharmacy departments in the Northern Region.

7.4.4 Results and Discussion

7.4.4.1 Number of preparations ordered by hospital pharmacies in the Northern Region

Of the 613 medicines with prolonged oral clearance identified from the BNF (British Medical Association & Royal Pharmaceutical Society, 1995), 212 (34.4%) were ordered by hospital pharmacy departments in the Northern Region during 1994 (Table 7.21). As with the OTC survey, the IMS data were ordering data and the assumption was made that all medicines ordered were subsequently dispensed to and used by the patients. Due to the high cost many of drugs, hospitals have strict stock management, only ordering and storing medicines that will be used before they expire.

In an attempt to control spiraling drug costs, hospital drug formularies have been introduced by most hospital pharmacy departments. Formularies contain a selective list of preparations based on efficacy and cost from which prescribers may choose an appropriate medicine. Furthermore, drugs not on the formulary are restricted and generally only consultants can prescribe them after authorisation from the senior pharmacist. The use of a formulary would reduce the number of preparations stocked by pharmacies and this would, in part, explain why the overall number of preparations with prolonged oral clearance (212 preparations) used was low compared with the range of prescribed medicines with prolonged oral clearance used in general medical practices in the Northern Region (552 preparations), during the same period. Of these 212 preparations, 75% were for medicines in the Central Nervous System, Infections and

Gastrointestinal Sections of the BNF, with these sections accounting for 30.2%, 29.7% and 14.6% of preparations with prolonged oral clearance, respectively.

When the 143 preparations with prolonged oral clearance used regularly and long-term by the elderly as identified by the Prescribed Medicines Prevalence Survey were considered, of the 212 preparations ordered by hospital pharmacy departments, only 58 (27.4%) were equivalent to those used regularly and long-term in the elderly (Table 7.21). These medicines were mainly Central Nervous System (32.8%) and Gastrointestinal (29.3%) medicines showing a slight difference from prescribed medicines dispensed in the Northern Region where of the 143 preparations, 36.4% were Gastrointestinal and 22.4% were Central Nervous System medicines.

Table 7.21 Number of preparations with prolonged oral clearance ordered by hospital pharmacy departments, by BNF, in the Northern Region during a one year period.

BNF Sectiom	All POC preps	POC preps ordered by hospital pharmacies		All Long-term POC preps[1]	Long-term POC preps[1] ordered by hospital pharmacies	
		No.	%		No.	%
01 Gastrointestinal System	111	31	14.6	52	17	29.3
02 Cardiovascular System	30	10	4.7	18	7	12.1
03 Respiratory System	60	13	6.1	16	5	8.6
04 Central Nervous System	126	64	30.2	31	19	32.8
05 Infections	167	63	29.7	2	1	1.7
06 Endocrine System	3	1	0.5	0	0	0.0
07 Obstetrics and Gynaecology	5	0	0.0	2	0	0.0
08 Malignant Disease	1	0	0.0	0	0	0.0
09 Nutrition and Blood	51	13	6.1	11	2	3.4
10 Musculoskeletal and Joint Disease	23	9	4.2	9	7	12.1
11 Eye	0	0	0.0	0	0	0.0
12 Ear, Nose and Oropharynx	36	8	3.8	2	0	0.0
Totals	**613**	**212**	**100.0**	**143**	**58**	**100.0**

[1] **Medicines that were identified by the Prescribed Medicines Prevalence Survey as being used regularly and long-term by the elderly in five districts of the Northern Region**

From Table 7.21, it can be seen that for all medicines with prolonged oral clearance and for medicines with prolonged oral clearance used regularly and long-term the number of preparations used was considerably lower for all BNF Sections, when compared with the Prescription Analysis Survey.

7.4.4.2 Dose type

When the 58 preparations with prolonged oral clearance used regularly and long-term by the elderly were analysed by dose type (Table 7.22), 88% were liquid oral medicines, the remainder being solid doses with prolonged oral clearance (5%) and powders and granules in sachets (7%). There were no preparations formulated as loose powders or oral gels ordered by hospital pharmacies. The 51 liquid oral medicines represented 88% of all preparations with prolonged oral clearance equivalent to those used regularly and long-term in the Prescribed Medicines Prevalence Survey. Of these, 74.5% were Central Nervous System (33.3%), Gastrointestinal (29.4%) and Cardiovascular (11.8%) system medicines.

Of the 17 liquid oral medicine preparations in the Central Nervous System Section of the BNF, 53% were for antidepressants, analgesics and anti-psychotics. These medicines are given after careful patient assessment and may require continual dose assessment and change. The use of liquid oral medicines in these situations is often preferable as it allows the prescriber to administer a range of different doses which would be difficult with solid oral doses. Of the 15 liquid oral Gastrointestinal medicines, 66.6% were for antacids and laxatives.

7.4.4.3 Quantities of medicines with prolonged oral clearance ordered by hospital pharmacies

A total of 13490 litres of liquid oral medicines, 44600 solid doses with prolonged oral clearance and 26300 sachets were ordered by NHS hospitals in the Northern Region, in 1994 (Table 7.23).

Of the liquid oral medicines ordered by hospital pharmacy departments 89.1% of the total quantity was for Gastrointestinal (46.3%), Central Nervous System (28%) or Infections (14.8%) medicines, with antacids (18.7%) and laxatives (76.8%) accounting for 95.5% of the Gastrointestinal medicines.

Of the 3780 litres of Central Nervous System liquids ordered, 78.8% were for anti-psychotics (41.4%), anti-epileptics (21.8%) or minor analgesics (15.6%). In acute situations where the patient may be in pain and not able to swallow, analgesics are often easier to administer as liquid oral medicines. Minor changes in doses are often required in anti-psychotics and anti-epileptics and using a liquid oral dose form allows these minor changes to be made more easily.

Table 7.22 Number of preparations for all medicines and medicines used regularly and long-term with prolonged oral clearance, by dose type, ordered by hospital pharmacies in the Northern Region in 1994

BNF Section	Number of Preparations														
	LOMs			Solids with POC			Powders & Oral Gels			Sachets			Total		
	All	Long-term		All	Long-term		All	Long- term		All	Long-term		All	Long-term	
		No.	%		No.	%		No.	%		No.	%		No.	%
01 Gastrointestinal System	27	15	29.4	0	0	0.0	0	0	-	4	2	50.0	**31**	**17**	**29.3**
02 Cardiovascular System	9	6	11.8	0	0	0.0	0	0	-	1	1	25.0	**10**	**7**	**12.1**
03 Respiratory System	13	5	9.8	0	0	0.0	0	0	-	0	0	0.0	**13**	**5**	**8.6**
04 Central Nervous System	56	17	33.3	2	1	33.3	0	0	-	6	1	25.0	**64**	**19**	**32.8**
05 Infections	54	1	2.0	4	0	0.0	0	0	-	5	0	0.0	**63**	**1**	**1.7**
06 Endocrine System	0	0	0.0	0	0	0.0	0	0	-	1	0	0.0	**1**	**0**	**0.0**
07 Obstetrics and Gynaecology	0	0	0.0	0	0	0.0	0	0	-	0	0	0.0	**0**	**0**	**0.0**
08 Malignant Disease	0	0	0.0	0	0	0.0	0	0	-	0	0	0.0	**0**	**0**	**0.0**
09 Nutrition and Blood	9	2	3.9	0	0	0.0	0	0	-	4	0	0.0	**13**	**2**	**3.4**
10 Musculoskeletal and Joint Disease	7	5	9.8	2	2	66.7	0	0	-	0	0	0.0	**9**	**7**	**12.1**
11 Eye	0	0	0.0	0	0	0.0	0	0	-	0	0	0.0	**0**	**0**	**0.0**
12 Ear, Nose and Oropharynx	4	0	0.0	4	0	0.0	0	0	-	0	0	0.0	**8**	**0**	**0.0**
Totals	**179**	**51**	**100.0**	**12**	**3**	**100.0**	**0**	**0**	-	**21**	**4**	**100.0**	**212**	**58**	**100.0**

Table 7.23 Quantities of all and long-term medicines with prolonged oral clearance (POC) ordered by NHS hospital pharmacies in the Northern Region in 1994

BNF Section	Liquid Oral Medicines				Solids				Sachets (No. x10^3)			
	All	Long-term		%	All	Long-term		%	All	Long-term		%
	Litres x10^3	Litres x10^3	%	Long-term[1]	No. x10^3	No. x10^3	%	Long-term[1]	No. x10^3	No. x10^3	%	Long-term[1]
01 Gastrointestinal System	6.3	5.86	75.3	93.0	0.0	0.0	0.0	-	9.9	1.1	17.5	11.1
02 Cardiovascular System	0.07	0.05	0.6	71.4	0.0	0.0	0.0	-	4.0	4.0	63.5	100.0
03 Respiratory System	0.21	0.02	0.3	9.5	0.0	0.0	0.0	-	0.0	0.0	0.0	-
04 Central Nervous System	3.78	1.03	16.7	34.4	8.4	4.7	94.0	56.0	5.7	1.2	19.0	21.1
05 Infections	2	0.01	0.1	0.5	16.7	0.0	0.0	0.0	3.0	0.0	0.0	0.0
06 Endocrine System	0	0.00	0.0	-	0.0	0.0	0.0	-	0.1	0.0	0.0	0.0
07 Obstetrics and Gynaecology	0	0.00	0.0	-	0.0	0.0	0.0	-	0.0	0.0	0.0	-
08 Malignant Disease	0	0.00	0.0	-	0.0	0.0	0.0	-	0.0	0.0	0.0	-
09 Nutrition and Blood	0.25	0.02	2.6	80.0	0.0	0.0	0.0	-	3.6	0.0	0.0	0.0
10 Musculoskeletal and Joint Disease	0.44	0.34	4.4	77.3	0.3	0.3	6.0	100.0	0.0	0.0	0.0	-
11 Eye	0	0.0	0.0	-	0.0	0.0	0.0	-	0.0	0.0	0.0	-
12 Ear, Nose and Oropharynx	0.44	0.00	0.0	0.0	19.2	0.0	0.0	0.0	0.0	0.0	0.0	-
Totals	**13.49**	**7.78**	**100.0**	**57.7**	**44.6**	**5.0**	**100.0**	**11.2**	**26.3**	**6.3**	**100.0**	**24.0**

[1]% of all medicines with prolonged oral clearance ordered, for medicines with prolonged oral clearance equivalent to those used regularly and long-term by the elderly, as identified by the Prescribed Medicines Prevalence Survey.

Of the total quantity of CNS liquid oral medicines equivalent to those used regularly and long-term in the Prescribed Medicines Prevalence Survey, 38% was for anti-epileptic medication, 32.2% for anti-psychotics and 24.1% was for antidepressants. This pattern of ordering differed from all medicines with prolonged oral clearance ordered by hospital pharmacies in that there were no liquid oral medicine analgesics ordered equivalent to those used long-term by the elderly and the proportion of anti-psychotics was lower for long-term medicines. This may have been because the hospital pharmacy department formularies used cheaper solid oral doses for these medicines and restricted the use of liquid oral medicines to paediatric use.

Of the 44,600 tablets with prolonged oral clearance ordered by hospital pharmacies, only 5000 tablets (11.2%) were for those medicines identified as being used regularly and long-term by the elderly. These medicines were from only two BNF sections: the Central Nervous System (4700 tablets, 94%) and Musculoskeletal and Joint Diseases (300 tablets, 6%) and all were effervescent tablets.

7.4.4.4 Number of sugars-free and sugars-containing medicines with prolonged oral clearance used regularly and long-term by the elderly, ordered by hospital pharmacies in the Northern Region in 1994.

