THE IMPACT OF COST-SHARING CHANGES ON PRESCRIPTION ANTIBIOTIC FILL RATES IN CHILDREN WITH OTITIS MEDIA

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ABSTRACT

From 1975, when the SPDP was initiated, until June 30, 1987, those with STD benefits paid a flat copayment per prescription, with the balance paid by the Province, directly to the pharmacy. On July 1, 1987 the cost-sharing scheme was changed to a deductible plus coinsurance in a nonassignment format. The assignment format returned on January 1, 1989. Children receiving SAP benefits retained first dollar coverage.

The objective of the present study was to determine the impact of these changes on prescription antibiotic fill rates for children aged 0 to 14 years, with an otitis media diagnosis in the physician claims data base. Children receiving SAP benefits served as the nonequivalent control group. The hypotheses were:

· the changes to STD benefits would have no impact on prescription antibiotic utilization rates in either group, and

· stratification of the time series on selected variables would not reveal a statistically significant impact when comparing pre- and post-intervention periods in either population.

The study was population-based and quasi-experimental, multiple time series by design. Data were gathered by record linkage of three Saskatchewan Health data bases: MCIB, PDSB, and the HIRF. Analysis included descriptive and interrupted time series analyses.

Each population demonstrated a statistically significant decrease ($p < 0.05$) in prescription antibiotic fill rates following the SPDP changes in STD benefits. However, the decrease experienced by the STD population was larger than seen in the SAP population by 2.569 prescriptions per 100 OM episodes.

The second set of null hypotheses was rejected in all cases except both levels of Parent type in the SAP group, Specialist level of MD type in the SAP group, and the South level of Location in both SAP and STD groups. Interpopulation differences were found on all categories except Location-South. The STD population consistently demonstrated a decrease, while the SAP population demonstrated no changes or increases in fill rates.

Overall the increased cost sharing for the SPDP STD beneficiaries negatively affected the fill rates of a necessary prescribed medication. Those considering increasing the patient cost share of a prescription drug program are cautioned that this may negatively affect the acquisition of necessary medications. This may worsen health outcome, and short-term savings may be offset by long-term expenses. Public program changes should include an evaluation component to facilitate such assessment.

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LIST OF ABBREVIATIONS

ACF: autocorrelation function

AFDC: Aid to Families with Dependent Children

AIN: active ingredient number

AOM: acute otitis media

AR: autoregressive

ARIMA: autoregressive-integrated-moving average

CASENO: case number

CHA: Community Health Association

CI: confidence interval

CID: Central Identification System

COME: chronic otitis media with effusion

COPE: California Copayment Experiment

CRVS: California Relative Value Scale

CSOM: chronic suppurative otitis media

DIN: drug identification number

EDS: Exception Drug Status

ENT: ear, nose, and throat

EENT: eye, ear, nose, and throat

FAGE: father's age

FAMSIZE: family size

GHC: Group Health Cooperative of Puget Sound

GP: general practitioner

HBM: health belief model

HIRF: Health Insurance Registration File

HMO: health maintenance organization

HSN: health services number

ICD-9: International Classification of Diseases, 9th Revision

MA: moving average

MAGE: mother's age

MCIB: Medical Care Insurance Branch

MCIC: Medical Care Insurance Commission

NHRDP: National Health Research and Development Program

NSAID: nonsteroidal anti-inflammatory drug

OM: otitis media

OME: otitis media with effusion

OTC: over-the-counter

PACF: partial autocorrelation function

PDSB: Prescription Drug Services Branch

PSI: Prescription Services Incorporated

RHIE: Rand Health Insurance Experiment

RMS: residual mean square

R.R.: relative risk

RXFILL: prescription fill

SAP: Saskatchewan Assistance Plan

SHRB: Saskatchewan Health Research Board

SHSP: Saskatchewan Hospital Services Plan

SPDP: Saskatchewan Prescription Drug Plan

STD: standard

TYPEOM: type of OM

UCLA: University of California at Los Angeles

UK: United Kingdom

URI: upper respiratory infection

USC: University of Southern California

1.0 Introduction

The *Royal Commission on Health Services* (Canada, 1964) recognized the importance of assuring that essential drug products be readily available at a reasonable cost in Canada. Although prescription drug benefits were not included in our national health insurance plan, all provinces and territories have since instituted some form of coverage for prescription drug products (Canada Health and Welfare, 1989).

A publicly funded prescription drug plan, operating with a formulary, was introduced in Saskatchewan in 1975. Every Saskatchewan Health Services beneficiary was eligible, except for those whose prescription costs were provided for by another agency, for example, all Registered Indians and others covered by Federal programs. The initial program was a fixed copayment plan with provisions for those residents receiving Saskatchewan Assistance Plan (SAP) benefits. A beneficiary paid a fixed amount (initially $2.00) for each prescription for a formulary product. Residents receiving SAP benefits paid less, depending on their level of coverage[1]. In January,

[1] There were three SAP plans. Plan One beneficiaries, over 18 years of age, paid a maximum copay of $2.00 and received insulin, oral hypoglycemics, parenteral vitamin B_{12}, allergenic extracts, oral contraceptives, and products used in megavitamin therapy at no charge. Beneficiaries under 18 years of age received all prescription formulary products, allergenic extracts, and megavitamins at no charge. Plan Two beneficiaries received all prescription formulary products, allergenic extracts, and megavitamins at no charge. Plan Three beneficiaries received all prescription formulary drugs and some non-formulary drugs at no charge, and lived in licensed, special-care homes or approved homes

1987 the maximum copay was $3.95 per prescription and $1.00 per vial of insulin and urine testing agents. SAP benefits were unchanged.

In July, 1987 the Saskatchewan Prescription Drug Plan (SPDP) was changed from a copayment scheme to a deductible plus coinsurance format for standard beneficiaries. The annual deductible was set at $125.00 per family if no member was over 65 years of age (senior citizen). For a single senior citizen, the annual deductible was set at $50.00. For a family with at least one member over 65 years of age, the annual deductible was set at $75.00. Once the deductible was met, the beneficiary was eligible for an eighty per cent reimbursement from the Prescription Drug Services Branch (PDSB) on prescription costs for formulary medications. Initially, within the nonassignment format, the consumer was responsible for paying the full price of prescriptions to the pharmacist and submitting receipts to the PDSB for reimbursement. This format was in effect from July 1, 1987 to December 31, 1988 and during this period the PDSB drug-claims data are limited to claims submitted by families who had reached the annual deductible. SAP benefits did not change and SAP claims data are complete.

On January 1, 1989, the introduction of a plastic, magnetic-strip, Saskatchewan Health Services card and a terminal directly linked to the PDSB allowed the calculation of the deductible and coinsurance at the point of prescription sale. This innovation facilitated the conversion of the

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licensed under the Mental Health Act, or were wards of the government.

program back to an assignment plan (the pharmacist, rather than the patient, was reimbursed by the PDSB) once the deductible had been reached. Hence, after reaching the deductible, the beneficiary no longer paid the full prescription price or submitted receipts for reimbursement. After the deductible was met, the beneficiary paid only the twenty per cent coinsurance at the pharmacy. Once again the PDSB data base was restored to a complete record of all benefits for all beneficiaries.

More recently the SPDP has undergone additional changes to the deductible amount and coinsurance proportion. On March 8, 1991, the coinsurance was increased to 25%. Special Care Home residents moved from the copayment program to the deductible plus coinsurance plan. SAP benefits did not change.

On May 19, 1992, the coinsurance was increased to 35%. Also, the deductible was increased and became semi-annual rather than annual. The semi-annual deductible, beginning January 1 and July 1, became $190.00 per family for families, $50.00 for single seniors, and $75.00 per family for senior families. If family prescription costs exceeded $375.00 in a semi-annual deductible period, the coinsurance was decreased to 10%.

On July 1, 1992, insulin and glucose testing agents were moved to the regular program and payment was the same as any for other formulary drug.

On March 19, 1993, the semi-annual deductible was changed again with different levels tied to ability to pay. Family Income Plan recipients now had a semi-annual deductible of $100.00 (decreased from $190.00). The semi-annual deductible for Saskatchewan Income Plan recipients and Guaranteed Income Supplement recipients in special care homes increased to $100.00. The semi-annual deductible for all other Guaranteed Income Supplement recipients increased to $200.00. The semi-annual deductible for all others, that is families, single seniors, and senior families, not exempt or approved for special support, increased to $850.00. The provision of a reduced deductible for families with prescription costs over $375.00 in a semi-annual deductible period was eliminated. However, special support was made available to families with high drug costs and an adjusted annual income of less than $50,000.00.

Canadian health policy, since the 1940's, has centred on ensuring improved access to health services (primarily physician and hospital services) for Canadian citizens. The primary mechanism for achieving equal access has been considered to be the removal of economic barriers via publicly funded hospital and medical insurance (Beck, 1973; Manga, 1987). The 1984 Canada Health Act consolidated the Hospital Insurance and Diagnostic Services Act of 1957 and the Medical Care Act of 1966 (Taylor, 1986). Its overall policy was stated as: "It is hereby declared that the primary objective of Canadian health policy is to protect, promote and

restore the physical and mental well-being of residents of Canada and to facilitate reasonable access to health services without financial or other barriers." (Taylor, 1986, p. 33).

Somewhat paradoxical, a continuing theme in Canadian health discourse, was the implementation of direct charges to patients, whether by physician extra-billing or some form of user fee (Barer, Evans, & Stoddart, 1979; Taylor, 1986). Saskatchewan was no exception, either in traditional health benefits or the occasional consideration of and experimentation with direct charges to patients. Although Saskatchewan's Drug Plan has always included some consumer cost sharing, the 1987 introduction of a deductible plus coinsurance was a departure from the previously established copayment scheme.

Such changes to health-services programs may have an impact on patient and provider behaviours, utilization of services, and health outcomes. Fortunately, the Saskatchewan Health data bases afforded the opportunity to evaluate changes to a health-services program.

This study evaluated the impact of changes in the SPDP from a copayment to a deductible plus coinsurance, and from a nonassignment to an assignment format, on the prescription antibiotic fill rates in children, aged zero to fourteen years, with an otitis media diagnosis on physician billing claims.

The goal was to provide a clearer picture of the impact of increased cost sharing on patient prescription purchase behaviour associated with what is considered to be a medically necessary medication. Therefore, this study did not address the issue of overutilization, one of the often cited justifications for implementing cost sharing (Dallek & Parks, 1981; Ginsburg & Manheim, 1973; Hall, 1966). Rather it addressed whether or not increased cost sharing affected use of necessary health care benefits. In addition, several socio-demographic variables were considered in order to determine whether or not certain sub-groups of the population were more affected by the cost-sharing changes than others.

The study design was a quasi-experimental, multiple time series with children receiving standard (STD) benefits and undergoing the cost-sharing change serving as the experimental group, and children receiving SAP benefits and experiencing no cost-sharing change serving as the comparison or quasi-control group. Monthly prescription antibiotic fill rates for otitis media diagnoses were calculated for both groups, for the years 1984 through 1986 inclusive, and 1989. Using time series analysis, data were forecasted for the intervening years of 1987 and 1988. The final data series were then analyzed for the impact of the cost-sharing changes within each study group.

All the data were gathered by record linkage of the following Saskatchewan Health data bases: Medical Care Insurance Branch (MCIB), Health Insurance Registration File (HIRF), and PDSB.

The importance and relevance of this study rest in its potential health policy implications. It addressed the question: Was the principle of equal access to medically necessary prescription medications, regardless of personal financial resources, maintained, despite cost-sharing changes to the Saskatchewan Prescription Drug Plan? It may also provoke future consideration of the effect of cost-sharing on longer-term health outcomes. That is, do savings today lead to greater costs in the future?

2.0 Literature Review

The review of the literature for this study concentrated on the following relevant areas: the diagnosis of interest, theoretical constructs of health behaviour and utilization, and the relationship between cost sharing and health services utilization. The diagnosis of interest was otitis media. The literature review, covering definition, epidemiology, pathophysiology, treatment, and failure to treat, supported the selection of otitis media as the diagnosis of interest because of the general consensus of necessity for antibiotic treatment of the condition.

The theoretical constructs of health behaviour and health care utilization of primary interest were the Andersen and Newman model and the use of health care episodes as a unit of analysis. The more general model, the health belief model, was also considered because of its contribution to the study of health behaviour.

The literature surrounding cost sharing and health services utilization is vast. Since this study was concerned with a provincial drug plan, the emphasis was on cost sharing and prescription drug utilization. However, the relationship between cost sharing and physician services utilization and health utilization by children was also discussed.

Much of the cost-sharing literature was from the United States. While the information was useful and valuable, it was the product of a different health delivery system. Because of the paucity of literature concerning cost sharing and prescription drug utilization in a Canadian setting, physician services were discussed to provide insight into the Canadian milieu. Several of these papers dealt with the introduction of Medicare.

The use of health services by children warranted special consideration because of the third-party nature of children's health care utilization. Children rely on others to access the health care system on their behalf. Therefore, behaviour associated with children's health may not follow the same pattern as for most adults.

2.1 Otitis Media

With many diseases and conditions, pharmaceutical therapy is often only one, among many possible options (*e.g.* diet, exercise, relaxation therapy, surgery), open to individuals and their physicians. Therefore to study possible changes in disease-specific drug utilization over time, a condition which was almost certain to be treated with a prescription drug was necessary. Otitis media (OM) is such a condition (Bluestone, 1988; DeMelker & Burke, 1988; Edelstein & Parisier, 1988; Maltby & Donaldson, 1989; McCracken, 1988; Wright, 1984). In addition, it is the most common diagnosis made by physicians who treat children (Bluestone, 1988) and

there is the potential to evaluate the consequences of failure to treat the condition. Children are also less likely to suffer from concomitant chronic conditions, which simplifies their medication profiles. For these reasons, otitis media in children was chosen as the condition of interest for this investigation.

