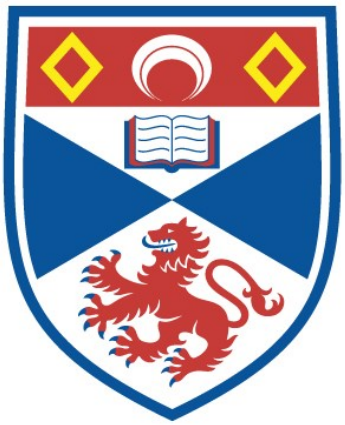
THE USE OF CLAIMS DATABASES IN PHARMACOECONOMICS RESEARCH : THE CASE OF DIVERSIFIED PRESCRIPTION SERVICES AND OTITIS MEDIA

Philip Booth

A Thesis Submitted for the Degree of PhD
at the
University of St Andrews



1999

The use of claims databases in pharmacoeconomics research:

the case of Diversified Prescription Services and otitis media.

M.Phil Dissertation, May 1999.
Supervisor: Prof. M. Malek.
Philip Booth

ProQuest LLC.
789 East Eisenhower Parkway
P.O. Box 1346
Ann Arbor, MI 48106 – 1346

List of contents

8. List of tables

9. Appendix I - costs associated with the treatment of otitis media episodes.

10. Appendix II - statistical analyses members with otitis media

11. Appendix III - statistical analyses- episodes of otitis media

12. Appendix IV - represcribing

13. Appendix V - Costs associated with treatment of chronic otitis media by assignment definition

Acknowledgements

I would like to thank Prof. M. Malek for the support he has given me in writing this dissertation but that simply wouldn't be enough! He has been by constant mentor for nine years, so far, and has never failed to provide me with the support and advice I have needed in both my academic and professional life.

I am for ever in his debt.

1. Introduction

This dissertation will examine the potential for using health claims databases in the economic evaluation of medicines. We examine the background and development of these 'new' sources of information and, taking a case study for a particular disease area, give an example of how the data can be used to perform an initial economic evaluation and inform the types of decisions health economists in the pharmaceutical industry routinely take.

1.1 The use of health economics in the pharmaceutical industry

In the face of steadily rising healthcare costs, countries throughout the world are struggling to reform their healthcare systems. Many of the reforms aim to control the use of technology either by limiting access or indirectly controlling prices. Despite being a small fraction of all healthcare spending, pharmaceuticals have not escaped the scrutiny of these reform efforts. Many governments see the rising price of drugs as a major problem, especially since the elderly population, which is increasing, represents the largest population segment for pharmaceutical consumption. World-wide efforts to control healthcare costs have led to an examination of the allocation of resources, with a focus on demonstrating cost-effectiveness as well as therapeutic value. To succeed, new drugs increasingly have to demonstrate they represent a more efficient use of scarce healthcare resources.

The randomised controlled trial has traditionally been employed as the vehicle for measuring treatment effects and are now routinely used to collect 'piggy-back' health economic data in order to display a product's 'value'. The justification for this lies in the fact that phase III trials, in particular, provide an opportunity for generating an **early** economic profile of a specific medicine. While being a valid argument, the issue remains that the RCT is necessarily concerned with *internal validity* (isolating the relationship between the cause and effect of a medicine) than *external validity* (generalisability to the wider population). The societal and population perspective, traditionally adopted by health economics, makes the latter aspect the most relevant and increases the need to identify data sources and methods that will allow generalisability to be improved. One such avenue may be the numerous health insurance claims databases found in the US.

1.2 The development of managed care, HMOs, PBMs and insurance databases

In the broadest sense of the phrase, managed care can embrace any form of monitoring or control of healthcare provision and/or financing which leads to action being taken to improve the situation. It is generally understood that 'improving the situation' means improvements from the payers point of view i.e. getting the same or better healthcare for reduced costs, better value for money (Rubens 1984). However, it is not uncommon for the phrase 'managed care' to be associated only with specific parts of the healthcare system. In particular, managed care is frequently taken to mean Health Maintenance Organisations (HMOs) and Preferred Provider Organisations (PPOs), which play a

prominent role in controlling costs, or to refer to specific tolls used by managed care operators such as formularies and drug utilisation reviews.

The definition given to managed care depends to a large extent upon the context and standpoint from which it is given. Therefore, as is to be expected from such a wide subject area opinions vary as to it's precise meaning.

Managed care is a phenomenon that is currently unique to the United States. Managed care covers all forms of healthcare provision in which some attempt is made to control the costs incurred, in contrast to indemnity insurance which has traditionally left the choice of healthcare to the individual and reimbursed claims for any treatment covered by that individual's insurance policy without involving providers or questioning the cost.

The wave of growth of managed care organisations in the US began at the beginning of the 1980s when escalating healthcare costs first caused employers to look seriously at alternative means of financing their employees healthcare. The number of plans offered began to escalate in line with the employers demands resulting in the development of a number of variations of managed care, each placing emphasis on a different aspect of the healthcare chain (Hudson 1989). For example, some plans emphasise the cost of healthcare per se, while others stress the importance of retaining customer choice or of the role played by preventative medicine in effective use of healthcare facilities. Hudson (1989) believes the three key reasons behind the successful growth of the managed care

sector in the last decade, and the evolution of healthcare plans into the form now familiar in US today are that:

1. many consumers and payers have been forced to put economic considerations ahead of freedom of choice as healthcare costs escalate.

2. in line with this switch in priorities, the medical profession has seen a decline in it's political and economic power and, as a result, has had to become more flexible in the services it provides.

3. the existence of a large number of newly qualified doctors has made recruiting of physicians by managed care organisations much easier, encouraging new start ups which would not previously feasible.

Managed care operates on a regional basis across the US which has led to the emergence of a very large number of managed care plans being offered to consumers in total. Most plans cover a well-defined geographical area, frequently centred on one city and rarely crossing state borders. However, the number of companies operating these numerous plans is comparatively small. Most operators offer a wide range of plans, either covering a number of geographic regions, or giving consumers within one or two areas a greater choice of the type of healthcare plan they opt for. This situation has arisen around the demands of employers who are the principal customers of managed care companies. In line with the switch in employers attention from traditional indemnity insurance to other

more effective means of healthcare financing, two important requirements which had to be accommodated were (Johnson 1991):

1. their desire to offer employees a choice of healthcare plan without needing to deal with a large number of managed care operators to achieve this, and

2. the need for large employers to offer cover to workers in many states, again without needing to deal with too many separate operators.

The companies now fulfilling these needs have origins in three sectors of the economy. Firstly, traditional indemnity insurers have adapted the services they offer to encompass managed care plans as a means of holding on top their existing customer base; secondly, the hospital sector has taken an active role in developing managed care, also as a means of competing for customers as consumers and payers become more demanding and discerning; and, thirdly, many new operators have entered the managed care arena attracted by the business opportunities becoming available in a traditionally non-competitive environment and by the support given to this type of healthcare provision by successive US governments. The diversity is illustrated by the composition of the top 10 players in the managed care industry in the US in 1993:

1. Kaiser Foundation Health Plans Inc. Private non-profit HMO, 12 plans offered.
2. Blue Cross and Blue Shield System. Non-profit insurance, 76 plans offered.
3. US Healthcare Inc.. Public, for profit HMO, 8 plans offered.

4. Prudential Health Care Inc. Mutual, for profit insurance, 29 plans offered.

5. CIGNA Healthcare Plans Inc. For-profit insurance, 45 plans offered.

6. United Healthcare Corp.. Public, for profit HMO, 18 plans offered.

7. Health insurance Plan of NY. Private, non-profit HMO, 3 plans offered.

8. Aetna Health Plans. For profit insurance, 25 plans offered.

9. Humana Inc. Investor owned healthcare company, 18 plans offered

10. PacificCare Health Systems Inc. Public, for profit HMO, 5 plans offered.

(Pharmamarkets report, 1991)

Characteristics common to a large number of managed care operators include the following:

1. operation on a state by state basis with marketing, finance, recruitment, etc. being undertaken centrally and the actual healthcare plans managed locally.

2. subsidiaries of one company will offer between them a variety of plans from indemnity insurance to HMOs and PPOs across a number of geographic areas.

3. customers are usually employers with contact with the general public.

4. separate HMOs, PPOs etc., have evolved to offer managed care plans to Medicare patients.

5. organisations frequently run by business professionals with no medical training.

6. centred around populated areas where there are sufficient healthcare providers for competition to exist and for contracts to be drawn up with a number of providers without limiting competition and shutting out individuals who do not subscribe to a specific plan.

7. operators have access to large amounts of healthcare outcomes and resource utilisation data.

Beyond these general characteristics, managed care plans and the companies operating them vary enormously depending upon the type of plan in question. it is important to understand the principal types of managed care plan offered and the characteristics of each in order to understand the US managed care market and resulting claims databases.

1.2.1 Health Maintenance Organisations (HMOs)

HMOs are currently the most popular type of managed care in the US and are second overall after traditional indemnity insurance plans (Promark report 1991). There were 575 HMOs in existence by the end of 1992 covering approximately 41.1 million lives or 16% of the US population. They also accounted for half of all plans offered by employers to their workforce.

Most HMOs encompass the following criteria in the administration of their plans

1. use of cost conscious providers
2. use of monitoring data to record healthcare utilisation

3. requirement that providers accept a share of the financial risk involved in healthcare provision (usually incorporating capitation agreements).

4. HMO must generate a significant proportion of each providers business if the plan is to effectively influence his prescribing habits.

5. the greater the market share held by an HMO the greater will be that plans ability to recruit new providers to its network.

There are five basic models of HMO distinguished primarily by the relationship between the HMO and the participating physicians (Healthscope report 1998). They are:

1. Staff Model HMO

The HMO employs all the physicians and providers who provide care for plan members and invests its own capital in provision of healthcare facilities in which the physicians operate. Practitioners receive an annual salary plus performance related bonus paid by the HMO and are limited to treating patients enrolled with their HMO.

2. Individual Practice Model

The HMO negotiates contracts with individual physicians over a wide geographic area; these physicians are not employed by the HMO and treat patients in their own independent surgeries. Payment is normally on a fee for service basis for each plan member treated or sometimes fee per patient; physicians can sign contracts with as many HMOs as they please.

3. IPA Model HMO

Independent Practice Association model. This is very similar to the Individual Practice Model with the exception that the HMO negotiates contracts with associations representing individual practices, who in turn negotiate contracts with their individual physician members. As above, payment is on a fee for service basis; physicians in this model are free to sign contracts with as many different HMOs as they please.

4. Group Model HMO

The HMO negotiates a contract with one large multi-speciality medical group practice which must accept provider risk sharing via payment of a capitated monthly fee (i.e. fixed monthly fee for each HMO enrolee regardless of the treatment actually given). Physicians can work for more than HMO.

5. This is the same as Group model HMO with the exception that the HMO contracts with a number of group practices rather than one large medical provider conglomerate. Payment is still on a capitated basis. Physicians can work for more than one HMO.

A survey carried out by the Congressional Budget Office (1992) calculated that HMOs reduce healthcare usage by 7% compared to unmanaged care and by 4% to fee for service care (which is categorised as partially managed care since many fee for service physicians make use of certain features of managed care such as utilisation reviews, to improve the efficiency of their practices). However, this improvement only applies to staff model

HMO. IPA model plans appear to achieve savings of only 3% and 1% respectively over unmanaged and fee for service care.

Staff model costs have been proven to be the most effective in controlling healthcare costs due to certain features (Promark 1991) inherent in their structure which enables the operating company to keep tighter control of the activities of healthcare providers as well as members. Such features that are unique to staff based models are:

- the ability to regulate the supply of physicians and hospital beds according to the size of the population served (achievable since healthcare providers are employees of the managed care company and company's own capital is invested in the provision of healthcare facilities).
- enforcement of the HMO's formulary is easier as all prescribers are employed by the HMO.
- physicians loyal to one plan have an incentive to follow more efficient prescribing practices since they will reap the benefits themselves in the form of bonus payments and lower premiums offered leading to a larger client base; in the same way, plan managers have an incentive to devise more efficient prescribing patterns will not be passed on to competitors as is frequently the case with more open models.

However, from the consumer's point of view the feature of HMOs which distinguishes them from other forms of managed care is the restrictions they place on consumer choice. In general, upon joining an HMO plan, consumers agree to obtain all their healthcare from physicians, hospital and specialists affiliated to that particular plan. Physicians are

seen as gatekeepers since access to other healthcare providers can occur only on their recommendation.

From a consumer's perspective, within the HMO sector there is a choice between two types of plan (Lowe 1992). The first is a fully insured plan which offers comprehensive medical coverage in exchange for a fixed monthly premium set in advance and not related to the amount of care actually used. Lower premiums can often be obtained in exchange for acceptance of a higher co-payment rate in the event of care being required. Hospital care requires a referral from the primary care physician chosen by the enrolled member, except in emergency cases and is also carried out in hospitals contracted to work for the HMO in question.

The second is an out of network plan (or open ended plan). This is a hybrid plan which combines the freedom of choice available through traditional fee for service indemnity insurance with the cost control of HMOs and operates in the same way as a fully insured plan but with the option to choose hospital and specialist care from providers outside the HMOs contracted network.

1.2.2 Preferred Provider Organisations (PPOs)

PPOs are the second most popular form of managed care after HMOs. They have been described as "remnants of the fee for service world" since they do not have the authority to accept financial risk for healthcare provision and do not have their own network of

physicians. Rather they collect an administrative fee to act as go between for consumers and healthcare providers. Physicians are paid according to a negotiated fee schedule for each patient treated, not on a capitated basis.

Providers agree a discount with PPO administrators in return for which PPOs will encourage their members to use these physicians. This is achieved by offering better premiums and/or lower co-payments to those consumers who obtain their healthcare from these preferred providers. The main reason for choosing a PPO in preference to an HMO is the fact that it enables consumers to retain an element of choice in respect to their healthcare provider. This is an important factor for many Americans who have become used to complete freedom with respect to choosing their physician.

Like HMOs, PPOs achieve cost savings through use of formularies and encouragement of cost-effective prescribing practices. However, They do not have the benefit of a high degree of control over the physicians working under their plan which increases the difficulty in enforcing such measures. A significant number of PPOs have recently applied to obtain a licence to allow them to assume some of the financial risk involved in healthcare provision. This would take the form of capitated arrangements with a number of physicians, though they would remain differentiated from HMOs since they would not have any restrictive control over the preferred providers listed by their plan and by virtue of offering consumers a choice of physician (in return for financial forfeit).

1.2.3 Exclusive Provider Organisations (EPOs)

These managed care plans fall halfway between PPOs and HMOs since they offer the same terms to physicians as PPOs in return for the same service but, like HMOs, they require their members to obtain their healthcare from the physicians listed by the plan (i.e. from the 'exclusive providers').

Despite a rapid initial growth in this type of plan, the penetration of EPOs is unlikely to increase at the same rate as HMOs and PPOs since it reduces consumer choice without having the means to control costs very rigidly. EPOs do not, therefore, offer a significant improvement over services which are already available through other organisations.

1.2.4. Physician Hospital Organisations (PHOs)

This type of organisation has arisen recently as healthcare providers see the need to become involved healthcare on a business level as well in a medical context. Physicians have progressed from entering managed care as a means of minimising losses to taking a proactive approach to this sphere of activity; a consequence of this shift in attitude has been the emergence of Physician Hospital Organisations. Alliances between HMOs and PHOs are rapidly increasing and this type of organisation is quickly assuming an important role within the managed care sector (personal communication 1998).

These organisations take the form of joint ventures created by physicians or hospital managers principally for the purpose of negotiating capitation agreements with HMOs. The agreements drawn up usually require a PHO to treat all (or a specified number of) an HMO's patients in respect of a certain disease or group of diseases in return for a fixed fee. The physicians' motive in setting up these organisations is that, once an agreement has been signed, the PHO concerned has effectively reduced competition for patients and has a guaranteed source of patients from each HMO with which it is contract. The benefit to patients is that, by virtue of the capitation agreement negotiated between their HMO and the healthcare providers, care can be provided more cheaply than it would normally be, thus helping to keep premiums down.

1.2.5 Point of Service Plans (POS Plans)

This recent development represents a further fragmentation of the managed care market since the aim of POS plans is also to provide a service which falls midway between HMOs and PPOs i.e. between rigorous cost-containment and complete freedom of choice. Point of service plans use a network of contracted providers from which enrolled members select a primary care physician to meet their healthcare needs. This physician also acts as a gatekeeper to control specialist services and hospital referrals. Care from a network provider is free to the patient at the point of service. However, unlike most HMOs care is also available from other physicians; for care of this nature the enrollee must pay at the point of service and is partially reimbursed at a later date. Financial incentives exist for physicians to refer enrollees to network specialists and other

providers, since use of network providers is the principal means of controlling costs through monitoring programmes and agreed discounts.

The benefits to consumers of these new point-of-service plans are:

- they offer consumers the freedom to change providers without changing their healthcare plan
- plan managers are able to extend their provider networks without being forced to make expensive investments (which many HMOs are likely to incur since their networks are often expanded by increasing the number of physicians employed by the plan).
- they are in a strong position are in a strong position to draw in more enrollees since they combine familiar indemnity services with many of the benefits of an HMO.

From the above examples it is clear that there is a strong correlation between the degree of control which is a managed care managed company has over healthcare providers and it's ability to control healthcare costs.

In addition to the plan operators described above, there are other players within the managed care environment who offer additional services to employers and consumers to ease the burden of their healthcare expenses. One of these are Pharmacy Benefit Managers who play a crucial role in the source of data for this analysis.

1.2.6 Pharmacy Benefit Management Companies (PBMs)

PBMs have received significant attention following the acquisition of the three largest by Merck and Co., SmithKline Beecham and Eli Lilley. This type of company is often a subsidiary of broader managed care organisations and it's role is to take the expertise gained from involvement with managed care plans and market that knowledge to HMOs, PPOs, third party administrators, self-insured employers etc., to advise them on how best to contain their prescription drug costs. PBMs in the US now cover approximately five times more patients than at the beginning of the decade.

In effect, PBMs act as consultants to healthcare providers and plan managers advising them on how to best reduce their pharmacy costs. As such, they add another layer of administration between drug manufacturers and plan managers/healthcare providers since their role includes purchasing pharmaceutical products from manufacturers on behalf of their own customers and their money is made by charging customers management fees in return for their services.

However, PBMs are in a strong position to oust traditional wholesalers and other distributors since their unique advantage is that they also encompass a wide range of cost-effectiveness techniques such as drug utilisation reviews and drug effectiveness comparisons, strict formulary management, outcomes analysis, generic substitution and emphasis on preventative medicine.

1.2.7 United Health Care, SmithKline Beecham and DPS

In May 1994 SmithKline Beecham announced it's $2.3 billion acquisition of DPS from United Healthcare, together with a minimum six year alliance with United, through which SB had exclusive rights to data on United's 1.6 million members.

DPS directly manages pharmaceutical benefits for 11 million people, placing it in third position after it's two main competitors, PCS (51 million) and Medco (33 million). SB intended to use the patient data to conduct outcome studies and develop disease management programmes. United was to continue to use the services of DPS for all it's HMOs.

DPS was founded in 1976 and incorporated 1n 1988, achieving sales of $142 million in 1993 (up from $43 million in 1992) with operating income of $39.9 million. It has been one of the fastest growing PBMs and is one of the largest , being used by around 300,000 physicians. It has a network of over 30,000 pharmacies, both chains and independents, representing over third of the US total. DPS claims to have been the first PBM to:

- develop formularies in open panel healthcare system HMOs.
- introduce mandatory generic drug programmes.
- install point-of-sale claims processing.
- create manufacturer volume purchase programmes for managed care.
- undertake drug outcome studies.

- introduce a national drug formula for self funded employers.

The SB deal differed in that it also included the tie-up with an HMO, bringing additional benefits, most notably, the exclusive right to supply PBM services to United's current and any of it's future owned HMOs. United was negotiating to acquire two additional non-staff model HMOs and indicated that it would use the proceeds of the DPS sale to fund an expansion programme.

SB highlighted (Pharmabusiness Report 1994) two key factors in determining the choice of DPS as a partner:

- the high proportion of HMO enrollees within it's formulary lives - whereas Medco and PCS (rival PBMs) are more directed towards employee health schemes, HMO lives represent 61% of DPS total coverage.
- it's experience of full capitation. As a result of it's United parentage, DPS has extensive experience of capitation.

1.3 Cost efficiency mechanisms and the emergence of health care data.

In order to control healthcare costs, managed care companies and Pharmacy Benefit Managers use a range of techniques centred around:

- the collection and interpretation of patient and product information to enable plan managers to implement more efficient health care polices

- financial tools generally aimed at getting the maximum amount of healthcare for a predetermined price.

The first of these particularly focuses on the drug utilisation review and provides a hint to the potential use of routinely collected data in health economics. DUR is an essential tool for managed care companies. They are achieved through the maintenance of complex databases of patient and product information which is then used to analyse and compare the cost-effectiveness compared to hospital treatment and to encourage prescribers and other healthcare providers to use the therapy which represents the best overall value for money in the long term.

There are three time frames which govern DUR techniques each of which can be used in isolation, but which together give managed care operators a very detailed picture of the impact an outcomes of the services they provide (Albern 1990).

Prospective DUR: occurs before the prescription is written and operates by profiling physicians who do not adhere to formularies and informing them of how to change their prescribing habits.

Concurrent DUR: occurs after the prescription is written but before it is dispensed by picking out 'outlying; drugs.

Retrospective DUR: occurs over a period of time after the prescription has been dispensed. This fits best with economic evaluation and involves a complex review of all aspects of the products usage including effectiveness in each patient, dosage required to produce results, min-max. dosage taken, degree of compliance etc. to be used for comparative studies and cost effectiveness.

DUR is carried out by a number of parties. In some instances HMOs collect their own data and have dedicated employees or even separate subsidiaries whose role is to carry out analyses, to telephone physicians where necessary and to draw up strategies for the future with respect to the company's approach to cost effective healthcare provision.

Some HMOs store their own data and carry out in-house analysis but then use their network pharmacists to interact with the physicians in their locality to increase compliance with the plan's objectives.

The explosion in the computerisation of health care data therefore stems from the original concept of tracking charge data within the accounting systems of healthcare institutions and providers, predominantly in the US, through to complete reviews of the costs and effects of prescribing decisions. Where as once we would have had to sort through medical records manually, we can now routinely access the same data, through computerised records, at apparently low cost and inconvenience down to the patient level.

The advantages for this type of data

are clear and include:

- the size of the population contained in the databases relative to other forms of patient data e.g. clinical trials
- the ability to examine trends in resource use over time
- the ability to examine patterns of care and treatment pathways.
- assessments of the resource impact of new medicines

However, more importantly for health economics, the real life and population based nature of claims databases means it should be possible to generate information with a high degree of external validity.

Despite the dramatic growth in this type of data, and potential for increasing the external validity of health economic studies, the applicability of it to health economics (in the pharmaceutical industry) has yet to be explored.

1.4 Hypotheses to be tested.

This analysis seeks to test the following hypotheses.

Claims databases can provide accurate information on:

- prevalence and incidence of a disease.
- the type and level of services used in the management of a disease.
- what complications are caused by the disease

- determine how much a specific disease costs in a managed care setting.

- compare these findings with the available literature

To date, most work has only discussed the value of databases using qualitative assessments. This work aims to examine the type, and value, of data that can be extracted following an attempt at a quantitative evaluation. We will then explore the issues highlighted by this study on the use of databases in HE and suggest how/when this information could be used in developing an economic assessment of a medicine.

We have chosen to start this assessment by examining the case of otitis media in children using an analysis performed with claims data from the United Healthcare Corporation HMO health care plans. Specifically, and in relation to the generic objectives outlined above, the purpose of the UHC analysis was to determine:

1) the prevalence of otitis media in the study population for the period 07/01/92-06/30/94.

2) what health services and therapy options are employed in the diagnosis and treatment of otitis media.

3) what serious complications are present in this population as a result of chronic otitis media.

4) what are the costs associated with the diagnosis and treatment otitis media in a managed care setting.

5) what are the comparative costs of treatment of acute and chronic otitis media in a managed care setting.

6) what are the comparative costs of treatment of acute and chronic otitis media when the initial antibiotic used in amoxycillin vs. amoxycillin/clavulanate vs. cefaclor.

1.5 Acute otitis media

Otitis media is a common infection of infancy and early childhood, with a peak age-specific incidence between the ages of 6 and 18 months. By 3 years of age, approximately three quarters of children will have had at least one episode of acute otitis media, more than one third will have had recurrent infections defined as three or more episodes, with incidence decreasing significantly after 6 years of age (Klein 1994).

In accordance with it's high prevalence, otitis media accounts for a considerable proportion of health care costs. It is estimated that 25% of all prescriptions in the US are fort treatment with oral antibiotics for acute otitis media. The cost of managing the disease in the US has been estimated to exceed $3.5 billion (Graham 1994).