Of the 212 preparations with prolonged oral clearance, 42 were generic and 170 were proprietary preparations. Of the 170 proprietary medicines, 50% were sugars-free and 35.9% sugars-containing, the remaining 14.1% was for medicines for which no information on sugar content could be obtained.

Of the 58 medicines equivalent to those used regularly and long-term by the elderly, 77.6% were proprietary preparations and 22.4% were generic preparations (Table 7.24 and Table 7.25), 41% were sugars-free and 50% were sugars-containing, with 2% being variable and no information available for 4 preparations (7%).

The level of generic medicines usage was lower than that for prescribed medicines dispensed in the general medical and dental services. In hospitals, pharmacists can dispense any brand of a medicine regardless of what is prescribed and are not obliged to dispense the proprietary brand as their community colleagues have to. Pharmaceutical companies, being aware of this, often offer branded products at competitive prices so that hospitals will use their products, in the hope that on discharge the patient will continue using the branded product in the community.

Table 7.24 Number of proprietary medicines with prolonged oral clearance, equivalent to those used regularly and long-term by the elderly, ordered by hospital pharmacies in the Northern Region in 1994, by sugar content and dose form

	Liquid oral medicines	%	Solids with POC	%	Powders/ oral gels	%	Sachets	%	Total	%
Sugars-free	18	47.4	1	33.3	0	-	2	50.0	**21**	**46.7**
Sugars-containing	17	44.7	2	66.7	0	-	1	25.0	**20**	**44.4**
No information	3	7.9	0	0.0	0	-	1	25.0	**4**	**8.9**
Totals	**38**	**100.0**	**3**	**100.0**	**0**	-	**4**	**100.0**	**45**	**100.0**

Table 7.25 Number of generic medicines with prolonged oral clearance, equivalent to those used regularly and long-term by the elderly, ordered by hospital pharmacies in the Northern Region in 1994, by sugar content and dose form

	Liquid oral medicines	%	Solids with POC	%	Powders/ oral gels	%	Sachets	%	Total	%
Sugars-free	3	23.0	0	-	0	-	0	-	**3**	**23.0**
Sugars-containing	9	69.0	0	-	0	-	0	-	**9**	**69.0**
Variable	1	1.0	0	-	0	-	0	-	**1**	**0.0**
No Information	0	0.0	0	-	0	-	0	-	**0**	**0.0**
Totals	**13**	**100.0**	**0**	-	**0**	-	**0**	-	**13**	**100.0**

Of the 45 proprietary medicines equivalent to those used regularly and long-term by the elderly, 47% were sugars-free and 44% were sugars-containing, with no information being available for 4 (8%) preparations (Table 7.24). Of these proprietary preparations, 38 were liquid oral medicines, of which 47.4% were sugars-free and 44.7% sugars-containing. Of the other 7 proprietary medicines, 3 were solids with prolonged oral clearance, of which 2 were sugars-containing and 4 were sachets, of which 2 were sugars-free and 1 sugars-containing. Dose forms other than liquid oral medicines are relatively new and only available for a few preparations. They also are more expensive and hospitals would probably avoid using them to reduce drugs costs. This is probably why these formulations represent a minority of those medicines with prolonged oral clearance ordered into hospital pharmacies.

Of the 13 generic medicines with prolonged oral clearance used regularly and long-term, only 23% were sugars-free, with 69% being sugars-containing and 1 (8%) variable (where the medicine may be formulated as sugars-free or sugars-containing); all 13 generic medicines with prolonged oral clearance were liquid oral medicines (Table 7.25).

The pattern previously observed in the Prescription Analysis Survey showing proprietary liquid oral medicines more likely to be sugars-free and generic liquid oral medicines more likely to be sugars-containing was also seen in the ordering data for hospital pharmacies in the Northern Region.

7.4.4.5 Quantities of sugars-free and sugars-containing medicines with prolonged oral clearance used regularly and long-term ordered by hospital pharmacy departments in the Northern Region in 1994

The 45 proprietary medicines with prolonged oral clearance equivalent to those used regularly and long-term by the elderly in the Prescribed Medicines Prevalence Survey accounted for 3090 litres of liquid oral medicines, 5000 tablets with prolonged oral clearance and 6400 sachets of powders and granules (Table 7.26). In terms of quantities ordered, of the liquid oral medicines, 46.9% (1450 litres) were sugars-free and 47.9% (1480 litres) were sugars-containing. Of the 5000 proprietary solid doses with prolonged oral clearance, 94% were sugars-free and 21.9% of the sachets were sugars-free (Table 7.26).

Of the 4690 litres of generic liquid oral medicines equivalent to those used regularly and long-term by the elderly and ordered by hospital pharmacies, 93.4% (4380 litres) were sugars-containing (Table 7.26).

These results for prolonged oral clearance medicines ordered by hospital pharmacies in the Northern Region over a one year period, show that generic liquid oral medicines were more likely to be sugars-containing compared with proprietary preparations. In terms of quantity, the sugars-free proportion of proprietary medicines ordered was lower than that found for the quantity of prescribed medicines prescribed. Overall hospital pharmacies tended to use fewer sugars-free medicines than in the primary care health services.

Table 7.26 Quantities of proprietary medicines with prolonged oral clearance potentially used regularly and long-term by the elderly, ordered by hospital pharmacies in the Northern Region in 1994

	LOMs (litres) $x10^3$	%	Solids (tablets) $x10^3$	%	Powders & oral gels (grams) $x10^3$	%	Sachets (number) $x10^3$	%
Proprietary medicines								
Sugars-free	1.45	46.9	4.7	94.0	0	-	1.4	21.9
Sugars-containing	1.48	47.9	0.3	6.0	0	-	4.1	64.0
Variable	0.16	5.2	0.0	0.0	0	-	0.9	14.1
Total	**3.09**	**100.0**	**5.0**	**100.0**	**0**	-	**6.4**	**100.0**
Generic medicines								
Sugars-free	0.31	6.6	0	-	0	-	0	-
Sugars-containing	4.38	93.4	0	-	0	-	0	-
Variable	0.0	0.0	0	-	0	-	0	-
Total	**4.69**	**100.0**	**0**	-	**0**	-	**0**	-

Hospital pharmacy departments, in a bid to reduce costs, try and use the cheapest available medicines possible, whether these be generics or proprietary medicines at artificially low prices and it may be that sugars-containing are being used in favour of sugars-free as they tend to be cheaper. Lack of understanding on the dangers to dental health by hospital pharmacists may be why sugars-free medicines are not being used.

7.4.5 Summary and Conclusions

To summarise, the use of medicines in hospitals was assessed by analysing hospital pharmacy ordering data for hospitals in the Northern Region. The overall use of medicines with prolonged oral clearance was lower than in primary care, with hospitals only using 212 of the 613 medicines with prolonged oral clearance, of which only 58 were used regularly and long-term by the elderly. The main findings from the survey were:

- The 212 medicines with prolonged oral clearance accounted for 13490 litres of liquid oral medicines and 44600 solid doses with prolonged oral clearance.
- Of the 58 medicines with prolonged oral clearance equivalent to those used regularly and long-term by the elderly, 51 were liquid oral medicines and 3 were solids with prolonged oral clearance, accounting for 7780 litres and 5000 solid doses being ordered respectively.
- Of the liquid oral medicines, 3090 litres were for proprietary medicines, of which 47% were sugars-free and 48% sugars-containing. Generic liquid oral medicines accounted for 4690 litres of which 7% were sugars-free and 93% sugars-containing.
- Of the solid doses with prolonged oral clearance, all were proprietary medicines, with 94% being sugars-free and 6% being sugars-containing.

APPENDIX 7.1

Number of preparations for and number of prescription items ($x10^3$) dispensed for medicines with prolonged oral clearance (POC) during a one year period (1994) by BNF therapeutic section, in England, the Northern Region and Newcastle.

				England					Northern Region					Newcastle				
						No. of prescriptions dispensed for preparations with prolonged oral clearance					No. of prescriptions dispensed for preparations with prolonged oral clearance					No. of prescriptions dispensed for preparations with prolonged oral clearance		
BNF Section	No. of preps. with POC	No. of preps. with POC used long-term	% used long-term	No. of preps with POC	% of total	All preps. ($x10^3$)	Long-term ($x10^3$)	% dispensed long-term	No. of preps with POC	% of total	All preps. ($x10^3$)	Long-term ($x10^3$)	% dispensed long-term	No. of preps with POC	% of total	All preps. ($x10^3$)	Long-term ($x10^3$)	% dispensed long-term
1.1	37	23	62.2	34	91.9	8059.3	7566.4	93.9	30	81.1	599.5	569.7	95.0	27	73.0	62.0	59.0	95.2
1.2	7	4	57.1	7	100.0	405.7	266.3	65.6	7	100.0	18.1	11.6	64.2	7	100.0	1.3	0.7	53.4
1.3	17	7	41.2	17	100.0	235.3	111.8	47.5	17	100.0	24.0	8.6	36.0	15	88.2	1.8	0.7	35.9
1.4	10	0	0.0	9	90.0	152.8	-	0.0	9	90.0	14.6		0.0	6	60.0	0.9	-	0.0
1.5	1	1	100.0	1	100.0	4.1	4.1	100.0	1	100.0	0.3	0.2	55.1	0	0.0	0.0	-	0.0
1.6	37	17	45.9	32	86.5	7857.1	7325.4	93.2	31	83.8	547.5	489.7	89.4	27	73.0	55.4	47.4	85.7
1.7	0	0	-	0	-	-	-	-	0	-	-	-	-	0	-	-	-	-
1.8	0	0	-	0	-	-	-	-	0	-	-	-	-	0	-	-	-	-
1.9	2	0	0.0	2	100.0	0.6	-	0.0	1	50.0	0.0	-	0.0	1	50.0	-	-	-
2.1	1	1	100.0	1	100.0	10.4	10.4	100.0	1	100.0	0.6	0.2	28.3	1	100.0	0.0	0.0	100.0
2.2	9	7	77.8	9	100.0	50.4	34.7	68.8	9	100.0	2.4	1.7	70.0	7	77.8	0.2	0.1	42.0
2.3	0	0	-	0	-	-	-	-	0	-	-	-	-	0	-	-	-	-
2.4	1	0	0.0	1	100.0	14.2	-	0.0	1	100.0	1.1	-	0.0	1	100.0	0.1	-	0.0
2.5	1	1	100.0	1	100.0	1.0	1.0	100.0	1	100.0	0.0	0.0	100.0	1	100.0	0.0	0.0	100.0
2.6	10	5	50.0	10	100.0	1467.1	143.1	9.8	9	90.0	163.6	35.2	21.5	8	80.0	23.8	4.3	18.2
2.7	0	0	-	0	-	-	-	-	0	-	-	-	-	0	-	-	-	-
2.8	0	0	-	0	-	-	-	-	0	-	-	-	-	0	-	-	-	-
2.9	2	1	50.0	2	100.0	5895.8	5895.8	100.0	1	50.0	428.1	428.1	100.0	1	50.0	41.5	41.5	100.0
2.10	0	0	-	0	-	-	-	-	0	-	-	-	-	0	-	-	-	-
2.11	1	0	0.0	1	100.0	0.6	-	0.0	1	100.0	0.0	-	0.0	1	100.0	0.0	-	0.0
2.12	5	3	60.0	5	100.0	135.6	99.4	73.3	4	80.0	7.2	5.7	79.1	4	80.0	0.7	0.6	83.6
2.13	0	0	-	0	-	-	-	-	0	-	-	-	-	0	-	-	-	-
3.1	13	5	38.5	12	92.3	719.4	159.3	22.1	9	69.2	93.2	63.2	67.8	8	61.5	8.9	6.8	76.2
3.2	0	0	-	0	-	-	-	-	0	-	-	-	-	0	-	-	-	-
3.3	1	0	0.0	1	100.0	21.5	-	0.0	1	100.0	2.6	-	0.0	1	100.0	0.1	-	0.0
3.4	17	1	5.9	17	100.0	1340.3	122.6	9.1	14	82.4	69.5	0.7	1.0	13	76.5	6.8	0.0	0.2
3.5	0	0	-	0	-	-	-	-	0	-	-	-	-	0	-	-	-	-
3.6	0	0	-	0	-	-	-	-	0	-	-	-	-	0	-	-	-	-
3.7	0	0	-	0	-	-	-	-	0	-	-	-	-	0	-	-	-	-