2.1.1 Definition

In the simplest terms, OM is an inflammation of the middle ear. However, the disease is complex, with an unconfirmed pathogenesis and controversial management. The literature is rife with confusing terminology and therefore necessitated further qualification. OM is usually described as acute otitis media (AOM), otitis media with effusion (OME), chronic otitis media with effusion (COME), or chronic suppurative otitis media (CSOM).

AOM is accompanied by the rapid onset of earache, fever, irritability (Bluestone, 1986; Giebink & Canafax, 1988; Lisby-Sutch, Nemec-Dwyer, Deeter, & Gaur, 1990) and often with a purulent effusion (Giebink & Canafax 1988). Synonymous terms are acute suppurative OM, acute bacterial OM, and purulent OM. When a child suffers from AOM repeatedly, that is, with effusion clearing between episodes, the term recurrent OM (ROM) is applied. ROM is usually diagnosed when there are three episodes of AOM in 6 months or four episodes in 12 months (Lisby-Sutch et al., 1990).

OME is virtually asymptomatic (Bluestone, 1986; Lisby-Sutch et al., 1990) and the accompanying effusion is seldom purulent (Giebink & Canafax, 1988). Synonymous terms are secretory OM, nonsuppurative OM, serous OM, persistent OM, and subacute OM. If the effusion persists for more than 2 or 3 months, it is called COME (Lisby-Sutch et al., 1990).

CSOM is an otitis media with a chronic discharge through a perforated tympanic membrane (Goycoolea, Hueb, & Ruah, 1991; Lisby-Sutch et al., 1990). It is 2 to 3 months or longer in duration and is also called chronic draining ear (Lisby-Sutch et al., 1990).

Saskatchewan Health uses *The International Classification of Diseases, 9th Revision* (ICD-9) (WHO, 1977) as its coding guide for diagnoses on physician billing claims. Although the ICD-9 codes include up to five digits, MCIB uses only the first three. There are two codes for OM, 381: Nonsuppurative Otitis Media and Eustachian Tube Disorders and 382: Suppurative and Unspecified Otitis Media. Categorization, based solely on MCIB billing claims, was therefore imprecise. The MCIB data have been criticized for this lack of detail (Strom, 1989) and primary chart review was one of the solutions recommended for this problem (Strom & Carson, 1990).

However, retrospective categorization of OM, even using primary sources, is not without its own problems. Biles, Buffler, and O'Donell (1980) performed a community study to determine the incidence of clinically diagnosed OM and middle ear effusion, based on a random sample of

physician records. Their attempts to categorize individual episodes as suppurative or nonsuppurative and acute or chronic through chart review were unsuccessful, because the records did not contain the necessary information. Approximately 70% of diagnosed episodes were not identified as suppurative or nonsuppurative in the record. Nor was categorization by the researchers possible, because there were no specific diagnostic criteria or treatment protocols in place at the care sites to allow for uniform retrospective classification.

Therefore the authors included all episodes found in the charts described as otitis media. They did take precautions to exclude external otitis and questionable cases that were identified only by nonspecific clinical indicators. Because the calculated rates and results were based on all diagnoses of OM, which were not standardized and without regard for type of OM, comparisons with other reported incidence rates were limited.

For the present investigation, where the outcome of interest was prescription antibiotic fill rates associated with a MCIB billing code for OM, crude categories based on three digits of ICD-9 were considered to be sufficient. Based on the experience of Biles et al. (1980), chart review of physicians' records may have added little to improving diagnostic specification.

2.1.2 Epidemiology

Teele, Klein, Rosner, and the Greater Boston Otitis Media Study Group (1989) reported a prospective cohort study they conducted in greater Boston to determine the epidemiology of AOM and the duration of middle ear effusion. They found that by 1 year of age, more than 60% of the children had had at least one episode of AOM and 17% had had three or more episodes. By the age of 3, more than 80% had experienced AOM and more than 40% had had three or more episodes. The peak incidence occurred between 6 and 12 months of age. They identified the following factors to be associated with an increased risk of AOM: male gender, sibling history of recurrent AOM, age less than 6 months, and not being breast fed.

Bluestone (1981) reported a second, smaller prevalence peak between 4 and 7 years of age. Also, Bluestone (1981) and Daly (1991) reported incidence to be higher in the colder seasons of fall, winter, and early spring.

2.1.3 Pathophysiology

Factors associated with an increased risk of OM in early childhood were: increased susceptibility to infections (especially upper respiratory infections), the abundant nasopharyngeal lymphoid tissue of infants and children (this may predispose them to infection and eustachian tube obstruction), drinking cow's milk rather than breast milk, and eustachian tube dysfunction (Lisby-Sutch et al., 1990).

The eustachian tube has three functions: protection from nasopharyngeal sound pressure and secretions, drainage of secretions into the nasopharynx, and ventilation to replenish gases that have been absorbed. The eustachian tube extends upward, backward, and laterally from the nasopharynx and opens into the upper anterior wall of the tympanic cavity. The immature tube is short and at a 10 degree angle compared to a 45 degree angle in an adult. This, combined with the supine position common for infant feeding, makes reflux into the middle ear cavity more common in children. Eustachian tube abnormalities are due to functional obstruction (compliance, inadequate opening) or mechanical obstruction (inflammation, external pressure) (Lisby-Sutch et al., 1990).

The most frequently isolated bacterial pathogens in OM are those found in the nasopharynx: *Streptococcus pneumoniae* 30%, *Haemophilus influenzae* 21% (up to 30% produce β lactamase), *Branhamella catarrhalis* 12% (up to 70% produce β lactamase), *Streptococcus pyogenes*, *Staphylococcus aureus*, and *Staphylococcus epidermidis* (Bluestone, 1988). Incidence figures varied among communities and health centres. Rabin (1993) of Calgary, Alberta reported rates of *Strep. pneumoniae* 43%, *H. influenzae* 26%, and *B. catarrhalis* 24% for his centre.

2.1.4 Treatment

In North America and the United Kingdom (UK), the treatment approach for AOM is antimicrobial therapy (DeMelker & Burke, 1988). The

rationale for this includes: 1) the marked decrease in suppurative complications of OM since the advent of antibiotics, 2) the identification of bacterial pathogens in most cases of OM, and 3) the better outcomes demonstrated in a small number of prospective studies in children treated with antibiotics compared to those not treated (DeMelker & Burke, 1988). This has been the predominant view (Bluestone, 1988; Edelstein & Parisier, 1988; Maltby & Donaldson, 1989; McCracken, 1988; Wright, 1984) despite studies illustrating the self-limiting nature of AOM (Edelstein & Parisier, 1988; Wright, 1984). Approximately 70 to 80 per cent of AOM cases resolve spontaneously in 72 hours, with no antibiotic treatment (Wright, 1984). The dilemma whether to treat or not is, of course, the inability to distinguish between children who will go on to develop complications from those who will not. Even those who suggest that antibiotics may not be necessary to treat OM concede that tradition, marketing, parental expectation, and the "something is better than nothing" attitude, will go a long way to preserving the antibiotic strategy for OM (Shaugnessy, 1993).

Many antimicrobial agents are effective in treating AOM, but there is some controversy over which is best for "first-line" therapy (Lisby-Sutch et al., 1990). The most commonly used agents are amoxicillin, cefaclor, erythromycin/sulfamethoxazole, co-trimoxazole, and amoxicillin/clavulanate (Lisby-Sutch et al., 1990; Maltby & Donaldson, 1989). *The Medical Letter*

("Drugs for Treatment," 1994) consultants continue to recommend amoxicillin as the drug of choice for most children with AOM.

While the use of antibiotics has been the standard therapy in the UK and North America, the Dutch tended to treat OM symptomatically, with decongestants and analgesics. Froom et al. (1990) has reported that only 31.2% of patients with OM are prescribed antibiotics in the Netherlands. This low antibiotic use may have been in response to a study published in *The Lancet* in 1981 (van Buchem, Dunk, & van't Hof). This was a double-blind study of 171 children (239 affected ears). There were four treatment groups: myringotomy[2] only, antibiotic only, antibiotic and myringotomy, and neither antibiotic nor myringotomy. All four groups received symptomatic treatment, hence the latter group represented the symptomatic treatment only group. The authors concluded that neither combined antibiotic and myringotomy nor either treatment alone was beneficial in most cases.

Saah, Blackwelder, and Kaslow (1982) criticized the Dutch study on several points. Some analyses were done on number of affected ears rather than number of patients. If bilateral disease was unevenly distributed across treatment groups, one treatment may have been unfairly weighted. They also questioned the appropriateness of certain outcome measures for the hypothesis under study. For example, was ear drainage a meaningful

[2] incision of the tympanic membrane for drainage.

measure of outcome in those with myringotomy compared to those without? Finally, statistical methodology was not described, no probability values were reported, and the power of the study was not discussed.

Froom et al. (1990) reported on an International Primary Care Network study in which physicians from national networks in nine countries participated. The physicians recorded data on up to 15 consecutive patients with a new episode of AOM. The objectives were to determine the relationship between physicians' diagnostic certainty and signs and symptoms, a history suggestive of AOM, and tympanic membrane examination, and to compare prescribing patterns for OM across countries. The participating physicians completed questionnaires on patient history, demographics, symptoms, and findings of tympanic membrane examination. There was a follow-up questionnaire 2 months after the initial study visit. Results were tested with χ^2 and logistic regression analyses.

Diagnostic certainty increased with the age of the child, from 58% certainty in patients aged 0 to 12 months, to 66% in those 13 to 30 months, and 73.3% certainty in those older than 30 months. Diagnostic certainty was also positively associated with findings of discharging pus or bulge on examination of the tympanic membrane.

Most patients were prescribed antibiotics with the exception of the Dutch. However, there were differences in duration of prescribed treatment. In the United States, the majority were prescribed an 8 to 10

day course, while in the UK the duration was 5 days and in the Netherlands it was 6 to 7 days. The more notable finding around prescribing was that those patients not given antibiotics reported a statistically significant higher recovery rate of 90.5% compared to 82.4% for the treated patients.

In ROM, the goal of treatment is to reduce the frequency of episodes. There are five options: antibiotic prophylaxis, myringotomy with or without tympanostomy tubes, adenoidectomy with or without tonsillectomy, other medical therapy, such as topical or systemic decongestants and antihistamines, or polyvalent pneumococcal vaccine (Bluestone, 1988; Paradise, 1980). If antibiotic prophylaxis is selected, amoxicillin or sulfisoxazole, at half the therapeutic dose, as a single bedtime administration, is recommended (Thoene & Johnson, 1991).

OME has a propensity to resolve spontaneously (Marchant & Collison, 1987). However, a persistent middle ear effusion is thought to produce hearing loss, which adversely affects language development (Marchant & Collison, 1987). Treatment can be medical (antibiotics at therapeutic doses) or surgical (tympanostomy tubes) (Lisby-Sutch et al., 1990; Marchant & Collison, 1987). CSOM requires antimicrobial therapy at therapeutic doses, possibly followed by antibiotic prophylaxis (Lisby-Sutch et al., 1990).

2.1.5 Failure to Treat

As stated earlier, one of the reasons for treating OM with antibiotics is the reduction in suppurative complications once associated with OM. These complications include meningitis, brain abscess, subdural empyema, lateral sinus thrombosis, and focal otitis encephalitis (Lisby-Sutch et al., 1990; Sagraves, Maish, & Kameshka, 1992; Wright, 1984). Wright (1984) using American Vital Statistics data, reported that in 1936 there were 4272 deaths attributed to OM and mastoiditis. By 1956 the deaths linked to OM had fallen to 383 and by 1976, to 106.

Extracranial complications also occur and include perforation of the tympanic membrane, mastoiditis, purulent or serous labyrinthitis, facial paralysis, acquired cholesteatoma, and hearing loss (Lisby-Sutch et al., 1990). Hearing loss is the most common complication of OM (Bluestone, 1981). The relationship of persistent or episodic hearing loss and impaired cognitive or language development is particularly troublesome (Teele, Chase, Meynuk, Rosner, & the Greater Boston Otitis Media Study Group, 1990), although the degree and duration of hearing loss associated with such impairments remains controversial (Bluestone, 1981).

Other nonsuppurative complications include adhesive OM, tympanosclerosis, and ossicular discontinuity, all of which can lead to conductive hearing loss. Some are more easily corrected surgically than others (Bluestone, 1981).

In conclusion, OM is a common disease of childhood, but not without serious consequences or controversy. The prevailing consensus, primarily because of the dramatic decrease in suppurative complications since the advent of antimicrobial therapy, is that antibiotic therapy is the treatment of choice for OM (Bluestone, 1988; Giebink, Canafax, & Kempthorne, 1991; Paradise, 1980; Wright, 1984). For this reason and because of its high incidence, OM was chosen as the diagnosis on which to focus the present investigation.

The diagnosis of OM provided a reasonable expectation of an associated prescription. Thus the assumption was made that a diagnosis of OM on a MCIB claim should have resulted in an antibiotic prescription claim in the PDSB and that linking data from these two data bases provided the means to calculate antibiotic prescription benefit utilization rates.

OM occurs primarily in children and can be very painful. It was postulated that if cost-sharing changes were to affect prescription benefit utilization, the impact would be less apparent in an acute childhood condition than in other conditions. Also, it was postulated that parents are more likely to forego medications for asymptomatic conditions, such as hypertension, in themselves than for acute conditions in their children.