Otitis media may be cause of fever significant pain and hearing loss in children. There is also concern that associated hearing loss may adversely affect speech and language learning and also the development of cognitive abilities. Although there is little consensus regarding these issues, it can be argued that aggressive treatment can be justified because of the risk of long term impairment of communication skills.

The condition can be divided into four clinical classifications; without effusion, acute, with effusion, and chronic (Thoene 1991). Otitis media without effusion can occur in the early stages or during resolution of the acute disease and, depending on duration, can be acute, sub-acute or chronic. Acute otitis media applies specifically to the rapid onset of the signs and symptoms of inflammation of the middle ear. Otitis media with effusion refers to the presence of fluid in the middle ear and is differentiated from the acute form by the absence of the signs and symptoms of acute middle ear inflammation. The condition can be further classified according to the type of effusion (serous, mucoid or purulent) and it's duration; acute (less than 3 months) and chronic (symptoms greater than 3 months) (used for this analysis).

The middle ear consists of three principal structures; the tympanic membrane, auditory ossicles and eustachian tube. Acute otitis media in early childhood appears to be related in large part to eustachian tube dysfunction. The eustachian tube has at least three important physiological functions in preventing infection and accumulation of effusion in the middle ear; protection against nasopharyngeal sound pressure and secretions; drainage and clearance of middle ear secretions into the nasopharynx; and ventilation of the middle ear to equilibrate gas pressure and atmospheric pressure. Infants are predisposed to otitis media because their Eustachian tubes are shorter, wider and lie more horizontally than those of older children and because development of the muscles governing opening and closing of the tube is incomplete.

An acute episode of otitis media usually results from the following sequence of events (Thoene 1991); the patient has an antecedent condition (viral infection or allergic reaction) that results in congestion of the respiratory mucosa of the upper respiratory tract; congestion of the mucosa in the eustachian tube results in obstruction of the tube at its narrowest segment; the secretions of the middle ear mucosa have no egress and thus accumulate; and if pathogenic bacteria that colonise the nasopharynx are present in the middle ear secretions prior to obstruction, they multiply, and an acute suppurative infection results.

The course of otitis media with effusion is less apparent. Fluid persists for weeks to months after every episode of acute otitis media , even though appropriate anti-microbial therapy has sterilised the middle ear.

1.5.1 Bacteriology

Although otitis media is defined as inflammation rather than infection, the majority of cases involve bacteria. Since isolation of the causative organisms is not generally attempted in an office setting, it is important that clinicians be familiar with the most common infecting organisms in order to choose the most appropriate treatment regimen. Based on anatomy, it is not surprising that the most frequently isolated bacteria in middle ear fluid are the same as those found in the nasopharynx. Streptococcus pneumoniae is consistently reported as the most common organism in otitis media causing approximately 30-40% of all cases (Edelstein 1988, Bluestone 1988).Heamophilus

influenzae is the second most common bacterial pathogen and is isolated in 20% of cases. The percentage of H. influenzae strains that are resistant to ampicillin and amoxycillin is increasing and accounted for 30% of isolates in several clinical studies of children with otitis media (Michaels 1981, Wald 1984, Lim et al 1980). Another common organism that appears to be increasing in frequency as a cause of otitis media is Branhamella catarrhalis, which has been reported in 7-20% of isolates cultured from middle ear effusions (Van Hare 1987, Shurin 1987). Streptococcus pyogenes and Staphylococcus aureus are also isolated from middle ear effusions in otitis media, but with a frequency of less than 10% (Witt 1988).

1.5.2 Management of otitis media

Complications resulting from acute otitis media such as menigititis and mastoiditis currently occur in less than 1% of cases (Marchant 1983). Other possible complications include perforation of the tympanic membrane, tympanic membrane scarring, ossicular discontinuity, facial paralysis and hearing loss (Roberts 1989, Tos 1988). In addition, recurrent episodes may lead to speech impairment and learning difficulties in small children (Brooks 1980, Menyuk 1980). Therefore, the primary role of antibiotic therapy in the management of otitis media is to prevent possible complications and provide symptomatic relief. The four key antibacterial agents used in the management of otitis media are presented below.

Ampicillin: this was at one time the most commonly prescribed antibiotic for otitis media and was considered the antibiotic of choice (Michaels 1981, Howie 1972, Jones 1974, Feder 1982), although this in longer the case due to it's limited spectrum of activity for example, H. influenzae (Thoene 1991). As a consequence, this was not included in the analysis as a distinct antibacterial grouping.

Amoxycillin: has the same antibacterial spectrum as ampicillin but differs in that it is better absorbed from the gastrointestinal tract. Therefore, a major advantage of amoxycillin over ampicillin is that it causes fewer gastrointestinal adverse reactions (Marchant 1983, Feder 1982). IN areas where the emergence of H. influenzae and B. catarrhalis is limited, amoxycillin remains the drug of choice for empiric therapy.

Amoxycillin-clavulanate: is an oral antibacterial combination consisting of the antibiotic amoxycillin and the B lactamase inhibitor potassium clavulanate. This widens the spectrum of activity to include B lactamase producing organisms such as H. Influenzae and B catarrhalis. Therefore, amoxycillin tends to be used for 'amoxycillin failures' or in areas where B-lactamase producing organisms are common (Klein 1994).

Cefaclor: a second generation cephalosporin effective against the common organisms implicated in acute otitis media (Eli Lilley 1988) although some strains of B lactamase producing B catarrhalis are resistant to cefaclor (Berman 1983). Frequently used in the same way as amoxycillin-clavulanate.

One frequently used non-antimicrobial therapy, employed in the management of otitis media are tympanostomy tubes. When a child with chronic otitis media fails to respond to pharmacological therapy or has documented hearing loss, a surgical opening of the tympanic membrane for the insertion of a ventilating tube (tympanostomy tube) may be indicated to equilibrate pressure and allow drainage of fluid from the middle ear. (Edelstein, 1988). Almost all chronic effusions are at least temporarily eliminated after this procedure (Bluestone, 1988). In 1994, this was the most common surgical procedure performed on children in the United States (Vogelgesang, 1984) with an estimated one million children having tympanostomy tubes inserted each year, at an annual cost of about $1 billion (Mandel, 1984)

2. Methods

The study was conducted using claims data for the period 07/01/92-06/30/94 from three UHC affiliated health plans. All three plans are independent practice association (IPA) plans providing coverage for physician, hospital and prescription drug services. The three plans were characterised as follows:

1) HMO 1 located in the Southeast with an approximate annual enrolment of 81,400.

2) HMO 2 located in the Northeast with an approximate annual enrolment of 175,700.

3) HMO 3 located in the midwest with an approximate annual enrolment of 99,000.

The combined approximate annual enrolment is 356,100.

2.1 Data sources

UHC's database includes member and provider enrolment information, physician, health facility and pharmacy claims. All files are linked by a member identification number which is assigned to the member by the health plan at the time of enrolment. A claim form containing information needed for identification procedures, supplies and specific drugs must be submitted in order for a health care provider to receive payment for any services provided to an enrolled member. It is these claims that provide the data elements for UHC's research database.

2.2 Claims identification

To initiate the study, the research database was searched for all otitis media claims (using ICD-9-CM diagnostic codes found in the ranges of 381., 382., and 385.1 - 385.19) occurring during the study time period of 07/01/92 - 06/30/94. A total of 156,832 claims were identified. Table 1 summarises the claims by file origination (either doctor or hospital) for four six month study periods by plan.

Eighty four percent of all claims for otitis media originated in doctor files. This is to be expected since otitis media is most often diagnosed and treated by physicians in an office based setting. The remaining sixteen percent of claims originated in hospital files either as a hospitalisation, an emergency room visit or an out patient clinic visit.

The claims were also examined by month of the year in which the claim originated. Figure 1 visually portrays the information. The claims demonstrate a seasonal component; declining during the summer and autumn months and increasing during the winter and spring months. This trend is consistent with the medical literature (Thoene and Johnson 1991) although possible reasons for this trend are not cited. Whether there are environmental and social factors which correlate with this trend is not known. It should be noted that, regardless of time of year, there are always claims present in the data for otitis media.

2.3 Case selection

A member was included in the study if he or she met the following criteria:

1. Age between 0 and 6 years as of June 30 1994 (high incidence period);

2. Continuous enrolment for the period of 07/01/91 - 06/30/94. For those members under two years of age, continuous enrolment since birth was necessary.

These selection criteria were applied to the member list and resulted in a total of 7967 members being eligible. Once identified all medical and pharmacy claims during the study period for each member were retrieved from the database and used for analysis and entered into a SAS database listings for each patient. The SAS system is a software system for data analysis and report writing and also enables you to store data values, retrieve them, modify data, compute simple statistics and create reports all in one SAS session. Further details on SAS and it's related procedures can be found in the SAS User Guide, Version 6, SAS Institute Inc, Cary NC.

2.4 Assignment to acute or chronic media groupings

ICD-9 codes were utilised to develop algorithms for assignment of the 7,967 members identified by case selection into acute or chronic acute otitis. The definitions were as follows:

1) assign a member to the acute group if at any time during the study period the following diagnosis codes were found in the claims history:

381-381.06... acute non-suppurative otitis media

381.4...non-suppurative otitis media not specified as acute or chronic (no previous evidence of OM therefore can't be chronic)

382-382.02... acute suppurative otitis media

382.04 unspecified suppurative otitis media

382.9 unspecified otitis media

2) assign a member to the chronic group if at an time during the study period or in the year prior to the study the following diagnosis codes or events were found in claims history:

381.1-381.19...chronic serious otitis media

381.2-381.29...chronic muted otitis media

381.3...other and unspecified chronic non-suppurative otitis media

382.1-382.3... chronic suppurative otitis media

385.1-385.19... adhesive middle ear disease

The acute group was further examined to determine which members within that group had evidence of acute otitis media that, because of continuing occurrences or length of time a single occurrence or prior history of chronic otitis media would more appropriately be classified as a member with chronic otitis media. The definitions were developed after a review of the literature (Jung and Rhee, 1991, in particular) and were as follows :

3 or more acute episodes within a running six month period.

or

CPT codes 69433-69437...tympanostomy requiring insertion of ventilating tube

or

CPT code 69424... ventilating tube removal when originally inserted by another physician, if the removal only occurred during the study period or in the year prior and there is no evidence of the insertion

or

any acute episode occurs for which drug therapy continues at least 30 days after the acute diagnosis

The ability to invoke this assignment protocol is dependant on identifying episodes of otitis media. Algorithms were developed to group the otitis media claims for individual members into episodes of care. The rules established to determine episodes of care are as follows:

1) Consider a drug claim for an oral antibiotic to be associated with otitis media if the gap between an office visit and the drug claim is not greater than 3 days.

2) Consider any subsequent drug claim to be associated with the otitis media episode if the gap between the first drug claim and any subsequent drug claim is not greater than seven days.

3) Consider any subsequent office visit to be associated with the otitis media episode if the gap between the first office visit or the gap between the drug claim and a subsequent office visit is not greater than 30 days.

4) In those cases where a drug claim precedes an office visit, consider the office visit to be associated with the drug claim if the gap between the drug claim and the office visit is not greater than 3 days.

Although completely arbitrary, these algorithms were based on UHC study protocols, expert opinion from physicians/UHC data managers and are consistent with similar studies in the area (White et al 1996).

2.5 Statistical methods

2.5.1 Explanation of the statistical tests used.

Statistical tests can be divided into two major classes: parametric and non-parametric. Parametric techniques make certain assumptions about the distribution of values in the population form from which samples are taken. Non-parametric methods do not involve assumptions about the population. All the parametric tests used in this analysis contain the assumption that sample values have a normal distribution. Whether a non-parametric or a parametric test is used it is assumed the sample data comes from random samples. Both groups of tests are also dependant upon the technique known as hypothesis testing.

Hypothesis testing is a method of choosing between a null hypothesis (normally stating there is no difference between the items under test) and an alternative hypothesis (a difference does exist between the items under test). Given a study with a single outcome measure and a statistical test, hypothesis testing can be summarised in three steps:

1) choose the significance level of the test i.e. with what level of certainty do we want to accept/reject the null hypothesis. (traditionally at the 5% level i.e. a 5% chance the event is due purely to chance, and hence a reasonably robust level of assurance).
2) Conduct the study, observe an outcome and compute the p-value (calculated significance level)
3) If the p value is smaller than the chosen significant level then reject the null hypothesis in favour of the alternative hypothesis; if not do not reject the null hypothesis.

2.5.2 Chi-square test

When dealing with categories rather than quantity variables and asking whether there is a significant difference between samples in proportions we have used a technique called the Chi-square test. This compares the frequency with which we'd expect certain observations to occur, if chance only were operating, with the frequency that actually occurred (Rowntree, 1983)

In this analysis, for the relationships of interest, tables of proportions were calculated from the SAS dataset (for an example see Appendix II, Table II-1). A null hypothesis was then set up for each relationship to be investigated; in all cases this stated that where differences were seen in the tabulated proportions, no significant difference actually existed. In order to reject the null hypothesis the calculated chi-square value X^2 had to be greater than that predicted at the 0.05 level of significance. Where this did occur, the null

hypothesis was rejected and the alternative hypothesis, a significant difference does exist, was accepted.

The SAS PROC FREQ procedure was used to perform Chi-square tests on the items of interest. This is a procedure that is descriptive in the sense that it produces frequency counts and cross-tabulation tables, allowing the investigator to describe data in a concise way. It is also a statistical procedure allowing you to analyse the relationships among variables. Frequency tables show the distribution of variable values. Cross-tabulation tables show combined frequency distributions for two or more variables.

The relationships tested using the chi-square analysis were:

- did any of the HMOs have a true greater proportion of otitis media claims than the other two HMOs.
- did either gender have a true greater proportion of claims than the other.
- did either gender have a higher proportion of claims for chronic or acute otitis media.
- did any of the HMOs have a true higher proportion of inserting tympanostomy tubes
- did either gender have a true higher proportion of insertion of tympanostomy tubes.
- was there an association between use of tympanostomy tubes and antibiotic therapy.

Problems do exist with using the Chi-square analysis (Bland 1992). Firstly, the data must be in frequencies i.e. the number of discrete objects occurring in different categories. The Chi-square will normally give false results if applied to data concerning the proportion or percentages of occurrences in the categories. Also, the categories must be mutually exclusive, so that one individual cannot be counted in more than one category.

A further important restriction on this form of test is that there should not be many categories for which the expected frequency is small. Quite what is meant by small is a matter of dispute amongst statisticians but two rules of thumb have been suggested (Rowntree 1983):

- if the number of categories is greater than 2, no more than 1/5 of the expected frequencies should be less than 5, and certainly none should be less than 1.
- if the number of categories is 2, both the expected frequencies should be 5 or larger.

If it is found when applying the test that the first rule has been broken it may be possible to combine categories until the offending expected frequencies have been suitably increased.

2.5.3 T-Test

For testing between means of item relationships in the data set, we chose the t-test as our method of testing for significant differences in the mean. The t-test is a parametric test of the difference between two samples. It is applicable only to data measured on an interval type scale (Bland 1992).

The null hypothesis of the t-test is that two sets of data are random samples from a common, normally distributed population, or from two identical normally distributed populations. Before applying this test we should have good reason not to suspect the variables measured don't have a normal distribution. In our analysis of items of interest, we have no reason to suspect then means do not come from a normal distribution.

The null hypothesis adopted is that there is no difference between the means of the populations from which the two samples were taken. The null hypothesis assumes that the observed difference between the sample means is due to the sampling process. The alternative hypothesis is that there is a difference between the means of the two populations, a difference which is being accurately reflected in the samples. A significance level of 0.05 is generally accepted as the appropriate level of significance required.

In this analysis the mean was calculated for each item of interest and t-testing performed, using the PROC TTEST SAS command. This computes sample means for each of the two groups of observations and tests the hypothesis that the population means are the same. Once performed (see Appendix II, Table II-7) a p-value of less than 0.05 was required to reject the null hypothesis i.e. there is a less than 5% chance that the means observed are not true differences. This is sufficient to reject the null hypothesis and to allow us to accept the alternative hypothesis that there is a difference between the means of the two samples.

The differences in means, for acute and chronic otitis media groups, tested in this analysis were:

- the number of acute and chronic otitis media episodes during the study
- the number of antibiotic claims
- the number of amoxycillin claims
- the number of amoxycillin/potassium clavulanate claims

- the number of antibiotic claims per episode
- the total drug cost per episode day
- the total cost per episode day
- amoxycillin used or not
- amoxycillin used first
- amoxycillin/potassium clavulanate not used
- amoxycillin/potassium clavulanate used first
- cefaclor used
- cefaclor used first

Also, a multiple t-test was performed for the total cost during an episode between each initial antibiotic group. This test (performed by the PROC MULTTEST SAS procedure) tests between means for a number of groups and replaces the need for performing individual t-tests. The hypotheses adopted still follow the same flow as for a 'traditional' t-test (i.e. null hypothesis assumes no difference) and the interpretation of the results also remains the same.

2.5.4 Logistic regression

In a situation where we want to investigate the relationship between the variation in a number of variables we turn to techniques called multivariate analysis. Multi-variate problems are common in research and in recent years there has been a substantial

development in statistical techniques and applications of multi-variate analysis. The multi-variate technique used in this analysis was logistic regression.

Multiple regression is a form of multi-variate statistics. Similar to simple regression where we fist a best straight line through the points on a scattergram and investigate the numerical relationship between variables, multiple regression works with one dependant variable (the outcome we are investigating) and many independent variables (the variable that predicts the association).

In fitting a statistical model to a set of data, sometimes the dependent variable is dichotomous, where as the independent variables are continuous, discrete or both. The form of regression used in this case is known as logistic regression (Johnston 1994). This applies maximum likelihood estimation after transforming the dependent variable into a logit variable (the natural log of the odds of the dependent occurring or not). In this way, logistic regression estimates the probability of a certain event occurring. Thus, logistic regression calculates changes in the log odds of the dependent variable, not changes in the dependent itself as with linear regression.

For this analysis, we elected to use logistic regression as we wanted to investigate the relationship between the dichotomous variables of being prescribed certain drugs as first line treatment, or not, and independent variables such as, for example, having chronic otitis media, or not, (i.e. discrete categories), and the patient's age at the start of an episode (i.e. continuous in nature).

Logistic regression also allows one to calculate odds ratios for individual risk factors where you believe a variety of factors may be contributing to the occurrence of certain events. Odds ratios are related to probability but the odds are defined as the number of persons who experience the event divided by the number of people not experiencing the event. An odds ratio of one implies the similar likelihood of an event occurring; the higher the ratio away from one the greater the odds of an event happening.

We chose a stepwise form of logistic regression due to the large number of independent variables that were included in a database of this size. A stepwise regression is performed by adding one independent variable at each step of the analysis until associations have been explored. The variables that show the best predictive ability are then listed. This analysis was performed using the PROC LOGISTIC command of SAS on the database. The dependant variable (the outcome of interest) needs to also be entered into the SAS command chain.

For example (see Appendix III, Table III-15), if we wish to determine which variables best predict whether a person receives amoxycillin as the first drug in an episode to otitis media we took the following steps:

- set up the appropriate SAS commands with receipt of amoxycillin as first drug in an episode as the dependant variable.
- run the SAS programme in order to perform the regression calculations.
- the SAS outputs will list the variables which best predict whether a person received amoxycillin as first drug in an episode. An odds ratio less than one means the variable

is NOT associated with receiving that drug and in some cases infers the other category is associated: an odds ratio greater than one implies it has a greater probability of influencing the outcome (dependant variable).

- from the odds ratios in Table III-15 we can see the following have a greater probability of receiving amoxycillin as the initial antibiotic:
    - episodes among members in the acute otitis media group
    - episodes among members not enrolled in HMO1 and HMO3
    - episodes among members with shorter length of episode
    - episodes among members who do not have otitis media episodes in the previous year; and
    - episodes among members who are female

This procedure was performed to investigate predictors for the following groups:

- amoxycillin as the initial drug
- amoxycillin/potassium clavulanate as the initial drug
- cefaclor as the initial drug

3. Data results

In the study population as a whole, for all otitis media codes combined, the prevalence rate for otitis media is 538 per 1000 members. Over 50% of all children between the ages of 0 and 6 years have had at least one claim for otitis media. Table 2 summarises this information.

It should be noted that the rates reported in this table are prevalence rates in the epidemiological sense, i.e. that fraction of members who have had otitis media (as evidenced by the presence of claims) during the study period. Incidence rates, the fraction of members who had the first occurrence of otitis media during the study period, were not determined for this study.

As table 2 shows, the prevalence of otitis media differs by age group and plan. The highest prevalence are found among children between the ages of one and two years. Among one year old children, 74% (739 per 1000) of continuously enrolled members have had an otitis media claim. For children under 2 years of age, the prevalence increases to 79% (790 per 1000) of continuously enrolled members. These rates are similar to those reported in clinical literature (Teele, 1989; Thoene and Johnson, 1991).

Among the individual plans the highest overall prevalence rate, 55% of continuously enrolled members (553 per 1000) was found in HMO2. The lowest rate, 51% (507 per 1000) was found in HMO1. Chi-square analysis of the association between plan and otitis

media shows a significant relationship (appendix II-I). A greater proportion of members in HMO2 have had claims for otitis media when compared to the other two plans.

Prevalence also differs by gender. Tables 3 and 4 summarise the information. In the study population as a whole, for all otitis media codes combined, the prevalence for all males (552 per 1000) is higher than for females (524 per 1000). Examination of the overall population by age group indicates that only in the 6 year old do females have a higher prevalence than males (477 per 1000 females compared to 454 per 1000 males).

The chi-square analysis of the association between gender and otitis media shows a significant relationship (appendix II, Table II-2). A greater proportion of males have otitis media claims when compared to females. These results are similar to other epidemiological studies reported in the literature (Teele 1989, Thoene and Johnson, 1991).

3.1 Assignment to acute or chronic otitis media

Classification of members into acute or chronic otitis media groups suggests that in any plan between 49% and 53% of members with otitis media between the ages of 0 and 6 would be considered chronic cases. For the overall study population 50% of all cases are classified as chronic. This result supports literature which identifies otitis media as a recurring disease in this population. Table 5 summarises the results of this study group

assignment for those members who met the inclusion criteria for selection into the study by gender and by plan.

Table 5 also provides the information concerning gender and assignment to acute or chronic otitis media groups. For all HMOs combined 48% of males and 52% of females are classified into the acute otitis media group. The opposite is true for the chronic otitis media group 52% of males and 48% of females are classified into the acute otitis media group.

Among individual plans there was some variation to this general rule. In HMOs 1 and 3, greater than 50% of males assigned to the chronic otitis media group; in HMO2, 50% of males are assigned to each group. For females, in HMOs 2 and 3 greater than 50% of females are assigned to the acute otitis media group; in HMO1 49% of females are assigned to that group.

Chi-square analysis of the association between gender and assignment to acute or chronic otitis media group shows a significant association. (appendix II, Table II-3). A greater proportion of males are assigned to the chronic group when compared to females. The opposite is true for assignment tot he acute group where a greater proportion of females are assigned. The gender differences found in this study are supported by the literature. (Teele, 1989).

Assignment to the chronic otitis media group was determined using several definitions described previously. Table 6 provides this information concerning number of members assigned to the chronic group based on the various definitions. Although a member could be considered as having chronic otitis media for multiple reasons, the definition category for this table was determined based on the first indication of chronic otitis media found within the claims history. For this reason, the number of members who were assigned to the chronic otitis media group because of tympanostomy tubes is minimal in comparison to the number of members who have had tympanostomy tubes inserted; a chronic otitis media diagnosis should precede the insertion of tympanostomy tubes appears to be the case in the study.

For all HMOs combined, the largest number of members (48%) were assigned to the chronic otitis media group due to antibiotic therapy lasting longer than 30 days. As noted previously, however, the association of antibiotic claims to a specific disease based on claims data has the potential for error and, therefore, may over report classification into the chronic otitis media group for this reason.

Another 21% of members were assigned because they had 3 or more acute episodes in a 6 month period of time. Slightly less than one fifth (19%) were assigned because of specific ICD 9 codes for chronic otitis media,.

3.2 Complications with otitis media

In a review of treatment options, Jung and Rhee (1991) suggested that complications from otitis media have significant morbidity. The complications identified are of two types - those occurring inside the confines of the temporal bone (including facial paralysis, perforation of the tympanic membrane, mastoiditis or hearing loss) and those occurring outside the confines of the temporal bone (including meningitis and abscesses). Jung and Rhee did not report prevalence rates for the complications identified, however, but did not suggest that these complications occur despite the use of antibiotics.