APPENDIX 7.1 (continued)

BNF Section	No. of preps. with POC	No. of preps. with POC used long-term	% used long-term	England					Northern Region					Newcastle				
				No. of preps with POC	% of total	No. of prescriptions dispensed for preparations with prolonged oral clearance			No. of preps with POC	% of total	No. of prescriptions dispensed for preparations with prolonged oral clearance			No. of preps with POC	% of total	No. of prescriptions dispensed for preparations with prolonged oral clearance		
						All preps. ($x10^3$)	Long-term ($x10^3$)	% dispensed long-term			All preps. ($x10^3$)	Long-term ($x10^3$)	% dispensed long-term			All preps. ($x10^3$)	Long-term ($x10^3$)	% dispensed long-term
3.8	0	0	-	0	-	-	-	-	0	-	0.1	-	0.0	0	-	-	-	-
3.9	29	10	34.5	29	100.0	6405.5	3041.5	47.5	25	86.2	259.6	129.2	49.7	19	65.5	24.7	11.1	44.7
3.10	0	0	-	0	-	-	-	-	0	-	-	-	-	0	-	-	-	-
4.1	10	4	40.0	9	90.0	246.9	181.5	73.5	9	90.0	18.3	12.9	70.4	7	70.0	1.8	1.0	54.2
4.2	27	6	22.2	27	100.0	330.8	160.8	48.6	22	81.5	15.4	8.8	57.2	15	55.6	1.8	1.6	85.0
4.3	8	3	37.5	8	100.0	94.7	53.3	56.3	7	87.5	6.5	1.7	25.6	5	62.5	0.5	0.1	18.2
4.4	0	0	-	0	-	-	-	-	0	-	-	-	-	0	-	-	-	-
4.5	2	0	0.0	1	50.0	4.3	-	0.0	1	50.0	0.5	-	0.0	1	50.0	0.1	-	0.0
4.6	9	2	22.2	9	100.0	346.6	179.5	51.8	8	88.9	19.3	9.8	50.5	7	77.8	1.7	0.6	35.0
4.7	36	7	19.4	35	97.2	8129.8	3664.9	45.1	35	97.2	1066.7	663.4	62.2	28	77.8	103.9	57.3	55.2
4.8	21	6	28.6	20	95.2	341.7	152.3	44.6	19	90.5	22.3	11.2	50.3	9	42.9	1.8	0.4	23.7
4.9	11	3	27.3	11	100.0	68.2	20.9	30.6	10	90.9	3.5	1.1	32.1	4	36.4	0.3	0.0	13.9
4.10	2	0	0.0	2	100.0	679.9	-	0.0	1	50.0	12.0	-	0.0	1	50.0	0.3	-	0.0
5.1	144	2	1.4	132	91.7	12027.3	84.5	0.7	116	80.6	755.0	3.6	0.5	88	61.1	77.9	0.3	0.4
5.2	8	0	0.0	8	100.0	425.2	-	0.0	8	100.0	28.6	-	0.0	7	87.5	3.1	-	0.0
5.3	7	0	0.0	4	57.1	109.1	-	0.0	4	57.1	7.6	-	0.0	4	57.1	0.8	-	0.0
5.4	2	0	0.0	2	100.0	17.0	-	0.0	1	50.0	0.3	-	0.0	1	50.0	0.1	-	0.0
5.5	6	0	0.0	5	83.3	578.7	-	0.0	4	66.7	28.9	-	0.0	2	33.3	1.9	-	0.0
6.1	2	0	0.0	2	100.0	5.0	-	0.0	2	100.0	0.1	-	0.0	1	50.0	0.0	-	0.0
6.2	0	0	-	0	-	-	-	-	0	-	-	-	-	0	-	-	-	-
6.3	1	0	0.0	1	100.0	260.8	-	0.0	1	100.0	17.2	-	0.0	1	100.0	1.2	-	0.0
6.4	0	0	-	0	-	-	-	-	0	-	-	-	-	0	-	-	-	-
6.5	0	0	-	0	-	-	-	-	0	-	-	-	-	0	-	-	-	-
6.6	0	0	-	0	-	-	-	-	0	-	-	-	-	0	-	-	-	-
6.7	0	0	-	0	-	-	-	-	0	-	-	-	-	0	-	-	-	-
7.1	0	0	-	0	-	-	-	-	0	-	-	-	-	0	-	-	-	-
7.2	0	0	-	0	-	-	-	-	0	-	-	-	-	0	-	-	-	-
7.3	0	0	-	0	-	-	-	-	0	-	-	-	-	0	-	-	-	-
7.4	5	2	40.0	4	80.0	75.8	56.1	74.0	4	80.0	3.4	2.4	69.5	4	80.0	0.5	0.2	46.7
8.1	0	0	-	0	-	-	-	-	0	-	-	-	-	0	-	-	-	-
8.2	1	0	0.0	1	100.0	26.3	-	0.0	1	100.0	1.0	-	0.0	1	100.0	0.1	-	0.0
8.3	0	0	-	0	-	-	-	-	0	-	-	-	-	0	-	-	-	-
9.1	12	4	33.3	10	83.3	218.4	138.8	63.6	10	83.3	7.1	4.4	62.5	8	66.7	0.6	0.3	55.1

APPENDIX 7.1 (continued)

BNF Section	No. of preps. with POC	No. of preps. with POC used long-term	% used long-term	England					Northern Region					Newcastle				
				No. of preps with POC	% of total	No. of prescriptions dispensed for preparations with prolonged oral clearance			No. of preps with POC	% of total	No. of prescriptions dispensed for preparations with prolonged oral clearance			No. of preps with POC	% of total	No. of prescriptions dispensed for preparations with prolonged oral clearance		
						All preps. ($x10^3$)	Long-term ($x10^3$)	% dispensed long-term			All preps. ($x10^3$)	Long-term ($x10^3$)	% dispensed long-term			All preps. ($x10^3$)	Long-term ($x10^3$)	% dispensed long-term
9.2	22	1	4.5	22	100.0	1780.1	62.0	3.5	19	86.4	84.7	7.2	8.5	17	77.3	10.8	0.6	5.2
9.3	0	0	-	0	-	-	-	-	0	-	-	-	-	0	-	-	-	-
9.4	0	0	-	0	-	-	-	-	0	-	-	-	-	0	-	-	-	-
9.5	10	3	30.0	9	90.0	417.3	312.5	74.9	8	80.0	28.8	23.0	79.9	6	60.0	1.4	0.9	68.8
9.6	6	3	50.0	5	83.3	34.4	28.2	82.0	5	83.3	4.6	4.1	89.2	5	83.3	0.8	0.5	62.2
9.7	1	0	0.0	1	100.0	82.0	-	0.0	1	100.0	2.4		0.0	1	100.0	0.2	-	0.0
9.8	0	0	-	0	-	-	-	-	0	-	-	-	-	0	-	-	-	-
10.1	22	8	36.4	21	95.5	684.0	316.9	46.3	20	90.9	33.5	16.5	49.3	15	68.2	2.9	1.7	56.9
10.2	1	1	100.0	1	100.0	22.0	22.0	100.0	1	100.0	2.4	0.4	17.8	1	100.0	0.2	0.0	4.8
10.3	0	0	-	0	-	-	-	-	0	-	-	-	-	0	-	-	-	-
11.1	0	0	-	0	-	-	-	-	0	-	-	-	-	0	-	-	-	-
11.2	0	0	-	0	-	-	-	-	0	-	-	-	-	0	-	-	-	-
11.3	0	0	-	0	-	-	-	-	0	-	-	-	-	0	-	-	-	-
11.4	0	0	-	0	-	-	-	-	0	-	-	-	-	0	-	-	-	-
11.5	0	0	-	0	-	-	-	-	0	-	-	-	-	0	-	-	-	-
11.6	0	0	-	0	-	-	-	-	0	-	-	-	-	0	-	-	-	-
11.7	0	0	-	0	-	-	-	-	0	-	-	-	-	0	-	-	-	-
11.8	0	0	-	0	-	-	-	-	0	-	-	-	-	0	-	-	-	-
11.9	0	0	-	0	-	-	-	-	0	-	-	-	-	0	-	-	-	-
12.1	0	0	-	0	-	-	-	-	0	-	-	-	-	0	-	-	-	-
12.2	0	0	-	0	-	-	-	-	0	-	-	-	-	0	-	-	-	-
12.3	36	2	5.6	31	86.1	1563.6	208.0	13.3	31	86.1	71.3	16.0	22.5	4	11.1	2.7	0.4	15.5
Totals	**613**	**143**	**23.3**	**572**	**93.3**	**61346.7**	**30424.0**	**49.6**	**520**	**84.8**	**4473.5**	**2530.3**	**56.6**	**391**	**63.8**	**445.4**	**238.1**	**53.5**

APPENDIX 7.2

Quantity of all medicines with prolonged oral clearance and those used long-term, dispensed in England, during a one year period (1994).

BNF Section	All Medicines with prolonged oral clearance				Long-term medicines with prolonged oral clearance			
	Liquids (litres x10^3)	Tablets (no. x10^3)	Powders and oral gels (grams x10^3)	Sachets (no. x10^3)	Liquids (litres x10^3)	Tablets (no. x10^3)	Powders and oral gels (grams x10^3)	Sachets (no. x10^3)
1.1	3454.0	162490.0	-	-	3232.2	159026.5	-	-
1.2	116.1	-	1938.3	3643.0	93.6	-	-	3643.0
1.3	60.7	11314.8	-	-	39.8	3874.8	-	-
1.4	31.8	-	-	-	-	-	-	-
1.5	3.2	-	-	-	3.2	-	-	-
1.6	2253.3	9056.3	182284.3	150533.9	2225.1	9056.3	178165.0	127759.5
1.7	-	-	-	-	-	-	-	-
1.8	-	-	-	-	-	-	-	-
1.9	-	-	236.3	68.5	-	-	-	-
2.1	1.1	-	-	-	1.1	-	-	-
2.2	12.0	-	-	-	7.2	-	-	-
2.3	-	-	-	-	-	-	-	-
2.4	5.5	-	-	-	-	-	-	-
2.5	0.6	-	-	-	0.6	-	-	-
2.6	2.4	153129.1	-	-	2.3	12236.7	-	-
2.7	-	-	-	-	-	-	-	-
2.8	-	-	-	-	-	-	-	-
2.9	-	349359.7	-	-	-	349359.7	-	-
2.10	-	-	-	-	-	-	-	-
2.11	0.2	-	-	-	-	-	-	-
2.12	-	-	-	13822.7	-	-	-	10206.8
2.13	-	-	-	-	-	-	-	-
3.1	134.7	-	-	-	36.4	-	-	-
3.2	-	-	-	-	-	-	-	-
3.3	4.5	-	-	-	-	-	-	-
3.4	198.0	-	-	-	22.2	-	-	-
3.5	-	-	-	-	-	-	-	-
3.6	-	-	-	-	-	-	-	-
3.7	-	-	-	-	-	-	-	-
3.8	-	-	-	-	-	-	-	-
3.9	1400.2	-	-	-	720.2	-	-	-
3.10	-	-	-	-	-	-	-	-
4.1	67.4	-	-	-	48.4	-	-	-
4.2	104.5	-	-	-	5.0	-	-	-
4.3	24.7	-	-	-	10.7	-	-	-
4.4	-	-	-	-	-	-	-	-
4.5	-	-	-	228.0	-	-	-	-
4.6	31.7	3464.1	-	1849.6	-	3464.1	-	1849.6
4.7	675.1	338051.2	-	2844.0	-	334490.8	-	203.0
4.8	142.5	10364.3	-	541.3	70.7	5993.4	-	-
4.9	9.5	4908.2	-	-	1.1	2286.9	-	-
4.10	293.1	-	-	-	-	-	-	-
5.1	1184.5	2240.2	-	108656.8	4.1	-	-	100.3
5.2	15.2	-	-	-	-	-	-	-
5.3	2.5	3176.3	-	-	-	-	-	-
5.4	2.2	-	-	-	-	-	-	-
5.5	6.4	553.8	-	272.2	-	-	-	-
6.1	-	-	-	436.8	-	-	-	-
6.2	-	-	-	-	-	-	-	-
6.3	-	9256.5	-	-	-	-	-	-
6.4	-	-	-	-	-	-	-	-
6.5	-	-	-	-	-	-	-	-
6.6	-	-	-	-	-	-	-	-
6.7	-	-	-	-	-	-	-	-
7.1	-	-	-	-	-	-	-	-
7.2	-	-	-	-	-	-	-	-
7.3	-	-	-	-	-	-	-	-
7.4	18.5	685.8	-	6.6	17.0	5.3	-	-
8.1	-	-	-	-	-	-	-	-
8.2	2.8	-	-	-	-	-	-	-
8.3	-	-	-	-	-	-	-	-
9.1	54.1	-	-	-	38.8	-	-	-
9.2	1.5	-	-	17278.3	-	6737.2	-	-
9.3	-	8865.3	-	-	-	-	-	-
9.4	-	-	-	-	-	-	-	-
9.5	6.0	31710.4	-	720.4	-	27634.3	-	-