Leibowitz, Manning, Keeler, et al. (1985) suggested the opposite. Their conjecture was that because childhood illnesses were more likely to be

acute and therefore self-limiting, care may be more easily foregone, than for chronic illnesses of adulthood, which do not go away. However, they did acknowledge the protectiveness of parents who would risk their own health before their children's.

2.2 Health Behaviour and Utilization

2.2.1 Health Belief Model

The Health Belief Model (HBM) is a social/psychology model to aid in the explanation of health behaviour (Rosenstock, 1990). It was developed in response to the limited success of various public health initiatives in the United States, in the 1950's. An example cited by Rosenstock (1990) was the poor response to the tuberculosis screening program, which involved mobile x-ray units located in various neighbourhoods, to screen residents at no charge.

The basic components of the HBM are: perceived threat, outcome expectations, and self-efficacy. Perceived threat has two dimensions: perceived susceptibility and perceived severity. Perceived susceptibility is an individual's subjective perception of personal probability of acquiring a particular illness. For example, in breast screening programs, it is the woman's perception of her own personal risk of developing or having breast cancer. If illness is already present, this dimension may be reformulated to address acceptance of diagnosis, estimation of resusceptibility, or susceptiblity to illness in general. These issues would have bearing on how

the individual responds to recommendations for treatment or coping with the illness. Perceived severity concerns the perception of the seriousness of the consequences of acquiring the illness or not treating an existing illness. The consequences may be social or clinical.

Outcome expectations involve perceived benefits and perceived barriers. Perceived benefits include the belief that any particular course of action is feasible and efficacious. Perceived barriers are any obstacles that hinder an individual from complying with recommendations. They may include expense, possible side effects, pain, convenience, and time.

Self-efficacy or efficacy expectation is the confidence of an individual to successfully complete the recommended action. For example, in order to quit smoking, individuals must feel capable of quitting.

Other variables which also are considered when applying the HBM are sociodemographic factors. Certain sociodemographic variables, such as education, may influence an individual's perception of susceptibility, severity, benefits, and barriers.

Although the HBM does help to understand the underlying psycho-social aspects of the behaviour under investigation, it was not a particularly useful theoretical model for the present investigation. Because this study was without direct access to the individuals in the study population, it was impossible to incorporate perceived threat, outcome expectation, and self-

efficacy into the design. These measurements are not possible in studies that use data from record linkage alone.

2.2.2 Andersen and Newman Model

Andersen and Newman (1973) developed a theoretical framework for examining health-services utilization (illustrated in Figure 2.1). It stresses the importance and contribution of both societal and individual determinants to the outcome - health-services utilization. They viewed health-services utilization as a type of individual behaviour, which may be explained as a function of individual characteristics, environmental characteristics, and the interaction between individual and societal forces. They condensed this view into three components: societal determinants, health-services system, and individual determinants, all contributing to the outcome of health-services utilization.

Health-services utilization has three dimensions: type, purpose, and unit of analysis. Type describes the particular form of health service, such as: hospital, physician, prescription drug, and so on. Purpose refers to the level or form of care: primary care, secondary care, tertiary care, and custodial care. The authors described primary care as stopping illness before it began (*e.g.* preventive medicine); secondary care as acute care involving diagnosis and treatment (*e.g.* infectious disease); tertiary care as care for chronic illness (*e.g.* diabetes); and custodial care as providing personal needs without treating the underlying disease (*e.g.* palliative care).

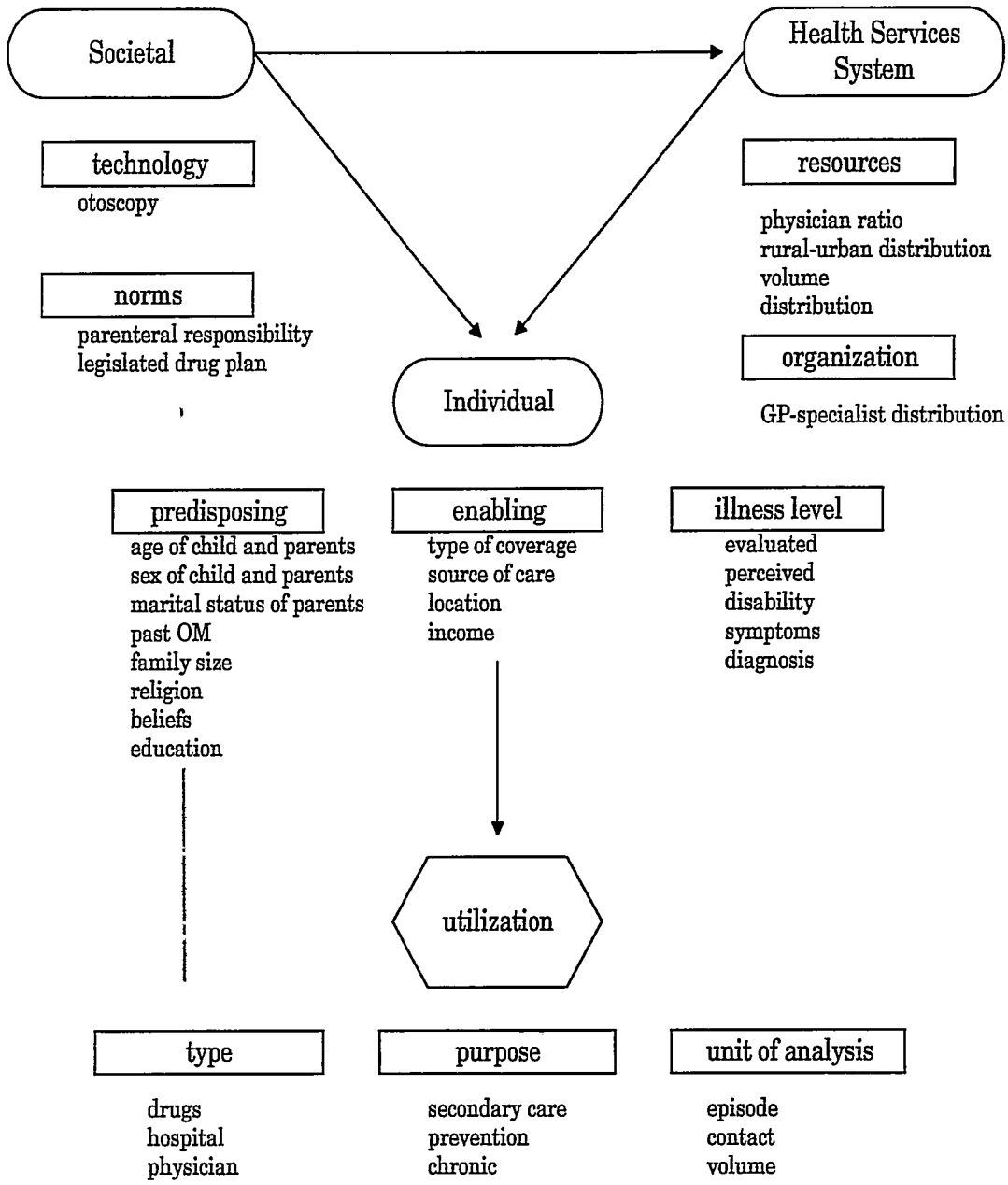

Figure 2.1: Andersen and Newman theoretical framework for examining health services utilization.

Adapted from Andersen, R. & Newman, J. F. (1973). Societal and individual determinants of medical care utilization in the United States. *Milbank Memorial Fund Quarterly, 51*, 95-124

The last dimension, unit of analysis, may be the initial contact with the system (*e.g.* physician visit); the volume of service (*e.g.* number of services received in a given time period); or an episode (*e.g.* initial contact through to resolution or some predefined end point).

Societal determinants influence both the health services system and the individual. There are two societal determinants: technology and norms. Technology encompasses the tools of providing health care, including drugs, equipment, and research. Historically as technology improved, hospitals began to be viewed as places to get well, rather than places to die. Norms reflect the beliefs and values of the society, and these may be formally legislated or simply widely held values. Examples would be: 1. the shift in the treatment of mental illness from institutionalization to out-patient treatment and 2. how health care is financed. In Canada, universal health insurance is both formally legislated and widely valued as a principle.

The health services system is the formal structure of health-care delivery. It has two components: resources and organization. Resources are the nuts and bolts of the system - labour and capital, and their volume and distribution. Examples are the physician per population ratio and geographical distribution of services (*e.g.* urban/rural split). Organization involves access and structure. Examples of access and structure include such things as economic barriers, the referral process, and finding the appropriate agency.

The individual determinants are divided into three factors: predisposing, enabling, and illness level. The predisposing factors refer to individual characteristics which can be used to predict an individual's propensity to use health services. These characteristics are independent of illness or its onset. They are one of three main types: demographic (age, sex, marital status), social structure (education, family size), and beliefs (health attitudes, health/medical knowledge).

The enabling factors are the means to use the system and are dichotomized into family and community factors. Family factors include income, health insurance, and regular source of care. The community factors are availability of service, price of service, and location.

Illness level encompasses both perceived illness and evaluated illness. Perceived illness includes symptoms, disability, and diagnoses, and is often the initial impetus to seek care. Diagnoses are included to capture the influence of the system on utilization (*i.e.* provider-induced utilization). Evaluated illness refers to the professionally defined illness and judged severity. It is a useful dimension for making judgements on probability of need for service.

The Anderson and Newman model was amenable to the present investigation and to record linkage of claims data. Much of the data reflected in their model were available in the Saskatchewan Health data bases. According to their framework, the outcome under study can be

described on the three dimensions as: 1) type = dispensed antibiotic prescription, 2) purpose = secondary care, and 3) unit of analysis = episode of care. The societal determinants, although not an explicit part of this investigation, were nonetheless present. They included the tools for diagnosis of OM (*e.g.* an otoscope) and the norms (*e.g.* widely held beliefs, such as nurturing children's health, and legislated programs, such as the SPDP).

Aspects or elements of resources and organization of the health services system were also present in this study. The resources included consideration of the rural-urban and north-south distribution of these resources. Cost sharing, as an economic barrier, and the source of care, GP or specialist, were elements of the organization of the health services system addressed in this study.

Finally, individual determinants were also considered. The predisposing factors were: age and gender of child, age and gender of parents, marital status of parents, past episodes of OM, and family size. The enabling factors were: type of coverage (STD vs. SAP), source of care, and residence. Illness level was inherent to the study, for in order to be included, there had to be a visit to a physician and a diagnosis of OM. Therefore, both perceived illness and evaluated illness were present.

2.2.3 Health Care Episodes

The notion of health care episodes attempts to capture the complexity of health care delivery, especially when being examined as a commodity (Hornbrook, Hurtado, & Johnson, 1985). Although health care is on occasion delivered as a single service, for example immunization, it is more often a series of services around a single concern. This is in contrast to other service industry products, such as hair cuts or automobile tune-ups. The series of services can be quite diverse, including laboratory tests, prescriptions, physician office visits, and hospitalizations.

Hornbrook et al. (1985, p. 168) defined "A 'health care episode' [as] . . . the period of time during which a specific disease process, illness, health care problem, or treatment process is present." They delineated four types of health care episodes: episode of disease, episode of illness, health maintenance episode, and episode of care.

An episode of disease is grounded in clinical parameters. It begins with a clinical diagnosis and ends with a clinically defined resolution. Because of uncertainty about the appropriateness of a diagnosis as the marker of illness, there is a distinction made between disease and illness. For example, hypertension is clinically defined as a disease but because of its asymptomatic nature many hypertensive patients are unlikely to feel ill.

An episode of illness is a single uninterrupted period of time during which an individual experienced signs and symptoms that are interpreted as an illness.

An episode of care refers to a series of temporally-related, health care services in response to a given disease, illness, or request on the part of a patient or provider. Limits may be placed on an episode of care, for example a single provider or an arbitrary time period.

Health maintenance episodes are those contacts with the health care system that are neither disease nor illness related (*e.g.* well baby clinics or cosmetic surgery).

The type most applicable to this study, and supported by the Andersen and Newman model, was the episode of care. Since the purpose of the study was to evaluate prescription antibiotic fill rates associated with MCIB claims for an OM diagnosis (*i.e.* temporally-related services), the episode of care was considered the logical choice. It was also well suited because the data source was record-linked, administrative data and therefore service based.

The parameters of a health-care episode are time, nature of the problem, resource use, and outcome. These vary slightly depending on the type of episode, but the emphasis here was on the episode of care with specific reference to the present investigation.

The time parameter logically describes the starting and stopping points of the episode. With a very strict interpretation of episode initiation, an episode of care begins with the request for an appointment but it more commonly begins with a patient's actual encounter with the system and less frequently with the diagnosis of an illness. Because the data source for this study was service-based claims, the starting point was the physician visit. The episode also included an antibiotic prescription dispensed within 3 days and subsequent visits within 14 days.

A stopping point can be the resolution of the condition, last contact with the provider, or an assigned time period. AOM may resolve spontaneously within 72 hours (Wright, 1984). When treated, it is customarily treated for 10 to 14 days (Bluestone, 1988). These considerations guided the decision to define the end-point of an OM episode as 14 days after the initial physician visit.

The nature of the problem classifies the episode, determining whether episodes can be grouped for meaningful comparison, measurement, or analysis. Useful concepts for classification are severity, phasing, and chronicity. Severity can be evaluated by a time-intensity gradient to describe effect on everyday life. Phasing involves breaking down the episodes into stages or phases, such as diagnostic period, active treatment period, maintenance, or flare. Chronicity is especially challenging because

of the vague commencement, unlikely resolution, and very long duration of chronic diseases.