3.3 Prevalence of complications associated with otitis media

The claims history for each member was searched for evidence of the presence of complications which may be related to otitis media. Specific ICD 9 diagnostic codes were selected based on the literature review (Meyerhoff, 1984; Jung and Rhee, 1991; Isaacson and Rosenfield, 1994):

315.3-315.39...development speech or language disorder

320-320.9 ...meningitis

322-322.9...meningitis of unspecified causes

383-383.9...mastoiditis

384.2-384.25...perforation of tympanic membrane

385.0-385.09...tympanic scarring

385.2...acquired abnormality of ear ossicles

385.23...ossicular discontinuity

385.3-385.35...destructive cholesteatoma

350-351.0...facial paralysis

386.3-386.35...labrynthitis

389.0-389.08...conductive hearing loss

389.2...mixed conductive and sensoineural hearing loss

389.8...other specified forms of hearing loss

389.9...unspecified hearing loss

784.5...speech disturbances V41.2...problems with hearing

These codes were grouped into 11 complications as follows:

Meningitis (320-322.9)

Mastoiditis

Perforation of tympanic membrane

Tympanic scarring

Acquired abnormality of ear ossicles

Ossicular discontinuity

Destructive cholsteatoma

Facial paralysis

Labrynthitis

Hearing loss (389.0-389.9, v41.2)

Speech and language disorders (315.3-315.39,784.5)

Table 7 summarises the information concerning the prevalence for the 11 complications for any otitis media diagnosis, for each plan separately and all HMOs combined. The 11 complications were also examined based on the grouping of otitis media into acute or chronic cases. Tables 8 and 9 summarise this information while Tables 10 and 11 present the same information concerning complications for those members with and without antibiotic therapy for otitis media.

Hearing loss and it's potential developmental sequelae, speech and language disorders were the two most commonly occurring complications. The prevalence rates are 33 per 1000 otitis media members and 11 per 1000 otitis media members respectively.

The prevalence rates for these complications are higher among those members classified into the chronic otitis media group. For hearing loss the overall prevalence rate was found to be 49 per 1000 chronic otitis media members. Evidence of speech and language disorders were found among 15 of every 1000 chronic otitis media members.

Finally, a comparison of the prevalence of these complications between those members with otitis media who have not received antibiotic therapy for the condition and those that have received antibiotic therapy shows higher prevalence for treated members. This should not be interpreted, however, as indicating any association of complications with the use of antibiotics. It may suggest that, at least for this study period of 2 years, not treating otitis media episodes with antibiotics does not show evidence of higher prevalence rates of complications.

Additionally, the comparison of prevalence between treated and untreated groups may reflect differences in severity of otitis media not discernible with claims data. Complications may be higher in the group with antibiotic treatment because that group has a more severe condition.

3.4 Use of tympanostomy tubes in chronic otitis media

Clinical literature identifies tympanostomy tubes as an acceptable treatment option for children with chronic otitis media either unresponsive to continued, non surgical therapy or having episodes recurring with increasing frequency (Meyerhoff, 1981; Gates et al, 1985; Jung and Rhee, 1991; Isaacson and Rosenfeld, 1994).

To determine which members with otitis media also had evidence of tympanostomy tubes, the claims history was searched for either an insertion of ventilating tubes or the surgical removal of ventilating tubes in the absence of an identified insertion. For the purpose of this study, identification of members who have had tympanostomy tubes was made from the group identified as having chronic otitis media.

Table 12 summarises the information by plan and gender for 771 members identified with tympanostomy tubes.

Overall, approximately 11% of members identified with chronic otitis media also had an adenoidectomy procedure meeting the criteria established during the study period.

Overall, 11% of males and 10% of females with chronic otitis media also had claims evidence of adenoidectomy. Differences can be noted by plan. HMO3 has the largest percentage of members who have had evidence of adenoidectomy while HMO2 has the lowest. The comparison of these results with other studies could not be made.

No claims evidence of adenoidectomy was found for any member in the acute otitis media group. This result was as expected given the clinical recommendations for adenoidectomy in the treatment of otitis media.

3.5 Episodes of care for otitis media.

For this study, an ICD-9 diagnosis code for otitis media was identified and the associated claims related to the index event grouped into an episode of care. The definitions used to accomplish this were defined previously since an episode of care was an important component in the ability to classify members into acute or chronic groups.

Although there are several possible ways of categorising the episodes of care identified for this study, five basic types were defined. They were:

1) episodes which are a single diagnosis event only.

2) episodes which initiate and end with a diagnosis (most often associated with an office visit) of OM i.e. includes a follow-up visit.

3) episodes which initiate with a diagnosis and end up with drug therapy.

4) episodes which initiate with drug therapy and end with a diagnosis

5) episodes which initiate and end with drug therapy.

Table 14 summarises the categorisation of 18,397 episodes into these 5 episode types.

For HMOs 1 and 2, the most common episode of care type, accounting for greater than 50% of all episodes, is that which initiates with an office visit and ends with an office visit. This suggests that practitioners in these plans rely heavily on a follow up office visit for resolution of the otitis media problem. IN HMO3, however, the most common episode type, accounting for 52% of the episodes, is that which initiates with an office visit and ends with drug therapy. In this place, a course of antibiotics is considered to be the final encounter.

The average length of days for an episode has been determined for each episode type based on the claims associated with the episode. For single diagnosis events this could only be determined as 1 day. Claims evidence beyond a single data of service could not be definitionally associated. Clinical literature was not found that reported the average length of an untreated episode of otitis media and, therefore, could not be applied to this data.

For episodes beginning and ending with a diagnosis event, the average length of an episode was determined from the initial date of service for the first event through the final data of service for the last event, inclusive. For those episodes where the last diagnosis event was a hospitalisation, the discharge date was considered the final date of service.

For episodes ending with an antibiotic claim the days supply based on the quantity dispensed was calculated and the last date of drug therapy was defined. This was then used as the final date of service. Given the definitional limitations of length of episode based on claims evidence, an overall average length of episode would not be a supportable calculation. It approximates, however, 21 days when single event diagnosis are removed. When the classification into acute or chronic group is considered, the average length of an episode for members classified as acute is 13 days; for members classified as chronic the average length of an episode is 36 days.

The average number of episodes during the 24 month study period for a member classified into the chronic group the mean number of episodes during the 24 month study period was 3.1. A t-test of the difference between number of episodes during the study and classification into acute or chronic otitis media found a significant difference (Appendix II II-7).

Over 50% of the identified episodes had a single office event associated with them as Table 15 summarises. Only a small number of episodes (4%) did not have an office event. For these 741 episodes the indexing otitis media diagnosis code appeared in either an emergency room or urgent care centre. The number of episodes with 4 or more associated office visits is, likewise, small. In each place, however, a small number of episodes had 10 or more office visits associated with them. One episode in HMO2 had 29 office visits associated with an episode of care based on the definitions of time windows specified for this study.

The episodes of care that were defined for this study were then categorised into two groups based on whether or not there was claims evidence that an antibiotic was used during the episode either as a prescription or administered during that course of an office visit. A total of 13137 episodes were categorised with antibiotic claims. For the remaining 5,260 episodes claims evidence of antibiotic use during the episode was not found. This does not mean that an antibiotic may not have been used as claims data does not allow for the ability to track physician sampling, or claims for antibiotics for which the total amount claimed in dollars was less than the members co-pay.

3.6 Episodes of care with antibiotic claims

The initial antibiotic claim within an episode of care was identified for 3 specific antibiotics (amoxycillin, amoxycillin/potassium clavulanate, and cefaclor), any other cephalosporin, any other antibiotic, and no antibiotic. Within the 'other cephalosporin' category there was claims evidence of 8 pharmaceutical agents: cefixime, cefadroxil, cefuroxime, ceftriaxone, cefprozil, cephradine, cefpodoxime proxetil and cephalexin. The 'other antibiotic' category included penicillins, tetracyclins, erythromycins, and their related compounds. Table 16 summarises this information for the antibiotic initiated within the episode.

For all antibiotics and HMOs, as expected, the number of claims is higher in the chronic otitis media group than acute (Appendix III, Table II 2).

During the study period, the number of antibiotic claims, the number of amoxycillin claims, the number of amoxycillin/potassium clavulanate were all higher in the chronic otitis media group than acute. Statistical tests confirmed these differences to be significant (Appendix II, Tables II8-10).

For all HMOs combined, amoxycillin is the initial choice for the largest percent of either acute or chronic episodes. Other antibiotics (including other penicillin, erythromycins etc) were the next most often prescribed, followed by amoxycillin/potassium clavulante and cefaclor, both of which are the initial antibiotic choice in less than 10% of all episodes. Slight differences are noted among plans. Other cephalosporins are prescribed least often. Figures 2-6 visually portray this information which could be considered a market share for the initiating prescribing decision for the antibiotics understudy.

Amoxycillin is the antibiotic used most frequently as the initiating antibiotic in the plans individually as well. This result is similar to that obtained by White et al 1996. The use of Augmentin and cefaclor as the initiating antibiotic is reasonably consistent across plans at approximately 6-10% of the episodes. The plans are noticeably different, however, in the number of episodes for which no antibiotic can be found in the acute OM group. HMO1 had the highest percentage of untreated episodes (43%) for members in that group.

Differences can be noted between members classified into the acute and chronic otitis media groups. Although the initial choice for the largest percent of episodes in either

group, amoxycillin was the initial antibiotic in 45% of the episodes identified among members classified into the acute group; 32% of the episodes identified among members classified into the chronic group had claims evidence of amoxycillin as the initial choice.

The use of both Augmentin and cefaclor (as measured by per cent of episodes with each drug as the initial antibiotic) increased in the group classified with chronic otitis media. Across the three plans, each drug is the initial antibiotic in approximately 10% of episodes found among members in the chronic group. There is some difference in the use of these two antibiotics by plan. When compared with cefaclor, Augmentin is the initial choice in a greater percent of episodes in HMO2; in HMO3 cefaclor is the initial choice in a greater per cent of the episodes.

The results of statistical analyses support these observations. Tests of the differences in means for the group assignment show that amoxycillin is used in a greater proportion of episodes for members classified into the acute OM group (Appendix III, Table III-5). Results also show amoxycillin is used first in a greater number of cases in the acute otitis media group than chronic, implying it's predominant use as a first line agent. Statistical tests confirm this is a significant difference.

Logistic regression of those episodes where amoxycillin is the initiating antibiotic produce odds ratios which show that:

1) episodes among members in the acute otitis media group

2) episodes among members not enrolled in HMO1 and HMO3

3) episodes among members with shorter length of episode

4) episodes among members who do not have otitis media episodes in the previous year; and

5) episodes among members who are female;

have a greater probability of having claims evidence of amoxycillin as the initial antibiotic (Appendix III, Table III-15).

Results show amoxycillin/potassium clavulanate, other cephalosporins and cefaclor are used more in chronic otitis media cases than acute. Statistical tests confirm these differences are statistically different (Appendix III – Tables 7- 12).

Logistic regression results (Appendix III-Table 16) found several significant variables associated with the use of amoxycillin/potassium clavulanate first in an episode of OM.

The odds ratios indicate that:

1) episodes among members in the chronic otitis media group

2) episodes among members not enrolled in HMO3

3) episode with more than one office or outpatient visit during the episode

4) episodes among members who are older

5) episodes among members enrolled in HMO1;

have a greater probability of having claims evidence of Augmentin as the initial antibiotic during an otitis media episode.

Similarly, cefaclor is used more often among members who have been classified with chronic OM (Appendix III, Tables III-9 and III-10). Logistic regression shows some differences between episodes where cefaclor is the initiating antibiotic when compared to amoxycillin/potassium clavulanate when other significant variables are considered. Logistic regression results show that:

1) episodes among members not enrolled in HMO2

2) episodes among members who are in the chronic otitis media group

3) episodes with emergency room visits

4) episodes among members who have had episodes in the year in the year prior to the study

5) episodes among members who are female

have a greater probability of having claims evidence of cefaclor as the initiating antibiotic during an otitis media episode (Appendix III, Table III-17).

Table 17 provides summary information concerning prescribing patterns for those episodes where claims for an initiating antibiotic can be identified. The majority of all episodes (63%) are resolved with a single course of therapy based on the evidence contained within claims data. For the specific antibiotic groups under study, 68% of episodes for which amoxycillin was the initiating antibiotic resolved with a single course of antibiotic therapy. Augmentin had 56% of episodes; cefaclor 59%; and other cephalosporins 58%. All other antibiotics as a group had 59% of episodes resolved with a single course of antibiotic therapy.

When the number of episodes with 2 antibiotic claims are considered, approximately 82% of the 13,137 episodes identified with associated antibiotic claims are resolved with what may be considered judicious use of antibiotics. Nonetheless there are present a number of episodes that show evidence of repeated use of antibiotics. Across the three plans, there was 165 episodes which had 10 or more associated antibiotic claims. HMOs and 2 both had where 20 or more antibiotic claims were associated with an episode.

For those episodes where more than one antibiotic claim was identified the second antibiotic claim was determined. The pattern that emerges is that whatever the initial choice, the secondary therapy will be the same drug for the largest percent of episodes. Thus, initial treatment with amoxycillin is followed by second therapy with amoxycillin. This is the case for both acute and chronic cases of otitis media (Appendix IV, Table IV - 1).

When the second antibiotic claim has been issued by the same provider as the first. there is a greater percentage of episodes for the same antibiotic. When a different provider has issued the second prescription, the largest percent of episodes have secondary therapy the same but it is consistently less than that seen when the same provider has issued both therapies. Acute and chronic otitis media cases show the same pattern (Appendix V, Tables IV-2 and IV-3).

It should be noted that the reasons for re-prescribing cannot be determined from claims data. Whether re-prescribing may be the result of treatment failure, non compliance, patient dissatisfaction with the dosage form may not be ascertained within the boundaries of claims data.

3.7 Episodes of care with no initiating antibiotic therapy

Across all plans for approximately 28% of the otitis media episodes summarised in Table 16 claims for antibiotic therapy were not identified. When acute or chronic otitis media group is considered, 31% of the episodes in the acute otitis media group did not have claims evidence of antibiotic use. HMO1 had the highest percent of acute otitis media episodes with no antibiotic claims, followed by HMO3. For chronic otitis media, HMO2 had the highest per cent of episodes with no antibiotic claims followed by HMO1. Comparison of this result with other studies could not be made. Clinical opinion is such that the decision not to employ antibiotics in the treatment of otitis media is a valid option. Not all factors which may contribute to this decision can be assessed in claims data, however, two factors, a differential diagnosis of non suppurative vs suppurative otitis media and the presence of tympanostomy tubes during the identified episodes could be examined.

The episodes were examined to determine if a differential diagnosis may have contributed to the decision concerning use of an antibiotic therapy at the start of an episode. The classification of non-suppurative vs suppurative otitis media was made using the ICD-9 groupings of otitis media and are as follows.

381-381.4...non suppurative otitis media

382-382.4...suppurative otitis media

382.9...otitis media, not otherwise specified

Table 18 summarises this information.

Chi-square analysis of the association between differential diagnosis and use of an antibiotic found a significant association (Appendix III, Table III-I). A smaller proportion of episodes with a non-suppurative diagnosis of otitis media during the episode had claims evidence of antibiotic therapy than would otherwise have been expected. Antibiotic therapy is generally employed, for treating episodes of otitis media for which the differential diagnosis is suppurative otitis media or is not specified as to type. There are, however, a large number of episodes (1878) for which a differential diagnosis of non-suppurative otitis media appeared in the claim.

The episodes were also examined to determine if the presence of tympanostomy tubes may be an explanatory factor between episodes with and without claims evidence of antibiotic use. Table 19 summarises this information

Chi-square analysis of the association between antibiotic therapy during an episode and the presence of tympanostomy tubes establishes a significant association (Appendix II, Table II-7). when tympanostomy tubes are present a smaller proportion of episodes have associated antibiotic therapy than would otherwise be expected. When tympanostomy tubes are not present a larger proportion of episodes have associated antibiotic therapy than would otherwise be expected.

3.8 Costs associated with the treatment of otitis media

For the purposes of this study health services and associated costs were grouped into four categories. Standard and plan specific CPT-4 and ICD-9 procedure codes were incorporated into a computer algorithm for assignment into the categories which were defined as follows:

1) Group 1: Physician Office/Outpatient Services

Claims with an ICD-9 code indicating otitis media or related diagnoses which could be identified as originating in physician offices or other outpatient facilities such as independent laboratories, one day surgi-centres, hospitalisations of less than day, audiology services and speech pathology services. The relevant ICD-9 codes are:

381-381.4...non-suppurative otitis media and eustachian tube disorders

381.5-381.9... Eustachian salpigitis and other non specified disorders of Eustachian tube

382-382.9...suppurative and unspecified otitis media

385.1-385.19...adhesive middle ear disease

384.2x...perforation of tympanic membrane

384.9...unspecified disorder of tympanic membrane

388.6...ottorhia

388.7...otalgia

388.8...other disorders of the ear

388.9...unspecified disorder of ear

Group 2: inpatient Hospitalisations

Claims identified as hospital admissions of minimally one night with an ICD -9 diagnosis code for otitis media or the other related conditions specified in the study protocol in the primary or secondary position (hospitalisations for which the admission and discharge day were the same date of service were assigned to the outpatient services).

Group 3: Emergency services

Claims with an ICD-9 codes in the in the primary or secondary position which could be identified either by coding conventions or site codes as originating in an emergency room, emergency services or urgi-centre.

Group 4: Drugs

Claims for prescriptive services or drugs administered in the physician's office for the pharmaceutical agents utilised in the treatment of otitis media. These included any of the following therapeutic classes and generic codes of drugs from UHC formulary:

021100 cephalosporins

021300 clindamycin

021400 erythromycin

021500 penicillins

021600 sulfonamides

021700 tetracyclines

071000 drugs affecting the ear

152200 decongestants

152300 combination antihistamine/decongestants

generic code 03643

generic code 09248

Dollars expended on health services associated with the diagnosis and treatment of otitis media totalled $2,744,819 across all plans for the 24 month period. Although a substantial dollar amount, this represents only a 0.4% of the total dollars expended by the 3 plans on behalf of all insured members for the same 24 months , an amount which equalled £616,509,537.

The cost centre accounting for the largest percent of otitis media dollars, 72% was physician and outpatient services. This was followed by drugs used in the treatment of otitis media which accounted for 15% of the otitis media expenditure. Table 20 provides this information for each of the plans included in the study for each 12 month period and the 24 month study period. Figure 7 visually portrays this information for the study period of 24 months.

Tables 21 and 22 provide the same information for those members classified with acute and chronic otitis media separately. Of the £2,744,819 of this total ($2,301,155) is expended on otitis media episodes for members classified into the chronic otitis media group; 16% ($433,665) is expended on otitis media episodes for members classified into the chronic otitis media group. Thus, 50% of the members with claims for otitis media

during the study period account for 84% of the total dollars expended by the health plans for this condition.

Statistical tests show the drug cost and total cost per episode is significantly higher in the chronic otitis media (Appendix III, Tables 3-4).

As expected, members with chronic otitis media have a larger percent of dollars expended for physician and outpatient services when compared to the acute cases. Acute cases, however, have a larger percent of dollars expended on emergency services and in-patient hospitalisations. Figure 8 visually portrays information.

Associated costs for chronic otitis media were also determined by chronic categorisation. Appendix V provides this information for all HMOs combined for each of the five assignment definitions, namely:

1) presence of an ICD-9 code for chronic otitis media

2) length of a single episode greater than 30 days

3) antibiotic drug therapy greater than 30 days

4) presence of tympanostomy tubes

5) having 3 or more otitis media episodes in a 6 month period

3.9 Costs associated with the treatment of otitis media by initiating antibiotic

Table 23-25 provide information concerning the costs associated with the treatment of otitis media when the initiating antibiotic is considered. Table 23 provides the information for all HMOs combined for all otitis media episodes. Table 24 provides the same information for episodes which occurred among members classified into the acute otitis media group. Table 25 provides the information for episodes which occurred among members classified into the chronic otitis media group. Appendix 1 provides the cost information for each plan separately. The costs centres are as previously reported, namely:

1) Group 1 : Physician Office/Outpatient services

Claim with an ICD 9 code indicating otitis media or related diagnoses which could be identified as originating in physician offices or other outpatient facilities such as independent laboratories, one-day surgi-centres, hospitalisations of less than 1 day, audiology services and speech pathology services.

2)Group 2: Inpatient hospitalisations

Claims identified as hospital admissions of minimally one night with an ICD-9 diagnosis code for otitis media or the other related conditions specified in the study protocol in the primary or secondary position. Hospitalisations for which the admission and discharge date were the same were assigned to outpatient services.

3) Group 3: Emergency services

Claims with an ICD 9 diagnosis code in the primary or secondary position which could be identified either by coding conventions or site code as originating in an emergency room, emergency service centre or urgi-centre.

4) Group 4 : drugs

Claims for prescriptive services or drugs administered in the physician's office for the pharmaceutical agents utilised in the treatment of otitis media, therapeutic classes and generic codes of drugs from the DPS formulary specified previously have been used.

As Table 23 shows, regardless of grouping into acute or chronic otitis media, when an episode does not have claims evidence of antibiotic use, the average amount paid per episode is approximately $87. Physician and outpatient services account for approximately 82% of the total costs for those episodes, emergency services approximately 9% and inpatient hospitalisations approximately 10%. Drug costs are minimal since there was no evidence of oral antibiotic use associated with the episode. The costs which appear in this category are for otic drops, primarily.

When evidence of oral antibiotic use during an episode can be found within the claims data the average amount paid per episode increases, ranging from $126 per episode for those episodes where amoxycillin is the initiating antibiotic to $255 per episode when cefaclor is the initiating antibiotic. When compared to episodes where there is no

evidence of oral antibiotic therapy, the per cent of total costs expended in physician and outpatient services, emergency services and hospitalisation are less..

Table 23 shows there is $40 less in the average amount paid per episode for episodes where amoxycillin/potassium clavulanate is the initial antibiotic used during an episode compared to those episodes where cefaclor is the initial antibiotic used during an episode. This is a statistically significant amount. (Appendix III, Table 18)

Cost per day of an episode was also determined and subjected to statistical analysis. These results show that there is a statistically significant difference between episodes where amoxycillin/potassium clavulanate is the initial antibiotic used during an episode and cefaclor is the initial antibiotic used. Cost per day is less for the amoxycillin/potassium clavulanate episodes.

4. Discussion

This discussion has been broken down into 3 sections:

4.1 What answers were we able to derive on questions specifically relating to otitis media?

4.2 What methodological issues arose during the analysis?

4.3 How could this information be used in health economics research in the pharmaceutical industry?

4.1 What answers were we able to derive on questions specifically relating to otitis media?

The discussion of results presented below proceeds in the order that research questions are outlined in the study proposal. Comments made are intended to act as a stimulus for broad discussion of the results among interested groups and identification of areas for further study.

4.1.1 What is the prevalence of otitis media in the study population for the period 07/01/92-06/30/94?

The results of this study support the information which can be found in the clinical literature concerning the prevalence of otitis media in children. During the study period, across all ages, over 50% of children have had claims for otitis media. The highest prevalence was found in children less than 2 years of age. The data also indicated that the prevalence of otitis media differed by gender, being higher among members who are male. There were also differences in prevalence rate by plan suggesting that there may be a geographical component potentially related to location.

It is possible that otitis media prevalence rates may also differ due to socio-economic status. This has been noted with other diseases. The plans which were available at the time of this study did not allow for the examination of this question, however, the inclusion of different plans, some of which have Medicaid enrolment, may provide information related to such a relationship.

4.1.2 What health services and therapy options are employed in the diagnosis and treatment of otitis media?

For a large number of the episodes of otitis media (74%) a conservative approach to the treatment option (either no treatment with an antibiotic or single antibiotic therapy) is found. The majority of all episodes (63%) are resolved with a single course of therapy

based on the evidence contained within claims data. For the specific antibiotic groups under study, 68% of episodes for which amoxycillin was the initiating antibiotic resolved with a single course of antibiotic therapy. When the number of episodes with 2 antibiotic claims are considered, approximately 82% of the 13,137 episodes identified with associated antibiotic claims are resolved with what may be considered judicious use of antibiotics.

For those episodes where more than one antibiotic claim was identified the second antibiotic claim was determined. and the pattern which emerges is: whatever the initial choice, the secondary therapy will be the same drug for the largest percentage of episodes. Thus initial treatment with amoxycillin is followed a second course of therapy.

When the second antibiotic claim has been issued by the same provider as the first, there is a greater percentage of episodes for the same antibiotic. When a different provider has issued the second prescription, the largest percent of episodes have secondary therapy the same, but it is consistently less that seen when the same provider has issued both therapies. The results, in part, substantiate the claims that provider preferences and familiarity with pharmaceuticals play a role in prescribing and re-prescribing patterns.

It should be noted that the reasons for re-prescribing cannot be determined from claims data. Whether re-prescribing may be the result of treatment failure, patient non-compliance, patient dissatisfaction with the dosage form, or adverse events, may not be ascertained within the bounds of claims data. This would be important information to

consider, particularly in those instances where re-prescribing is the result of treatment failure.

A total of 771 members (19% of the members with chronic otitis media) had claims evidence of tympanostomy tubes. Significant association was found by plan suggesting that there is some regional differences in the use of tympanostomy tubes. The nature of this difference may be of further interest but the ability to explore this difference may not be possible within the boundaries of claims data.