APPENDIX 7.2 (continued)

BNF Therapeutic Section	All Medicines with prolonged oral clearance				Long-term medicines with prolonged oral clearance			
	Liquids (litres x10^3)	Tablets (no. x10^3)	Powders and oral gels (grams x10^3)	Sachets (no. x10^3)	Liquids (litres x10^3)	Tablets (no. x10^3)	Powders and oral gels (grams x10^3)	Sachets (no. x10^3)
9.6	1.4	1650.6	-	-	0.6	1650.6	-	-
9.7	27.1	-	-	-	-	-	-	-
9.8	-	-	-	-	-	-	-	-
10.1	122.3	8134.7	-	6060.4	95.1	5445.8	-	-
10.2	11.9	-	-	-	11.9	-	-	-
10.3	-	-	-	-	-	-	-	-
11.1	-	-	-	-	-	-	-	-
11.2	-	-	-	-	-	-	-	-
11.3	-	-	-	-	-	-	-	-
11.4	-	-	-	-	-	-	-	-
11.5	-	-	-	-	-	-	-	-
11.6	-	-	-	-	-	-	-	-
11.7	-	-	-	-	-	-	-	-
11.8	-	-	-	-	-	-	-	-
11.9	-	-	-	-	-	-	-	-
12.1	-	-	-	-	-	-	-	-
12.2	-	-	-	-	-	-	-	-
12.3	86.5	14497.1	6775.6	59.5	0.1	5431.9	-	-
Total	**10569.6**	**1122908.4**	**191234.5**	**307022.0**	**6732.2**	**926694.3**	**178165.0**	**143762.2**

APPENDIX 7.3

Quantity of all medicines with prolonged oral clearance and those used long-term, dispensed in the Northern Region, during a one year period (1994).

BNF Therapeutic Section	All Medicines with prolonged oral clearance				Long-term medicines with prolonged oral clearance			
	Liquids (litres x10^3)	Tablets (no. x10^3)	Powders and oral gels (grams x10^3)	Sachets (no. x10^3)	Liquids (litres x10^3)	Tablets (no. x10^3)	Powders and oral gels (grams x10^3)	Sachets (no. x10^3)
1.1	266.1	11651.8	-	-	252.7	11252.7	-	-
1.2	5.4	-	31.8	239.5	4.2	-	-	239.5
1.3	5.4	1270.9	-	-	2.7	427.9	-	-
1.4	2.4	-	-	-	-	-	-	-
1.5	0.2	-	-	-	0.1	-	-	-
1.6	157.1	607.3	11571.5	11204.3	152.7	607.3	11069.9	8723.7
1.7	-	-	-	-	-	-	-	-
1.8	-	-	-	-	-	-	-	-
1.9	-	-	-	0.8	-	-	-	-
2.1	0.1	-	-	-	-	-	-	-
2.2	0.6	-	-	-	0.4	-	-	-
2.3	-	-	-	-	-	-	-	-
2.4	0.3	-	-	-	-	-	-	-
2.5	-	-	-	-	-	-	-	-
2.6	0.2	16485.6	-	-	0.2	3136.5	-	-
2.7	-	-	-	-	-	-	-	-
2.8	-	-	-	-	-	-	-	-
2.9	-	25871.2	-	-	-	25871.2	-	-
2.10	-	-	-	-	-	-	-	-
2.11	-	-	-	-	-	-	-	-
2.12	-	-	30.6	722.0	-	-	-	596.9
2.13	-	-	-	-	-	-	-	-
3.1	17.2	-	-	-	12.0	-	-	-
3.2	-	-	-	-	-	-	-	-
3.3	0.6	-	-	-	-	-	-	-
3.4	10.3	-	-	-	0.1	-	-	-
3.5	-	-	-	-	-	-	-	-
3.6	-	-	-	-	-	-	-	-
3.7	-	-	-	1.0	-	-	-	-
3.8	-	-	-	-	-	-	-	-
3.9	60.8	-	-	-	33.5	-	-	-
3.10	-	-	-	-	-	-	-	-
4.1	5.0	-	-	-	3.4	-	-	-
4.2	4.6	-	-	-	2.7	-	-	-
4.3	1.7	-	-	-	0.3	-	-	-
4.4	-	-	-	-	-	-	-	-
4.5	-	-	3.1	32.3	-	-	-	-
4.6	2.0	206.6	-	110.7	-	206.5	-	88.9
4.7	64.5	71244.2	-	233.2	-	70585.6	-	19.5
4.8	7.1	90.0	-	63.9	3.7	365.2	-	-
4.9	0.5	238.9	-	-	0.1	97.6	-	-
4.10	3.5	-	-	-	-	-	-	-
5.1	78.9	139.2	-	6577.1	0.2	-	-	4.0
5.2	1.0	-	-	-	-	-	-	-
5.3	0.2	207.5	-	-	-	-	-	-
5.4	-	-	-	-	-	-	-	-
5.5	0.4	33.0	-	10.8	-	-	-	-
6.1	-	-	-	9.5	-	-	-	-
6.2	-	-	-	-	-	-	-	-
6.3	-	538.9	-	-	-	-	-	-
6.4	-	-	-	-	-	-	-	-
6.5	-	-	-	-	-	-	-	-
6.6	-	-	-	-	-	-	-	-
6.7	-	-	-	-	-	-	-	-
7.1	-	-	-	-	-	-	-	-
7.2	-	-	-	-	-	-	-	-
7.3	-	-	-	-	-	-	-	-
7.4	0.9	26.7	-	0.6	0.7	2.6	-	-
8.1	-	-	-	-	-	-	-	-
8.2	0.1	-	-	-	-	-	-	-
8.3	-	-	-	-	-	-	-	-
9.1	2.3	-	-	-	1.6	-	-	-
9.2	0.1	-	30.6	866.5	-	763.8	-	-
9.3	-	860.4	-	-	-	-	-	-
9.4	-	-	-	-	-	-	-	-
9.5	0.4	1806.5	-	40.9	-	1535.3	-	-

APPENDIX 7.3 (continued)

BNF Therapeutic Section	All Medicines with prolonged oral clearance				Long-term medicines with prolonged oral clearance			
	Liquids (litres x10^3)	Tablets (no. x10^3)	Powders and oral gels (grams x10^3)	Sachets (no. x10^3)	Liquids (litres x10^3)	Tablets (no. x10^3)	Powders and oral gels (grams x10^3)	Sachets (no. x10^3)
9.6	0.1	269.6	-	-	-	269.6	-	-
9.7	0.8	-	-	-	-	-	-	-
9.8	-	-	-	-	-	-	-	-
10.1	6.1	872.2	-	62.9	4.0	395.7	-	-
10.2	1.3	-	-	-	0.3	-	-	-
10.3	-	-	-	-	-	-	-	-
11.1	-	-	-	-	-	-	-	-
11.2	-	-	-	-	-	-	-	-
11.3	-	-	-	-	-	-	-	-
11.4	-	-	-	-	-	-	-	-
11.5	-	-	-	-	-	-	-	-
11.6	-	-	-	-	-	-	-	-
11.7	-	-	-	-	-	-	-	-
11.8	-	-	-	-	-	-	-	-
11.9	-	-	-	-	-	-	-	-
12.1	-	-	-	-	-	-	-	-
12.2	-	-	-	-	-	-	-	-
12.3	8.2	921.7	546.5	2.9	-	391.1	-	-
Total	**716.4**	**134152.3**	**12214.1**	**20179.1**	**475.6**	**115908.6**	**11069.9**	**9672.4**

APPENDIX 7.4

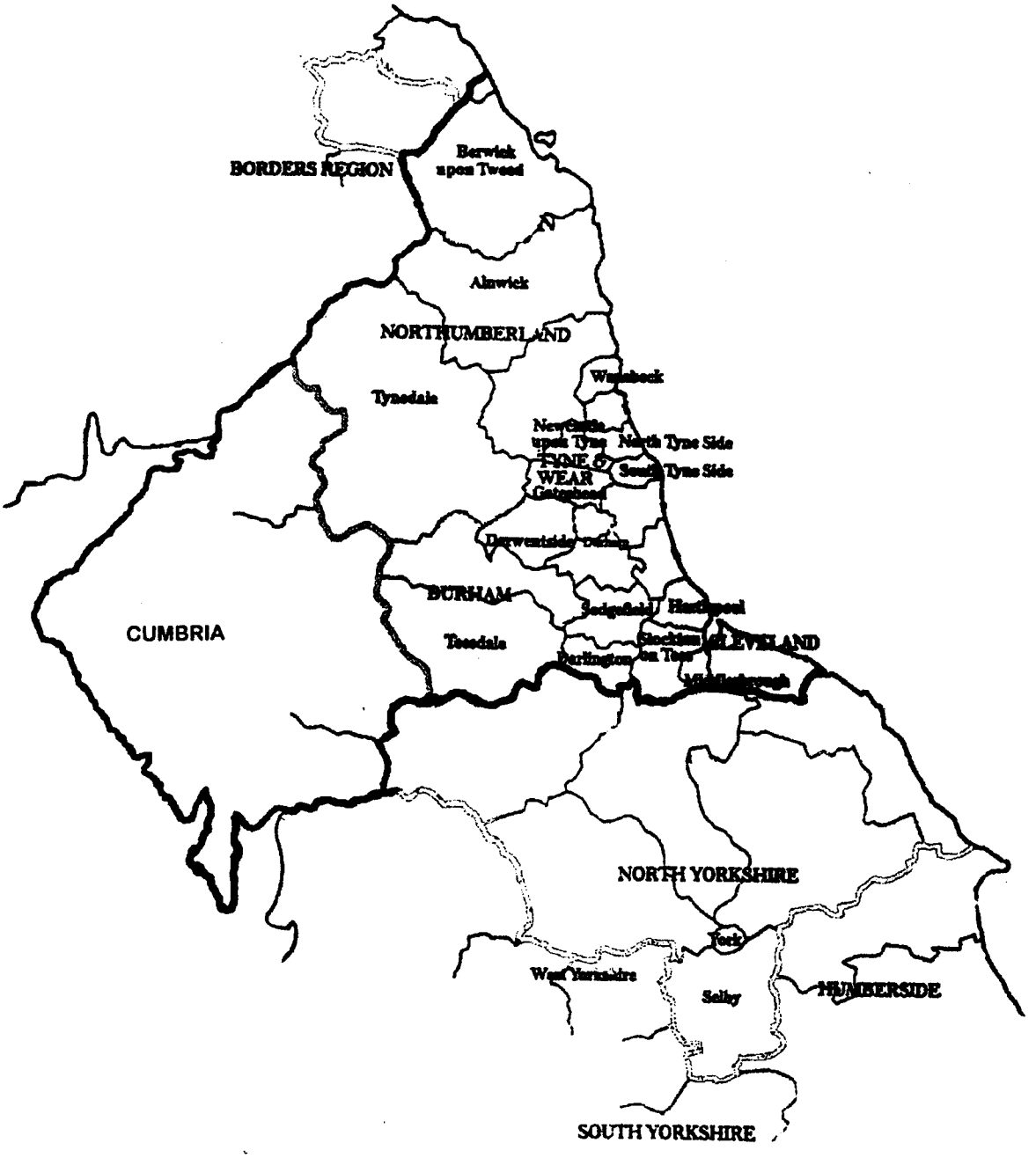
Quantity of all medicines with prolonged oral clearance and those used long-term, dispensed in Newcastle, during a one year period (1994).