Another option for grouping episodes is the use of existing coding or classification guides, such as the ICD-9. Fortunately in the present study, the condition of interest was quite narrowly defined and the ICD-9 was used by the MCIB for coding physicians' claims.

Resource use addresses the linking of medical services to an episode - what services belong to a specific episode? Can the researcher be sure a particular service does not belong to a new episode? There are two approaches to dealing with this dilemma. The first is to appeal to medical judgment and the second, if using an administrative data base, is to use a chronological approach. In the present investigation both approaches were employed. The OM literature was used to ascertain the course of a typical OM illness and the data bases were relied upon to provide an accurate sequence of events.

Outcome as utilized by Hornbrook et al. (1985) was concerned with health status of the patient, whether measured by functional outcome (*i.e.* patient's health status in absolute or relative terms) or the contribution of the medical care to the health status (*i.e.* relative to other contributing factors, such as initial status, compliance, and environment). Simply put, they addressed the question: Is the patient better?

The present investigation did not address this question per se. It addressed the question: Did the patient have a prescription filled? This did not tell us anything about the final health outcome; rather, based on expert opinion, it was an intermediary step to the final outcome of improved health. For the purposes of the present investigation, this was adequate. However, it did illustrate the next logical step in reasoning - does cost sharing in the short term have the same effect in the long term? For example, if cost sharing produced economic savings for the insurer in the short term because prescriptions were not being filled, would the savings be sustained or offset in the future by increased hospital and physician expenditures due to poorly managed OM?

This is a macro view of the effects of cost sharing. At the micro level, patients or parents may not consider a single episode of OM as influencing the future health of themselves or their children. Therefore, possible long-term effects may not play a role in the immediate decision whether or not to fill a prescription for an antibiotic. However, the present investigation was concerned primarily with the macro analysis of the effects of cost sharing.

2.3 Cost Sharing and Health-Services Utilization

Cost sharing in the health sector has usually been justified by the belief that it prevented unnecessary and inappropriate use (Dallek & Parks, 1981; Ginsburg & Manheim, 1973; Hall, 1966; Hurley & Johnson, 1991). This view was closely tied to the insurance industry's notion of moral

hazard. Moral hazard assumed that if one did not share in the risk for the insured event, then the insured person was more likely to experience that insured event than one who was not insured. Therefore, a person insured for physician visits or prescription drugs who did not share in the cost of the services, was more likely to incur a physician visit or a prescription drug than someone who was not insured or shared in the cost.

This was, of course, provided that the insured person had some discretionary control over the insured event (Soderstrom, 1978). For example, moral hazard would not apply to crop insurance for hail damage, since the individual cannot influence whether or not it hailed. The discretionary control over decisions to obtain health services may appear obvious but could be debated in a life-threatening or emergency situation.

Another argument (Barer et al., 1979; Hurley & Johnson, 1991) is that cost sharing heightens consumer awareness of health care costs. What impact this has had on actual behaviour was unknown.

The ability to heighten awareness of costs may be influenced by the type of cost sharing (Hurley & Johnson, 1991). A fixed copayment was not related to the actual cost of the service. It was the same, whether the service cost $2.00 or $200.00. A deductible, however, required the consumer to pay the actual service cost up to a fixed amount. What may vary here, among consumers, was the number of services used to reach the deductible. Therefore depending on the type of services and the associated costs used by

an individual, the ability of cost sharing to heighten awareness of overall health costs was unclear.

Hurley and Johnson (1991) questioned the soundness of assuming that making decisions about health care based on cost alone was a good thing. Informational problems for the consumer may limit their ability to choose the most appropriate medication. Therefore, decisions based on price may not necessarily be desirable.

Barer et al. (1979) also described the basic supply-demand model and the *personal responsibility* philosophy used in supporting cost sharing. The supply-demand model implied that increasing out-of-pocket expenses to health-care consumers automatically decreased demand and thereby utilization, which led to a reduction in costs.

The personal responsibility philosophy became popular when reports, such as the Canadian government's white paper: *A New Perspective on the Health of Canadians* (Lalonde, 1974), suggested that ever increasing health-care technology may contribute little to improving health status and that environmental and life-style factors may be the key to improved health status. This was viewed, by some, as a need for taking a greater personal responsibility in individual health care and even paying for the required care as well. That is, if people fell ill through their own choice or life-style, then they should pay for the resulting medical expenses.

These views were not without critics. Hall (1966) wrote that the real issue of cost-sharing investigations was the ability of cost sharing to control over-utilization of health services. A definition of over-utilization was difficult to devise. He found it was very difficult for people to judge what an unnecessary service was, except in individual cases where all the facts were available. He also wondered how it was possible to prevent unnecessary care without also circumventing necessary care. He cited a common concern, that if people forego or postpone appropriate care, it will eventually result in a heavier illness burden and even greater costs.

Dallek and Parks (1981) were especially concerned with the impact of cost sharing among the American indigent population. The poor were especially sensitive to cost sharing. Only the poor could be affected by such seemingly nominal fees of $1 to $3. This was in agreement with Ginsburg and Manheim (1973), who noted that the price elasticity (responsiveness to price changes) of demand for health services was variable among the population.

In addition, there was the role of the health care provider in this scenario (Barer et al., 1979; Dallek & Parks, 1981; Ginsburg & Manheim, 1973; Hall, 1966). It may be the patient who initiated contact with the system, but it was provider who admitted, prescribed, ordered tests, and so on. Under a fee-for-service system, this influence on utilization cannot be ignored (Barer et al., 1979).

There are four major types of cost sharing: deductible, coinsurance, copayment, and indemnity (Ginsburg & Manheim, 1973). With a deductible, the consumer pays the full cost of services up to a certain point, after which the insurance commences. Coinsurance involves payment of a specified portion, usually a percentage, of service costs. A copayment is a fixed, and often nominal, amount paid for each service. [In Canada, copayments, coinsurance, deductibles, and any authorized charge have also been called utilization fees, deterrent fees (Soderstrom, 1978), or user fees (Sutherland & Fulton, 1988)]. Indemnity means the insurer provides a fixed payment to the consumer for each service, no matter what the actual cost, which may or may not result in cost sharing.

There are two ways to administer the reimbursement portion of cost-sharing arrangements: assignment and nonassignment. Assignment means that patients pay only their portion to the provider and the provider is reimbursed by the insurer for the balance. This was the initial and is the current form of reimbursement used by the SPDP. Nonassignment means the patient pays the full amount of the service charge to the provider and then submits receipts to the insurer for reimbursement. This type of reimbursement scheme was used by the SPDP for 18 months, from July 1, 1987 to December 31, 1988.

2.3.1 Physician-Services Utilization in Canada

The introduction of Medicare in Canada sparked the interest of several researchers. It was an opportunity to study utilization when economic barriers were lowered or removed.

Greenhill (1971) reported on an Alberta study conducted in 1968, the year before the implementation of the Alberta Health Care Insurance Act. The study examined utilization rates between those with no insurance and those with private health insurance. Its purpose was to study the pattern of health care utilization in Alberta before the introduction of the Alberta Health Care Insurance Act. There were plans to later report on utilization following the introduction of the Act and any differences between the two phases. The researcher also hoped to delineate the predisposing factors that contribute to health services utilization. The study was an interview survey within two medical catchment areas: an urban centre, Edmonton, and a rural region, Red Deer. A systematic, random sample of the voter enumeration lists was employed.

Those with insurance used hospitals and physicians more than the uninsured. The percentage of urban insured and rural insured who reported having seen a physician in the previous two weeks was 18.5 and 17.3, respectively. The percentages with a hospital stay in the previous year were 14.2 and 19.7. In contrast, the urban and rural uninsured reporting having seen a physician was 9.7% and 6.5%, and 13.4% and 11%

had a hospital stay. The insured were also more likely to have used a prescribed medication in the two weeks prior to the interview (urban and rural insured: 31.4% and 32.8%; urban and rural uninsured: 15.9% and 17.3%).

Although the incidence of perceived morbidity was higher for the insured than the uninsured, the difference in perceived morbidity did not approach the difference in utilization between the two groups. The perceived morbidity percentages were as follows: urban and rural insured, 7.5% and 7.3%; and urban and rural uninsured, 5.5% and 4.8%. However, the table describing perceived morbidity simply reported the percentage of subjects that reported their health as *poor*. It was therefore difficult to judge the adequacy of the morbidity measure.

Also, 28.2% of the urban uninsured were 18-24 years old, compared to 18.8% of the urban insured, 8.7% of the rural uninsured, and 11.2% of the rural insured. This may contribute to the low perceived morbidity of the urban uninsured compared to the urban and rural insured, since younger people may perceive themselves to be healthier.

In addition, the samples appeared to contain no unemployed individuals. Other studies have shown these individuals as more likely to be in poor health (D'Arcy & Siddique, 1987). The unemployed are also more likely to be uninsured, since third-party insurance is often an employee benefit. Exclusion of the unemployed would underestimate the level of

morbidity in the uninsured group. Inclusion of the unemployed may shift the emphasis from the possible over-utilization of the insured to the possible under-utilization of the uninsured.

Lastly, there was no description of type of insurance, source of enrollment (self-directed or through employer), comprehensiveness, and cost-sharing levels. It is conceivable that the type of plan could also affect utilization.

McDonald, McDonald, Steinmetz, Enterline, and Salter (1973) reported on a study performed in Québec before the introduction of a medical insurance plan in that province. A paper describing the post phase was also published and a discussion of it follows.

The authors conducted a household survey, from August 1, 1969 through July 31, 1970, of 6000 dwelling units in Montréal. The findings were confined to 4961 interviews using the full-interview form. They found a greater unmet need for physician services in low income groups, compared to higher income groups.

Need was measured by asking questions relating to the occurrence of certain symptoms during the previous 12 months. These particular symptoms were selected because the researchers believed they warranted a physician's advice. The symptoms included: 1. for all adults - cough of two or more weeks duration, weight loss unless due to a diet, and backache or sciatica; 2. for men 45 years or older - breathlessness or chest pain on

exercise, difficulty urinating; 3. for women 25 to 44 years - irregular periods, and bleeding between periods; 4. for women 25 years or older - stiffness, pain or swelling of joints, and incontinence; 5. for anyone 65 years or older - trouble with feet and difficulty getting around; and 6. for children less than 17 years - measles, discharging ear, tonsillitis, bronchitis, diarrhea, convulsions, and poisoning. Symptoms of adults were generally more pronounced in lower income families, compared to higher income families. However, the proportion seeking medical attention for the symptoms increased with income. Symptoms of children did not show a consistent trend according to income, but medical attention increased with income, as it did in the adults.

The authors, therefore, predicted an increase in physician visits with the introduction of the Québec health insurance plan in November 1970 because the plan guaranteed complete coverage for all physician services. This prediction was tempered with the caveat that this would only prove true if cost was the primary determinant of physician utilization, rather than other possible factors, such as beliefs and attitudes.

Enterline, Salter, McDonald, and McDonald (1973) reported on the post-insurance phase in Québec. Similar to the pre-insurance phase study described above, a household survey was conducted between August 1, 1971 and July 31, 1972. As predicted, utilization by those in lower income groups increased following the introduction of Québec's medical insurance plan.

The two lowest income groups, < $3000 and $3000-4999 annual family income, experienced an 18.2% and 9.1% increase respectively, in physician visits per person per year. The middle income group experienced no change. Interestingly, a decrease in utilization by those in higher income groups was found (a 3.9% decrease for the $9000-14,999 group and a 9.4% decrease for the $15,000 and higher group). The authors speculated this may have been due to increased waiting times both for appointments and in physicians' offices, because of the greater utilization originating in the lower income groups, and that this change might have been felt more acutely by previous users, that is, those in high income groups.

To address the issue of whether increased utilization was likely to improve health, Enterline's group looked at changes in care for the same symptoms described above in the McDonald et al. (1973) paper. Before Medicare the proportion of these symptoms which resulted in a physician consultation varied from 59 per cent in the lowest income group to 70 per cent in the highest income group. This difference disappeared after the introduction of Medicare and, overall, the proportion of important presenting symptoms, for which physicians were consulted, increased from 62 per cent to 73 per cent. Therefore, the authors concluded that the removal of economic barriers may improve health, consistent with their earlier prediction of increased utilization.

Saskatchewan's utilization of health services also came under scrutiny in the early years following the introduction of Medicare. Badgley, Hetherington, Matthews, and Schulte (1967) examined the impact of Medicare on one Saskatchewan town. This town, given the pseudonym of Wheatville, was surveyed in 1960 and 1965. The initial survey used local hospital, public health nurse, and physician records, and a household survey of one-third of the heads of households. In the second survey, 23% of household heads were interviewed and rates of hospitalization were obtained from the provincial department of public health. The local physicians declined to participate in the second survey. The following measures were used to evaluate health and thereby, the effectiveness of the Medicare program: mortality statistics, hospital admissions, hospital morbidity statistics, sickness survey, physician utilization, and utilization of health personnel.

Because of the size of Wheatville, significant changes in mortality were not expected. Given mortality figures alone, it would not appear that health status had changed with the introduction of Medicare. The authors noted that mortality figures did not reflect the impact of new programs, when the standard of health was already high and half the population survived beyond 65 years.

Hospital admission rates, in addition to reflecting level of illness, were also a function of how hospital bills were paid and how medical

practice was organized. The authors found a decrease in the rate of hospitalization for Saskatchewan and for Wheatville, since the introduction of Medicare. The provincial rate decreased by 4.6% and in Wheatville, the number of separations from the hospital decreased by 22 per 1000 insured persons.