Chi-square analysis also found gender to have a significant association. A greater proportion of males had claims evidence of tympanostomy tubes. It was also found that tympanostomy tubes are a contributing factor in the decision not to use antibiotics during an otitis media episode, as one would expect. Nonetheless, a number of members (786) received an antibiotic while tympanostomy tubes were present. Whether this represents necessary duplicative therapy cannot be determine with claims data.

Claims evidence of adenoidectomy were found for 434 (11%) of members with chronic otitis media. There were no members classified in the acute otitis media group with claims evidence for this procedure.

4.1.3 What serious complications are present in this population as a result of chronic otitis media?

Of the 11 complications examined in this study, hearing loss and the related developmental sequelae of speech and language disorders were the two most common complications at prevalence of 33 per 1000 otitis media members and 11 per 1000 otitis media members respectively. Prevalence differences were found among members classified with acute or chronic otitis media. As expected, prevalence rates were higher in the chronic otitis media group.

The clinical literature cited for this study did not report results. Further, the prevalence rates for hearing loss and speech and language disorders among members who do not have otitis media is not known. Further study of complications should begin by examining these comparative differences.

4.1.4 What are the costs associated with the diagnosis and treatment of otitis media in a managed care setting?

A total of $2,744,819 were expended across the three health plans for the 24 month study period. The largest cost centre was physician and outpatient services accounting for 72% of the dollars. This is as expected since otitis media is considered to be a condition treated in the outpatient setting. Nonetheless, overall 7% of the dollars expended in treating otitis media are for in-patient hospitalisations and 6% for emergency services..

When no oral antibiotic treatment can be associated with otitis media episodes, a greater percentage of total costs are expended in these two costs categories. The increased costs of drugs when claims evidence of oral antibiotics are found may, therefore, be off-set by the decreased percentage of costs of emergency services and inpatient hospitalisations. Psychological advantages may also accrue if antibiotic use decreases emergency services and in patient hospitalisations, particularly given that the population under study is a paediatric one.

4.1.5 What are the comparative costs of treatment of acute and chronic otitis media in a managed care setting?

Although members classified with chronic otitis media make up 50% of the population of members identified with otitis media, they account for the largest portion of total dollars expended for this condition. Of the $2,744,819, 84% of this total ($2,301,155) is expended on otitis media episodes for members classified into the chronic otitis media group.; 16% ($433,665) is expended on otitis media episodes for members classified into the acute otitis media group.

As expected members with chronic otitis media have a larger percentage of dollars expended for physician and outpatient services when compared to the acute cases. Acute cases have a larger percent of dollars expended on emergency services and in-patient hospitalisations.

4.1.6 What are the comparative costs of treatment of acute and chronic otitis media when the initial antibiotic used is amoxycillin vs amoxycillin/clavulanate vs cefaclor?

Regardless of grouping into acute or chronic otitis media, when an episode does not have claims evidence of antibiotic use, the average amount paid per episode is approximately $87. Physician and outpatient services account for approximately 82% of the total costs for those episodes, emergency services approximately 9% and inpatient hospitalisations approximately 10%. Drug costs are minimal since there was no evidence of oral antibiotic use associated with the episode. What costs appear in this category are for otic drops primarily.

When evidence of oral antibiotic use during an episode can be found within the claims data, the average amount paid per episode increases, ranging from $126 per episode for those episodes when amoxycillin is the initiating antibiotic to $255 per episode when cefaclor is the initiating antibiotic. When compared to episodes where there is no evidence of oral antibiotic therapy, the per cent of total costs expended in physician and outpatient services, emergency services and inpatient hospitalisations are less.

The use of oral antibiotics during an otitis media episode contributes to an increase in the total average amount paid per episode but given the evidence, may be off set by decreases in the relative amounts expended in some high cost centres such as emergency rooms and inpatient hospitalisations. This should not be overlooked in the discussion of the relative advantages of oral antibiotic therapy.

When comparing the costs of episodes where amoxycillin/clavulanate is the initiating antibiotic with those where cefaclor is the initiating antibiotic, the average amount paid per episode is less with amoxycillin/clavulanate.. The $40 difference is a significant one and is consistently the same when acute or chronic otitis media grouping is considered. Given the differences noted in the logistic regression and discriminant analysis results this difference may be partially explained by the emergency services found to be a significant explanatory variable for cefaclor use. It may be that hospital based physicians may have more familiarity with cephalosporin antibiotics generally, and therefore prescribe them as a class more frequently.

Cost per day of an episode was also determined and subjected to statistical analysis. These results show that there is a statistically significant difference between episodes where amoxycillin/potassium clavulanate is the initial antibiotic used during an episode and cefaclor is the initial antibiotic used. Cost per day is less for the amoxycillin/potassium clavulanate episodes ($1.40 per episode day).

The largest cost advantage, however, is with amoxycillin. The cost difference between amoxycillin and amoxycillin/potassium clavulanate as measured by average amount paid per episode is $89. The cost difference as measured by cost per episode is $2.40.

4.2 What methodological issues arose during the analysis?

Generally, the areas of debate in using claims data relate to validity issues i.e.:

- coding errors

- diagnosis

- linkage between the dispensing of a drug and the patients compliance, actual dosing, appropriateness of use etc.

- confidentiality

- appropriateness of the population of the databases to other settings of care.

- the continuity of the patient records e.g. drop outs etc.

In the case of this analysis, there are four distinct areas of debate:

1) Case selection

2) Group assignment

3) Assessment of complications with otitis media

4) Cost assignment

4.2.1 Limitations of case selection

As highlighted earlier, and as with all research studies, limitations must be placed on the ability to generalise the results beyond the sample and setting employed. This study adopted a traditional approach of case selection followed by assignment to groupings

relevant to the overall analysis. The limitations that exist because of the case selection process adopted in this study include:

1. Representativeness

The study population is limited to those people enrolled in the three UHC model health plans. Therefore demographic factors, including socio-economic status and employment status, are likely to make this population unique. Generalisation of results is appropriate only to similar populations.

2. Random selection

Because the database contains historical information randomisation, as employed in a conventional clinical trial, was not employed in this study. Any member meeting the inclusion criteria were entered into the study.

3. Geographical representativeness

The three health plans included in the study are located in three states. Some patient, provider and practice differences could not be identified from the UHC database. Caution should be exercised in generalising to other regions.

4. Date source constraints

Although claims data present unique advantages when utilised as a research tool, there are also constraints introduced (Ray, 1989 and Weiner, 1990).

The key constraints are:

a. Dependency on coding which because of variations in coding, errors in coding, incompleteness of coding and the non specificity of some coding, may result in errors of classification. No methods have yet been published on how to assess the magnitude and effect of these errors.

b. The underlying purpose of claims data may contribute to errors of classification. Providers may submit claims for the sake of expediency of payment with less regard for the accuracy of the claim. This may contribute to over or under identification of disease episodes.

4.2.2 Limitations of group assignment

Likewise with group assignment, errors will exist largely due to:

1) dependency on coding

Variation in coding, errors in coding, incompleteness of coding and the non-specificity of some coding may result in errors of classification. This may result in over or under identification of acute or chronic otitis media cases.

2) subjectivity of the diagnostic process

Medical literature suggests that the medical diagnostic process is a combination of science and art-dependant in many cases on the experimental component of the clinicians training. The decision to diagnose a presenting condition as acute or chronic acute otitis media is made by individual clinicians with varying levels of experience. This cannot be controlled for within the bounds of claims data.

3) Heterogeneity of groups

Clinical opinion was utilised to determine the definitions for assignment into groups. In the case of chronic otitis media assignment was based on 5 different possible definitions. This may result in a group with greater individual differences than is apparent.

4) Definition of groups

Age in years was assigned based on age at the end of the study period. Even so, there will be members who because of age less than six months, cannot be classified with chronic otitis media due to a lack of medical history.

5) tympanostomy tube indicator

any member included in this study with claims for tympanostomy tubes was categorised as chronic even though the tympanostomy tube procedure may have had a non otitis media diagnosis code associated with it (i.e. chronic tonsillitis or chronic sinusitis). The use of tympanostomy tubes as a treatment modality for other conditions has not been established but if nevertheless may, if employed, over assign some members into the chronic group.

6) definition of an episode of otitis media

the research questions for this study concern the antibiotic therapy employed in treating otitis media. Oral antibiotic drug claims were therefore used to determine episodes of care. Other studies may employ different index events to determine otitis media episodes.

Comparison of the results of this study must take definitional differences into consideration.

In addition the association of a drug claim with a diagnosis code has the potential for error. Particularly when a drug may be prescribed for a number of different conditions (as is the case with antibiotics) and the disease in question may have a number of associated conditions (e.g. pharyngitis, tonsillitis etc.), the assignment of a drug claim to a diagnosis could result in the over identification of drug treatment with one specific disease. In this analysis, potential errors were minimised by utilising short time windows.

7) determination of time windows for episodes of care

The time windows employed in this analysis are arbitrary, though based on clinical/expert opinion..

4.2.3 Limitations to the assessment of complications associated with otitis media

Some limitations should be considered in interpreting the results related to complications associated with otitis media. The limitations include but are not necessarily limited to:

1) Association of complications with otitis media.

Claims data were searched for any evidence of complications among those members identified for this study. Whether the conditions occurred because of otitis media cannot be stated with certainty. Studies of the prevalence rates of these 11 complications in a population of 0-6 year old members not having otitis media were not performed.

2) Diagnostic codes for hearing loss.

Only the presence of an ICD-9 diagnosis code for hearing loss was used. Because tests for conductive hearing loss may be used in the differential diagnosis of otitis media, claims with CPT-4 procedure indicating hearing tests only were not included. This may result in the underreporting of hearing loss as a complication, the extent is not known.

3) Definitions of acute and chronic otitis media.

The classification of members into acute or chronic otitis media has limitations previously described. Comparative differences in the prevalence rates for the 11 complications identified should also refer to these limitations.

4) Association of drug therapy with otitis media.

The association of any drug therapy with a specific disease is subject to errors of assignment. Members with evidence of antibiotic therapy during an otitis media episode may have had another condition for which the antibiotic was prescribed. Over reporting would result, the extent of which is not known.

4.2.4 Limitations of cost assignment

Several limitations concerning the costs reported in this study should be noted.

1) Specificity of costs incurred by specified plans only.

The costs associated with the identified claims and reported for this study are the costs incurred directly by UHC plans and the costs incurred by the patient as co-pay only. The

amount reported does not include any amounts specified as the responsibility of another insurance program through co-ordination of benefits.

2) Format of inpatient hospitalisation charges

The ability to decompose inpatient hospitalisation costs into component costs (facility charges, pharmacy costs, etc.) does not exist. Therefore, the inpatient hospital costs reported are total costs paid for each hospitalisation with a primary or secondary ICD-9 code of interest and length of stay of at least overnight.

3) Definition of direct costs

Dollar amounts reported are an assessment of direct costs only. For this study, direct costs are defined as those costs for which a managed care plan incurs costs. Other costs which may be defined as direct by other researchers are not included , nor are any indirect costs. Although indirect costs (including lost time from work or school, etc.) may increase the overall costs of otitis media, claims data do not allow for assessment of such associated costs.

4) Member eligibility

Costs of services included in the claims data of UHC plans are those for which a member has eligibility. The extent and costs of certain treatments are not included in a benefit structure cannot be ascertained from this data source. In the case of otitis media this includes the extent and costs of OTC medications whose use may or may not be initiated as the result of physician recommendation.

5) Co-pay benefit structures

The unreported use of any treatment whose total cost does not equal the costs assessed to the member as co-pay. Any pharmaceutical agent ordered by the physician in a quantity which results in costs less than member co-pay will be underreported.

4.3 How could this information be used in health economics research in the pharmaceutical industry?

Lair (1996) argues that retrospective data sources can assist economic study data needs in seven ways.

1) identifying appropriate economic endpoints.

2) defining the patterns of usual care and spectrum of current therapy.

3) determining episode duration.

4) highlighting adverse events.

5) determining sample size for economic endpoints.

6) identifying important economic stratifying variables.

7) quantifying compliance expectations.

Linking these areas to the otitis media analysis shows information in these areas can readily be extracted.

1) identifying appropriate economic endpoints.

In economic components of clinical trials, it is important to determine the usual progression of utilisation events that most accurately represent the course of treatment. These events mesh with and are often responsive to the clinical parameters measured in the study but are far less known. In addition, the array of secondary endpoints are not easily identified prior to some initial analysis of the events likely to occur.

In this study, the key cost driver was physician and outpatient services (72% of total costs). This was followed by drug therapy (15% of total costs). Chronic otitis media consumed 84% of total costs i.e. 50% of members account for 84% of total otitis media incurred costs.

Within severity groups, chronic cases have the largest percent of costs expended for emergency physician and outpatient services. Acute cases have the largest per cent of dollars expended on emergency services and in-patient hospitalisations.

This indicates the areas we should focus our attention on when collecting resource use data as part of an economic trial.

2) defining the patterns of usual care and spectrum of current therapy.
Patterns of health care can be reconstructed from administrative databases. For a particular diagnosis, treatment options can be arrayed and alternative therapies described. For example, is drug therapy the only option or are other procedures used.

In our study, a conservative approach to treatment (no treatment or single antibiotic therapy) is adopted in 74% of cases. The majority of episodes are resolved with a single course of drug therapy. For HMOs combined amoxycillin is the antibiotic used most frequently as the initiating antibiotic and is used in a greater proportion of acute cases. Amoxycillin/clavulanate and cefaclor showed increased use in the chronic otitis media group.

In the cases of re-prescribing, it would appear that whatever the initial choice, the secondary therapy will be the same in the majority of cases.

Tympanostomy tube insertion is reserved for those patients in the chronic group only, confirming it's use in 'treatment failures'.

From all this data it should be possible to construct a flow of patient pathways, along with probabilities of going down those routes with associated costs, in order to construct an economic model of treatment. From this we could construct a model investigating the possible impact of a new therapy along with appropriate sensitivity analyses to investigate the impact of certain key variables. Using estimates of possible effectiveness of a new drug, it would then be possible to derive a cost break-even price for a new drug (at various degrees of effectiveness) to inform commercial pricing decisions.

3) determining episode duration.

Secondary data can portray the appropriate episode window for clinical and economic studies. If the episode is defined based only on the expected duration necessary to demonstrate clinical efficacy, the economic effects may be missed if the cost of the therapy process does not mirror the clinical efficacy pattern.

In this study the average length of an episode is 13 days for members classified as acute and 36 days for those classified as chronic. This would suggest we would need to collect data on chronic patients for nearly 3 times longer than for acute. As we don't know if an

episode is going to acute or chronic at the outset, this would set the data collection period for all patients involved in an economic trial.

4) highlighting adverse events.

It is likely that many of the diseases under consideration for clinical trials will be chronic. Historically, it has been difficult to either identify subjects for a clinical trial that are free from confounding co-morbidities that could complicate the identification of adverse events or distinguish between symptoms of a co-morbidity and a potential adverse event. Claims data can be useful to address this issue.

Claims databases can also be useful in calculating the treatment cost of adverse drug reactions. These data can subsequently be used in different types of pharmacoeconomic studies.

In this study, adverse events relating to pharmaceutical therapy were not assessed as part of this study. Complications arising from otitis media were showed to be hearing loss and speech and language disorders to be most prevalent. For some diseases, theoretically, we could have provided data on the distribution of co-morbidities in the population and used that to infer differentiation of adverse events and symptoms associated with the co-morbidities most likely associated with the primary diagnosis.

5) determining sample size for economic endpoints.

Again, this was not considered as part of the original research proposal, however, theoretically, the robustness of sample size calculations should be improved by actual estimates of the probability of occurrence of key cost drivers.

Otitis media is not necessarily the easiest of conditions to highlight this potential aid to outcomes research. Instead, think of a database that could provide estimates of admission to nursing home for a particular condition e.g. dementia. We could extract estimates for a control group from such a database and use that rate of admission to calculate the precise estimates of the sample size necessary to detect potential differences between a control group and treatment group.

6) identifying important stratifying variables.

Important stratification variables and randomisation criteria may not always be obvious in studies of clinical or economic outcomes. Basic descriptive analyses can be conducted using claims databases to help identify within and between group differences in disease prevalence, utilisation patterns or other factors.

In this study factors highlighted as having an effect on resource utilisation would appear to be:

gender

location of HMO

age of patient

acute Vs chronic disease classification

This should help those individuals designing outcomes research trials to ensure an appropriate balance is secured between a control and active group.

7) quantifying compliance expectations.

Often clinical and economic trials assume full compliance with the target agent – an often inaccurate assumption that can have a critical impact on outcomes assessment. This might be a reduction in the theoretical effectiveness of a drug, prolongation from a lack of effect or even unnecessary prescriptions.

Claims databases can be used to estimate baseline expectations regarding these compliance assumptions and/or derive assessments of the possible impact of poor compliance in the drug treatment of some disease groups. A measure of compliance can be developed by using an algorithm which links diagnosis, drug and dosing information. While some of this behaviour would not be permitted in a clinical trial setting, poor utilisation patterns and poor compliance are often the norm and need to be taken into account when planning the design of a trial as well as in the interpretation of trial based estimates of economic parameters.

This was not possible within the remit of this analysis but is possible if continuous patient diagnosis, drug and dosing information were linked.

While accepting databases do have a role to play in health economics research, care should still be taken in utilising this information. A recent CMR report (CMR, 1998)

recently investigated the potential benefit to the pharmaceutical industry of automated databases in the context of health economics research. They concluded automated databases do have relevance for health economics research and could be used either alone or in conjunction with other data sources but that consideration should be given to using different databases in a complimentary manner rather than in isolation.

They also suggest:

- allocating time and personnel to understand the unique characteristics of each database.
- accessing pharmacoepidemiological skills to ensure an appropriate study design which controls for potential biases so as to maximise internal validity.
- expressing information needs simply to the data provider recognising that they do not profess to be experts in health economics.
- taking an iterative approach to study design working closely with the data providers.
- working with experts who understand automated databases.
- working with the data providers to support data developments in a way that will increasingly reflect health economics needs.

Willis et al (1993) suggest the following should be considered when using claims databases for outcomes research.

1. choosing an appropriate database

There are two major concerns in selecting a database: the patient population and the structure and content of the database files. The covered population must contain patients

or cohorts of patients appropriate to the research question. It is important that the study population does not have unique characteristics that may affect the generalisability of the study findings. Characteristics such as the stability of the patient population covered by the plan, or the frequency of healthcare utilisation outside that covered by the plan, will affect the suitability of the database for outcomes research. Likewise, if the patient population contains significant subgroups with special healthcare needs, this may skew the results. For example, recently insured individuals may exhibit high utilisation rates attributable to new access to healthcare services. If the insurance plan has a high level of benefits in a particular health service sector, the covered population may also have an inordinate level of healthcare utilisation. Health services utilisation also depends on the rates of illness or injury prevailing among the covered population (e.g. individuals from the manufacturing sector may have higher rates of accident, causing high utilisation of healthcare). In general, co-payments for prescription drugs reduce the rate of drug utilisation (Harris 1990, Leibowitz 1985, Levy 1992, Nelson 1984).

The second area of concern is the structure and contents of the database. A review of the many variables included in the database, and their definitions, should determine it's content and completeness. However, while the database may list the necessary elements, the quality of this information must be verified, especially the way the information is captured by the claims processing system. A recent evaluation of a claims system showed it's validity in predicting in hospital mortality, but uncovered a wide variation in sensitivity to nonfatal outcomes or quality of care (Iezzoni et al 1993). The ease with which information can be retrieved from individual files into the analytical research files

is also critical for determining the amount of time and resources needed to conduct the evaluation.

Linkages among prescription drug, administration and medical and hospital databases are essential for developing patient-specific, longitudinal files for specific purposes (Hartzema 1992). The process for using these files often includes combining, or linking, these , several data files, resolving discrepancies and completing missing information (Roos 1993). In order to be linked, the files must have common data elements that identify unique patients or providers. For example, claims databases which identify drug utilisation by contract holder (i.e. those which combine all family utilisation under the name of one insured member) could not support a study on patient-specific episodes of care.

Linkages with other databases are the key to enlarging the scope of the research to allow additional hypothesis testing. For example, if patient zip code information in an administrative file is linked with census data files, the researcher would also have access to information about the patient's socio-economic status.

2. Evaluating the completeness and validity of the database.

When a claims database is used for outcomes research, the completeness and the validity of the database should be assessed. The procedures for reimbursement of services and documentation of the claims will affect the integrity of the database. Where claims must be submitted for reimbursement, the claims database generally captures the majority of

information about patient information utilisation of healthcare, including drugs. However, when compensation is made through capitated plans rather than fee for service arrangements, the database may be less complete. For example, physician identifiers within a prescription drug claim database may be erroneous since reimbursement is rarely affected by the accuracy of this field. The lag between the time when the service was supplied and when the claims information was entered into the database will also affect the completeness of the database. However, electronic claims submission systems for prescription drug claims have greatly reduced the lag time for prescription drug claim information.

Outcomes research usually requires use of original patient data either to validate claims data or to obtain additional information (Anagaran 1991, Grady 1992, Lohr 1990, Strom 1991). Claims databases are currently designed to record information about drug utilisation but not the effects of this utilisation on the patient. For example, a database will report the prescribed medication but will not indicate the degree the prescribed medication but will not indicate the degree of efficacy or adverse effects. As a result, additional data, such as medical chart information, is often necessary to determine the results associated with drug utilisation, severity of illness and the rationale behind changes in medication prescribing.

The data should be checked for internal validity . It must be established whether the data make sense given what is known from clinical experience or from other research or

reports. Diagnostic data may be verified by checking the occurrence of laboratory tests or prescription of medications that are unique to the specific diagnosis (Roos et al 1993). Diagnostic information may also be verified by comparing the database information with information from medical charts or a disease registry. Another useful method of cross checking is to compare physician inpatient service claims with institutional hospital claims.

3. Identification of confounding factors

The outcomes researcher must identify the factors in the claims database that can influence the generalisability of the findings. Insurance coverage and inclusion in a claims database affect healthcare utilisation , thereby skewing any generalisation of claims data research to the uninsured population (Hafner-Eaton 1993). Multiple options for insurance produce multiple factors that may each affect healthcare utilisation (Garfinkel 1986).

Determining the clinical condition of the patient is often confounded by the difficulty in capturing accurate diagnostic and procedural information. Co-morbidity and complications can be assessed from claims databases that collect multiple diagnoses and multiple procedures for each claim.

Geography is another common confounding factor. Regional database information is not always appropriate for national studies since there are regional variations in healthcare utilisation, practice patterns or malpractice rates (Localio 1993, Mendenhall 1984, Welch 1993). Since charges and/or payments vary across countries, US states, healthcare settings

and providers, the data must be adjusted before comparisons can be made among prescription or healthcare costs obtained from different regions. In addition, the degree of patient adherence to drug therapy can be a confounding factor since the records do not show if a medicine has been consumed.

4. Other considerations

When claims data are used for economic analysis the issue of identifying and measuring healthcare costs is an important consideration. Claims data typically show billed charges and payment amounts but not costs or resources consumed. Cost accounting methods could be used to determine the costs of services for an economic analysis. However, since few institutions have mechanisms for determining the true costs associated with the provision of care, proxies for costs, such as charges or payments, are often used. Charges could be converted into costs by using recognised cost to charge ratios such as those used for the Medicare system, although the extent to which derived costs reflect true costs is questionable.

Research using insurance claims databases also requires that patient confidentiality be preserved. This requirement is often accomplished by removing patient names.

Generally, the aim of any health economic evaluation is to select from a range of treatment alternatives. The basic steps in any evaluation are:

1) identification of the issue to be addressed, including selection of perspective.

2) selection of competing therapies

3) selection of evaluation of technique

4) design of study including:

- data to be collected
- patient group to be studied (inclusion criteria)
- time horizon of analysis
- sources(s) of data

4) collection of data on costs and outcomes associated with each therapy.

5) analysis of results

6) interpretation and recommendations based on results.

Clearly there is significant overlap between this process, the suggestions put forward by Lair and the otitis media analysis; any method that contributes information to this process will be useful in conducting a pharmacoeconomic analysis particularly in highlighting relevant comparators, endpoints, sample size, relevant patient sub-groups and study time horizons.

However, the role of databases should not only be focused on assisting individual study design. The database used in this analysis could certainly have been used to look at a number of broader outcomes research questions, beyond otitis media and beyond just the outcomes associated with pharmaceuticals, such as:

- the total costs incurred, for each HMO, for all diseases and treatments and breaking them down into program budgets to see how and where each HMO spends it's resources relative to other HMOs.

- ranking the diseases that incur most cost (on an annual or lifetime basis) to inform targeting decisions.
- ranking the patient subgroups which incur the most cost either in total or on a per patient basis (e.g. by age, sex, disease etc.).
- construction of patient flow models in order to see the paths patients taken through an HMO, if any bottle necks exists etc.
- examining the costs following surgical interventions.
- comparing service delivery patterns e.g. re-admission rates against national statistics for certain procedures to see, as a proxy, if any groups of patients are being discharged too early.
- reviewing the prescribing data to check for appropriateness of use, overuse and underuse.
- trying to assess the adherence to treatment guidelines and protocols and/or predicting the cost effects of introducing new ones.
- identifying the appropriate comparator in a pharmacoeconomic study. Most economic studies will want to compare itself against the currently used treatment (in some countries, such as Australia, it's required as part of the economic submission). In most cases, the most commonly used alternative can be derived from the claims database without the need for any study.