BNF Therapeutic Section	All Medicines with prolonged oral clearance				Long-term medicines with prolonged oral clearance			
	Liquids (litres x10^3)	Tablets (no. x10^3)	Powders and oral gels (grams x10^3)	Sachets (no. x10^3)	Liquids (litres x10^3)	Tablets (no. x10^3)	Powders and oral gels (grams x10^3)	Sachets (no. x10^3)
1.1	34.5	2447.4	-	-	31.0	1805.7	-	-
1.2	0.4	-	1.0	5.3	0.3	-	-	5.3
1.3	0.4	85.6	-	-	0.2	30.5	-	-
1.4	0.2	-	-	-	-	-	-	-
1.5	-	-	-	-	-	-	-	-
1.6	15.4	11.0	1062.2	1084.6	14.9	11.0	1028.9	810.1
1.7	-	-	-	-	-	-	-	-
1.8	-	-	-	-	-	-	-	-
1.9	-	-	-	-	-	-	-	-
2.1	-	-	-	-	-	-	-	-
2.2	-	-	-	-	-	-	-	-
2.3	-	-	-	-	-	-	-	-
2.4	-	-	-	-	-	-	-	-
2.5	-	-	-	-	-	-	-	-
2.6	-	2440.8	-	-	-	408.3	-	-
2.7	-	-	-	-	-	-	-	-
2.8	-	-	-	-	-	-	-	-
2.9	-	2124.9	-	-	-	2124.9	-	-
2.10	-	-	-	-	-	-	-	-
2.11	-	-	-	-	-	-	-	-
2.12	-	-	1.0	61.7	-	-	-	52.3
2.13	-	-	-	-	-	-	-	-
3.1	1.5	-	-	-	1.1	-	-	-
3.2	-	-	-	-	-	-	-	-
3.3	-	-	-	-	-	-	-	-
3.4	0.9	-	-	-	-	-	-	-
3.5	-	-	-	-	-	-	-	-
3.6	-	-	-	-	-	-	-	-
3.7	-	-	-	-	-	-	-	-
3.8	-	-	-	-	-	-	-	-
3.9	5.6	-	-	-	2.9	-	-	-
3.10	-	-	-	-	-	-	-	-
4.1	0.4	-	-	-	0.2	-	-	-
4.2	0.5	-	-	-	0.4	-	-	-
4.3	0.1	-	-	-	-	-	-	-
4.4	-	-	-	-	-	-	-	-
4.5	-	-	-	2.4	-	-	-	-
4.6	0.2	15.3	-	1.5	-	13.2	-	1.4
4.7	7.3	6485.6	-	12.3	-	6480.9	-	0.8
4.8	1.0	1.1	-	5.9	0.3	-	-	-
4.9	0.1	8.8	-	-	-	4.3	-	-
4.10	0.1	-	-	-	-	-	-	-
5.1	8.1	22.9	-	586.8	-	-	-	1.6
5.2	0.1	-	-	-	-	-	-	-
5.3	-	19.4	-	-	-	-	-	-
5.4	-	-	-	-	-	-	-	-
5.5	-	-	0.1	0.9	-	-	-	-
6.1	-	-	-	0.1	-	-	-	-
6.2	-	-	-	-	-	-	-	-
6.3	-	38.0	-	-	-	-	-	-
6.4	-	-	-	-	-	-	-	-
6.5	-	-	-	-	-	-	-	-
6.6	-	-	-	-	-	-	-	-
6.7	-	-	-	-	-	-	-	-
7.1	-	-	-	-	-	-	-	-
7.2	-	-	-	-	-	-	-	-
7.3	-	-	-	-	-	-	-	-
7.4	0.1	0.5	-	-	0.1	-	-	-
8.1	-	-	-	-	-	-	-	-
8.2	-	-	-	-	-	-	-	-
8.3	-	-	-	-	-	-	-	-
9.1	0.2	-	-	-	0.1	-	-	-
9.2	-	-	-	112.7	-	58.2	-	-
9.3	-	75.8	-	-	-	-	-	-
9.4	-	-	-	-	-	-	-	-
9.5	-	117.3	-	-	-	85.7	-	-

APPENDIX 7.4 (continued)

BNF Therapeutic Section	All Medicines with prolonged oral clearance				Long-term medicines with prolonged oral clearance			
	Liquids (litres x10^3)	Tablets (no. x10^3)	Powders and oral gels (grams x10^3)	Sachets (no. x10^3)	Liquids (litres x10^3)	Tablets (no. x10^3)	Powders and oral gels (grams x10^3)	Sachets (no. x10^3)
9.6	0.1	33.4	-	-	-	33.4	-	-
9.7	0.1	-	-	-	-	-	-	-
9.8	-	-	-	-	-	-	-	-
10.1	0.4	83.9	-	2.8	0.3	41.3	-	-
10.2	0.2	-	-	-	-	-	-	-
10.3	-	-	-	-	-	-	-	-
11.1	-	-	-	-	-	-	-	-
11.2	-	-	-	-	-	-	-	-
11.3	-	-	-	-	-	-	-	-
11.4	-	-	-	-	-	-	-	-
11.5	-	-	-	-	-	-	-	-
11.6	-	-	-	-	-	-	-	-
11.7	-	-	-	-	-	-	-	-
11.8	-	-	-	-	-	-	-	-
11.9	-	-	-	-	-	-	-	-
12.1	-	-	-	-	-	-	-	-
12.2	-	-	-	-	-	-	-	-
12.3	-	58.5	26.9	-	-	15.9	-	-
Total	78.2	14070.4	1091.2	1877.1	51.8	11113.3	1028.9	871.5

APPENDIX 7.5
Map of the Northern Region Health Authority Boundary in 1994



APPENDIX 7.6
Map of the Tyne Tees Television Coverage Area

APPENDIX 7.7

Types of common sweetening agents found in OTC preparations with prolonged oral clearance

Sugars-free OTC Medicines

	Liquids	Solids	Powders & oral gels	Sachets	Total
No Sugar	17	0	7	2	**26**
Saccharin	19	15	4	3	**41**
Saccharin+Sorbitol	10	3	0	0	**13**
Sorbitol	1	1			**2**
Lycasin	3				**3**
Glycerol	2				**2**
Aspartame		1		1	**2**
Saccharin+Malitol	1				**1**
Saccharin+Maize Starch					**0**
Saccharin+Lactose				1	**1**
Saccharin+Aspartame					**0**
Sorbitol+Malitol	2				**2**
Sorbitol+Isomalt	1				**1**
Lycasin+Sorbitol	5				**5**
Lycasin+Saccharin	5				**5**
Glycerol+Saccharin	1			1	**2**
Glycerol+Aspartame				1	**1**
Acesulfame+Isomalt					**0**
Saccharin+Glycerol+Sorbitol	1				**1**
Saccharin+Lactose+Cyclamate				1	**1**
Sorbitol+Saccharin+Xylitol			3		**3**
Sorbitol+Glycerol+Cyclamate	1				**1**
Sorbitol+Saccharin+Cyclamate		4			**4**
Lycasin+Saccharin+Glycerol	3				**3**
Lycasin+Saccharin+Cyclamate	2				**2**
Glycerol+Lycasin+Sorbitol+Cyclamate+ Acesulfame	4				**4**
Total	**78**	**24**	**14**	**10**	**126**

APPENDIX 7.7 (continued)

Sugars-containing OTC Medicines

	Liquids	Solids	Powders & oral gels	Sachets	Total
Sucrose	34	18	5	5	**62**
Sucrose+Glucose	7	7	3	0	**17**
Sucrose+Saccharin	5	8	0	4	**17**
Sucrose+Glucose + Saccharin	9	0	0	0	**9**
Sucrose+Sorbitol	12	2	0	0	**14**
Glycerol+Sorbitol+Cyclamate	1				**1**
Sucrose+Glucose Syrup+Saccharin	1				**1**
Sucrose+Glucose+Sorbitol		1			**1**
Sucrose+Glucose+Saccharin+Sorbitol	1				**1**
Sucrose+Saccharin+Cyclamate				3	**3**
Sucrose+dextrose+Dried Starch		1			**1**
Sucrose+Sorbitol+Saccharin		1			**1**
Glucose+Sucrose+Fructose	3				**3**
Glucose+Cyclamate+Acesulfame	1				**1**
Glucose+Treacle+Cyclamate+Acesulfame	1				**1**
Lactose+Galactose+Epilactose+Fructose+ Lactulose	1				**1**
Lactose+Galactose+Epilactose+Lactulose	1				**1**
Lactulose+Galactose+Lactose	1				**1**
Glucose+Saccharin+Cyclamate				1	**1**
Glycerol+Sorbitol+Sucrose	1				**1**
Sucrose+Glucose Syrup	3	2	1		**6**
Sucrose+Treacle	2				**2**
Cyclamate+Sucrose				1	**1**
Sucrose+Aspartame		1			**1**
Glucose+Saccharin		2		1	**3**
Glucose+Treacle	1				**1**
Dextrose+Saccharin		2			**2**
Glucose Syrup+Saccharin	2				**2**
Glucose		1		1	**2**
Dextrose				1	**1**
Glucose Syrup	3				**3**
Total	**90**	**46**	**9**	**17**	**162**

CHAPTER 8

OVERALL DISCUSSION AND IMPLICATIONS

8.1 INTRODUCTION

The series of five observational surveys conducted in this study focused on an assessment of the use of medicines with prolonged oral clearance in the elderly in the U.K. These medicines with a prolonged clearance from the oral cavity included liquid oral medicines, chewable tablets, buccal and sublingual tablets and pastilles and lozenges. If these formulations include an acidogenic sweetening agent, they could pose a risk to dental health and it was important that an estimate of this risk was made. Many elderly take large numbers of medicines to alleviate the age-associated increase in morbidity: in 1997 they were dispensed 49% of all 500 million prescription items dispensed in the UK (Department of Health, 1998). As the population of elderly individuals in the UK increases, with more elderly retaining natural teeth into old age (Todd & Lader, 1991), the extent of use of prolonged oral clearance medicines and their sugars content could potentially become a significant problem. In view of this there was a need for this aspect of medicines utilisation to be quantified on an individual and population basis. Many studies have looked at medicine use and dental health, whether it be sugars and liquid oral medicines (Burt *et al.*, 1988; Hobson, 1985; James & Parfitt, 1953; Maguire *et al.*, 1996; Roberts & Roberts, 1979) or medicines with specific oral effects (Baker *et al.*, 1991; Bertram *et al.*, 1979; Peters, 1989), however no studies have looked at a collective group of medicines with prolonged oral clearance from the oral cavity.