The diagnostic mix of hospital stays in Wheatville changed following the introduction of Medicare. There were fewer complications with pregnancy. The rate for elective surgery declined slightly, while the provincial rate increased by 9%. The number of diagnoses for senility increased and the number of psychoneurotic disorders more than doubled, from 10 per 1000 in 1960 to 26 per 1000 in 1964.

The sickness survey revealed that, although the amount of sickness had decreased from the time of the first survey, the differences between the social classes had widened. In 1960, 68% of the upper class reported specific symptoms, compared to 77% of the lower class. In 1965, it was 33% of the upper class, compared to 75% of the lower class. When subjects were asked: "What effect has medicare had on your health?", 20% responded that it had improved. The removal of economic barriers was the most frequently cited reason for the improvement. However, 80% felt that everyone's health had improved because of Medicare.

Since the local physicians did not participate in the second study, physicians' patient load could not be examined directly. But many

Wheatville residents thought the doctors were busier and that the quality of care had improved. Provincially, physician utilization increased by 9.3% from 1963 to 1964, but levelled off in 1965 with an increase of 0.27%.

Utilization of health personnel, such as dentists, public health nurses, and chiropractors varied by social class. The gap increased between 1960 and 1965. In 1960, 30% of the population saw a public health nurse regardless of social class. In 1965, 44% of the upper class reported visiting a public health nurse, compared to 19% of the lower class. The trend was reported to be similar for dentists and chiropractors. This difference was viewed by the authors as a reflection of how each group interpreted how and when a doctor should be used. The effect of Medicare was to allow lower income groups to place greater responsibility for care in the hands of physicians rather than other health personnel, while the more affluent viewed the physician as a coordinator and obtained more referrals and visited other physicians and health personnel.

In summary, the authors concluded that although all residents had received benefit from Medicare and access had increased, an imbalance in the health of the population remained. It appeared then that improved access and subsequent increased utilization of physician services did not necessarily translate into improved health for all.

A more extensive study in Saskatchewan was conducted by Beck (1973). Data were gathered by sampling the files of the Medical Care

Insurance Commission (MCIC) and the Saskatchewan Hospital Services Plan (SHSP) from 1963 to 1968. Income data, for the sample families, were gathered from the Saskatchewan Treasury Branch. Since the two Saskatchewan Health data bases, MCIC and SHSP, did not share a common, unique identifier with the Treasury Branch, a computer program was developed to track the necessary income records.

The primary focus of the study was economic class and access to physician services. Rather than looking at actual utilization, the proportion of an economic class that did not receive medical services was used as a measure of accessibility. In 1963, 47 per cent of the lowest class compared with 10 per cent of the highest income class had no contact with physicians' services. With time and familiarity with Medicare, the disparity decreased, but had not disappeared completely by 1968. Nonusers in the lowest income group decreased to about 30% from 47%, compared to a consistent 10-15% of the higher income groups being nonusers.

By the late sixties, concern about the escalating costs of health care was being expressed (Beck, 1974, 1976; Beck & Horne, 1980). In 1968, Saskatchewan introduced a copayment of $1.50 on physician office visits and $2.00 for home, emergency, or hospital out-patient visits, and a hospital utilization fee of $2.50 per day for the first 30 days and $1.50 per day thereafter, to a maximum of 90 consecutive days, as a measure to control the increase of costs.

The purpose of the 1974 study was to determine the impact of the copayment on poor families (defined as using 70% or more of their incomes for food, shelter, and clothing). Adjustments were made for inflation and farm families. Therefore, the study definition of poor included an income range of $1550 (1963) for a family of one to $1800 (1968) for a family of five or more. The analysis was confined to the first year following the introduction of the copay.

Samples were drawn from the SHSP's Master Registration File. The sample sizes were about 40,000 families for each year of 1963 through 1968. Data were collected from the Master Registration File, MCIC, and the Treasury Branch. A subsample meeting the study definition of poor, were drawn from this sample to meet the objectives of this study.

A regression model was used to analyze the effects of the explanatory variables: family income, spouse absent (*i.e.* single parent), family size, age of family head, urban, copayment, and time. The dependent variable was quantity of services - number of physician services per family per year. No interaction effects were considered. With the introduction of the copayment for physician services, Beck found an 18 per cent decrease in utilization of physicians' services by the poor. He compared this to the estimated 6-7% decrease experienced by the whole population. The calculation of this estimate was not described. When general practitioner (GP) services alone were analyzed, the poor experienced a 14% decrease. Types of service were

also compared with patient-elective services declining more than physician - elective services. As Beck stated, a major policy issue is at stake with such an intervention. Copayments may well reduce costs, but may also affect access of the needy to the services. This was an important consideration, since access based on need, rather than personal financial resources, has been central to Canadian health policy.

Beck's 1976 paper expanded on the study described above, by looking at long-run effects and interaction terms. As above, repeated cross-section, random samples were drawn from Saskatchewan Health data bases for each year of 1963 through 1971. The user fees (both the copayment and the hospital utilization fee) were removed in 1971. This particular report used data from 1966 through 1971.

Again using a regression model, Beck concluded that the copayment resulted in a decrease in family utilization of physician services (regression coefficients for copayment dummy variables were negative and statistically significant).

Beck and Horne (1980) reported on a broader analysis of the 1968 out-patient copayment and hospital utilization fee. The sampling was as described above, extended to include 1973. The study period for analysis of ambulatory services was 1963 to 1973 and for hospital services it was 1966-1973.

To estimate the amount and direction of change in utilization due to the out-patient copayment, they used regression and a trend estimate to calculate an estimate of use for 1968 to 1971, as if no copayment had existed. They then compared this to the regression model containing the copayment predictor variable. The results indicated a 5.66% reduction in utilization of physician services due to the copayment.

This was further supported by comparing welfare family utilization of physician services to non-welfare family utilization. Welfare recipients were not charged the copayment and therefore, served as a *quasi-control* group. Using the same analytical technique as above, they found both groups experienced a decrease in utilization, but the copayment group experienced a larger decrease in use. For example, in 1968 the copayment group experienced an 8.85% decrease, while the welfare group showed a 7.24% decrease. Therefore, the net effect of the copayment on physician-services utilization was -1.61%.

In summary, the utilization of physician services seemed to have increased in various Canadian provinces, following the introduction of Medicare. The lower socioeconomic groups were shown to contribute the most to this increase. There was support that this was due, at least partly, to previously unmet needs and cannot be simply dismissed as overutilization. The Badgely et al. (1967) observation that hospital use decreased following Medicare may mean people were seeking physician care

sooner and thereby avoiding hospital care. This illustrates the inter-related nature of sectors of the health care delivery system. The introduction of copayment decreased utilization most profoundly for the poor. Beck and Horne (1980) used welfare recipients as a quasi-control group and found they also experienced a decrease, albeit smaller, in utilization following a copayment introduction, despite being exempt. It appeared that Medicare has removed or decreased economic barriers, thereby increasing access, especially for those in lower socioeconomic groups and that cost sharing compromised that access.

2.3.2 Prescription-Drug Utilization

The most ambitious attempt to investigate the relationship between health services utilization and patient cost sharing was the Rand Health Insurance Experiment (RHIE). It was a population-based, randomized controlled trial, sponsored by the US federal government (Lohr et al., 1986). The study followed the use of medical services and health status over a three or five year period between November, 1974 and January, 1982. The six sites involved were chosen to represent four American census regions and the urban-rural split. The six sites were Dayton, Ohio; Seattle, Washington; Fitchburg, Massachusetts; Franklin County, Massachusetts; Charleston, South Carolina; and Georgetown County, South Carolina. Exclusion criteria included annual incomes greater than $58,000 (1984 dollars); head of household eligible or soon to be eligible for Medicare;

participation in the Supplementary Security Program; eligible for Medicare because of end stage renal disease; household members older than 61 at start of study; eligible for military medical system; and those indefinitely institutionalized. The study did include families receiving Medicaid and low-income families were over-sampled.

Allocation of families to a plan was random, but ensured a similar distribution of health and expenditure characteristics across plans (Leibowitz, Manning, Keeler, et al., 1985). Before actual enrollment in a plan, subjects were interviewed three times (screening, baseline, and enrollment interviews). The Massachusetts and South Carolina samples were interviewed only twice, baseline and enrollment. Six percent of the sample refused the screening interview. Another 9% of the original sample refused the baseline interview. The enrollment interview found an additional 9% refusal. Finally, a further 11% refused the offer of enrollment. Therefore, the final sample was 65% of the original.

The final study sample contained more than 7700 people in over 2700 families, enrolled in one of fourteen plans (Lohr et al., 1986). The fourteen plans varied in level of cost-sharing and the maximum out-of-pocket expenditure was tied directly to income. One plan was completely without charge and was referred to as *the free plan*. The other thirteen plans consisted of a coinsurance plus a $150.00 deductible. Nine of the thirteen plans had a 25% or 50% coinsurance up to a maximum dollar expenditure

(MDE) of $1000.00 or 5%, 10%, or 15% of family income, whichever was less. Three plans had a 95% coinsurance with the same MDE as the previous nine plans. The fourteenth plan had a 95% coinsurance on ambulatory care up to $150.00 per person or $450.00 per family and care beyond this point was free, with all inpatient care being free. Families were offered only the plan to which they had been randomly allocated (Lohr et al., 1986).

All plans covered ambulatory and hospital care, preventive services, all dental services (except nonpreventive orthodontia), all prescription and certain over-the-counter (OTC) drugs, most supplies and durable medical equipment, psychiatric and psychological services (except psychotherapy visits beyond 52 per person per year), other personal medical services (except cosmetic surgery for preexisting conditions), and audiology, optometry, and speech therapy (Leibowitz, Manning, Keeler, et al., 1985).

Leibowitz, Manning, and Newhouse (1985) reported on the prescription medication utilization aspect of the experiment. It was found that individuals with more generous insurance bought more prescription medications. All cost-sharing plans showed significantly lower medication expenditures compared to the free plan. The number of prescriptions per capita was significantly higher on the free plan than on any of the cost-sharing plans. However, the cost per prescription was not significantly

related to the type of plan. There was no attempt to ascribe medical necessity to prescription medications obtained during the study.

Lohr et al. (1986) went on to address whether the effect of cost-sharing was the same for all classes of drugs. Twenty-four categories of drugs were divided into six groups: 1) therapies for chronic or specific conditions (*e.g.* antihypertensives and diabetic agents); 2) tranquilizers, sleeping pills, and antidepressants; 3) pain remedies; 4) gastrointestinal symptomatic agents (*e.g.* antacids); 5) agents for infections (*e.g.* cold remedies and antibiotics); and 6) preventive agents (*e.g.* oral contraceptives and vitamin B_{12}). In addition they studied some specific agents: benzodiazepines and oral penicillin, amoxicillin, and ampicillin.

In only two of the 23 categories (the category of fluoride products was excluded in the adult analysis) was use higher under cost-sharing. They were antihypertensives (clonidine and methyldopa) and oral hypoglycemics. Neither difference was significant. However the likelihood of any use was significantly lower under cost-sharing for the following categories: mild analgesics; narcotic analgesics; cold remedies; all penicillins; erythromycins; and tetracyclines. Statistical significance was approached for anorexiants; minor tranquilizers; nonsteroidal anti-inflammatory drugs (NSAIDs); antispasmodics; and bronchodilators. There was no difference on the remaining ten categories (*e.g.* insulin and oral contraceptives). Overall, the proportion of adults with at least one drug use on a cost-sharing plan was

50-70% of the free plan participants. (The results for children will be discussed in Section 2.3.3)

Foxman et al. (1987) evaluated the effect of cost-sharing on antibiotic use within the RHIE. For this particular analysis they assigned each of the 14 possible plans to one of two categories: 1) the free plan, and 2) all plans with some element of cost-sharing. The data on antibiotic prescriptions were gathered from insurance claims submitted by 5765 people who participated in the entire second year of the study.

Each antibiotic prescription was linked to a diagnosis. In most instances the prescribing physician noted the diagnosis on the insurance form. In other cases a RHIE physician assigned a diagnosis after reviewing the patient's profile. Ninety-seven per cent of the claims had a linked diagnosis. The authors devised four diagnostic categories to aid in evaluation of the appropriateness of the antibiotic. They were: 1) viral conditions, 2) viral-bacterial conditions, 3) bacterial conditions, and 4) other.

The dependent variable was the number of prescriptions purchased. Statistical analysis included rate ratios with 95% confidence intervals and multiple regression.

Adults on the free plan used 86% more antibiotics than those on cost-sharing plans. In both groups those with the lowest incomes used the least antibiotics. However the effect was more pronounced in the cost-sharing group. The highest income group of the free plan used 1.02 antibiotics per

person compared to 0.78 in the lowest income group. For the cost-sharing group the respective numbers were 0.65 and 0.37 antibiotics per person.

To determine whether cost-sharing influenced the over or under-utilization of antibiotics, the researchers examined the proportion of use across the four diagnostic categories described above. The distribution of the categories did not differ much between the cost-sharing plans. Viral conditions were responsible for 17% and 16% of antibiotics for free and cost-sharing plans respectively. On all four categories, use remained higher for the free plan participants. The increased use ranged from 56% more for viral-bacterial diagnoses to 97% more for viral conditions. And for bacterial conditions, where use is most likely appropriate, the antibiotic use was 95% higher on the free plan. Therefore, cost-sharing decreased appropriate use, as well as inappropriate use.

This study moved retrospectively from the antibiotic prescription to the diagnosis. So we know almost every prescription had a diagnosis but we cannot determine for how many diagnoses a prescription was written but never filled or never claimed.