The information databases contain can also be used to help guide broader issues of pharmaceutical research throughout the development process. For example:

1) generating prevalence and 'cost-of illness' estimates in order to assess current high cost, high volume disease areas

2) to understand the burden of illness in terms of incidence, progression, severity and to assess the economic viability of compounds in early development.

3) provide assessment of compliance in order to facilitate decisions on dosing, quality of drug consumption, new drug formulations etc.

4) give assessments of the extent of adverse event issues with current treatments.

5) using all of these to help guide and inform pharmaceutical research priorities.

In a UK context, we clearly don't have the same availability of these types of insurance databases that so closely link financial tracking and the delivery of care. A considerable amount of data are recorded in the course of treatment such as diagnostic and treatment data as well as some outcome data, which are usually held in casenotes. The NHS captures enormous amount of detail but these seldom get translated into usable data. Casenotes in England still tend to be handwritten, specific to the site of treatment and are difficult to interpret. However, computerisation of case notes offers scope for their development. If it is to be turned into data then challenges do exist e.g. standardised coding systems would be essential. e.g. the International Classification of Disease but with regular updates on new diseases. However, the right sort of data does exist if only we could find a way of making it accessible and robust.

Possibly the nearest databases we currently have in the UK, to the ones seen in the US, are prescription databases such as DIN-LINK (The Doctors Independent Network,

Compufile Group, Woking UK), GPRD (General Practice Research Database, GP Database Research Company, London UK) and MEDIPLIUS (IMS UK Ltd, London UK) along with MEMO (Tayside Medicines Monitoring Unit, University of Dundee, Scotland) that attempts to track all forms of care. GPRD and MEMO were set up primarily to provide supplementary sources of data for the evaluation of drug safety, DIN-LINK and MEDIPLUS to provide information to support the marketing of pharmaceuticals. However, these have been criticised (CMR Report 1997) for:

- being complex and difficult to access the required information.
- the outputs depending on the skill of the operator.
- insufficient level of detail on outcomes.
- other than MEMO there is insufficient detail on secondary care activity
- representativeness, MEMO is largely restricted to Tayside (for secondary care data) whilst the others encompass less than 12% of the total population of the UK

Clearly, what is required in the UK are databases of a broader nature than we currently possess and more in line with what we see in the US (but ideally possessing more 'outcome' data than they currently do). This would enable all of those involved in the delivery of care to assess how that care is delivered in the UK and how appropriate it actually is. Given the increased emphasis on cost control in the NHS, this is more likely than ever going to drive through the links between financial data and delivery of care (as we see in the managed care environment in the US). This may mean, especially with the development of IT and the NHS Net, that the time for more integrated NHS data collection is about to emerge. This will be vital for the pharmaceutical industry in a time

of constrained NHS resource, in order to track how health care is delivered, understand areas of unmet need and provide a baseline to highlight the value of the products it produces relative to current care.

5. Conclusions

Most claims databases should be able to provide the following information to inform an economic evaluation of a medicine.

1) identifying appropriate economic endpoints.

2) defining the patterns of usual care and spectrum of current therapy.

3) determining episode duration.

4) highlighting adverse events.

5) determining sample size for economic endpoints.

6) identifying important economic stratifying variables.

7) quantifying compliance expectations.

However, the data held by claims databases can also be used to guide the wider research agenda. For example:

1) confirming prevalence and incidence rates to validate internal estimates.

2) deriving direct cost of illness estimates so an understanding can be gained of the impact imposed by the disease.

3) deriving progression and severity rates with cost estimates to assess the economic viability of compounds in early development.

4) providing assessment of compliance with current treatments. This could inform future decisions about a products dosing etc.

5) giving assessments of the extent of adverse event issues with current treatments.

6) using all of these to help derive economic analyses of current treatments.

In both cases, the following should be considered when a database is chosen for any economic assessment.

1) does the database hold a cohort of patients appropriate to the disease?

2) is the database completed both fully and accurately?

3) are there any confounding factors in the data that will influence the generalisability of the findings?

On the basis of the research contained in this dissertation, we would put forward the argument that the information that can be obtained from health care databases has an invaluable role in guiding the design of economic studies conducted by the pharmaceutical industry. Furthermore, the use of this information in steering the research agenda, should also be emphasised.

6. References

Albern T 1990. Drug utilisation reviews; types and issues. Journal of managed care 2:23-26.

Angaran DM 1991. Selecting, developing and evaluating indicators. Am Journal of Hospital Pharmacy 48: 1931-1937.

Berman S Lauer BA 1983. A controlled trail of cefaclor vs amoxycillin for treatment of acute otitis media in early infancy. Pediatr Infect Dis 2: 30-3.

Bland M 1992. An introduction to medical statistics. Oxford Medical Publications.

Bluestone CD 1984. state of the art; definitions and classifications. in Lim DJ, Bluestone CD, Klein JO, Nelson JD eds. Recent advances in otitis media with effusion; proceedings of the 3rd international symposium. Philadelphia. Decker 1-4.

Bourke GJ, Daly LE 1989. Interpretation and uses of medical statistics. Blackwell Publications.

Brooks DN 1980. Possible long term consequences of middle ear effusion. Ann Otol Rhinol Laryngol 89 (Suppl 68) 246-8.

Carlin SA, Marchant CD, Shurin PA, et al 1987. Early recurrences of otitis media: reinfection or relapse? Journal of Paediatrics 110 (1):20-25.

CMR International report 1997. Can UK automated databases provide relevant information for heath economics research. Centre for Medicines Research International.

Congressional Budget Office Report 1992. The impact of HMOs on healthcare costs and quality.

Edelstein DR, Parisier SC, 1988. Otitis media. Comp Ther. 14:37-45.

Eli Lilley and Co. Cefaclor package insert. Indianapolis June 1988.

Feder HM 1982. Comparative tolerability of ampicillin, amoxycillin and trimethoprim-sulfamethoxazole suspensions in children with otitis media. Antimicrob Agents Chemother 21: 426-7.

Feldman W, Morny J, Dulberg C. 1988. Trimethropin - sulfamethoxazole v amoxycillin in the treatment of acute otitis media. CMAJ 139 (10): 961-964.

Gable CB, Friedman RB 1992. Pharmacoepidemiology studies in automated claims databases: methodological issues. Journal of Research in Pharmaceutical Economics 4(4): 53-67.

Garfinkel SA, Schlenger WE, McLeroy KR, Bryan FA, York BJG 1986. Choice of payment plan in the Medicare capitation demonstration. Medical Care 24: 628-640.

Gates GA, Wachtendorf C, Hearne EM, Holt GR 1985. Treatment of chronic otitis media with effusion: results of tympanostomy tubes. American Journal of Otolarngology 6 (3): 249-253

Grady ML (ed) 1992. Medical effectiveness research data methods. Agency for Health care Policy and Research, Rockville, Md. AHCPR publication No. 92-0056.

Haefner-Eaton C 1993. Physician utilisation disparities between the uninsured and insured: comparisons of the chronically ill, acutely ill and well non-elderly population. Journal of the Am Med Association 269:787-792.

Harris BL, Stergachis A, Reid LD 1990. The effect of drug co-payments on utilisation and cost of pharmaceuticals in a health maintenance organisation. Medical Care 28: 907-917.

Hartzema AG, Porta MS, Tilson HH (Eds) 1992. Pharmacoepidemiology: an introduction, 2nd ed. Harvey Whitney Books, Cincinatti.

Healthscope report 1998. Managed care terminology.

Howie VM, Ploussard JH, Sloyer J 1975. The 'otitis-prone' condition. Am J Dis Child 129: 676-678.

Howie VM, Ploussard JH 1992. Efficacy of fixed combination antibiotics versus separate components in otitis media. J Infect Dis 29: S181-4.

Hudson H 1989. Managed care terms. Internet report. www.hcfa.com.

Iezzoni LI, Hotchkin EK, Ash AS, Schwartz M, Mackiernan Y 1993. MedisGroups databases; the impact of data collection guidelines on predicting in-hospital mortality. Medical Care 31: 277-283.

Isaacson G, Rosenfeld RM 1994. Care of the child with tympanostomy tubes: a visual guide for the paediatrician. Paediatrics 93 (6) 924-929.

Johnson M 1991. Managed care in Europe? Heath Affairs 2: 1063-1068.

Johnston WD 1994. Essentials of bio-statistics. Davis Press.

Jones FD 1974. Treatment of otitis media in paediatric practice; amoxycillin versus ampicillin. J Infect Dis 129: S187-8.

Jung TTK, Rhee CK 1991. Otolaryngologoc approach to the diagnosis and management of otitis media. Otolaryngologic Clinics of North America 24 (4):931-945.

Klein JO. Otitis media. Clinical Infectious Diseases 19: 823-833.

Lair TJ. 1996. Using retrospective databases in the design of prospective clinical and economic studies. Drug Information Journal 30: 679-691.

Leibowitz A, Manning WG, Newhouse JP 1985. The demand for prescription drugs as a function of cost-sharing. Social Science and Medicine 21:1063 - 1069.

Levy RA 1992. Prescription cost sharing: economic and health impacts and implications for health policy. Pharmacoeconomics 2: 219-237.

Lim DJ, Lewis DM, Scaham JL, Birck HG 1980. Antibiotic resistant bacteria in otitis media with effusion. Ann Otol Laryngol 89 (suppl 68): 278-80.

Localio AR, Lawthers AG, Bengtson JM, Herbert LE, Weaver SL 1993. Relationship between malpractice claims and caesarean delivery. Journal of the American Medical Association 269: 366-373.

Lohr KN 1990. Use of insurance claims data in measuring quality of care. International Journal of Technology Assessment in Health Care 6: 263-271.

Lowe P. 1992. Consumer choice in plan selection. Pharmatrends 2: 190-191.

Mandel EM, Rockette HE, Paradise JL et al 1991. Comparative efficacy of erythromycin-sulfisoxazole, cefaclor, amoxycillin or placebo for otitis media with effusion in children. Pedatr Infect Die J 10 (12):899-906.

Marchant CD, Shurin PA 1983. Therapy of otitis media. Pediatr Clin North Am 30: 281-96.

Mendenhall RC, Moynihan CJ, Radecki SE 1984. The relative complexity of primary care provided by medical specialists. Medical Care 22: 987-1001.

Menyuk P 1980. Effect of persistent otitis media in language development. Ann Otol Rhinol Laryngol 89 (suppl 68): 257-63.

Meyerhoff WL 1981. Use of tympanostomy tubes in otitis media. Annals of Otolaryngology 90: 537-542.

Michaels RH, 1981. Marginal comment; ampicillin resistant Haemophilus influenzae and otitis media. Am J Dis Child 1135: 403-5.

Nelson AA, Reeder CE, Dickson WM 1984. The effect of a Medicaid co-payment programme on the utilisation and cost of prescription services. Medical Care 22: 724-736.

Personal communication 1998. Kaiser Permanante.

PharmaBusiness report 1994. PBMs: how much! Vol 4:27-28.

PharmaMarket report 1991. The future of US healthcare.

Promarket report 1991. The future of healthcare in Europe: will it follow the US?

Ray WA, Grivven MR 1989. Use of Medicaid data for pharmacoepidemiology. American Journal of Epidemiology 129 (4):837 - 849.

Roberts JE, Burchinal MR, Collier AM, Ramey CT, Koch MA, Henderson FW. Otitis media in early childhood and cognitive, academic and classroom performance of the school aged child. Paediatrics 83: 477-85.

Roos LL, Mustard CA, Nicol JP, McLerran DF, Malend DJ 1993. Registries and Administrative data: organisation and accuracy. Medical Care 31: 201-212.

Rowntree D 1983. Statistics with confidence. Pelican Press.

Rubens A 1994. The future of managed care? Journal of Pharmacy Management 418: 57-59.

Shurin DA, Van Hare GF 1986. Therapy of otitis media caused by branhamella catarrhalis. Drugs 31 (Suppl 3): 122-4.

Strom BL, Carson JL, Halpern AC, Schinnar R, Snyder ES 1991. Using a claims database to investigate drug-induced Stevens-Johnson Syndrome. Statistics in Medicine 10: 565-576.

Teele DW, Klein JO, Rosner BA 1989. Epidemiology of otitis media in children. Ann Otol Rhinol Laryngol 89 (Suppl 68):5-6.

Thoene DE, Johnson CE 1991. Pharmacotherapy of otitis media. Pharmacotherapy 11 (3):212-221.

Tos M 1988. Sensorineural hearing loss in acute and chronic middle ear disease. Acta Otolaryngol (Stockholm) 457 (Suppl): 87-93.

Van Hare GF, Shufin DA, Marchant CD, Calrin S, Kim CH 1987. Acute otitis media caused by branhamella cattarrhalis: biology and therapy. Rev Infect Dis 9: 16-27.

Wald ER 1989. Changing trends in the microbiology of otitis media with effusion. Pediatr Infect Dis 3: 380-3.

Weiner JP, Powe NR, Steinwachs DM, Dent G 1990. Applying insurance claims data to assess quality of care: a compilation of potential indicators. QRB (Dev):424-438.

Welch WP, Miller ME, Welch HG Fisher ES Wennenberg JE 1993. Geographic variation in expenditure for physicians services in the United States. New England Journal of Medicine 328: 621-627.

White LW, Holiman JT, Tepedino JT 1996. Antimicrobials prescribed for otitis media in a paediatric Medicaid population. Am J Healh-Syst Pharm 53: 2963-2969.

Willis NJ, Patwell JT 1993. The role of insurance claims databases in drug therapy outcomes research. Pharmacoeconomics 5(4): 223-230.

Witt RL, 1988. Otitis media; an overview of treatment. Del Med J. 60: 69-71.