The surveys were carried out as an assessment of prevalence of long-term use of prescribed and over-the-counter liquid oral medicines in five Districts within the Northern Region, an analysis of prescriptions dispensed in the general medical and dental services on a national, regional and local basis, together with an analysis of hospital pharmacy use and community pharmacy supply on a regional basis. Medicines are obtained by consumers within the UK's health care system by fairly diverse means and it was important that the planning of these surveys took this into account, along with the equally diverse means by which data on supply of medicines are collated by various bodies within the National Health Service as well as the commercial sector.

This chapter combines an overall critical review of the project and interpretation of the important results, with a consideration of the implications and suggestions for future research.

8.2 CRITIQUE OF METHODS

To assess the overall of use of medicines with prolonged oral clearance, five surveys were undertaken. Two of these were concerned with estimating the prevalence of use of medicines with prolonged oral clearance in the elderly in the North East of England and three surveys assessed the overall consumption of medicines with prolonged oral clearance in England, the Northern Region and Newcastle.

Having assessed what the data sources were and which might be accessible to carry out the surveys, the methods described used the most comprehensive which were available and retrievable with the manpower and time available for the study.

The Prescribed Medicines Prevalence Survey and OTC Medicines Prevalence Survey were both general medical practice based and both used personal medical information. The use of these data required Ethics Committees' permission with assurance that all the data collected would remain completely confidential and that no individuals details would be discussed. The need to maintain strict confidentiality took high priority in the methodology used. All patients in the Prescribed Medicines Prevalence Survey and OTC Prevalence Survey were given a code which identified the practice where they were registered and their practice medication record number. This ensured that no data could be traced back to the patient. Commercially sensitive information was also treated with strict confidentiality; all prescribing data and those obtained from commercial sources were aggregated by therapeutic section only and no reference made to individual medicines in these surveys.

8.2.1 Sampling

In the Prescribed Medicines Prevalence Survey, the practices chosen were selected from a list of practices received from the Family Health Services Authorities (FHSAs) for the five districts. Due to the vast amount of data that it was anticipated would be collected, it was decided that ten general medical practices would be selected from a sampling frame containing only comprehensively computerised practices. In the event all the general medical practices in the five districts of the Northern Region selected met this inclusion criterion and all practices at the time of sampling had list sizes of 5,000 patients or more.

The main aim in both the Prescribed Medicines Prevalence Survey and OTC Medicines Prevalence Survey was to identify regular (once daily or alternate day) and long-term (3 months or longer) use of medicines with prolonged oral clearance. Regular use was defined as at least 'once daily' or 'alternate day', however all instances of use identified were at least 'once daily'. The time period of three months was chosen as minimum length of treatment to define long-term use as most medicines used for acute conditions such as infections would not be used for longer than this time period, and this was also the time scale chosen by a similar prevalence survey undertaken with children (Maguire & Rugg-Gunn, 1994).

The methodology used in the two prevalence surveys varied in that the survey for prescribed medicines looked at all 20,371 elderly patients registered at the 10 practices and details of those patients taking medicines with prolonged oral clearance were entered onto a database. In contrast, the prevalence survey for OTC medicines used a sub-sample of 50% of the elderly patients of ten general medical practitioners at the ten general medical practices, producing a total sample of 2322. These patients were sent questionnaires and asked to list their medication, which was then entered into the database and analysed. Statistical advice on sample size confirmed that 2322 patients would form an adequate sample for the OTC Medicines Prevalence Survey.

The surveys of overall consumption of medicines with prolonged oral clearance looked at prescribing, dispensing and ordering data for prescription and OTC medicines within the primary healthcare service (Prescription Analysis Survey and OTC Medicines Survey), and ordering data for prescribed medicines within the secondary healthcare service (Hospital Drug Ordering Survey). The surveys used 100% samples of these data; prescribing data was from 100% of all prescriptions dispensed in primary care, 'over the counter' data recorded 100% of all OTC medicines ordered by pharmacies in the Channel 3 North-East TV area and the hospital ordering data included 100% of all medicines with prolonged oral clearance ordered by hospitals. Although the coverage for Channel 3 North East and the Northern Region Health Authority were not identical, it was felt the two areas coincided sufficiently well to provide a reasonable estimate of OTC medicine use in the Northern Region.

8.2.2 Data collection

The study looked at the use of medicines with prolonged oral clearance used regularly and long-term by the elderly as well the overall use of medicines with prolonged oral clearance. Careful consideration was given to the data collection methods of each survey to ensure that the

most accurate data could be retrieved. However, since the surveys have been completed, with the advance in computing technology, it would now be possible to improve and speed up data collection if a similar study were carried out in the future. Data collected from a practice could now be downloaded straight from the computer system of the general medical practice, rather than printing it off and then manually transferring the data to a database. The surveys looking at the overall use of medicines with prolonged oral clearance used PACT and PCA prescribing data which were also entered into a database manually. PACT and PCA data are now available electronically and such a format would have considerably reduced the time taken to collect and analyse these data. PCA data took less time to analyse than PACT and they were used for England. Unfortunately PCA data were not available for the Northern Region nor Newcastle, requiring the use of PACT which involved additional calculations before data entry. The formats of data varied slightly in that PCA data, which were used for England were based on where the prescription was dispensed and PACT data, which were used for the Northern Region and Newcastle were based on the location of the prescriber. PCA data are dispensing data (i.e. what was actually dispensed) and PACT data are prescribing data (i.e. what was actually prescribed). In most cases these two are identical and the data provided by the two formats would be comparable, however for some drugs there may be slight discrepancies between PCA and PACT data. PCA data for England included data on overall quantities already calculated. In view of the volume of data involved, it was felt that this was the most appropriate use of the manpower available. As an electronic version of PACT is now available, this could be used in any future surveys of this nature as all national, regional and district level data would be of the same format.

The data collection for the surveys, although time consuming, was relatively straightforward. The general medical practices were very helpful in providing access to the computerised patient records, as well as giving permission to contact their patients for the questionnaire survey. Likewise, the Prescription Pricing Authority and Prescribing Unit were very helpful and gave full access to PACT and PCA data, as well hospital drug ordering data. The major problem encountered in the data collection was access to overall use of 'Over the Counter' medicines data. This was originally to be collected from pharmaceutical wholesalers, who were happy to provide good quality data for all sales of OTC medicines to community pharmacies. This had already been proved to be a successful method of data collection (Maguire & Rugg-Gunn, 1994). However in this study, these data from two multinational companies was not made available even after many attempts to contact these companies. It was unfortunate to have to reject the data

provided by the pharmaceutical wholesalers, and find another source of data that could provide an overall estimate of the use of OTC medicine with prolonged oral clearance.

Another area where the data provision was poor was the generic manufacturers regarding the sugars content of generic medicines with prolonged oral clearance. Proprietary manufacturers provided concise information on the types and amounts of sweetening agents in medicines with prolonged oral clearance, whereas the generic manufacturers were only able to state that the medicine was sugars-free or sugars-containing for most cases and were not able to provide information on the actual sugars content.

In the analysis of these surveys two assumptions had to be made and taken into consideration when looking at the results. Data collected for the overall use of medicines in hospitals in the Northern Region and the overall use of OTC medicines were ordering data. It was assumed that these ordered medicines were subsequently dispensed to, or bought by the patient and then consumed by the patient and not lost through wastage due to poor stock control in pharmacies. The second assumption was patients' compliance was good and that all medicines prescribed and dispensed were ultimately consumed by the patient. However, research has shown that patient compliance in the elderly may be poor (Robertson, 1985; Salzman, 1995), and this is currently an issue the Royal Pharmaceutical Society of Great Britain is investigating further following the publication of their report 'From compliance to concordance' (Royal Pharmaceutical Society of Great Britain, 1997). This report suggests that up to 50% of the elderly may not be complying with their medication and that compliance is further reduced with increased number of tablets taken and increased frequency of dosing. The Society recommends that the issue of compliance be included in the NHS research and development programme.

8.3 OVERALL FINDINGS

8.3.1 Prevalence of use of medicines with prolonged oral clearance in the elderly

The literature review in Chapter 3 revealed no published information on the prevalence of long-term use of medicines with prolonged oral clearance in the elderly, and the possible effects on dental health. This study was the first known determination of the prevalence of use of these medicines in the elderly population.

To ensure that an overall picture of prevalence of all medicines was obtained, two surveys, one looking at prescribed medicines (Chapter 5) and the other at 'over the counter' (OTC)

medicines (Chapter 6) were undertaken. These surveys showed prevalence rates of 9.8% and 1.1% for regular and long-term use of prescribed and OTC medicines with prolonged oral clearance in the elderly population sampled. Of the 2002 elderly patients taking prescribed medicines regularly and long-term, 68% were female, which was higher than the proportion of females in the Northern Region and England which was approximately 58% in 1995 (Office for National Statistics, 1995). Of the 2002 patients, 46% were ≥75 years, which was higher than proportion of ≥75 year olds registered at the ten practices which was 34%. Statistical analysis showed that females aged 75 years and over were more likely to be taking medicines with prolonged oral clearance regularly and long-term ($p<0.0001$). Extrapolated to the five districts and regionally, the number of elderly patients taking prescribed medicines of this nature regularly and long-term would be 24588 and 60544 elderly patients respectively based on the elderly population of the 5 districts and the Northern Region being 250900 and 617800 respectively, in 1995 (Office for National Statistics, 1995). Extrapolation of the data for England and the UK could be made but the regional differences in medicine use may result in this being inaccurate. The numbers of patients identified in the OTC Medicines Prevalence Survey were too low to carry out any statistical analysis; 1.1% prevalence accounted for 17 patients. However, if these OTC sales were indicative of the rest of the five Districts and the Region, then the number of elderly patients taking OTC medicines regularly and long-term would be 3021 and 7261 patients respectively.

In addition, the OTC Medicines Prevalence Survey showed that 46% of all the respondents to the questionnaire had some natural teeth. This would indicate that up to 13500 elderly patients in the five districts and 34400 regionally may be at risk from dental caries if the medicines with prolonged oral clearance were sugars-containing.

8.3.2 Medical problems for which medicines with prolonged oral clearance are commonly used long-term

The two prevalence surveys showed that prescribed medicines were more likely to be used regularly and long-term than over the counter (OTC) medicines. Prescribing instances recorded for regular long-term use of a medicine prescribed for an elderly patient showed that of the total of 2796 long-term prescribing instances, over half (54%) were for gastrointestinal medicines, in particular, laxatives and antacids. The Prescription Analysis Survey confirmed this finding with the majority of prescriptions dispensed for prolonged oral clearance medicines nationally, regionally and locally being for gastrointestinal medicines. Of all medicines dispensed in 1994 to

the elderly, 10.5% were for gastrointestinal problems (Prescription Pricing Authority, 1995), which would suggest that gastrointestinal medicines are more likely to be prescribed as medicines with prolonged oral clearance. This most likely related to the dose form: most gastric conditions are a result of excess acidity and a liquid oral medicine or chewable tablet can neutralise this acid more effectively than a solid oral dose form designed for immediate swallowing since a greater surface area of medicine is produced for contact with the gastric acid.