On January 1, 1972 the California State Department of Health Care Services introduced a $1.00 copayment for each of the first two physician visits in a month and a 50¢ copayment for each of the first two prescriptions in a month eligible under the Medicaid program and payable to the provider (Brian & Gibbens, 1974; Roemer, Hopkins, Carr, & Gartside,

1975). The copayments were only applied against those Medicaid beneficiaries who had some additional financial resources. This defined the comparison groups (*i.e.* copayers vs. noncopayers). The only way California could impose the copayments by law was to present the initiative as an experiment and it became known as the California Copayment Experiment (COPE). It is worth noting that 3 months before COPE was initiated the Medi-Cal Reform Program was implemented. This Program included the requirement of prior authorization by a State Medicaid Consultant, for more than two ambulatory services or more than two prescriptions per month.

Data were collected from a number of sources including: 1) provider claims, 2) pre- (late 1971) and post-copayment (9 months) surveys of Medi-Cal recipients (Beneficiary Surveys I and II), 3) mail questionnaires to Medi-Cal providers, and 4) household survey of average Californians (administered at the same time as the Beneficiary Survey II and called the Average Californian Survey).

COPE was evaluated independently by researchers from two institutions: the Center for Health Services Research at the University of Southern California (USC) (Brian & Gibbens, 1974) and the School of Public Health at the University of California at Los Angeles (UCLA) (Roemer et al., 1975). Each was discussed in turn with an emphasis on the prescription drug utilization portion of the experiment.

The USC team compared prescription drug utilization in the last month before copayment was introduced (*i.e.* December, 1971), with March, 1972 to evaluate the impact of the copayment. Drugs were classified as *critical* (for serious conditions where cessation of therapy would have immediate and dramatic consequences, *e.g.* phenytoin, insulin, warfarin); *needed but not critical* (no immediate consequences to cessation of therapy, but possible gradual deterioration, *e.g.* methyldopa, hydrochlorothiazide); *broad range* (cessation does not equal a lack of needed care, *e.g.* barbiturates including phenobarbital, chloral hydrate); *preventive* (primarily birth control pills); and *all other drugs*. Some classification was questionable. For example, phenytoin was considered a critical agent while phenobarbital, another common anticonvulsant, was classified as a broad range agent.

They reported virtually no decrease in the use of drugs for serious illnesses among copayers. This was based on critical and needed drugs demonstrating increased or only small decreases in use, following the introduction of a copayment. Neither critical nor needed drugs showed a decrease greater than 4% among copayers. The noncopayers demonstrated an almost universal increase in utilization.

COPE also included a survey portion. The researchers found no difference between copayers and noncopayers in their responses to a

question inquiring if they had failed to fill a prescription given to them in the last four weeks.

A possible explanation for this could be that noncopayers answered in the affirmative because they felt this was the more proper response. Respondents may answer with how they would like to have behaved rather than with how they actually did behave (Kerlinger, 1986) or with responses they believe will please the questioner (Schlesselman, 1982).

The authors concluded that the decrease in procurement of drugs by the copayers was a result of decreased physician visits and decreased prescribing to those with the copayment obligation. Use of critical drugs showed a decrease among copayers ranging from a 1.8% change among blind and disabled beneficiaries to a 3.2% change among Aid to Families with Dependent Children (AFDC) beneficiaries. Noncopayers exhibited an increase in use ranging from a 3.4% change among blind and disabled beneficiaries to a 6.1% change among Old Age Security beneficiaries. Copayers had an increase in needed and preventive drug use but this was not as pronounced as in the noncopayer group. The largest decreases for all Medi-Cal Aid categories were for broad range and all other drugs (up to a 13.3% change for AFDC copayers in the broad range category).

The authors did recognize certain limitations to their study: 1) the differences between the copayers and noncopayers, 2) the differences among the aid categories (*i.e.* subgroups may behave differently), 3) data gathered

from different time periods, 4) not all providers collected the copay, and 5) introduction of nearly simultaneous additional measures (*i.e.* the requirement of prior authorization for more than two ambulatory services or more than two prescriptions per month). They concluded that copayment contributed to a lower utilization, especially for less serious conditions with no reduction in care for significant conditions.

Invited reviewers of the USC publication reiterated many of the limitations cited by the researchers themselves, but with greater emphasis (Greenlick, 1974; Myers, 1974). Myers (1974) emphasized the other Medi-Cal reforms, the short post period, the poor control group, the fact that some providers decided to forego the copayment, and that the AFDC recipients demonstrated the greatest changes.

Myers (1974) did not dismiss the significance of the contiguous Medi-Cal reforms as easily as did the USC group, especially since they provided no data to convince her otherwise. She stated that the post period was simply too short to assess the deterrent effect of a copayment. The differential effect shown by AFDC recipients compared to other adult aid categories was particularly troublesome for her and she suggested that it should have provoked some discussion because it suggested that mothers and children were foregoing care. Myers claimed if this was the case, the wrong people were being affected. The fact that some providers waived the

copayment meant the effect on the beneficiary was lost and the result was simply a fee reduction for the provider.

Greenlick (1974) focused on the limitations of the claims data. Some claims data were not used because of inconsistent submission (*e.g.* diagnosis code was not on the claims tape for noninstitutional providers because of a systems error). Also copayment status was not always correctly coded. This necessitated claims being matched to the Central Identification System (CID) tapes. There were many nonmatches. Greenlick believed these problems severely compromised the data and rendered them worthless, although he did concede that the drug utilization data were less vulnerable than other utilization data.

Roemer et al. (1975) analyzed the COPE data to assess the impact of the copayment on long term health and costs. The authors, unable to analyze the complete data set, selected the AFDC beneficiaries within three counties: San Francisco, Tulare, and Ventura for their sample. The final sample size was 10,687 in the copayment group and 29,975 in the no-pay group. Because of the dissimilarity between the two groups, inherent because of the State decision to apply the copayment only against those with additional financial resources, the researchers decided to compare relative levels of utilization. They did this by converting utilization rates from the penultimate quarter before the introduction of the copayment to a

common index figure of 100. A total time period of 18 months was evaluated (six months before the copayment and 12 months after).

The prior authorization requirement, introduced in the last quarter before the copayment was introduced, produced a decrease in utilization in ambulatory visits in both the copayment and no-pay groups. Following the introduction of the copayment, the copayment group had a much lower utilization rate compared to the no-pay group (*i.e.* relative to the base period for the index). This decreased utilization was also apparent for diagnostic services and prescription drugs.

Hospitalization rates following the copayment revealed the opposite trend. Index rates for the copayment group were higher than the no-pay group for the first three quarters of the copayment period. The copayment group dropped below the no-pay group in the final quarter of the study. The authors speculated that this increase in hospitalization rates was due to postponement of ambulatory care on the part of the copayment group.

The introduction of the permission requirement before the copayment muddied the interpretation of the effect of the copayment on utilization. However, the differential between the two groups widened after the copayment, which lent support to the negative effect of the copayment on utilization.

Dyckman (1979) criticized Roemer et al. for failing to use formal statistical tests. He demonstrated that no statistical test would support

their conclusions. However, Dyckman did commend the authors for questioning the common assumption that a decrease in utilization was always good.

Nelson and Quick (1980) also discussed the Roemer et al. paper. They considered the confounding by the physician copayment on the effect of the prescription copayment to be significant. After all, a patient must see a physician to receive a prescription. Therefore, prescription utilization may be down solely because of the decreased utilization of physician services.

It should also be noted that the tables produced by Roemer et al. reporting doctor's office visits and hospital patient rates in both rates per 100 eligible and study calculated index rates, showed that the copayment group had lower rates per 100 eligible right from the start. The conversion to a base index rate of 100 obscured this observation. Granted, the differential did increase, but the initial lower rates also warranted consideration.

Other American studies (Harris, Stergachis, & Ried, 1990; Nelson, Reeder, & Dickson, 1984; Reeder & Nelson, 1985; Soumerai, Avorn, Ross-Degnan, & Gortmaker, 1987; Soumerai, Ross-Degnan, Avorn, McLaughlin, & Choodnovskiy, 1991; Weeks, 1973) were natural experiments. Unlike the RHIE, a random, controlled trial, these studies applied the experimental method to the natural social setting. They used variations and

combinations of before and after tests and comparison groups, but without the strict criteria of the random controlled trial.

Weeks (1973) took advantage of the introduction of a prepaid prescription drug program, for a defined group of the United Automobile Workers membership, to examine the impact of such a program on prescription drug utilization. The program included a copayment of $2.00 for each prescription. Then the Community Health Association (CHA), one of the delivery participants, lowered the copayment from $2.00 to $1.07. Therefore, Weeks expanded the study to evaluate the impact of a change in copayment as well. Only this portion of the study was considered.

The study was carried out at one of the CHA clinics. All clients, both eligible and ineligible, who visited the clinic to see one of nine physicians during the study weeks, were asked to complete a questionnaire. The questionnaire collected information on demography, health, and prescriptions received. If the prescription received was filled at the clinic, the pertinent information was retrieved from the dispensary's records. Otherwise, the patients were sent a letter asking for the dispensing information. Therefore, the data included both prescribing and dispensing information. This acknowledged the potential role of the provider in prescription drug utilization.

The reduced copay came into effect on October 1, 1969. Therefore, data were collected for the weeks of September 22 and October 20. The sample consisted of predominantly working families.

After October, there was a large increase in prescribing for eligible clients, with a larger increase for males compared to females. In the September study week, the percentage of eligible males receiving a prescription was 53.4%. In the October study week, this percentage increased to 72.1%. For women, it increased from 53.2% to 69.1%. The percentage of eligible clients receiving multiple prescriptions also increased. The percentage receiving two or more prescriptions at one visit increased from 37.5 to 49.5.

The other change was in the percentage of clients who had their prescriptions filled at the CHA clinic. It increased from 77.1 to 84.1 after the reduction in copayment. So it appeared that the decrease had some influence on where to have the prescription filled.

Also, the *not known whether dispensed* group decreased from 14.6% to 7% after the decrease in copayment. Perhaps then, the decrease in copayment also influenced the decision whether or not to have a prescription filled at all.

Nelson et al. (1984) evaluated the effect of a Medicaid drug copayment in South Carolina. South Carolina introduced a 50¢ per prescription drug copayment in January, 1977. The hypotheses were: "A

copayment for prescription drugs in a Medicaid program decreases the utilization rate for prescription services" and "A copayment for prescription drugs in a Medicaid program decreases the expenditure for prescription services" (Nelson et al., 1984, p. 726). Utilization rate and expenditure were operationalized as number of prescriptions per eligible recipient and average cost per eligible recipient, respectively.

The study design was a modified *before-after with control group*. South Carolina was the experimental group, experiencing the copayment, and Tennessee, a state without a copayment, was selected as the control group. The before period was 1976 and the after period was 1977-1979, inclusive. All data were collected from Medicaid claims files.

Three counties in each of three population density strata, in each state, were randomly selected. The Medicaid residents of these counties, during 1976-1979, served as the study groups. Inclusion criteria were continuous coverage for 1976 and the receipt of more than five prescriptions. Subjects were followed monthly while eligible. If eligibility ceased, they were removed from the sample, even if eligibility was regained. The final sample sizes were 17,811 for the experimental group (South Carolina) and 27,841 for the control group (Tennessee).

The two groups were statistically significantly different on the four demographic variables: age, sex, race, and eligibility category. However given the sample size, it is not surprising to see significant χ^2 statistics.

The groups were in fact relatively similar in age, sex, and eligibility category, but quite dissimilar in race. The South Carolina group was 71% nonwhite, while the Tennessee group was 37.6% nonwhite.

South Carolina's monthly utilization rate was steadily increasing in 1976. It dropped in 1977 with the copay introduction and from there remained relatively constant through the next twenty months. Then the rate fluctuated, but it never established a positive trend reminiscent of 1976. The annual rates peaked at 24.8 prescriptions in 1976, dropped to 23 prescriptions in 1977, and regained somewhat in 1978 and 1979, with 23 and 24 prescriptions, respectively.

The monthly utilization rate in Tennessee steadily increased during the study period. The annual mean rates rose from 33.1 prescriptions in 1976 to 37.9 in 1979.

As for mean expenditure, South Carolina increased during 1976 and immediately dropped in January 1977. This was followed by an increase. The mean annual expenditures were: $133 in 1976; $130 in 1977; $133 in 1978; and $153 in 1979. In Tennessee, the monthly expenditure increased over the whole study period. The annual expenditure increased each year from $159 to $174 to $203, and finally to $235 in 1979.

Examination of monthly utilization rates, in South Carolina stratified on race (*i.e.* white compared to nonwhite), showed a drop in level of service and expenditure for both groups. However, nonwhite recipients did not

experience the same recovery in rates and expenditures as their white counterparts.

Statistical analyses included OLS (ordinary least squares) regression and ARIMA (autoregressive-integrated-moving average) time series procedures. Both null hypotheses were rejected. The slopes for the pre-copay period of all four series were positive and significant. After copayment, only the slope for the South Carolina utilization rate changed significantly and it was reduced. The level of all four series decreased significantly after copay. However, the South Carolina series decreased by a larger amount than the Tennessee series. South Carolina decreased by 0.19 prescriptions per eligible recipient more than did Tennessee and the average monthly expenditure was $0.48 lower than in Tennessee, after the copay was introduced.