7. Figures

Figure 1- Claims by month

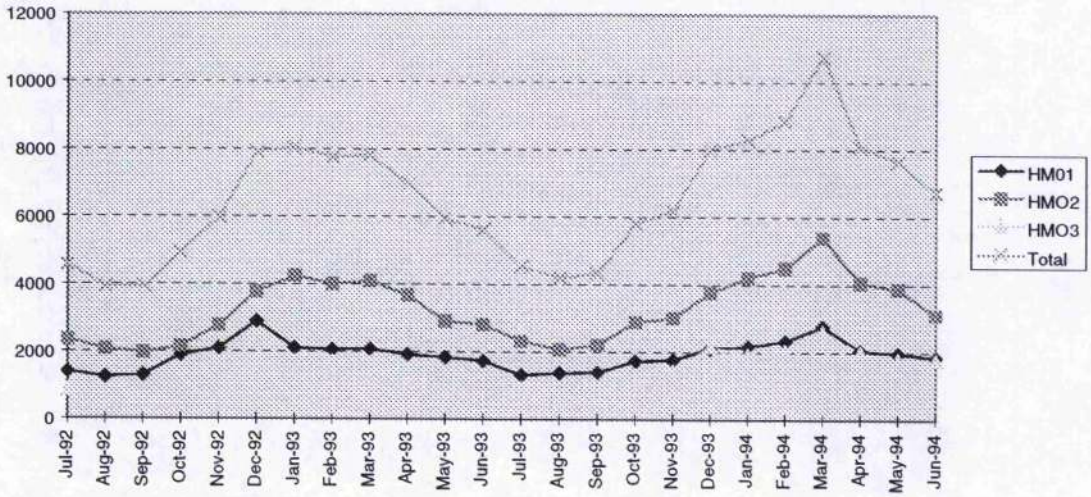


Figure 2 - % of episodes with initiating antibiotic - all HMOs combined

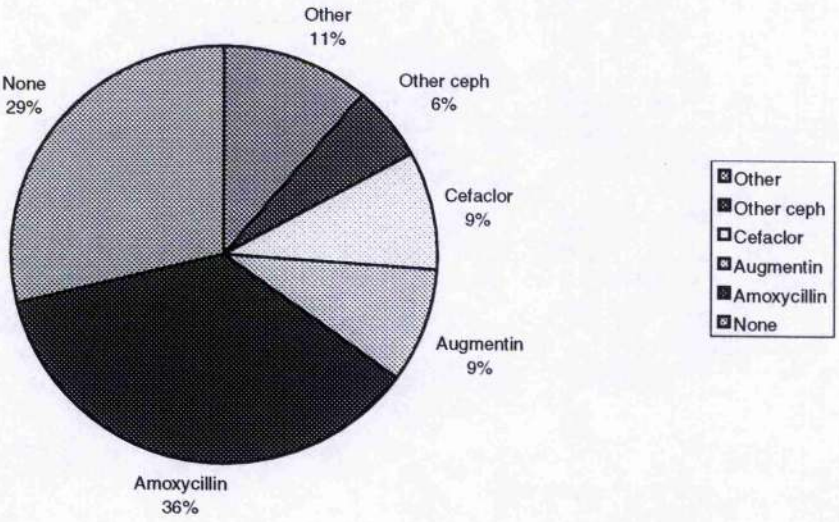


Figure 3a - % of episodes with initiating antibiotics - acute OM, all HMOs

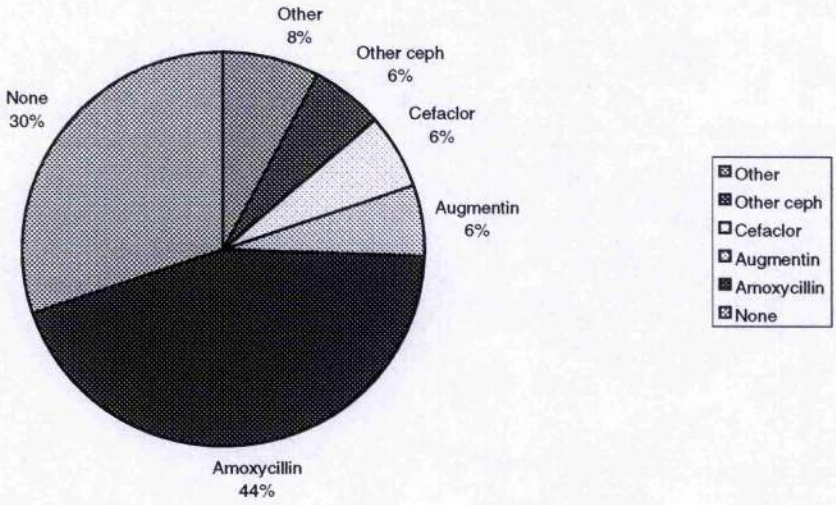


Figure 3b - % of episodes with initiating antibiotics - chronic OM, all HMOs

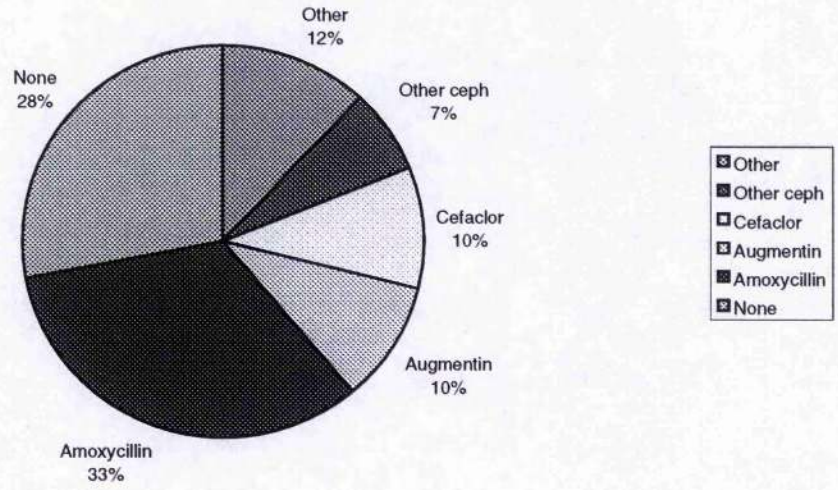


Figure 4a - % of episodes with initiating antibiotics - Acute OM, HMO1

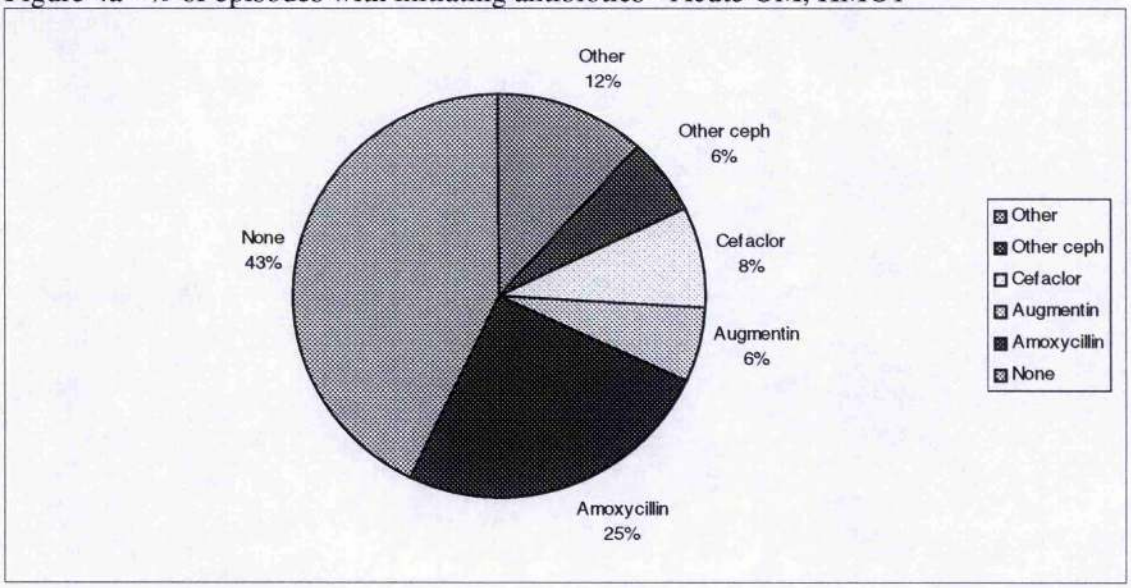


Figure 4b - % of episodes with initiating antibiotics - chronic OM, HMO1

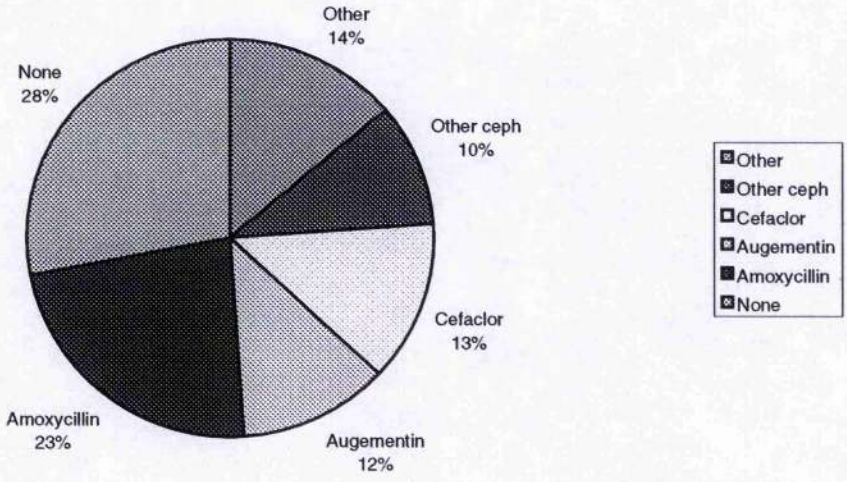


Figure 5a - % of episodes with initiating antibiotics - acute OM, HMO2

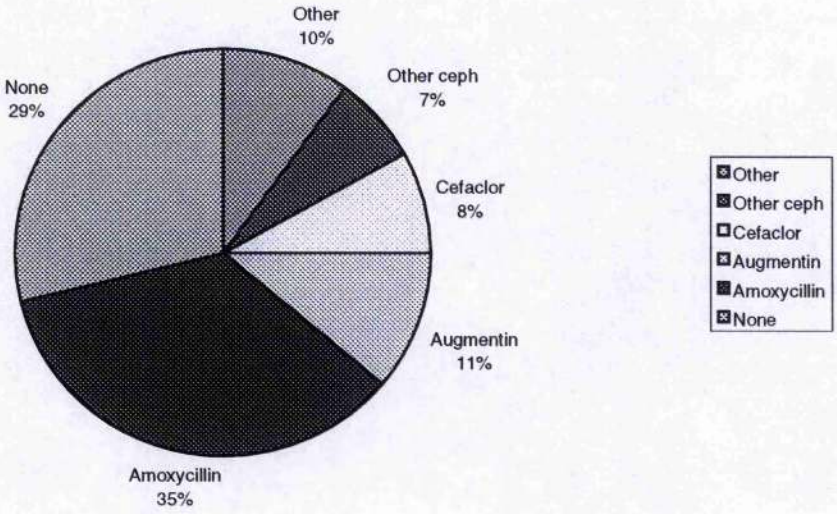


Figure 5b - % of episodes with initiating antibiotics - chronic OM, HMO2

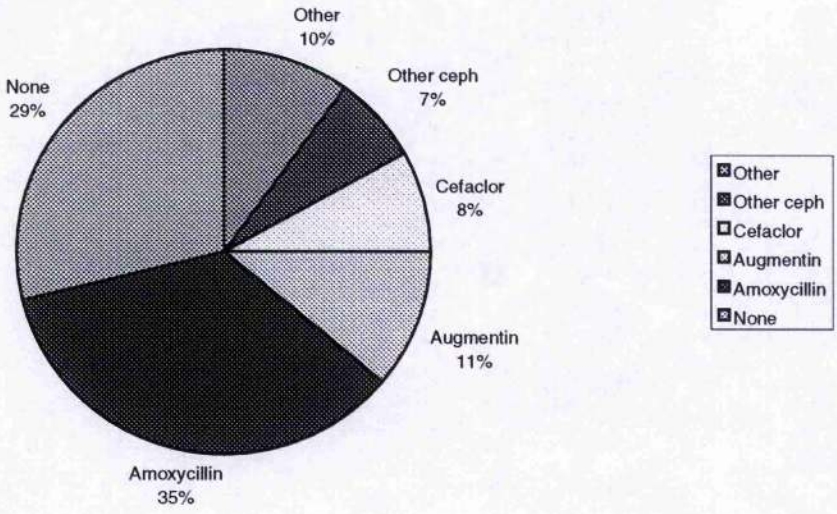


Figure 6a - % of episodes with initiating antibiotics - acute OM, HMO3

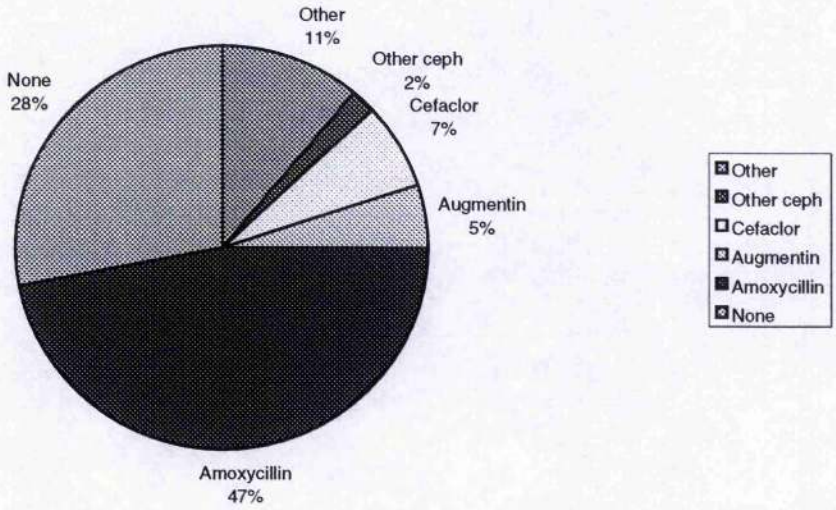


Figure 6b - % of episodes with initiating antibiotics - chronic OM, HMO3

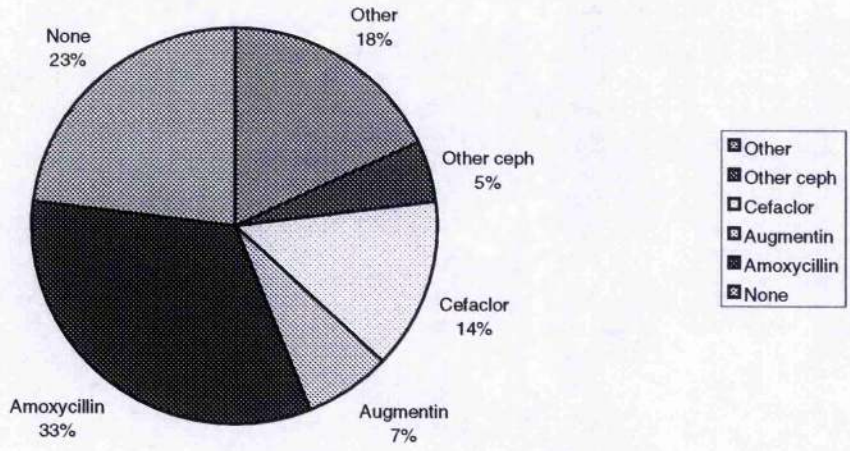


Figure 7 - Costs associated with the diagnosis and treatment of otitis media

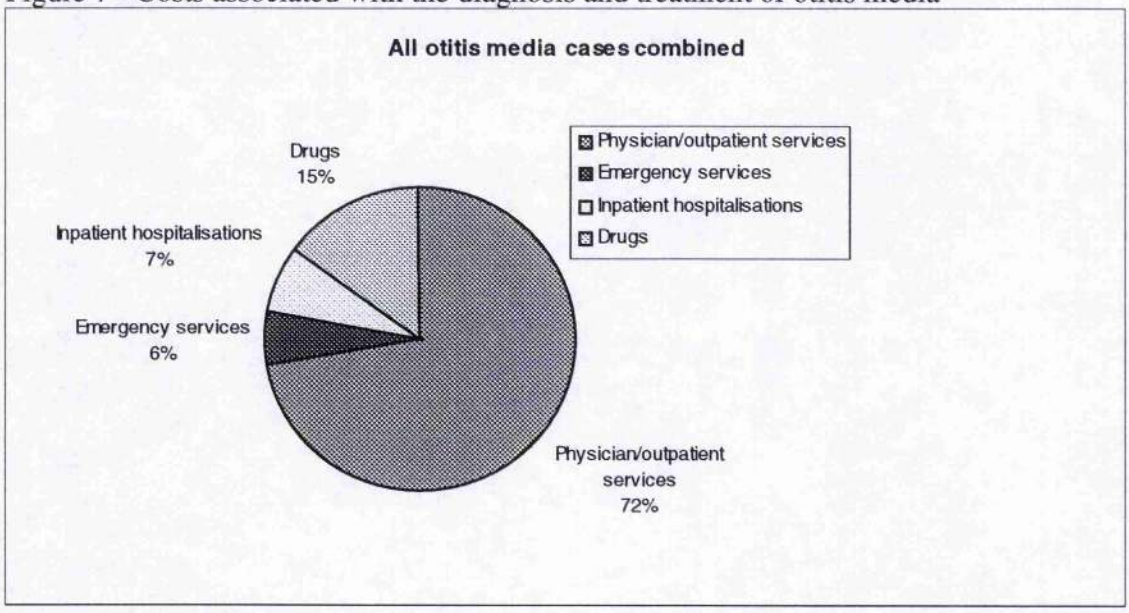


Figure 8a -costs associated with the diagnosis and treatment of otitis media

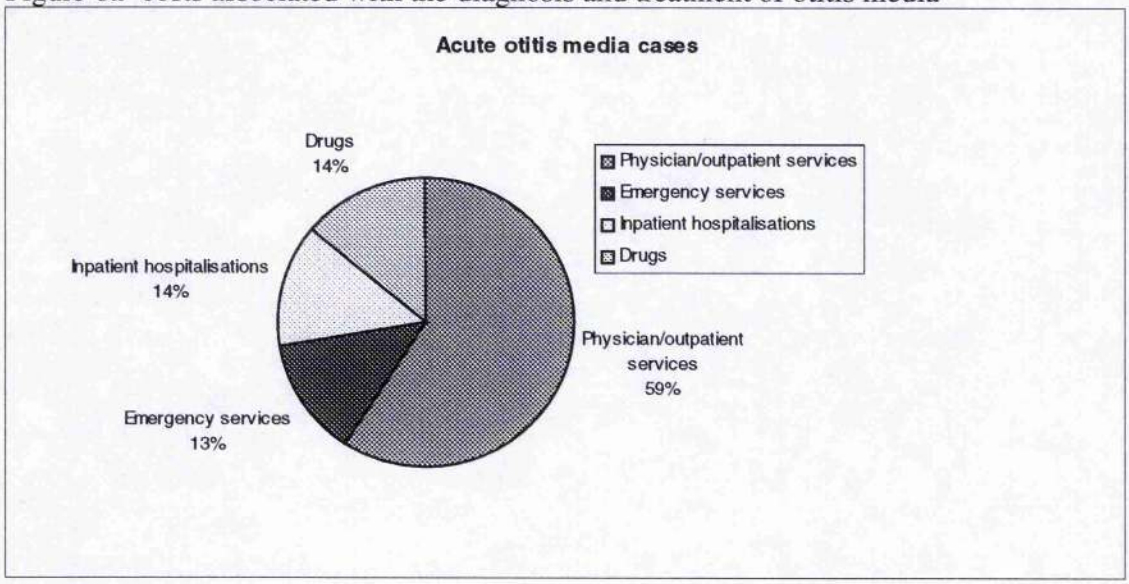
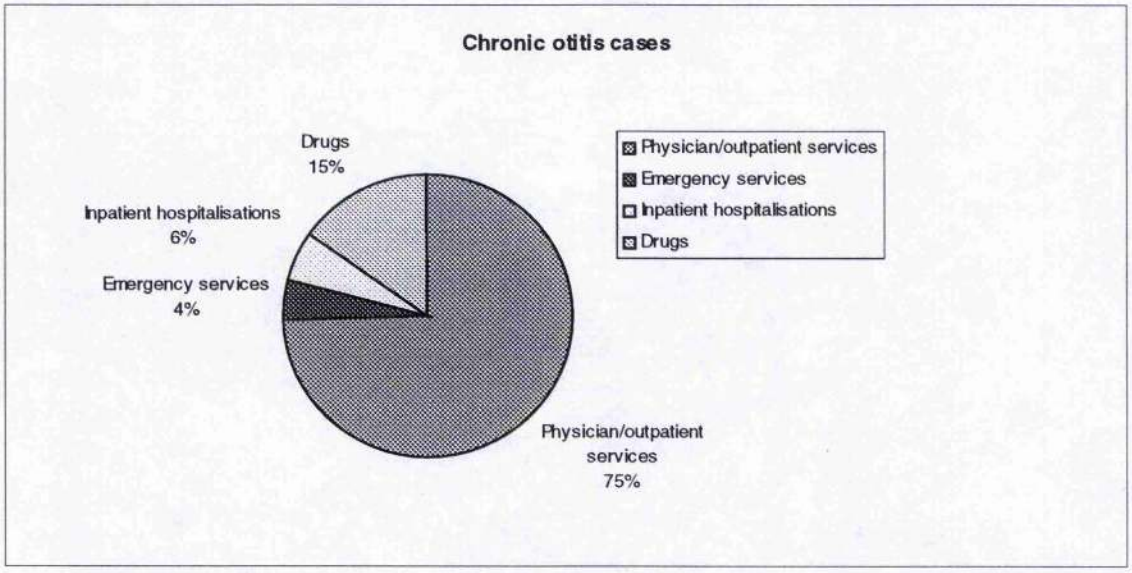


Figure 8b - costs associated with the diagnosis and treatment of otitis media



8. Tables

Table 1 - otitis media claims origination

Plan	07/01/92-12/31/92	01/01/93-06/30/93	07/01/93-12/31/93	01/01/94-06/30/94	Plan total
HMO1	Dr: 8721 Hl: 2062	Dr: 9495 Hl: 2179	Dr: 7879 Hl: 1769	Dr: 10,697 Hl: 2414	Dr: 36,792 HL: 8424 45,216
HMO2	Dr: 12,791 Hl: 2272	Dr: 18,668 Hl: 3070	Dr: 14,162 Hl: 2092	Dr: 21,569 Hl: 3597	Dr: 67,190 Hl: 11,031 78,221
HMO3	Dr: 4746 Hl: 649	Dr: 7273 Hl: 1436	Dr: 6053 Hl: 1146	Dr: 10,175 Hl: 1917	Dr: 28,247 Hl: 5148 33,395
Total	Dr: 26,258 Hl: 4983	Dr: 35,436 Hl: 6685	Dr: 28,094 Hl: 5007	Dr: 42,441 Hl: 7928	Dr: 132,229 Hl: 24,603 156,832

No. of doctor claims
No. of hospital/facility claims

Table 2 - Otitis media prevalence rates - study population
All otitis media codes combined

Plan				Age	group			
	<1	1	2	3	4	5	6	Total
HMO1	219	433	312	253	223	201	201	1842
	810	576	410	395	455	479	505	3630
	270	752	761	641	490	420	398	507
HMO2	459	946	866	676	592	563	539	4641
	1852	1331	1090	1007	1011	1010	1086	8387
	248	710	794	671	586	557	496	553
HMO3	269	409	235	156	164	147	539	1484
	964	514	289	244	273	278	1086	2788
	279	796	813	639	601	529	496	532
Total	947	1788	1413	1085	979	911	844	7967
	3626	2421	1789	1646	1739	1767	1817	14805
	261	739	790	659	563	516	465	538

otitis media cases
No. continuously enrolled
Rate per 100

Table 3 - otitis media prevalence rates - all otitis media episodes combined (males)

Plan				Age	group			
	<1	1	2	3	4	5	6	Total
HMO1	110	227	162	144	123	110	113	989
	403	302	209	222	248	254	272	1910
	273	752	775	649	496	433	415	518
HMO2	248	511	436	343	305	291	266	2400
	936	691	543	509	511	505	555	4250
	265	740	803	674	597	576	479	565
HMO3	150	217	134	76	85	89	43	794
	486	269	154	124	130	150	105	1418
	309	807	870	613	654	593	410	560
Total	508	955	732	563	513	490	422	4183
	1825	1262	906	855	889	909	932	7578
	278	757	808	658	577	539	453	552

otitis media cases
No. continuously enrolled
Rate per 100

Table 4 - otitis media prevalence rates - all otitis media episodes combined (females)

Plan				Age	group			
	<1	1	2	3	4	5	6	Total
HMO1	109	206	150	109	100	91	88	853
	407	274	201	173	207	225	233	1720
	268	752	746	630	483	404	378	496
HMO2	211	435	430	333	287	272	273	2241
	916	640	547	498	500	505	531	4137
	230	680	786	669	574	539	514	542
HMO3	119	192	101	80	79	58	61	690
	478	245	135	120	143	128	121	1370
	249	784	748	666	552	453	504	504
Total	439	833	681	522	466	421	422	3784
	1801	1159	883	791	850	858	885	7227
	244	719	771	660	548	491	477	524

otitis media cases
No. continuously enrolled
Rate per 100

Table 5 - Acute or chronic assignment.

Plan	Gender	Acute otitis media	Chronic otitis media	Total
HMO1	Male	450	539	989
	Female	422	431	853
	Total	872	970	1842
	Percent mems	47	53	
HMO2	Male	1205	1195	2400
	Female	1179	1062	2241
	Total	2384	2257	4641
	Percent mems	51	49	
HMO3	Male	343	451	794
	Female	371	319	690
	Total	714	770	1484
	Percent mems	48	52	
All HMOs	Male	1998	2185	4183
	Female	1972	1812	3784
	Total	3970	3997	7967
	Percent mems	50	50	

Number of males assigned
Number of females assigned
Total number of members assigned
Percent of members assigned

Table 6 - chronic otitis media assignment

Plan	Assignment definition	Prior year No. assigned	Study period No. assigned	Total
HMO1	ICD - 9 code	114	111	225
	Episode>30 days	20	82	102
	Drug therapy>30 days	118	291	409
	Tympanostomy tubes	10	9	19
	3+ acute episodes	77	138	215
	Plan total	339	631	970
HMO2	ICD - 9 code	168	271	439
	Episode>30 days	52	211	263
	Drug therapy>30 days	356	724	1080
	Tympanostomy tubes	16	6	22
	3+ acute episodes	179	274	453
	Plan total	771	1486	2257
HMO3	ICD - 9 code	23	68	91
	Episode>30 days	12	59	71
	Drug therapy>30 days	146	290	436
	Tympanostomy tubes	13	6	19
	3+ acute episodes	56	97	153
	Plan total	250	520	770
ALL HMOs	ICD - 9 code	305	450	755
	Episode>30 days	84	352	436
	Drug therapy>30 days	620	1305	1925
	Tympanostomy tubes	39	21	60
	3+ acute episodes	312	509	821
	Plan total	1360	2637	3997

Table 7 - Prevalence of complications associated with otitis media

Plan	Members with otitis media		Meningitis	Complications Mastoiditis	Tympanic Perforation	Tympanic Scarring	Abnormality ear ossicles	Ossicular Discontinuity	Cholesteatoma	Facial Paralysis	Labrynthitis	Hearing Loss	Speech Language
HMO1	1842	Number	20	4	7	0	0	0	0	3	1	21	18
		Rate (per 1000)	11	2	4	0	0	0	0	2	0.5	11	10
HMO2	4641	Number	18	10	31	2	0	0	3	3	0	175	57
		Rate (per 1000)	4	2	7	0.4	0	0	0.6	0.6	0	38	12
HMO3	1484	Number	5	3	12	1	0	0	0	1	2	64	13
		Rate (per 1000)	3	2	8	0.6	0	0	0	0.6	1	43	9
All HMOs	7967	Number	43	17	50	3	0	0	3	7	3	260	88
		Rate (per 1000)	5	2	6	0.4	0	0	0.4	0.9	0.4	33	11

Table 8 - Prevalence of complications associated with otitis media - Acute

Plan	Members with otitis media		Meningitis	Complications Mastoiditis	Tympanic Perforation	Tympanic Scarring	Abnormality ear ossicles	Ossicular Discontinuity	Cholesteatoma	Facial Paralysis	Labrynthitis	Hearing Loss	Speech Language
HMO1	1842	Number	6	0	1	0	0	0	0	1	1	3	3
		Rate (per 1000)	7	0	1	0	0	0	0	1	1	3	3
HMO2	4641	Number	7	1	1	0	0	0	0	1	0	54	18
		Rate (per 1000)	3	0.4	0.4	0	0	0	0	0.4	0	23	8
HMO3	1484	Number	3	0	2	1	0	0	0	0	1	6	5
		Rate (per 1000)	4	0	3	1	0	0	0	0	1	8	7
All HMOs	7967	Number	16	1	4	1	0	0	0	2	2	63	26
		Rate (per 1000)	4	0.2	1	0.2	0	0	0	0.5	0.5	16	7

Table 9 - Prevalence of complications associated with otitis media - Chronic

Plan	Members with otitis media		Meningitis	Complications Mastoiditis	Tympanic Perforation	Tympanic Scarring	Abnormality ear ossicles	Ossicular Discontinuity	Cholesteatoma	Facial Paralysis	Labrynthitis	Hearing Loss	Speech Language
HMO1	1842	Number	14	4	5	0	0	0	0	2	0	18	15
		Rate (per 1000)	14	4	5	0	0	0	0	2	0	18	15
HMO2	4641	Number	11	9	30	2	0	0	3	2	0	121	39
		Rate (per 1000)	5	4	13	0.9	0	0	1	0.9	0	54	17
HMO3	1484	Number	2	3	10	0	0	0	0	1	1	58	8
		Rate (per 1000)	3	4	13	0	0	0	0	1	1	75	10
All HMOs	7967	Number	27	16	45	2	0	0	3	5	1	197	62
		Rate (per 1000)	7	4	11	0.5	0	0	0.7	1	0.2	49	15

Table 10 - Prevalence of complications associated with otitis media - no antibiotic therapy

Plan	Members with otitis media		Meningitis	Complications Mastoiditis	Tympanic Perforation	Tympanic Scarring	Abnormality ear ossicles	Ossicular Discontinuity	Cholesteatoma	Facial Paralysis	Labrynthitis	Hearing Loss	Speech Language
HMO1	396	Number	1	1	1	0	0	0	0	1	0	3	3
		Rate (per 1000)	3	3	3	0	0	0	0	3	0	8	8
HMO2	683	Number	3	1	4	0	0	0	0	0	0	23	5
		Rate (per 1000)	4	1	6	0	0	0	0	0	0	34	7
HMO3	194	Number	1	0	3	0	0	0	0	1	0	7	0
		Rate (per 1000)	5	0	15	0	0	0	0	5	0	36	0
All HMOs	1273	Number	5	2	8	0	0	0	0	2	0	33	8
		Rate (per 1000)	4	2	6	0	0	0	0	2	0	26	6

Table 11 - Prevalence of complications associated with otitis media - antibiotic therapy

Plan	Members with otitis media		Meningitis	Complications Mastoiditis	Tympanic Perforation	Tympanic Scarring	Abnormality ear ossicles	Ossicular Discontinuity	Cholesteatoma	Facial Paralysis	Labrynthitis	Hearing Loss	Speech Language
HMO1	1446	Number	19	3	6	0	0	0	0	2	1	18	15
		Rate (per 1000)	13	2	4	0	0	0	0	1	0.7	12	10
HMO2	3958	Number	15	9	27	2	0	0	3	3	0	152	52
		Rate (per 1000)	4	2	7	0.5	0	0	0.8	0.8	0	38	13
HMO3	1290	Number	4	3	9	1	0	0	0	0	2	57	13
		Rate (per 1000)	3	2	7	0.8	0	0	0	0	2	44	10
All HMOs	6694	Number	38	15	42	3	0	0	3	5	3	227	80
		Rate (per 1000)	6	2	6	0.4	0	0	0.4	0.7	0.4	34	12

Table 12 - Tympanostomy tube insertions

Plan	Gender	No. members with chronic otitis media	No. members with tymp. tubes	% members with tymp tubes
HMO1	Male	539	139	26
	Female	431	100	23
	Total	970	239	25
HMO2	Male	1195	217	18
	Female	1062	151	14
	Total	2257	368	16
HMO3	Male	451	97	22
	Female	319	67	21
	Total	770	164	21
	Male	2185	453	21
Total	Female	1812	318	18
	Total	3997	771	19

Table 13 - Adenoidectomy procedures

Plan	Gender	No. members with chronic otitis media	No. members with ad. edctomy	% members with ad ectomy
HMO1	Male	539	70	13
	Female	431	44	10
	Total	970	114	12
HMO2	Male	1195	117	10
	Female	1062	93	9
	Total	2257	210	9
HMO3	Male	451	64	14
	Female	319	46	14
	Total	770	110	14
	Male	2185	251	11
Total	Female	1812	183	10
	Total	3997	434	11

Table 14 - episodes of otitis media.