8.3.3 Overall prolonged oral clearance medicine consumption: long- and short-term

Overall, there were no great differences in the prescribing of all prolonged oral clearance medicines, and those medicines with prolonged oral clearance likely to be prescribed long-term in the elderly. However, there was some indication that those medicines commonly prescribed which were also available 'over the counter'; for example, minor analgesics such as paracetamol, were more likely to be prescribed than bought in the more socially deprived district of Newcastle compared with the Northern Region and nationally. The scale of use of 'over the counter' (OTC) prolonged oral clearance medicines, in terms of quantities, was previously unknown. In a study of overall use of medicines by children by Rylance *et al* (Rylance *et al.*, 1988), 55% of medicines dispensed to children were on prescription, however there was no indication as to whether all these were Prescription Only medicines. The remaining 45% of medicines used were OTC medicines, with 40% purchased in pharmacies. No similar research has previously been described in the elderly.

The present survey of overall consumption of 323 General Sales List and Pharmacy Only OTC products with prolonged oral clearance, indicated that the quantity purchased over the counter; 0.11 million litres, and 16.8 million solid oral doses with POC in the Northern Region, was equivalent to approximately 14% of the quantity of all prolonged oral clearance medicines dispensed within the general medical and dental services in the Northern Region.

Once the hospital pharmacy consumption figures were included, the prolonged oral clearance medicine market (both long- and short-term) amounted to approximately 0.73 million litres of liquid oral medicines plus 134.25 million solid doses with prolonged oral clearance, dispensed in primary and secondary care, in the Northern Region. If these figures are extrapolated in terms of the ratio of Regional to National prescribing found in the Prescription Analysis Survey, which was 1:14 in terms of number of prescriptions dispensed, and assuming all dispensed medicines were consumed, the national consumption rate of liquid oral medicines was approximately 10.22

million litres plus 1879.43 million solid doses per year. However, this is obviously an over-estimate of actual consumption rates since compliance with medication is variable; between 25% and 50% of elderly patients do not to take their medicines as prescribed (Robertson, 1985; Salzman, 1995).

As medicines with prolonged oral clearance formed four distinct categories in terms of dose form (liquids, solids, powder/oral gels and sachets), it was necessary to analyse the quantity data according to the different units of measurement (e.g. litres for liquid oral medicines compared with number of units for solids with prolonged oral clearance). This form of analysis, by dose unit has only previously been reported for liquid oral medicines in relation to their use in children (Maguire & Rugg-Gunn, 1994; Roberts & Roberts, 1979). This analysis by dose form was important as it highlighted major differences in the prescribing of sugars-free and sugars-containing medicines between dose forms, which is discussed in the next section (8.3.4). In addition, this analysis by dose form also highlighted a potential problem which was not considered during the planning stages of the study. Of the 134.3 million solid doses with prolonged oral clearance used overall in the Northern Region, 94.8 million (71%) were effervescent tablets. Prior to administration, these tablets are dispersed in water, where an acid-base reaction explodes the tablet into the solution. Most tablets contain an excess of a weak acid (usually citric acid) to ensure the reaction is completed as well as giving the final solution a pleasant flavour. The resulting solution is quite often acidic and therefore may put the patient at risk of dental erosion if consumed regularly and long-term. Other studies have looked at the potential of medicines to cause dental erosion. In a survey looking at juvenile arthritis (Sullivan & Kramer, 1983) and two groups of children, one chewing aspirin and the other swallowing aspirin whole, dental erosion was reported in those children taking the chewable form of aspirin. A case study looking at a women taking a chewable vitamin has also described dental erosion (Giunta, 1983). No studies have described the long-term effects of effervescent tablets in the elderly in terms of dental health and this is one area which would benefit from further research.

8.3.4 Sugars content of medicines with prolonged oral clearance used regularly and long-term

The studies carried out here indicated that 49% of all OTC liquid oral medicine consumption and 59% of all solid OTC medicine consumption in the Northern Region was sugars-free in terms of quantity, whereas the long-term prescribing data show that 71% of prescribing instances for long-term prolonged oral clearance preparations (identified in the Prescribed Medicines

Prevalence Survey) were definitely sugars-free. In terms of prescriptions suitable for long-term use dispensed in the Northern Region, 73% were for sugars-free medicines and, as far as quantities were concerned, 60% of liquid oral medicines and 88% of solid doses with prolonged oral clearance dispensed were sugars-free.

Overall it appeared that sugars-free medicines with prolonged oral clearance were being used more than sugars-containing and it may be that manufacturers have responded to the increasing pressure from health professionals and reformulated existing sugars-containing medicines, producing new sugars-free products. In particular, manufacturers of paediatric medicines have increased their range of sugars-free medicines accordingly, providing an expanding range for the prescriber and purchaser to choose from, particularly for minor analgesics and cough and cold remedies. However, choosing the form that an alternative sweetener should take is important, and problems have been encountered when formulating sugars-free products for international markets. The regulatory status of an alternative sweeteners varies between countries, and where there are few manufacturers of a sweetener, bulk transportation over large distances may be necessary, often leading to considerable practical problems.

The data from the Prescription Analysis Survey showed that in 71% of the prescribing instances for the 143 preparations identified as being used regularly and long-term by the elderly, sugars-free medicines were being prescribed. However closer examination of the data showed that there were major differences between dose forms and between generic and proprietary prescribing. Of all formulations of generic liquid oral medicines, 81% were sugars-containing compared with only 8% of proprietary liquid oral medicine preparations and for liquid oral medicines, 52% of all prescribing instances were for generic medicines with prolonged oral clearance, 48% for proprietary liquid oral medicines. This has very important implications for prescribing as medicines prescribed generically were more likely to be dispensed as sugars-containing, and if used long-term, as the medicines in this survey were, the potential risk to dental health is increased.

In terms of the patients actually at risk, approximately 46% of the elderly patients surveyed in the OTC Medicines Prevalence Survey were dentate. If this proportion was extrapolated to the 20371 elderly in the ten general medical practices surveyed in the Prescribed Medicines Prevalence Survey, then this would indicate 921 dentate elderly (approximately 4.5%) were taking medicines with prolonged oral clearance regularly and long-term. From the Prescribed Medicines Prevalence Survey, 26% of the prescribing instances were for sugars-containing medicines,

increasing the risk of dental caries in these patients. However when generic prescribing and dose form was considered, the risk was greater, with 80.6% of prescribing instances for generic liquid oral medicines being sugars-containing.

This aspect is of particular concern as more and more medicines are running out of patents and are being formulated by generic manufacturers. If reformulation of these medicines with acidogenic sweetening agents is permitted and the pressure on general medical practitioners to prescribe generically continues, then patients taking these medicines regularly and long-term may be at increased risk. Generic manufacturers are not bound legally to produce sugars-free medicines, in fact, as long as the medicine is bioequivalent, any 'inert' excipient can be included (Hobson & Fuller, 1987).

8.3.5 Generic and proprietary medicines

Generic prescribing, that is prescribing medicines by their chemical name, continues to increase in the UK, so that almost 60% of all medicines dispensed in 1997 were generics (Department of Health, 1998). This aspect of prescribing was explored further in the prevalence and prescription analysis surveys. Of the 143 medicines with prolonged oral clearance used regularly and long-term, 42 were generics which accounted for 144 different formulations manufactured by 27 different pharmaceutical companies. This had a great impact on dispensing as the formulation of medicine varied depending on who manufactured it and what the pharmacy stocked.

Data from the Prescribed Medicines Prevalence Survey showed that 52% of the prescribing instances were for generic medicines. Even proprietary medicines not available as generics were being prescribed generically as was the case for ispaghula husk sachets which were prescribed generically 33% of the time. This rate is slightly lower than average rate of generic prescribing in England and the Northern Region which currently stands at 60% and 67%, respectively (Department of Health, 1998). This lower rate of generic prescribing may be partly due to the fact that of the 143 medicines with prolonged oral clearance many were proprietary gastrointestinal medicines (antacids). Although these medicines have been on the market for many years, there is no direct generic equivalent for them due to their complex mixture of ingredients.

All OTC preparations with prolonged oral clearance identified during the setting up of the OTC database were proprietary preparations, however, OTC generic medicines with prolonged oral clearance are being developed. A number of solid dose OTC generics have been on the market for a few years and recently medicines such as paracetamol suspension have started to be marketed and sold as OTC generics. This production commenced after action by pharmaceutical manufacturers in response to large non-pharmacy supermarkets insisting on breaking Resale Price Maintenance (RPM) rules. These rules state that all OTC medicines should be price-fixed to discourage competition over pharmaceuticals between pharmacies and other retail outlets. The supermarkets disagreed with this and arranged for their 'own brand' generic OTC medicines to overcome this price fixing. This move has raised the public profile of generic manufacturers. Previously, in the dispensing process the manufacturer of the generic formulation was normally not identifiable from the prescription dispensed to the patient, which is usually dispensed in a brown bottle from a large dispensing pack. The European Community is urging pharmaceutical manufacturers to introduce prepackaged patient packs containing one months supply of a medicine where the manufacturer will be clearly identified. As the generic manufacturer is more clearly identifiable as a result of these changes, they may be forced to formulate more dental 'friendly' products if the consumer demands it.

8.3.6 Prescribing of medicines with prolonged oral clearance

The two prevalence surveys have shown that the prevalence of use of prolonged oral clearance medicines in the elderly, especially generic medicines may pose a threat to dental health of dentate elderly.

The greatest threat is from generically prescribed liquid oral medicines, the majority of which were sugars-containing. The main therapeutic areas of use of these generic liquids were for gastrointestinal problems and in particular laxatives. This aspect of use should become a focus for dental health promotion in the elderly. Rather than going through the costly process of reformulating the medicine, rational prescribing may improve the situation, such as reducing the use of laxatives by ensuring the patient is given good dietary advice and avoiding taking medicines that cause constipation where possible. Where laxatives are used, their prescribing could be monitored to restrict them to short-term use.

8.4 IMPLICATIONS AND RECOMMENDATIONS

The results of the surveys presented here have a number of implications as far as prolonged oral clearance medicines and their use in the elderly is concerned. These can be most comprehensively discussed as they affect the professional bodies concerned.

8.4.1 For government

Tougher legislation by government with regard to the manufacture of generic medicines is required in terms of regulation of the incorporation of sugars in medicines destined for long-term use. There is also a need for generic manufacturers to compile accurate drug information with regard to the sugars content of medicines which is readily available for professional use. This would show commitment to cost-effective, efficacious drug therapies and to dental health. Sugars contained in a preparation should no longer be treated as inert ingredients but rather as active substances which can cause dental caries.

The government could possibly influence the use of sugars-free medicines in a number of ways. It could offer general medical practitioners inducements to prescribe sugars-free, reimburse pharmacists the difference in price for dispensing sugars-free, or it could help generic manufacturers by subsidising the production of sugars-free medicines.

8.4.2 For manufacturers

Pharmaceutical manufacturers have a central role in the issue of medicines and dental health: they need to ensure that all new medicines with prolonged oral clearance are available sugars-free especially if the data sheet indicates possible long-term use. Secondly, there is a need to continue the reformulation of older sugars-containing prolonged oral clearance medicines as sugars-free and phase out the production of sugars-containing medicines. This might be achieved through the development of alternative dose forms which are more readily formulated with an alternative sweetener. This move from sugars-containing to sugars-free formulations has been seen in the actions of manufacturers of proprietary medicines but generic companies have been slow to follow. The main reason appears to be cost as in the competitive market place companies are continually trying to reduce overheads to offer the cheapest products.