Reeder and Nelson (1985) conducted another study around the 50¢ prescription drug copayment introduced in January, 1977 by the South Carolina Medicaid program. They considered the impact of the copayment introduction on the utilization of ten particular drug categories: antihistamines; anti-infectives; cholinergic agents; adrenergic agents; cardiovascular drugs; analgesics and antipyretics; psychotherapeutic agents; sedatives and hypnotics; diuretics; and gastrointestinal agents. The only difference in design, from the study described above, was the minimum number of prescriptions received. In this study, the requirement was six,

rather than five. "Utilization was defined as the mean dollar expenditure per eligible recipient per month for drugs covered under the Medicaid program." (Reeder & Nelson, 1985, p. 399).

The introduction of the copay was associated with an immediate and significant effect on level of utilization in all medication categories studied, except analgesics and sedatives and hypnotics. However, only 4 of the 10 medication categories demonstrated sustained, significant decreases in utilization and these were: cardiovascular agents, cholinergic agents, diuretics, and psychotherapeutic agents.

The cardiovascular series declined in both level and slope, following the introduction of the copayment. The level dropped by 18¢ and the slope decreased from 0.02 to 0.00. The cholinergic level dropped by 25¢ and the slope by 0.02. Diuretics decreased in level by 13¢ and slope by 0.01. The psychotherapeutics agents demonstrated a drop in level of 28¢ and slope of 0.03.

The authors were particularly concerned by the reduction in utilization of cardiovascular and diuretic agents because these are used to treat congestive heart failure and hypertension. These conditions are chronic and failure to treat may have serious consequences for both the individual and the health care system. Curbing drug utilization may have decreased initial costs, but if hospitalization was the long-term consequence, the costs could be much higher.

Soumerai et al. (1987) studied the effects of two successive changes to the Medicaid program in New Hampshire; first, an imposed three-prescription cap on the number of prescriptions per month and second, the replacement of the cap, eleven months later, with a patient copay of $1.00. The authors used this natural experiment to study the impact of these changes on: individual access to prescription drugs; use of *essential* versus *ineffective* medications and expensive versus less expensive agents; compensatory mechanisms to maintain utilization, for example increasing quantities of prescriptions since a concurrent policy change allowed a maximum of 90 days supply; and overall economics.

The study design was a time series analysis with a comparison group. New Jersey experienced no changes in their program and served as the comparison group. Medicaid prescription claims data for 48 months (20 months before the cap, 11 months during the cap, and 17 months with the copay) from the two states were analyzed and compared. All New Hampshire Medicaid recipients were included, while, because of its larger population, a 30% random sample of New Jersey recipients was included. Because nursing home recipients were exempted from the cap (after two months) and the copay, they were excluded from the study.

The authors were interested in any differential impact the changes may have had. It was reasoned that the elderly, disabled, and chronically ill, with a high base-line drug use, would be at particular risk. Therefore,

multiple-drug recipients, that is, those who received an average of three or more prescriptions per month and at least one every quarter during 1980, were identified. In the New Hampshire Medicaid population, this group was only 8% of the population but accounted for 47% of all prescriptions for the base year of 1980. As suspected, this group was predominantly elderly, disabled, and female.

Sixteen prescription medications varying in clinical importance, from *essential* to *effective* to *ineffective*, and prescription cost were included in the study. The essential drugs included: insulin, propranolol, thiazides, furosemide, methyldopa, lithium, and digoxin. The effective drugs were: ASA, acetaminophen, propoxyphene in combination with either ASA or acetaminophen, and ibuprofen. The ineffective drugs were: ergoloid mesylates for senile dementia, Donnatel®, propoxyphene as a single agent, and dicyclomine.

The results showed that the policy changes had the greatest effect on the multiple-drug recipients. The average number of prescriptions filled per patient per month in this group dropped from 5.2 before the cap to 2.8 during the cap. After the cap, the rate began to rise and was 4.7 by the end of the study period. The other recipients experienced a smaller, but significant, drop in use (17%), with the introduction of the cap. The switch to copay saw the rate increase to precap levels. The New Jersey average number of prescriptions per patient per month remained constant at 1.2 ±

0.07 throughout the entire study period. Despite the concurrent change in policy that allowed physicians to increase quantity prescribed, the average prescription size increased by only eleven units per prescription.

The researchers found that after the introduction of the cap, the decrease in the number of prescriptions for ineffective medications was greater than the decrease for the essential medications. However, there were large drops in utilization of several essential medications. Insulin dropped by 28%, furosemide by 30%, thiazides by 28%, and digoxin by 45%. When the cap was replaced by the copayment, prescription levels, for nine of the sixteen medications, increased significantly; however, these were not described.

Those prescription medications with the least cost had the greatest decrease in use at 46%, followed by moderately priced at 30%, and the most expensive decreased by 23%. This would be the expected gradient under a cap program.

As for the economics of the policy changes, the cap resulted in New Hampshire Medicaid experiencing a 19% decrease in average drug expenditures or a decrease of $1.87 per recipient per month. The authors estimated a saving of $780,000 per year in medication reimbursements for the New Hampshire Medicaid program because of the cap. And they conservatively estimated that the copayment saved New Hampshire Medicaid $400,000 per year. However, as noted, these estimates did not

take into consideration increased costs for patients or use of other health care services because of a decrease in utilization of essential drugs.

Soumerai et al. (1991) later expanded their analysis of the New Hampshire Medicaid prescription cap to include outcomes. They hypothesized that placing limits on the number of prescriptions reimbursed by Medicaid may lead to deterioration of health or admission to a nursing home, either because of a need for greater care or because nursing homes were exempt from the cap after two months. Deteriorating health may also lead to hospital admission.

A cohort of particularly vulnerable recipients was selected from the New Hampshire Medicaid population and compared to a similar group from New Jersey, where no limits were placed on prescription drugs. Both groups were followed for 36 months (14 months before the cap, 11 months during the cap, and 11 months after with copay). All data on enrollment, drug use, and hospital and nursing home admissions were collected from the two state Medicaid claims files.

Inclusion criteria for the two vulnerable cohorts were: eligibility for Medicare; at least ten months enrollment during the base-line year (July 1, 1980 to June 30, 1981); at least 60 years of age; white (because of the low black population in New Hampshire); living in the community at base-line with no nursing home claims within the previous six months; received an average of three or more prescriptions per month and a least one per

quarter of base-line year; and medication indicated for one or more of the following five illnesses: diabetes, heart disease, chronic obstructive pulmonary disease and asthma, seizures, or conditions requiring anticoagulant treatment. Since the researchers did not wish to rely on outpatient diagnoses, the regular receipt, before the cap, of certain medications, served as markers for these conditions. Statistical analyses included survival and time series analyses.

With the introduction of the cap, the New Hampshire group experienced a 35% drop in drug use. After the switch to copay, rates rose again to approach baseline. The New Jersey group saw no change.

Nursing home admissions prior to the cap were similar in New Hampshire and New Jersey, 2.3% and 2.1% respectfully. The two survival curves diverged after the cap. By the end of the cap period, 10.6% of New Hampshire and 6.6% of New Jersey subjects had been admitted to nursing homes.

To evaluate comorbidity, the analysis was stratified on use of three or more classes of drugs (multiple drug use serving as a proxy for comorbidity) versus use of less than three drugs. As above, the survival curves were similar before the cap and diverged after the cap. However, the divergence after the cap was larger. In this subgroup, 14.4% of New Hampshire patients had been admitted to nursing homes compared to 6.2% of their

New Jersey counterparts. For those taking fewer than three drug classes, there was no significant difference between the two states.

Hospital admission survival curves were not as dramatic. In the high comorbidity subgroup, the two states had similar curves before the cap. After the cap, the New Hampshire group showed a trend towards increased admission but it was not statistically significant. No difference was found between the two groups in those who took fewer than three drugs.

Harris et al. (1990) studied the effect of increasing levels of copayment on total drug utilization, utilization of certain classes of drugs, and total drug costs in a group of health maintenance organization (HMO) enrollees. Before July 1, 1983, employees of the state of Washington received drugs at no charge. On July 1, 1983 a copay of $1.50 per prescription was introduced. A year later, July 1, 1984, this copay was increased to $3.00. The following year, July 1, 1985, the copayment amount did not change, but was now $3.00 per 30 days supply, rather than per prescription. Also, at this time, the enrolled members lost coverage for all over-the-counter (OTC) drugs, except insulin, and a copay, of $5.00 for all outpatient visits to physicians, physician assistants, nurse practitioners, optometrists, and physical therapists and $25.00 for emergency room visits, was introduced.

These enrollees became the study cohort and were followed for four years (July 1, 1982 to June 30, 1986). A comparison cohort, who

experienced no changes, was selected from the same HMO, the Group Health Cooperative (GHC) of Puget Sound. Data were collected from GHC's automated files. The unit of analysis was the individual enrolled. The outcome variables were number of prescriptions, drug ingredient costs to GHC, and average drug ingredient cost per prescription. The researchers also compared use of *essential* drugs: antihypertensives, cardiac agents, diabetic agents, and thyroid agents, to *discretionary* drugs: analgesics, NSAIDs, cough and cold products, and skeletal muscle relaxants. The effect of the year three removal of OTC coverage was analyzed by examining the number of OTC drugs used by enrollees. Statistical analysis included difference in adjusted means for each year and analysis of the covariance.

During the entire study period, the copay cohort experienced an 11% decrease in drug use, while the comparison group increased its use by 15.8%. Discretionary drug use dropped with each change to the cost-sharing scheme among the copayment group. The drops were 12.7%, 7.9%, and 7.9% for each year respectively. The comparison group experienced little change (-0.5%) after the first year and increases the following two years (8.2% and 2.7%, respectively). Essential drug use increased in both groups. Only the year two introduction of a $3.00 copay produced a significant decrease of 13% in essential drug use in the copay group.

In Canada, Greenlick and Darsky (1968) reported on a private drug insurance plan in Windsor, Ontario. They compared prescription drug

utilization between those paying for prescriptions out-of-pocket and those who belonged to a pharmacy-sponsored prescription prepayment plan, Prescription Services Incorporated (PSI). Although medical necessity as such was not used, a tentative attempt was made to consider the patient-perceived seriousness of the illness for which the medication was prescribed, by evaluating therapeutic class.

The age-adjusted rate, prescriptions per person per year, was 4.2 for PSI subscribers, compared with 2.19 for out-of-pocket payers. Single adults, those most likely to easily meet prescription expenses out-of-pocket, had the smallest differential utilization increase under PSI. By contrast, those least likely to meet out-of-pocket expenses for prescriptions, for example widows, had the greatest differential utilization increase under PSI. This suggested that a prescription prepayment plan reduced economic barriers and increased access to prescription utilization.

The greatest differential utilization rates between PSI and community users by therapeutic class were for EENT (eye,ear,nose,throat), dermatological, antispasmodic, and gastrointestinal drugs. The smallest differences were found for hormones, diuretics, and analgesics. The authors concluded that patients with out-of-pocket payments were more discretionary about which prescriptions to have filled.

In summary cost sharing decreased the use of prescription drugs. This was the general consensus despite the wide variation in types of

populations studied and study designs employed. The study populations included: a general population randomly sampled (Leibowitz, Manning, Keeler, et al., 1985; Leibowitz, Manning, & Newhouse, 1985; Lohr et al., 1986; Foxman et al., 1987); an HMO (Harris et al., 1990); private drug plans (Greenlick & Darsky, 1968; Weeks, 1973); and state Medicaid programs (Nelson et al., 1984; Reeder & Nelson, 1985; Soumerai et al., 1987; Soumerai et al., 1991). The study designs included: random control trial (Foxman et al., 1987; Leibowitz, Manning, Keeler, et al., 1985; Leibowitz, Manning, & Newhouse, 1985; Lohr et al., 1986); natural experiments of strong design incorporating control groups, before and after periods, and adequate lengths of observation (Harris et al., 1990; Nelson et al., 1984; Reeder & Nelson, 1985; Soumerai et al., 1987; Soumerai et al., 1991); and natural experiments of weaker design lacking one or more of the elements described above (Greenlick & Darsky, 1968; Weeks, 1973).

Several studies demonstrated differential effects of cost sharing. These were mainly on income and therapeutic class of medication. Cost sharing affected those of lower income more profoundly than those with higher income (Foxman et al., 1987). Appropriate or essential medication use was affected by cost sharing. This decrease was sometimes less than that found for the inappropriate or ineffective agents (Soumerai et al., 1987), but significant nonetheless. Nor were all groups of essential medications universally affected. Lohr et al. (1986) found a decrease in use

for penicillins, erythromycins, and tetracylines, while Reeder and Nelson (1985) found 4 out of 10 categories (cardiovascular, cholinergic agents, diuretics, and psychotherapeutic agents) sustained significant decreases. The notable exception to this trend was the USC analysis of the COPE (Brian & Gibbens, 1974) which found no significant impact of cost sharing on use of drugs for serious illness. However, this may have been a reflection of the limitations of the study, in particular the differences between the copayers and noncopayers, the differences among the aid categories (*i.e.* subgroups may behave differently), and the other changes to the program including prior authorization and a copayment for physician visits.

Finally, Soumerai et al. (1991) evaluated the long-term effects of these types of interventions. They discovered that the introduction of a prescription cap was followed by an increase in nursing home admissions and this was most pronounced in multiple-drug users.

The present investigation borrowed much from these earlier studies. It was a natural experiment, using a large publicly administered data base, with a control group and before and after time periods. To establish associated morbidity with a prescription, the present study derived a particular diagnosis from the physician billing data base. This was unlike the Medicaid studies (Nelson et al., 1984; Reeder & Nelson, 1985; Soumerai et al., 1987; Soumerai et al., 1991) described above, which used prescription

drug use as a proxy for morbidity. It also moved prospectively from diagnosis to prescription, in contrast to the Foxman et al. (1987) study. Therefore, it addressed diagnosis-specific fill rates and not general or aggregate utilization rates.