Plan	Episode Type	No. of episodes	Average no. of days in episode
HMO1	Dx	824	1
	Dx-Dx	1404	30
	Dx-Rx	1974	23
	Rx-Dx	71	20
	Rx-Rx	34	44
	All episodes	4307	
HMO2	Dx	1988	1
	Dx-Dx	3150	29
	Dx-Rx	5394	21
	Rx-Dx	162	24
	Rx-Rx	80	41
	All episodes	10774	
HMO3	Dx	576	1
	Dx-Dx	946	33
	Dx-Rx	1704	26
	Rx-Dx	56	19
	Rx-Rx	34	47
	All episodes	3316	
Total	Dx	3388	1
	Dx-Dx	5500	30
	Dx-Rx	9072	22
	Rx-Dx	289	22
	Rx-Rx	148	43
	All episodes	18397	

Table 15 - Office visits per episode

Plan	Number of office visits					
	0	1	2	3	4+	Total
HMO1	202	2376	937	333	459	4307
	5	55	22	8	11	
HMO2	440	6552	2189	783	810	10774
	4	61	20	7	8	
HMO3	99	1856	723	300	338	3316
	3	56	22	9	10	
All HMOs	741	10784	3849	1416	1607	18397
	4	59	21	8	9	

Number of episodes
Per cent of episodes

Table 16 - Initiating antibiotic within otitis media episodes

Plan	Initiating antibiotic	Acute otitis media		Chronic otitis media	
		No. episodes	% episodes	No. episodes	% episodes
HMO1	None	580	43	822	28
	Amoxycillin	342	25	675	23
	Amox/Clav	83	6	348	12
	Cefaclor	114	8	396	13
	Other ceph	80	6	2971	10
	Other	160	12	410	14
HMO2	None	1011	27	2033	29
	Amoxycillin	1921	52	2543	36
	Amox/Clav	229	6	760	11
	Cefaclor	166	4	540	8
	Other ceph	158	4	476	7
	Other	217	6	720	10
HMO3	None	308	28	506	23
	Amoxycillin	516	47	719	32
	Amox/Clav	53	5	166	7
	Cefaclor	74	7	314	14
	Other ceph	21	2	117	5
	Other	122	11	400	18
Total	None	1899	31	3361	27
	Amoxycillin	2779	45	3937	32
	Amox/Clav	365	6	1274	10
	Cefaclor	354	6	1250	10
	Other ceph	259	4	890	7
	Other	499	8	1530	12

Table 17 - Frequency of prescribed therapy

Plan	Frequency of prescribed therapy	Amox/clln	Augmentin	1st antibiotic Cefaclor	Other cephs	Other
HMO1	1Rx	682	243	300	219	354
	2Rx	172	101	105	70	103
	3+Rxs	163	87	105	88	113
HMO2	1Rx	3135	562	441	375	545
	2Rx	767	197	129	127	219
	3+Rxs	562	230	136	132	173
HMO3	1Rx	759	120	206	70	305
	2Rx	255	41	77	26	102
	3+Rxs	221	58	105	42	115
All HMOs	1Rx	4576	925	947	664	1204
	2Rx	1194	339	311	223	424
	3+Rxs	946	375	346	262	401

Table 18 - Suppurative vs non-suppurative otitis media diagnosis and treatment

Plan	Otitis category	No anti-biotic treatment Number	%	Anti-biotic treatment Number	%	Total number	%
HMO1	Non-s	352	25	675	23	1027	24
	Supp	200	14	501	17	701	16
	Unspec	850	61	1729	60	2579	60
HMO2	Non-s	903	30	893	12	1796	17
	Supp	552	18	2077	27	2629	24
	Unspec	1589	52	4760	62	6349	59
HMO3	Non-s	209	26	310	12	519	16
	Supp	240	29	874	35	1114	33
	Unspec	365	45	1318	53	1683	51
All HMOs	Non-s	1464	28	1878	14	3342	18
	Supp	992	19	3452	26	4444	24
	Unspec	2804	53	7807	59	10611	58

Table 19 - Antibiotic therapy during an episode and presence of tympanostomy tubes

Plan	Drug therapy	No tubes present	Tubes present	Total
HMO1	No antibiotic	1248	154	1402
	Antibiotic	2669	236	2905
HMO2	No antibiotic	2541	503	3044
	Antibiotic	7366	364	7730
HMO3	No antibiotic	694	120	814
	Antibiotic	2316	186	2502
All HMOs	No antibiotic	4483	777	5260
	Antibiotic	12351	786	13137

Table 20 - annual and study period costs associated with the treatment of otitis media - all otitis media cases combined

Plan	Treatment period	Physician outpatient services	Emergency services	inpatient hosp.	drugs	Total costs
HMO1	7/92-6/92	1048	102	2	856	1048
		272,358	17,269	4177	46,669	340,473
		260	169	2088	55	325
		80%	5%	1%	14%	
	7/93-6/94	1361	154	8	1083	1361
		345,033	26,964	42,606	66,325	480,929
		254	175	5326	61	353
		72%	6%	9%	14%	
	Study	1842	241	10	1469	1842
	Period	617,391	44,233	46,783	112,995	821,402
		335	184	4678	77	446
		75%	5%	6%	14%	
HMO2	7/92-6/92	2743	227	18	2320	2743
		443,169	35,558	34,510	92,770	606,008
		162	157	1917	40	221
		73%	6%	6%	15%	
	7/93-6/94	3470	255	23	2930	3470
		527,673	42,191	63,899	124,804	758,567
		152	165	2778	43	219
		70%	6%	8%	16%	
	Study	4641	459	39	3975	4641
	Period	970,842	77,749	98,410	217,574	1,364,575
		209	169	2523	55	294
		71%	6%	7%	16%	
HMO3	7/92-6/92	775	58	7	669	775
		171,293	12,402	15,260	32,648	231,603
		221	214	2180	49	300
		74%	5%	7%	14%	
	7/93-6/94	1177	84	12	995	1177
		218,046	12,402	39,562	49,143	327,239
		185	214	3297	49	278
		67%	5%	12%	15%	
	Study	1484	132	19	1290	1484
	Period	389,340	32,890	54,822	81,791	558,842
		262	249	2885	3845	377
		70%	6%	10%	15%	
All HMOs	7/92-6/92	4566	387	27	3845	4566
		886,820	65,229	53,947	172,087	1,178,084
		194	169	1998	45	258
		75%	5%	5%	15%	
	7/93-6/94	6008	493	43	5008	6008
		1,090,753	89,643	146,067	240,272	1,566,735
		182	182	3397	48	261
		70%	6%	9%	15%	
	Study	7967	832	68	6734	7967
	Period	1,977,573	154,872	200,015	412,360	2,744,819
		248	186	2941	48	345
		72%	6%	7%	15%	

Number of members
Amount paid (in $)
Amount paid per member
Percent of total costs

Table 21 - annual and study period costs associated with the treatment of otitis media - acute otitis media cases

Plan	Treatment period	Physician outpatient services	Emergency services	inpatient hosp.	drugs	Total costs
HMO1	7/92-6/92	382	42	0	283	382
		21,887	7055	0	6127	35,069
		57	168	0	22	92
		62%	20%	0%	17%	
	7/93-6/94	569	64	5	392	569
		38,484	10,067	15,465	9489	73,504
		68	157	3093	24	129
		52%	14%	21%	13%	
	Study	872	103	5	589	872
	Period	60,371	17,122	15,465	15,616	108,573
		69	166	3093	27	125
		56%	16%	14%	14%	
HMO2	7/92-6/92	1143	87	7	947	1143
		65,580	13,073	11,105	14,292	104,050
		57	150	1586	15	91
		63%	12%	11%	14%	
	7/93-6/94	1591	112	8	1283	1591
		89,959	17,689	22,187	20,979	150,814
		57	158	2773	16	95
		60%	12%	15%	14%	
	Study	2384	195	15	1914	2384
	Period	155,540	30,762	33,292	35,271	150,814
		65	158	2219	18	63
		61%	12%	13%	14%	
HMO3	7/92-6/92	275	20	1	220	275
		15,006	3698	950	3759	23,413
		55	185	950	17	85
		64%	16%	4%	16%	
	7/93-6/94	540	30	3	425	540
		30,754	6632	12,394	7034	56,815
		57	221	4131	17	105
		54%	12%	22%	12%	
	Study	714	49	4	561	714
	Period	45,761	10,330	13,344	10,793	80,228
		64	211	3336	19	112
		57%	13%	17%	13%	
All HMOs	7/92-6/92	1803	149	8	1450	1803
		102,473	23,826	12,055	24,178	162,532
		57	160	1507	17	90
		63%	13%	7%	15%	
	7/93-6/94	2697	206	16	2100	2697
		159,198	34,387	50,046	37,502	281,133
		59	167	3128	18	104
		57%	12%	18%	13%	
	Study	3970	347	24	3064	3970
	Period	261,671	58,213	62,101	61,680	443,665
		66	168	2588	20	112
		59%	13%	14%	14%	

Number of members
Amount paid (in $)
Amount paid per member
Percent of total costs

Table 22 - annual and study period costs associated with the treatment of otitis media - chronic otitis media cases

Plan	Treatment period	Physician outpatient services	Emergency services	inpatient hosp.	drugs	Total costs
HMO1	7/92-6/92	666	60	2	573	666
		250,471	10,214	4177	40,543	305,405
		376	170	2088	71	459
		82%	3%	1%	13%	
	7/93-6/94	792	90	3	691	792
		306,549	16,897	27,141	56,836	407,424
		387	188	9047	82	514
		75%	4%	7%	14%	
	Study	970	138	5	880	970
	Period	557,020	27,111	31,318	97,379	712,829
		574	196	6264	111	735
		78%	4%	4%	14%	
HMO2	7/92-6/92	1600	140	11	1373	1600
		377,589	22,485	23,406	78,478	501,957
		236	161	2128	57	314
		75%	4%	5%	16%	
	7/93-6/94	1879	143	15	1647	1879
		437,714	24,502	41,712	103,825	607,753
		233	171	2781	63	323
		72%	4%	7%	17%	
	Study	2257	264	24	2061	2257
	Period	815,303	46,987	65,117	182,303	1,109,711
		361	178	2713	88	492
		73%	4%	6%	16%	
HMO3	7/92-6/92	500	38	6	449	500
		156,287	8704	14310	28,889	208,190
		313	229	2385	64	416
		75%	4%	7%	14%	
	7/93-6/94	637	54	9	570	637
		187,292	13,856	27,168	42,109	270,425
		295	257	3019	74	425
		69%	5%	10%	16%	
	Study	770	83	15	729	770
	Period	343,579	22,560	41,478	70,997	478,615
		446	272	2765	97	622
		72%	5%	9%	15%	
All HMOs	7/92-6/92	2766	238	19	2395	2766
		784,347	41,403	41,893	147,909	1,015,552
		284	174	2205	62	367
		77%	4%	4%	15%	
	7/93-6/94	3308	287	27	2980	2766
		931,555	55,256	96,021	202,771	1,015,552
		282	193	3556	70	367
		72%	4%	77%	16%	
	Study	3997	485	44	3670	3997
	Period	1,715,902	96,659	137,914	350,680	2,301,154
		429	199	3134	96	576
		75%	4%	6%	15%	

Number of members
Amount paid (in $)
Amount paid per member
Percent of total costs

Table 23 - costs associated with the treatment of otitis media by initiating antibiotic

All HMOs combined

All otitis media episodes

Plan	Initiating antibiotic	Physician outpatient services	Emergency services	inpatient hosp.	drugs	Total costs
All HMOs	None	5007	256	16	126	5260
		371,764	39,182	43,511	1088	455,545
		74	153	2719	9	87
		82%	9%	10%	0%	
	Amoxycillin	6489	352	24	6716	6716
		610,970	53,275	62,133	117,700	844,078
		94	151	2589	18	126
		72%	6%	7%	14%	
	Amoxycillin/clavulanate	1610	82	10	1639	1639
		232,706	14,834	19,670	85,926	353,136
		145	181	1967	52	215
		66%	4%	6%	24%	
	Cefaclor	1132	130	7	1604	1604
		188,393	24,914	28,483	85,901	409,802
		166	192	4069	54	255
		68%	6%	7%	21%	
	Other ceph	1969	42	7	1149	1149
		303,236	6476	18,665	65,176	278,710
		154	154	2666	57	243
		75%	2%	7%	23%	
	Any other antibiotic	1969	104	8	2029	2029
		303,236	16,192	27,552	56,569	403,549
		154	156	3444	28	199
		75%	4%	7%	14%	
	Total	17,746	966	72	13,263	18,397
		1,977,573	154,872	200,015	412,360	2,744,820
		111	160	2778	31	149
		72%	6%	7%	15%	

Number of members
Amount paid (in $)
Amount paid per member
Percent of total costs

Table 24 - costs associated with the treatment of otitis media by initiating antibiotic

All HMOs combined

Acute otitis media episodes

Plan	Initiating antibiotic	Physician outpatient services	Emergency services	inpatient hosp.	drugs	Total costs
All HMOs	None	1752	146	7	46	1899
		74,735	23,464	11,120	343	109,682
		43	161	1589	7	58
		68%	21%	10%	0%	
	Amoxycillin	2641	145	11	2779	2779
		119,787	19,329	29,809	22,125	191,050
		45	133	2710	8	69
		63%	10%	16%	12%	
	Amoxycillin/clavulanate	347	19	2	365	365
		17,107	3577	4338	11,791	36,813
		49	188	2169	32	101
		46%	10%	12%	32%	
	Cefaclor	323	34	3	354	354
		15,997	5980	15,322	12,477	49,776
		50	176	5107	35	141
		32%	12%	31%	25%	
	Other ceph	250	9	1	259	259
		12,049	1513	1512	8694	23,768
		48	168	1512	34	92
		51%	6%	6%	37%	
	Any other antibiotic	470	31	0	499	499
		21,997	4350	0	6250	32,597
		47	140	0	13	65
		67%	13%	0%	19%	
	Total	5783	384	24	4302	6155
		261,671	58,213	62,101	61,680	443,665
		45	152	2588	14	72
		59%	13%	14%	14%	

Number of members
Amount paid (in $)
Amount paid per member
Percent of total costs

Table 25 - costs associated with the treatment of otitis media by initiating antibiotic
All HMOs combined
Chronic otitis media episodes

Plan	Initiating antibiotic	Physician outpatient services	Emergency services	inpatient hosp.	drugs	Total costs
All HMOs	None	3255	110	9	80	3361
		297,029	15,718	32,391	745	345,883
		91	143	3599	9	103
		86%	5%	10%	0%	
	Amoxycillin	3848	207	13	3937	3937
		491,183	33,946	32,324	95,575	653,028
		128	164	2486	24	166
		75%	5%	5%	15%	
	Amoxycillin/clavulanate	1263	63	8	1274	1274
		215,600	11,257	15,332	74,135	316,324
		171	179	1917	58	248
		68%	4%	5%	23%	
	Cefaclor	1216	96	4	1250	1250
		254,507	18,934	13,162	73,424	360,027
		209	197	3290	59	288
		71%	5%	4%	20%	
	Other ceph	882	33	6	890	890
		176,345	4963	17,153	56,481	254,942
		200	150	2859	63	242
		71%	2%	7%	22%	
	Any other antibiotic	1499	73	8	1530	1530
		281,239	11,842	27,552	50,319	370,952
		188	162	3444	33	242
		76%	3%	7%	14%	
	Total	11,963	582	48	8961	12,242
		1,175,902	96,659	137,914	350,680	2,301,155
		143	166	2873	39	188
		75%	4%	6%	15%	

Number of members
Amount paid (in $)
Amount paid per member
Percent of total costs

9. Appendix I - costs associated with the treatment of otitis media episodes.

Table I-I - costs associated with the treatment of otitis media by initiating antibiotic

HMO1

All otitis media episodes

Plan	Initiating antibiotic	Physician outpatient services	Emergency services	inpatient hosp.	drugs	Total costs
HMO 1	None	1320	90	4	44	1402
		114,736	13,455	16,238	445	144,874
		87	149	4059	10	103
		79%	10%	11%	0%	
	Amoxycillin	991	51	1	1017	1017
		129,048	6914	2074	22,375	160,411
		130	136	2074	22	158
		81%	4%	1%	14%	
	Amoxycillin/clavulanate	417	32	1	431	431
		68,722	5914	1000	23,003	98,639
		165	185	1000	53	229
		70%	6%	1%	23%	
	Cefaclor	493	41	1	510	510
		110,095	9210	7310	28,538	155,153
		223	225	7310	56	304
		71%	6%	5%	18%	
	Other ceph	371	14	1	377	377
		87,224	2406	1512	21,774	112,916
		235	172	1512	58	300
		77%	2%	1%	20%	
	Any other antibiotic	542	45	3	570	570
		107,566	6333	18,649	16,859	149,407
		198	141	6216	30	262
		72%	4%	13%	11%	
	Total	4134	273	11	2949	4307
		617,391	44,233	46,783	112,995	821,402
		149	162	4253	38	191
		75%	5%	6%	14%	

Number of members
Amount paid (in $)
Amount paid per member
Percent of total costs

Table I-2 - costs associated with the treatment of otitis media by initiating antibiotic

HMO1

Acute otitis media episodes

Plan	Initiating antibiotic	Physician outpatient services	Emergency services	inpatient hosp.	drugs	Total costs
HMO1	None	527	55	2	18	580
		23,767	8305	4568	165	36,805
		45	151	2284	9	63
		65%	23%	12%	0%	
	Amoxycillin	326	16	1	342	342
		16,000	1815	2074	3110	22,999
		49	113	2074	9	67
		70%	8%	9%	13%	
	Amoxycillin/clavulanate	73	12	0	83	83
		3584	2470	0	3127	9181
		49	206	0	38	111
		39%	27%	0%	34%	
	Cefaclor	104	10	1	114	114
		5765	2095	7310	4156	19,326
		55	210	7310	36	170
		30%	11%	38%	21%	
	Other ceph	77	2	1	80	80
		4172	235	1512	2599	8518
		54	118	1512	32	106
		49%	3%	18%	30%	
	Any other antibiotic	144	18	0	160	160
		7082	2200	0	2458	11,740
		49	122	0	15	73
		60%	19%	0%	21%	
	Total	1251	113	5	797	1359
		60,371	17,122	15,465	15,616	108,574
		48	152	3093	20	80
		56%	16%	14%	14%	

Number of members
Amount paid (in $)
Amount paid per member
Percent of total costs

Table I-3 - Costs associated with the treatment of otitis media by initiating antibiotic

HMO1

Chronic Otitis Media Episodes

Plan	Initiating antibiotic	Physician outpatient services	Emergency services	inpatient hosp.	drugs	Total costs
HMO 1	None	793	35	2	26	822
		90,969	5149	11,669	280	108,067
		115	147	5835	11	131
		84%	5%	11%	0%	
	Amoxycillin	665	35	0	675	675
		113,048	5099	0	19,265	137,412
		170	146	0	29	204
		82%	4%	0%	14%	
	Amoxycillin/clavulanate	344	20	1	348	348
		65,138	3444	1000	19,876	89,458
		189	172	1000	57	257
		73%	4%	1%	22%	
	Cefaclor	389	31	0	396	396
		104,330	7115	0	24,382	135,827
		268	230	0	62	343
		77%	5%	0%	18%	
	Other ceph	294	12	0	297	297
		83,052	2171	0	19,175	104,398
		282	181	0	65	352
		80%	2%	0%	18%	
	Any other antibiotic	398	27	3	410	410
		100,483	4133	18,649	14,401	137,666
		252	153	6216	35	336
		73%	3%	13%	11%	
	Total	2883	160	6	2152	2848
		557,020	27,111	31,318	97,379	712,828
		193	169	5220	45	242
		78%	4%	4%	14%	

Number of members
Amount paid (in $)
Amount paid per member
Percent of total costs

Table I-4 costs associated with the treatment of otitis media by initiating antibiotic

HMO2

All otitis media episodes

Plan	Initiating antibiotic	Physician outpatient services	Emergency services	inpatient hosp.	drugs	Total costs
HMO 2	None	2916	118	8	69	3044
		202,171	16,493	13,741	532	232,937
		69	140	1718	8	77
		87%	7%	6%	0%	
	Amoxycillin	4281	255	16	4464	4464
		347,159	37,105	37,372	70,970	492,606
		81	146	2336	16	110
		71%	7%	8%	14%	
	Amoxycillin/clavulanate	977	37	7	989	989
		128,330	6208	14,597	50,872	200,007
		131	168	2085	51	202
		64%	3%	7%	25%	
	Cefaclor	664	60	2	706	706
		92,058	6208	9106	36,018	145,118
		139	168	4553	51	206
		63	3%	6%	26%	
	Other ceph	623	26	6	634	634
		79,178	3574	17,153	34,178	134,083
		127	137	2859	54	211
		59%	3%	13%	25%	
	Any other antibiotic	912	42	3	937	937
		121,945	6433	6440	25,003	159,821
		134	153	2147	27	171
		76%	4%	4%	16%	
	Total	10,373	538	42	7799	10,744
		970,842	77,749	98,410	217,574	1,364,575
		94	145	2343	28	127
		71%	6%	7%	16%	

Number of members
Amount paid (in $)
Amount paid per member
Percent of total costs

Table I- 5 Costs associated with the treatment of otitis media by initiating antibiotic

HMO2

Acute Otitis Media Episodes

Plan	Initiating antibiotic	Physician outpatient services	Emergency services	inpatient hosp.	drugs	Total costs
HMO 2	None	943	65	4	26	1011
		39,395	9988	5601	153	55,137
		42	154	1400	6	55
		72%	18%	10%	0%	
	Amoxycillin	1810	112	8	1921	1921
		81,011	14,522	20,384	14,789	130,706
		45	130	2548	8	68
		62%	11%	16%	11%	
	Amoxycillin/clavulanate	221	6	2	229	229
		10,997	867	4338	6867	18,896
		50	145	2169	30	114
		47%	4%	19%	29%	
	Cefaclor	146	22	1	166	166
		7049	3350	2969	5528	18,896
		48	152	2969	33	114
		37%	18%	16%	29%	
	Other ceph	152	6	0	158	158
		6876	1063	0	5431	13,370
		45	177	0	34	85
		51%	8%	0%	41%	
	Any other antibiotic	208	7	0	217	217
		10,212	973	0	2502	13,687
		49	139	0	12	63
		75%	7%	0%	18%	
	Total	3480	218	15	2717	3702
		155,540	30,762	33,292	35,271	254,865
		45	141	2219	13	69
		61%	12%	13%	14%	

Number of members
Amount paid (in $)
Amount paid per member
Percent of total costs

Table I- 6 Costs associated with the treatment of otitis media by initiating antibiotic

HMO2

Chronic Otitis Media Episodes

Plan	Initiating antibiotic	Physician outpatient services	Emergency services	inpatient hosp.	drugs	Total costs
HMO 2	None	1973	53	4	43	2033
		162,776	6505	8140	379	177,808
		83	123	2035	9	87
		91%	4%	5%	9%	
	Amoxycillin	2471	143	8	2543	2543
		266,148	22,584	16,988	56,180	361,900
		108	158	2123	22	142
		73%	6%	5%	16%	
	Amoxycillin/clavulanate	756	31	5	760	760
		117,333	5341	10,259	44,005	176,938
		155	172	2052	58	233
		66%	3%	6%	25%	
	Cefaclor	518	38	1	540	540
		85,010	4586	6137	30,490	126,223
		164	121	6137	56	234
		67%	4%	5%	24%	
	Other ceph	471	20	6	476	476
		72,303	2511	17,153	28,747	120,714
		154	126	2859	60	254
		60%	2%	4%	24%	
	Any other antibiotic	704	35	3	720	720
		111,733	5460	6440	22,501	146,134
		159	156	2147	31	203
		77%	4%	4%	15%	
	Total	6893	320	27	5082	7072
		815,303	46,987	65,117	182,303	1,109,710
		118	147	2412	36	157
		74%	4%	6%	16%	

Number of members
Amount paid (in $)
Amount paid per member
Percent of total costs

Table I- 7 Costs associated with the treatment of otitis media by initiating antibiotic

HMO3

All Otitis Media Episodes

Plan	Initiating antibiotic	Physician outpatient services	Emergency services	inpatient hosp.	drugs	Total costs
HMO 3	None	771	48	4	13	814
		54,857	9234	13,532	110	77,733
		71	192	3383	8	95
		71%	12%	17%	0%	
	Amoxycillin	1217	46	7	1235	1235
		134,762	9255	22,687	24,355	54,489
		165	201	3241	20	249
		65%	5%	12%	13%	
	Amoxycillin/clavulanate	216	13	2	219	219
		35,654	2711	4073	12,051	54,489
		165	209	2036	55	249
		65%	5%	8%	22%	
	Cefaclor	382	29	4	388	388
		68,350	7768	12,067	21,345	31,710
		179	268	3017	55	230
		62%	7%	11%	20%	
	Other ceph	138	2	0	138	138
		21,991	496	0	9223	31,710
		159	248	0	67	230
		69%	2%	0%	29%	
	Any other antibiotic	515	17	2	522	522
		73,725	3426	2462	14,707	94,320
		143	202	1231	28	181
		78%	4%	3%	15%	
	Total	3239	155	19	2515	3316
		389,340	32,890	54,822	81,791	558,843
		120	212	2885	33	169
		70%	6%	10%	14%	

Number of members
Amount paid (in $)
Amount paid per member
Percent of total costs

Table I- 8 Costs associated with the treatment of otitis media by initiating antibiotic

HMO3

Acute Otitis Media Episodes

Plan	Initiating antibiotic	Physician outpatient services	Emergency services	inpatient hosp.	drugs	Total costs
HMO 3	None	282	26	1	2	308
		11,573	5171	950	25	17,719
		41	199	950	12	58
		65%	29%	6%	0%	
	Amoxycillin	505	17	2	516	516
		22,776	2992	7351	4225	4561
		45	176	3675	8	86
		61%	8%	20%	11%	
	Amoxycillin/clavulanate	53	1	0	53	53
		2525	240	0	1796	4561
		48	240	0	34	86
		56%	5%	0%	39%	
	Cefaclor	73	2	1	74	74
		3183	535	5043	2793	11,554
		44	268	5043	38	156
		27%	5%	44%	24%	
	Other ceph	21	1	0	21	21
		1001	215	0	664	1880
		48	215	0	32	90
		53%	12%	0%	35%	
	Any other antibiotic	118	6	0	122	122
		4702	1177	0	1291	7170
		40	196	0	11	59
		66%	16%	0%	18%	
	Total	1052	53	4	788	1094
		45,761	10,330	13,344	10,793	80,228
		43	195	3336	14	73
		57%	13%	17%	13%	

Number of members
Amount paid (in $)
Amount paid per member
Percent of total costs

Table I- 9 Costs associated with the treatment of otitis media by initiating antibiotic

HMO3

Chronic Otitis Media Episodes

Plan	Initiating antibiotic	Physician outpatient services	Emergency services	inpatient hosp.	drugs	Total costs
HMO 3	None	489	22	3	11	506
		43,284	4063	12,582	86	60,015
		89	185	4194	8	119
		72%	7%	21%	0%	
	Amoxycillin	712	29	5	719	719
		111,986	6263	155,336	20,130	153,715
		157	216	3067	28	214
		73%	4%	10%	13%	
	Amoxycillin/clavulanate	163	12	2	166	166
		33,129	2471	4073	10,255	49,928
		203	206	2036	62	301
		66%	5%	8%	21%	
	Cefaclor	309	27	3	314	314
		65,167	7233	7024	18,255	97,976
		211	268	2341	62	312
		67%	7%	7%	21%	
	Other ceph	117	1	0	117	117
		20,990	281	0	8559	29,830
		179	281	0	73	255
		70%	1%	0%	29%	
	Any other antibiotic	397	11	2	400	400
		69,023	281	2462	13,417	87,151
		174	281	1231	34	218
		79%	1%	3%	15%	
	Total	2187	102	15	1727	2222
		343,579	22,560	41,478	70,997	478,614
		157	221	2765	41	215
		72%	5%	8%	15%	