Progression to sugars-free from sugars-containing medicines with prolonged oral clearance is not a simple process and there many issues to be considered. Sucrose has a number of properties which make it an ideal excipient in the production of pharmaceuticals. It has a preservative

action, good bulking properties and prevents crystallisation in liquids. In addition there are certain problem areas with regard to the manufacture of sugars-free medicines with prolonged oral clearance. Firstly, manufacturers have not always been aware of which POC medicines are prescribed long-term. Secondly, it has been proprietary pharmaceutical manufacturers who have made the most progress in moves to provide sugars-free medicines with alternative sweetening agents. In contrast, generic manufacturers, by trying to produce the cheapest drug available have not been able to provide prescribers and dispensers with suitable range of sugars-free alternatives. This difficulty has been due partly to the discrepancy between the costs of using EC subsidised sugars-based sweetening agents rather than more expensive alternative sweetening agents which are the non-subsidised (Bonds & Fields, 1991). Governments' failure to provide incentives to make necessary regulatory changes have compounded the problem as old habits die hard and manufacturers are reluctant to replace best sellers with new products where there would appear to be no demand. Some newer dosage forms such as effervescent tablets have been introduced to replace the more traditional liquid oral medicines in recent years. Their longer shelf life and reduced bulk provide many advantages over liquid oral medicines. However, with some of these alternative dose forms a potential new risk to dental health has emerged due to the high acid content of some of these products. This threat may put dentate individuals who need regular and long-term medication at risk from dental erosion.

8.4.3 For prescribers

The prescribing of medicines with prolonged oral clearance is ultimately the responsibility of the general medical practitioner (who may be acting on the recommendations of a consultant). However, the nature of the formulation received by the patient in terms of its sugars content is controlled by a number of organisations and professions all of whom have an integral responsibility to the patient to ensure that they receive a medicine which is safe and effective. Prescribers of medicines are under pressure to control their drug budgets tightly and therefore the present degree of use of generic medicines is unlikely to decrease. However, prescribers should be aware of the risks to dental health posed by the long-term use of liquid oral medication, and consider the following points when prescribing to the elderly:

1. Where possible, the elderly should be prescribed solid dosage forms.

2. Where a medicine with prolonged oral clearance is necessary long-term, if available a sugars-free equivalent should be used.

3. Specificity when prescribing long-term is crucial; failure to state 'sugars-free' when prescribing generically may result in a sugars-based preparation being dispensed where an equivalent sugars-free proprietary form is available. Computer systems in general medical practices could be programmed to automatically place the words 'sugars-free' every time a medicine with prolonged oral clearance is prescribed.

4. Dentate patients taking a medicine with prolonged oral clearance which is sugars-based should be encouraged to brush their teeth using a fluoride toothpaste after taking the medication, providing the medication is not highly acidic. They should attend for regular dental care to ensure that comprehensive dental preventive measures can be undertaken as an adjunct to medical management.

Since the majority of prescriptions for medicine with prolonged oral clearance used regularly and long-term in the elderly are provided by general medical practitioners, with or without the advice of hospital physicians, practical information and support regarding the use of sugars-free alternatives, especially in long-term therapy, should be provided by the medical, dental and pharmacy professions.

8.4.4 For dispensers

If a medicine is prescribed generically without 'sugars-free' being specified on the prescription the pharmacist can decide which preparation to dispense and can choose a sugars-free or sugars-containing preparation. As pharmacies are businesses and sugars-free preparations are usually more expensive than sugars-containing, then the pharmacist may opt to give sugars-containing. Pharmacists may also dispense sugars-containing preparations if they fail to understand about sugars-containing medicines with prolonged oral clearance and the risk to dental health. However, studies have shown a reasonable level of knowledge and awareness of the sugars-free option amongst pharmacists (Maguire *et al.*, 1999).

Most community pharmacies now keep patient medication records and are encouraged to do so by the Pharmaceutical Society by Great Britain, which through the Pharmacy Services Negotiating Committee offer remuneration for offering this service (Royal Pharmaceutical Society of Great Britain, 1998). In addition, a pick-up service from general medical practices for repeat prescriptions which has been recently introduced will ensure that a particular pharmacy will dispense for the same patient all the time. In this situation the pharmacist has the opportunity to

identify sugars-based medicines with prolonged oral clearance and provide advice with regard to suitably equivalent solid dose forms or sugars-free alternatives. However, unless pharmacists are aware of the potential they have to monitor and intervene in the dispensing of sugars-containing medicines with prolonged oral clearance the situation is unlikely to change. Repeat prescriptions are a particular problem; they could be treated separately and a special payment made to encourage pharmacists to optimise sugars-free dispensing, allowing the pharmacist full reimbursement for providing a sugars-free proprietary equivalent to a medicine generically prescribed, if the medicine was for long-term use. In addition, pharmacists should be encouraged to 'persuade' prescribers to use sugars-free medicines where possible and even contact the prescriber if they identify a problem. This need only be in the short-term until the generic manufacturers were able to produce more sugars-free alternatives. The use of 'over the counter' (OTC) medicines with prolonged oral clearance is an opportunity for pharmacists to provide advice to consumers regarding sugars-free medicines. Many of these OTC products are taken on a regular basis (e.g. cough medicines and analgesics) subjecting a significant proportion of the purchasing population to an increased sugar intake. The elderly users, and carers administering these medicines may not be aware of this source of sugar and maybe unaware of the increased risk of dental disease.

Pharmacists could request more information from manufacturers regarding the constituents of medicines, and act as an informed source to advise medical practitioners on the sugars content of products. The National Pharmaceutical Association has not updated its newsletter on sugars content of liquid medicines since December 1995 (Personal Communication, NPA Information Department, 1998) and this information is no longer current as many medicines have since been formulated as generics.

A national database, perhaps maintained by the Department of Health, which included information on the sugars-content of all medicines with prolonged oral clearance and was updated regularly, by perhaps electronic links to pharmaceutical companies, should be available to all health professionals. Such a database could be made available on-line over the Internet to allow easy access by the relevant professions.

8.4.5 For health promoters

Health promotion in the UK involves the health promotion departments of the health authorities, pharmacies, general medical practices, dental practices and hospitals. Health

promoters need the proper resources and information on the risks associated with sugars-containing medicines, the types of medicines involved and the advice to give in order to work effectively. A team approach is needed to dealing with this issue, involving all health professionals and health promotion teams. Their main target group is the consumer whose knowledge and attitude must be changed. Patients must be educated on the potential risk and what they might do to minimise risk. If patients start to demand sugars-free medicines then the health professions and manufacturers will have to listen.

8.4.6 For the consumer

The outcome of health care issues is influenced considerably by consumers whether they be patients, purchasers or carers. They can however only act on existing knowledge and raising their level of awareness with regard the forms of medication available must be the initial step. The targeting of specific groups such as carers of the chronically ill elderly would concentrate these efforts more effectively. Patients rely on health professionals for advice and may look to pharmacists, general medical practitioners and dentists for information on the risks to dental health from sugars-containing pharmaceuticals. Patient groups such as the Consumers Association may also have a role to play, seeking information from the relevant health professionals and relaying this to the patient. Existing attitudes are often hard to change and it may be difficult to persuade an elderly person who lacks understanding on the risks associated with sugars-containing medicines to actively ask for sugars-free medicines. Many of the comments made on the questionnaires returned by the elderly in the OTC Medicines Prevalence Survey, showed that the elderly were not aware that sugars-free medicines were available nor were they aware of any problems associated with sugars-containing medicines.

8.5 FURTHER WORK

The research in this study has concentrated on the elderly aged 60 years and over. Future work is needed to assess that 16 to 60 year olds are not at risk from sugars-containing medicines with prolonged oral clearance.

Another area of interest is the use of effervescent tablets which form an acidic solution upon dissolution and may contribute towards dental erosion. Future work is required to assess the risk of these medicines to dental health and the prevalence of their use, especially in light of the

increase in the use of medicines such as aspirin 75mg effervescent tablets for prevention of coronary heart disease.

The increase in the use of generic 'over the counter' medicines should be investigated to monitor their formulation with regard to sugars content. It is important that they do not follow the path of prescribed generics being formulated as sugars-containing medicines.

The increasing number of generic formulations and the rapid change of ownership of generic manufacturers introduces continual change in the generic market and the sugars content of formulations of medicines with prolonged oral clearance should be monitored. A database of these medicines should be devised, perhaps using a database similar to the one created in this study and this should be kept current. With advances in information technology and the internet, this database could be made available to all relevant professionals and provide up to date information on all medicines with prolonged oral clearance.

Research into the change in patterns of use of sugars-free medicines with prolonged oral clearance in the elderly and other groups of the population should be ongoing, to record and monitor progress, in the quest for optimal dental health.

CHAPTER 9

CONCLUSIONS

The study had one main aim and four subsidiary aims. Using two prevalence surveys and three surveys looking at overall use of medicines with prolonged oral clearance, these aims were addressed and the following conclusions can be drawn:

9.1. Main aim

- The prevalence of use of **prescribed** medicines with prolonged oral clearance used regularly and long-term by the elderly in ten practices in five districts of the Northern Region of England was 9.8%, representing 2002 patients aged ≥60 years who were taking 143 medicines with prolonged oral clearance 2796 times overall.

- The prevalence of use of **'over the counter'** (OTC) medicines with prolonged oral clearance in a sub-sample of patients in 10 practices in 5 districts of the Northern Region was 1.1% representing 17 patients aged ≥60 years taking 13 OTC medicines with prolonged oral clearance 17 times overall.

9.2. Subsidiary aims

9.2.1. Of the 2002 patients taking **prescribed** medicines with prolonged oral clearance regularly and long-term, 68% were female and 54% aged 60 to 74 years, and of the patients taking **OTC** medicines with prolonged oral clearance, 47% were female and 77% aged 60 to 74 years.

9.2.2. The main medical problems of patients taking **prescribed** medicines with prolonged oral clearance regularly and long-term and patients responding to the questionnaire in the **OTC** Medicines Prevalence Survey were cardiovascular and musculoskeletal. The main therapeutic areas for the **prescribed** medicines with prolonged oral clearance used regularly and long-term were Gastrointestinal, Cardiovascular and Central Nervous System. The main therapeutic areas for **OTC** medicines were Gastrointestinal and Nutrition and Blood.

9.2.3. In terms of sugar-content, 81% of the prescribing instances for **prescribed** generic liquid oral medicines were for sugars-containing medicines, compared with only 8% of the prescribing instances for proprietary liquid oral medicines (Prevalence Survey of prescribed medicines). Of all 909 prescribing instances for generic solids with prolonged oral clearance, 94% were sugars-free; 44% of 342 prescribing instances for proprietary prescribed POC solids. Of the 17 instances of regular and long-term use of OTC medicines with prolonged oral clearance, identified in the **OTC** Prevalence Survey, 41% were sugars-containing.

9.2.4. The volume of medicines with prolonged oral clearance **supplied** overall (in primary and secondary care) in the Northern Region was 0.73 million litres and 134.3 million solid doses of **prescribed** medicines with prolonged oral clearance and 0.11 million litres and 16.8 million solid doses or **OTC** medicines, over a one year period (1994).

9.2.5. Generic prescribing was substantial with 52% of the 2796 prescribing instances for medicines with prolonged oral clearance used regularly and long-term by the elderly, and 60% of all 2.51 million prescriptions dispensed for medicines potentially used regularly and long-term by the elderly in the Northern Region (in 1994) were generically prescribed. In terms of quantity, 41% of liquid oral medicines and 78% of solid doses with prolonged oral clearance and potentially used regularly and long-term by the elderly, dispensed in the Northern Region over a one year period (1994) was generically prescribed.

This study, through a series of surveys has shown that the elderly, of whom almost 50% were dentate, are taking medicines with prolonged oral clearance regularly and long-term, with prescribed medicine use being greater than OTC medicine use. These medicines with prolonged oral clearance, especially generically prescribed liquid oral medicines are likely to be sugars-containing and pose a threat to the dental health of these dentate elderly.

CHAPTER 10

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