Number of members
Amount paid (in $)
Amount paid per member
Percent of total costs

10. Appendix II - statistical analyses members with otitis media

Table II-I Chi-square analysis, otitis media diagnosis by plan

Plan	Otitis media Yes	No	
HMO1	1842	1788	3630
	(1953)	(1677)	
HMO2	4641	3746	8387
	(4513)	(3874)	
HMO3	1484	1304	2788
	(1500)	(1288)	
	7967	6388	14,805
X^2=21.9	df=2	p<0.05*	

Table II-2 Chi-square analysis, otitis media diagnosis by gender

Gender	Otitis media Yes	No	
Male	4183	3395	7578
	(4078)	(3500)	
Female	3784	3443	7227
	(3889)	(3338)	
	7967	6388	14,805
X^2=11.9	df=1	p<0.05*	

Table II-3 Chi-square analysis, otitis media group by gender

Gender	Yes	No	
Male	1998	2185	4183
	(2084)	(2099)	
Female	1972	1812	3784
	(1886)	(1898)	
	3970	3997	7967
X^2=14.9	df=1	p<0.05*	

Table II-4 Chi-square analysis, insertion of tympanostomy tubes by plan

Plan	Insertion of tubes		
	Yes	No	
HMO1	239	731	970
	(187)	(783)	
HMO2	368	1889	2257
	(435)	(1822)	
HMO3	164	606	770
	(149)	(621)	
	771	3226	3997
X^2=32.6	df=2	p<0.05*	

Table II-5Chi-square analysis, insertion of tympanostomy tubes by gender

Gender	Insertion of tubes		
	Yes	No	
Male	453	1732	2185
	(421)	(1764)	
Female	318	1494	1812
	(350)	(1462)	
	771	3226	3997
X^2=6.6	df=1	p<0.05*	

Table II-6 Chi-square analysis, antibiotic therapy during an episode and presence of tympanostomy tubes

Tymp tubes	Antibiotic therapy		
	Yes	No	
Yes	786	777	1563
	(1116)	(447)	
No	12,351	4483	16,834
	(12,020)	(4813)	
	13,137	5260	18,397
X^2=373	df=1	p<0.05*	

Table II-7 T-test - number of episodes during study

Severity	N	Mean	St.Dev	DF	T	p-value
Acute	3032	1.63	0.84	6692.0	-44.91	<0.05*
Chronic	3662	3.11	1.64			

Table II-8 - number of antibiotic claims during study

Severity	N	Mean	St.Dev	DF	T	p-value
Acute	3032	1.61	0.89	6692.0	-47.6643	<0.05*
Chronic	3662	5.45	4.36			

Table II-9 - number of amoxycillin claims

Severity	N	Mean	St.Dev	DF	T	p-value
Acute	3032	0.93	0.75	6692	-13.0055	<0.05*
Chronic	3662	1.23	1.11			

Table II-10 - number of amoxycillin/potassium clav. claims during study

Severity	N	Mean	St.Dev	DF	T	p-value
Acute	3032	0.14	0.39	6692.0	-28.8466	<0.05*
Chronic	3662	0.63	0.87			

11. Appendix III - statistical analyses- episodes of otitis media

Table III-1 Chi-square analysis, suppurative Vs Non-suppurative otitis media diagnosis by treatment

Diagnosis	Antibiotic treatment		
	Yes	No	
Nonsupp	1878	1464	3342
	(2386)	(956)	
Supp	3452	992	4444
	(3173)	(1271)	
Unspecified	7807	2804	10,611
	(7577)	(3034)	
	13,137	5260	18,397
X^2=488	df=2	p<0.05*	

Table III-2 - T-test, number of antibiotic claims per episode

Severity	N	Mean	St.Dev	DF	T	p-value
Acute	4256	1.14	0.3639	13135	-32.154	<0.05*
Chronic	8881	2.25	2.2225			

Table III-3 - T-test, total drug cost per episode day

Severity	N	Mean	St.Dev	DF	T	p-value
Acute	4256	1.20	1.19	13135	-6.2827	<0.05*
Chronic	8881	1.34	1.18			

Table III-4 - T-test, total cost per episode day

Severity	N	Mean	St.Dev	DF	T	p-value
Acute	4256	6.52	15.78	13135	-1.5505	<0.05*
Chronic	8881	6.98	15.90			

Table III-5 - T-test, amoxycillin not used

Severity	N	Mean	St.Dev	DF	T	p-value
Acute	4256	0.34	0.47	13135	-16.4614	<0.05*
Chronic	8881	0.49	0.50			

Table III-6 - T-test, amoxycillin used first

Severity	N	Mean	St.Dev	DF	T	p-value
Acute	4256	0.65	0.48	13135	22.9417	<0.05*
Chronic	8881	0.44	0.50			

Table III-7 - T-test, amoxycillin/potassium clav. not used

Severity	N	Mean	St.Dev	DF	T	p-value
Acute	4256	0.90	0.30	13135	25.5189	<0.05*
Chronic	8881	0.74	0.44			

Table III-8 - T-test, amoxycillin/potassium clav. used first

Severity	N	Mean	St.Dev	DF	T	p-value
Acute	4256	0.09	0.28	13135	-9.3953	<0.05*
Chronic	8881	0.14	0.35			

Table III-9 - T-test, cefaclor not used

Severity	N	Mean	St.Dev	DF	T	p-value
Acute	4256	0.89	0.31	13135	17.7303	<0.05*
Chronic	8881	0.76	0.42			

Table III-10 - T-test, cefaclor used first

Severity	N	Mean	St.Dev	DF	T	p-value
Acute	4256	0.08	0.28	13135	-9.4639	<0.05*
Chronic	8881	0.80	0.40			

Table III-11 - T-test, other cephalosporin not used

Severity	N	Mean	St.Dev	DF	T	p-value
Acute	4256	0.93	0.26	13135	19.0329	<0.05*
Chronic	8881	0.80	0.40			

Table III-12 - T-test, other cephalosporin used first

Severity	N	Mean	St.Dev	DF	T	p-value
Acute	4256	0.06	0.24	13135	-7.4882	<0.05*
Chronic	8881	0.10	0.30			

Table III-13 - T-test, any other antibiotic not used

Severity	N	Mean	St.Dev	DF	T	p-value
Acute	4256	0.85	0.36	13135	23.1925	<0.05*
Chronic	8881	0.66	0.47			

Table III-14 - T-test, any other antibiotic used first

Severity	N	Mean	St.Dev	DF	T	p-value
Acute	4256	0.12	0.32	13135	-8.1885	<0.05*
Chronic	8881	0.17	0.38			

Table III -15 stepwise logistic regression, amoxycillin as first drug in an episode

Variable coding scheme		
Variable descriptor	Value=0	Value=1
Chronic otitis indicator	acute	chronic
HMO1 indicator	not HMO1	HMO1
Log length of episode	n/a	n/a
HMO3 indicator	not HMO3	HMO3
no. episodes prior to study	n/a	n/a
Female	male	female

Step	Variable	Chi-square	p-value
1	Chronic otitis indicator	506.100	<0.5*
2	HMO1 indicator	346.900	<0.5*
3	Log length of episode	54.544	<0.5*
4	HMO3 indicator	42.988	<0.5*
5	no. episodes prior to study	44.347	<0.5*
6	Female	5.611	<0.5*

Odds ratios (Amoxycillin used during first episode)

Variable	Ratio
Chronic otitis indicator	0.532
HMO1 indicator	0.408
Log length of episode	0.827
HMO3 indicator	0.727
no. episodes prior to study	0.908
Female	1.090

Table III -16 stepwise logistic regression, amoxycillin/potassium clav. as first drug in an episode

Variable coding scheme

Variable descriptor	Value=0	Value=1
Chronic otitis indicator	acute	chronic
HMO3 indicator	not HMO3	HMO3
Office/outpatient visits	n/a	n/a
Age at start of episoden/a	n/a	
HMO1 indicator	not HMO1	HMO1

Step	Variable	Chi-square	p-value
1	Chronic otitis indicator	87.6951	<0.5*
2	HMO3 indicator	40.5886	<0.5*
3	Office/outpatient visits	12.7580	<0.5*
4	Age at start of episode	13.4133	<0.5*
5	HMO1 indicator	4.0130	<0.5*

Odds ratios (Amoxycillin/potassium clav. used during first episode=1)

Variable	Ratio
Chronic otitis indicator	1.687
HMO3 indicator	0.649
Office/outpatient visits	1.057
Age at start of episode	1.061
HMO1 indicator	1.134

Table III -17 stepwise logistic regression, cefaclor. as first drug in an episode

Variable coding scheme		
Variable descriptor	Value=0	Value=1
HMO2 indicator	not HMO2	HMO2
Chronic otitis indicator	acute	chronic
Emergency visits	n/a	n/a
No. episodes prior to study	n/a	n/a
Female	male	female

Step	Variable	Chi-square	p-value
1	HMO2 indicator	165.8000	<0.5*
2	Chronic otitis indicator	76.8054	<0.5*
3	Emergency visits	24.5417	<0.5*
4	No. episodes prior to study	22.9201	<0.5*
5	female	5.8776	<0.5*

Odds ratios (Cefaclor used during first episode=1)

Variable	Ratio
HMO2 indicator	0.512
Chronic otitis indicator	1.631
Emergency visits	1.612
No. episodes prior to study	1.099
Female	1.140

Table III-18 Multtest procedure - total cost analysis based on the initial antibiotic during an episode

Multtest coefficients

Test	Amoxycillin	Amoxycillin/clav	Cefaclor	Other ceph	Other anti
Amox vs amox\clav	1	-1	0	0	0
Cef vs amox/clav	0	-1	1	0	0
Oth ceph vs amox\clav	0	-1	0	0	1
Oth anti vs amox\clav	0	-1	0	1	0

Multtest tables

Variable	Statistic	Amoxycillin	Amoxycillin/clav	Cefaclor	Other ceph	Other anti
Cost	Mean	125.7	215.4	255.5	242.6	198.9
	Std dev	303.1	397.3	533.5	458.2	543.0
	N	6716	1639	1604	1149	2029

Test	p-value
Amox vs amox\clav	<0.05*
Cef vs amox/clav	<0.05*
Oth ceph vs amox\clav	>0.05
Oth anti vs amox\clav	>0.05

Variable	Statistic	Amoxycillin	Amoxycillin/clav	Cefaclor	Other ceph	Other anti
Cost per day	Mean	5.7	8.1	9.5	8.8	6.2
	Std dev	15.6	14.4	21.7	17.2	10.3
	N	6716	1639	1604	1149	2029

Test	p-value
Amox vs amox\clav	<0.05*
Cef vs amox/clav	<0.05*
Oth ceph vs amox\clav	<0.05*
Oth anti vs amox\clav	>0.05

Variable	Statistic	Amoxycillin	Amoxycillin/clav	Cefaclor	Other ceph	Other anti
Antibiotic claims	Mean	1.7	2.1	2.1	2.1	2.1
	Std dev	1.6	2.2	2.0	2.0	2.2
	N	6716	1639	1604	1149	2029

Test	p-value
Amox vs amox\clav	<0.05*
Cef vs amox/clav	>0.05
Oth ceph vs amox\clav	>0.05
Oth anti vs amox\clav	>0.05

Variable	Statistic	Amoxycillin	Amoxycillin/clav	Cefaclor	Other ceph	Other anti
Length of episode	Mean	23.8	31.3	30.2	32.5	30.9
	Std dev	28.2	35.0	33.4	36.1	35.1
	N	6716	1639	1604	1149	2029

Test	p-value
Amox vs amox\clav	<0.05*
Cef vs amox/clav	>0.05
Oth ceph vs amox\clav	>0.05
Oth anti vs amox\clav	>0.05

12. Appendix IV - represcribing

Table IV - I represcribing after initial antibiotic

1st drug	2nd drug	Acute OM		Chronic OM		Total	
		No. episodes	% of 1st drug	No. episodes	% of 1st drug	No. episodes	% of 1st drug
Amox	Amox	131	36.69	633	35.50	764	35.70
	Amox\clav	41	11.48	250	14.02	291	13.60
	Cefaclor	66	18.49	249	13.97	315	14.72
	Other ceph	28	7.84	167	9.37	195	9.11
	Other	91	25.49	484	27.15	575	26.87
	Total	357	100	1783	100	2140	100
Amox/clav	Amox	3	4.62	82	12.63	85	11.90
	Amox\clav	33	50.77	254	39.14	287	40.20
	Cefaclor	11	16.92	74	11.4	85	11.90
	Other ceph	7	10.77	96	14.79	103	14.43
	Other	11	16.92	143	22.03	154	21.57
	Total	65	100	649	100	714	100
Cefaclor	Amox	6	11.32	53	8.77	59	8.98
	Amox\clav	4	7.55	116	19.21	120	18.26
	Cefaclor	21	39.62	204	33.77	225	34.25
	Other ceph	5	9.43	69	11.42	74	11.26
	Other	17	32.08	162	26.82	179	27.25
	Total	53	100	604	100	657	100
Other ceph	Amox	3	7.69	57	12.78	60	12.37
	Amox\clav	3	7.69	83	18.61	86	17.73
	Cefaclor	5	12.82	32	7.17	37	7.63
	Other ceph	16	41.03	164	36.77	180	37.11
	Other	12	30.77	110	24.66	122	25.15
	Total	39	100	446	100	485	100
Other	Amox	13	16.05	96	12.90	109	13.21
	Amox\clav	12	14.81	108	14.52	120	14.55
	Cefaclor	10	12.35	130	17.47	140	16.97
	Other ceph	12	14.81	99	13.31	111	13.45
	Other	34	41.98	311	41.80	345	41.82
	Total	81	100	744	100	825	100

Table IV - 2 represcribing after initial antibiotic - same provider for first and second antibiotic claim

1st drug	2nd drug	Acute OM		Chronic OM		Total	
		No. episodes	% of 1st drug	No. episodes	% of 1st drug	No. episodes	% of 1st drug
Amox	Amox	91	42.72	390	40.04	481	40.52
	Amox\clav	20	9.39	123	12.63	143	12.05
	Cefaclor	30	14.08	118	12.11	148	12.47
	Other ceph	15	7.04	79	8.11	94	7.92
	Other	57	26.76	264	27.10	321	27.04
	Total	213	100	974	100	1187	100
Amox/clav	Amox	0	0	52	12.87	52	11.50
	Amox\clav	30	62.50	179	44.31	209	46.24
	Cefaclor	6	12.50	40	9.90	46	10.18
	Other ceph	4	8.33	54	13.37	58	12.83
	Other	8	16.67	79	19.55	87	19.25
	Total	48	100	404	100	452	100
Cefaclor	Amox	1	3.45	21	6.07	22	5.87
	Amox\clav	2	6.90	60	17.34	62	16.53
	Cefaclor	14	48.28	142	41.04	156	41.60
	Other ceph	2	6.90	34	9.83	36	9.6-
	Other	10	34.48	89	25.72	99	26.40
	Total	29	100	346	100	375	100
Other ceph	Amox	2	6.25	32	11.59	34	11.04
	Amox\clav	2	6.25	46	16.67	48	15.58
	Cefaclor	3	9.38	20	7.25	23	7.47
	Other ceph	14	43.75	115	41.67	129	41.88
	Other	11	34.48	63	22.83	74	24.03
	Total	32	100	276	100	308	100
Other	Amox	10	16.95	48	10.55	58	11.28
	Amox\clav	6	10.17	56	12.13	62	12.06
	Cefaclor	7	11.86	73	16.04	80	15.56
	Other ceph	10	16.95	59	12.97	69	13.42
	Other	26	44.07	219	48.13	245	47.67
	Total	59	100	455	100	514	100

Table IV - 3 represcribing after initial antibiotic- different provider for first and second antibiotic claim

1st drug	2nd drug	Acute OM		Chronic OM		Total	
		No. episodes	% of 1st drug	No. episodes	% of 1st drug	No. episodes	% of 1st drug
Amox	Amox	40	27.78	243	30.04	283	29.70
	Amox\clav	21	14.58	127	15.70	148	15.53
	Cefaclor	36	25.00	131	16.19	167	17.52
	Other ceph	13	9.03	88	10.88	101	10.60
	Other	34	23.61	220	27.19	254	26.65
	Total	144	100	809	100	953	100
Amox/clav	Amox	3	17.65	30	12.24	33	12.60
	Amox\clav	3	17.65	75	30.61	78	29.77
	Cefaclor	5	29.41	34	13.88	39	14.89
	Other ceph	3	117.65	42	17.14	45	17.18
	Other	3	17.65	64	26.12	67	25.57
	Total	17	100	245	100	262	100
Cefaclor	Amox	5	20.83	32	12.40	37	13.12
	Amox\clav	2	8.33	56	21.71	58	20.57
	Cefaclor	7	29.17	62	24.03	69	24.47
	Other ceph	3	12.50	35	13.57	38	13.48
	Other	7	29.17	73	28.29	80	28.37
	Total	24	100	258	100	282	100
Other ceph	Amox	1	14.29	25	14.71	26	14.69
	Amox\clav	1	14.29	37	21.76	38	21.47
	Cefaclor	2	28.57	12	7.06	14	7.91
	Other ceph	2	28.57	49	28.82	51	28.81
	Other	1	14.29	47	27.65	48	27.12
	Total	7	100	170	100	177	100
Other	Amox	3	13.64	48	16.61	51	16.40
	Amox\clav	6	27.27	52	17.99	58	18.65
	Cefaclor	3	13.64	57	19.72	60	19.29
	Other ceph	2	9.09	40	13.84	42	13.50
	Other	8	36.36	92	31.83	100	32.15
	Total	22	100	289	100	311	100

100311

13. Appendix V - Costs associated with treatment of chronic otitis media by assignment definition

Table V-1 Costs associated with the treatment of otitis media by initiating antibiotic
All HMOs
Chronic otitis media - presence of ICD-9 code

Plan	Initiating antibiotic	Physician outpatient services	Emergency services	inpatient hosp.	drugs	Total costs
HMO 1	None	858	13	4	18	876
		106,065	2388	18,141	141	126,835
		124	184	4535	8	145
		84%	2%	14%	0%	
	Amoxycillin	587	23	1	603	603
		72,303	2989	103	10,889	86,234
		123	128	103	18	356
		84%	3%	0%	13%	
	Amoxycillin/clavulanate	235	7	1	235	235
		44,656	945	1000	13,558	60,159
		190	135	1000	58	256
		74%	2%	2%	22%	
	Cefaclor	208	14	0	212	212
		54,152	1839	0	12,471	68,462
		260	131	0	59	323
		79%	3%	0%	18%	
	Other ceph	138	6	3	141	141
		35,127	1117	8928	8843	54,015
		255	186	2976	63	383
		65%	2%	17%	16%	
	Any other antibiotic	221	7	0	225	225
		43,375	841	0	5558	49,774
		196	120	0	25	221
		87%	2%	0%	11%	
	Total	2247	70	9	1434	2292
		355,679	10,068	28,172	51,460	445,379
		158	144	3130	36	194
		80%	2%	6%	12%	

Number of members
Amount paid (in $)
Amount paid per member
Percent of total costs

Table V-2 Costs associated with the treatment of otitis media by initiating antibiotic
All HMOs combined
Chronic Otitis Media - Episode>30 days

Plan	Initiating antibiotic	Physician outpatient services	Emergency services	inpatient hosp.	drugs	Total costs
HMO	None	639	20	2	21	656
		50,241	3564	4927	254	58,986
		79	178	2463	12	90
		85%	6%	8%	0%	
	Amoxycillin	1155	75	3	1183	1183
		157,165	12,935	5742	30,759	206,601
		136	172	1914	26	175
		76%	6%	3%	15%	
	Amoxycillin/clavulanate	309	22	1	309	309
		44,837	4383	3132	18,076	70,428
		145	199	3132	58	228
		64%	6%	4%	26%	
	Cefaclor	334	37	2	349	349
		69,015	7713	8454	20,084	105,266
		207	208	4227	57	302
		66%	7%	8%	19%	
	Other ceph	250	8	2	250	250
		49,268	1796	5626	14,796	71,486
		197	225	2813	59	286
		69%	2%	8%	21%	
	Any other antibiotic	390	24	2	396	396
		70,599	4172	15,834	13,892	104,497
		181	174	7917	35	264
		68%	4%	15%	13%	
	Total	3077	186	12	2508	3143
		441,125	34,563	43,715	97,861	617,264
		143	186	3643	39	196
		71%	6%	7%	16%	

Number of members
Amount paid (in $)
Amount paid per member
Percent of total costs

Table V-3 Costs associated with the treatment of otitis media by initiating antibiotic
All HMOs combined
Chronic Otitis Media - Prescription claim>30 days

Plan	Initiating antibiotic	Physician outpatient services	Emergency services	inpatient hosp.	drugs	Total costs
HMO	None	625	24	1	22	649
		42,131	2808	2918	173	48,030
		67	117	2918	8	74
		88%	6%	6%	0%	
	Amoxycillin	1134	61	5	1147	1147
		178,910	11,843	15,103	38,897	244,753
		158	194	3021	34	213
		73%	5%	6%	16%	
	Amoxycillin/clavulanate	429	21	2	434	434
		77,648	3974	3360	28,166	113,148
		181	189	1680	65	261
		69%	3%	3%	25%	
	Cefaclor	363	27	1	368	368
		82,478	6898	975	26,103	116,454
		227	255	975	71	316
		71%	6%	1%	22%	
	Other ceph	313	12	1	315	315
		62,137	1171	2598	22,834	88,740
		199	98	2598	72	282
		70%	1%	3%	26%	
	Any other antibiotic	481	20	5	487	487
		113,675	3410	10,925	20,287	148,297
		236	171	2185	42	305
		77%	2%	7%	14%	
	Total	3345	165	15	2773	3400
		556,980	30,103	35,879	136,460	759,422
		167	182	2392	49	223
		73%	4%	5%	18%	

Number of members
Amount paid (in $)
Amount paid per member
Percent of total costs

Table V-4 Costs associated with the treatment of otitis media by initiating antibiotic
All HMOs combined
Chronic Otitis Media - tympanostomy tubes

Plan	Initiating antibiotic	Physician outpatient services	Emergency services	inpatient hosp.	drugs	Total costs
HMO	None	74	1	1	1	76
		17,228	156	6406	15	23,805
		233	156	6406	15	313
		72%	1%	27%	0%	
	Amoxycillin	26	0	1	26	26
		4991	0	3605	435	9031
		192	0	3605	17	347
		55%	0%	40%	5%	
	Amoxycillin/clavulanate	7	0	1	8	8
		557	0	2545	555	3657
		80	0	2545	69	457
		15%	0%	70%	15%	
	Cefaclor	21	1	0	21	21
		3923	80	0	971	4974
		187	80	0	46	237
		79%	2%	0%	19%	
	Other ceph	8	0	0	8	8
		2060	0	0	403	2463
		257	0	0	50	308
		84%	0%	0%	16%	
	Any other antibiotic	26	1	0	27	27
		4156	235	0	503	4894
		160	235	0	19	181
		85%	5%	0%	10%	
	Total	162	3	3	91	166
		32,915	471	12,556	2882	48,824
		203	157	4185	32	294
		67%	1%	26%	6%	

Number of members
Amount paid (in $)
Amount paid per member
Percent of total costs

Table V-5 Costs associated with the treatment of otitis media by initiating antibiotic
All HMOs combined
Chronic Otitis Media - 3+ acute episodes in 6 month period

Plan	Initiating antibiotic	Physician outpatient services	Emergency services	inpatient hosp.	drugs	Total costs
HMO	None	1059	52	1	18	1104
		81,364	6802	0	162	88,328
		77	131	0	9	80
		92%	8%	0%	0%	
	Amoxycillin	946	48	3	978	978
		77,813	6229	7792	14,595	106,409
		82	130	2591	15	109
		73%	6%	7%	14%	
	Amoxycillin/clavulanate	283	13	3	288	288
		47,900	1955	5296	13,781	68,932
		169	150	1765	48	239
		70%	3%	8%	20%	
	Cefaclor	290	17	1	0	300
		44,939	2406	3733	13,795	64,932
		155	142	3733	46	239
		69%	4%	6%	21%	
	Other ceph	173	7	0	176	176
		27,753	879	0	9605	38,237
		160	126	0	55	217
		73%	2%	0%	25%	
	Any other antibiotic	381	21	1	395	395
		49,434	3183	793	10,079	63,489
		130	152	793	26	161
		78%	5%	1%	16%	
	Total	3132	158	9	2155	3241
		329,203	21,454	17,593	62,017	430,267
		105	136	1955	29	133
		77%	5%	4%	14%	

Number of members
Amount paid (in $)
Amount paid per member
Percent of total costs