Since cost sharing appeared to affect appropriate drug use, as well as inappropriate use, the present study focused on a condition where a prescription antibiotic was considered standard therapy. This narrowed the generalizability of the results, but very specifically addressed the effect of cost sharing on appropriate use.

While the RHIE sampled the general population, the remaining studies were peculiar to certain groups of a population. The present study was based on an almost complete geo-political population (less Registered Indians). This population has been relatively stable and representative (Strom & Carson, 1990). Lastly, although beyond the scope of the present investigation, the study may foster examination of long-term effects of diminished prescription antibiotic fill rates, since failure to treat may result in outcomes which could be tracked on the Saskatchewan Health data bases.

2.3.3 Children and Cost-sharing

The RHIE also afforded the opportunity to address the impact of cost-sharing on utilization of health services by children (Anderson, Brook, & Williams, 1991; Foxman et al., 1987; Leibowitz, Manning, Keeler, et al.,

1985; Lohr et al., 1986; Valdez et al., 1985). Leibowitz, Manning, Keeler, et al. (1985) reported interim results on the use of medical services by children. In this particular paper, the fourteen plans of the RHIE, described above, were grouped as follows: 1) the free plan; 2) six plans with a 25% coinsurance up to the MDE; 3) three plans with 50% coinsurance up to the MDE; 4) three plans with 95% coinsurance up to the MDE; and 5) one plan with 95% coinsurance on ambulatory care up to $150.00 per person or $450.00 per family and care beyond this point was free and is referred to as *the individual deductible plan.* Three sites with varying lengths of data collection were included: Dayton with three years, Seattle with two years, and Massachusetts with two years. Analysis was limited to children 13 years and younger.

The authors proposed that since children's diseases were, for the most part, acute but self-limiting and, since much of pediatric care was preventive, the demand for children's health services may be more price responsive than adult-health care, because more discretion was possible. However, they also recognized that parents may be less willing to forego health care for their children than for themselves.

The probability of at least one office visit decreased as level of cost-sharing increased and as children aged. For example, 95% of children aged 0 to 4 years and 85% of children 5 to 13 years, under the free plan had at least one office visit, while 82% of children aged 0 to 4 years and 68% of

children aged 5 to 13, under the 95% coinsurance plan, had at least one outpatient visit. There was no consistent relationship between cost-sharing and hospital utilization among older children. However in younger children, an inverse relationship was apparent.

To improve understanding of the effect of cost-sharing, the authors examined "episodes of treatment" for children and adults in Dayton using three years of data. An episode of treatment consisted of one or more medical services related to a given problem.

The mean number of episodes for children declined from 4.4 per year under the free plan, to 2.6 under the 95% coinsurance plan. For adults the comparable figures were 5.2 and 3.1, respectively. Episodes were categorized further by acute, chronic, or well-care. The free plan episodes were distributed as follows: 63% for acute care, 13% for chronic care, and 24% for well-care. All cost-sharing plans grouped together as one had fewer episodes on each type, compared to the free plan. They had 72% as many acute care episodes, 63% as many chronic care episodes, and 76% as many well-care episodes. It appeared that cost-sharing affected well-care less than either acute or chronic care.

Valdez, Brook, et al. (1985) proceeded to examine whether the reduction in care due to cost-sharing had an effect on health status of the children. This analysis used data from all sites with a sample size of 1844 children, aged 0 to 13 at the time of enrollment. The sample was divided

into two, those under the free plan compared to all others under the various cost-sharing plans.

Health status was measured on four dimensions: physiologic function, physical health, mental health, and general health perceptions. Nine measures were used to asses these dimensions. The five measures of physiologic function were: anemia, hay fever, middle ear fluid, hearing loss, and visual acuity. Physical health was measured by role limitation, for example, at play or school activities. Mental health and general health were measured by rating scales: Mental Health Rating Index and General Health Rating Index.

To assess differential vulnerability to cost-sharing, children were identified as either typical (average values on all characteristics) or *at risk* (scored in the lowest quarter of a health perceptions measure or had the physiologic condition at enrollment). It was also perceived that children who were both at risk and poor would possibly be at the greatest disadvantage. *Poor* children were those from families with incomes in the lowest quarter of the enrollment income distribution. *Nonpoor* were those in the top half of the income distribution.

The authors could not identify any significant difference in health status between the two groups. Among the children at risk, both poor and nonpoor, there was no difference between the two groups. However, among the poor, those under the free plan were less likely to have anemia than

those under a cost-sharing plan (8% versus 22%). The difference was not statistically significant, but the authors considered the difference potentially clinically significant.

Haggerty (1985) and Starfield and Dutton (1985) questioned the above papers on several points. Haggerty's (1985) methodological concerns included the small sample size, the loss of nearly 40% of the original sample, and the inability to analyze certain subgroups, such as those less than a year old and the chronically ill.

The nature of the plans themselves may have made interpretation difficult. The MDE could be reached very early in the year by some families, especially lower income families, and thereby receive free care for the remainder of the year. These families may well have attenuated any difference. Also the coverage was more generous than most existing insurance programs. Therefore, this extensive coverage may have produced a ceiling effect, in that, beyond a certain point, additional care has little impact on health status or measures. He also noted that among the poor, six of the eight measures reported were worse for the cost-sharing group.

Starfield and Dutton (1985) expressed little surprise over the findings of Leibowitz, Manning, Keeler, et al. (1985) that cost-sharing decreased utilization. But they thought it important to note that expenditures for the free plan were only 25-31% higher than the 95% plan and not as exorbitant

as feared by some, however, the MDE level may have influenced this difference as well.

Starfield and Dutton (1985) also saw limitations to the Valdez, Brook, et al. (1985) paper. The sample size was much too small to detect anything but very large differences. They also stated that the measures used were not particularly well suited to elucidating the impact of differential utilization, because most of the individual measures lacked sensitivity and specificity, and none of the scales had a normal distribution. Parental reports on health of children may be problematic, because contact with the health system may influence the measurement. Health may appear to worsen, but is actually a reflection of improved knowledge and information through increased access.

Another factor that may have contributed to the negative findings of Valdez, Brook, et al. (1985) was the fact that results of the initial medical screening of 60% of the sample were reported to the respective physicians. It was conceivable that this information could have affected care delivery.

Since all the cost-sharing plans were analyzed together, the authors were unable to analyze the effect of the level of cost-sharing among the poor versus the nonpoor.

Starfield and Dutton (1985) also questioned the generalizability of the findings. Leibowitz, Manning, Keeler, et al. (1985) did not include the South Carolina site in their analysis. Of all the sites, South Carolina had

the highest proportion of poor families. The overall refusal rate of 35% could be problematic, but since differences were not reported it was difficult to assess.

Lohr et al. (1986) included an analysis of the impact of cost-sharing on specific diagnoses by comparing the free plan to all others. They used an *episode of care* approach where an episode consisted of a visit and its associated services (*e.g.* laboratory tests or prescriptions) or a series of visits which belonged together. All services in the year under study (year two of the RHIE) for a chronic condition constituted an episode. While for acute conditions, visits and associated services within 14 days of each other formed a single episode. Of particular interest to the present investigation was the diagnosis of OM in children.

The probability of an episode of care for OM (both acute and not otherwise specified) was significantly lower for poor children on cost-sharing plans. For these children the probability of use (*i.e.* an episode) was 68% of that of the free plan (statistically significant at $p < 0.1$). For nonpoor children on cost-sharing plans the probability of use was 94% that of the free plan (not significant).

Lohr et al. (1986) also reported on the use of drugs by children. Design and analysis were as discussed above in Section 2.3. Cost-sharing reduced the probability of any use for all children on two drug categories: cold remedies and antibiotics. The cost-sharing rates were 55% of the free

plan rates for cold remedies, 68% for all penicillins, and 47% for erythromycins. This effect was more pronounced for poor children. For these children, the rates of use for any of the antibiotics were less than 50% of those on the free plan. Erythromycins were as low as 31%.

Foxman et al. (1987), as mentioned above, also described the effect of cost-sharing on the use of antibiotics by children. Like the adults, children on the free plan used more antibiotics, 73% more than their cost-sharing counterparts.

Anderson et al. (1991) used the RHIE data to examine the effect of cost-sharing on the use of office-based medical care by children. This analysis used data from the second year of enrollment. The researchers used episodes of care, with an episode including all services received by the child for a particular condition or problem. Like the Valdez et al. (1985) study, all cost-sharing plans were grouped together and compared to the free plan.

The study sample contained 2016 children aged 15 or younger at the beginning of the study year. There were four measures of utilization: number of episodes, dollar charges, California Relative Value Scale (CRVS) units of service, and charge per unit of service. The CRVS system categorizes professional services into one of four types: medical, surgical, pathology, or radiology.

Cost-sharing decreased the probability of an episode, number of episodes, and expenditures per year. With cost-sharing, the probability of at least one episode of care decreased by 22%. The number of episodes and total charges decreased by about 30%.

Scott et al. (1990) took a somewhat different tact in studying the impact of increased prescription drug cost-sharing. Rather than studying the effect on utilization, they evaluated the effect on physician prescribing at an urban health centre.

Prior to January 1, 1983, this health centre provided free health services, including prescription and OTC drugs, to children. In 1983, a charge for prescription and OTC drugs was levied against those not covered by a third party (primarily Medicaid for this centre's population). Therefore, the group affected was the near-poor and ineligible for Medicaid. This group became the experimental group, while those covered by Medicaid became the comparison group.

The design was pre-to-post test and three hypotheses were tested: 1) an increase in proportion of less expensive antibiotics prescribed to both groups; 2) a decrease in proportion of decongestants prescribed to both groups; and 3) the change would be greater for the experimental group. The hypotheses were driven by the theory that physicians would use their knowledge of the family's financial situation when deciding if and what to

prescribe for children with upper respiratory infections (URI) (*i.e.* common colds) or AOM.

The researchers considered antibiotics to treat AOM as *essential* and decongestants and antihistamines to treat colds as *nonessential.* Antibiotics were divided into two groups based on cost. The high cost group included: co-trimoxazole, erythromycin/sulfamethoxazole, and cefaclor. The low cost group included: amoxicillin, penicillin, and sulfisoxazole. The study ran for six months (three months pre and three months post). Episodes of URI and AOM, for this period, were randomly selected from the clinic data base. The final sample size was 55 episodes AOM pretest, 90 episodes AOM posttest, 75 episodes URI pretest, and 67 episodes URI posttest. Statistical analysis was limited to χ^2 and Fisher exact test.

In the Medicaid group during the pre-test phase 80% of the antibiotics prescribed were from the low-cost group. Post-test this decreased to 76.3%. While in the self-paid group, 60% of the antibiotics prescribed were low cost in the pre-test phase and increased to 87.1% in the post-test phase. This change in the self-paid group was statistically significant using χ^2; the change in the Medicaid group was not statistically significant. As for the use of decongestants, both groups showed a decrease in use in the post-test phase with an overall decrease of 13.6% from pre-test to post-test.

In summary the RHIE found that cost sharing decreased health utilization by children. The influence of cost sharing on physician office visits increased as the child aged. Well-care episodes appeared to be affected the least by cost sharing, but these accounted for less than 25% of the episodes. The poor were especially vulnerable to cost sharing. They were the least likely to see a physician for OM and they were also the least likely to use antibiotics. Despite these findings the RHIE did not demonstrate a statistically significant difference in health status between the cost-sharing and free plans. However, the researchers did concede there may be a clinically significant difference between the two groups for anemia. The health status portion of the study was found lacking in its methodology and its inability to examine more vulnerable subgroups.

Finally, Scott et al. (1990) examined the effect of cost sharing on physician prescribing for children with an URI or OM. He found that prescribing of low-cost antibiotics increased with an increase in cost sharing.

The effect of cost sharing on the drug utilization of children has not been extensively investigated. The present study expands that body of literature.

2.4 Summary

In summary, OM was chosen as the condition of interest because the prevailing consensus is that antibiotic therapy is the treatment of choice.

The Anderson and Newman model was the preferred model of health services utilization for the present investigation. It was well suited to record linkage of claims data and many of the variables contributing to the model were available in the Saskatchewan Health data bases. All three determinants: societal, health services system, and individual, were well represented in the data. Finally, the outcome under study can be described on their three health-utilization dimensions as: 1) type = dispensed antibiotic prescription, 2) purpose = secondary care, and 3) unit of analysis = episode of care.

An episode of care for OM was chosen as the unit of analysis. It was considered the logical choice, since the purpose of the study was to evaluate prescription antibiotic fill rates associated with MCIB claims for an OM diagnosis (*i.e.* temporally-related services). It was also supported by the Andersen and Newman model and was compatible with a service-based data source of record-linked, administrative data.

Following the introduction of Medicare, the utilization of physician services seemed to have increased in various Canadian provinces. The introduction of a copayment for physician services in Saskatchewan decreased utilization most profoundly for the poor. It appeared that Medicare removed or decreased economic barriers, thereby increasing access, especially for those in lower socioeconomic groups and that cost sharing comprised that access.

Over-all, cost sharing decreased the use of prescription drugs. Differential effects of cost sharing were found mainly on income and therapeutic class of medication. Cost sharing affected those of lower income more profoundly than those with higher income and appropriate or essential medication use was also affected. An evaluation of the long-term effects of these types of interventions found that the introduction of a prescription cap was followed by an increase in nursing home admissions and this was most pronounced in multiple-drug users.

The RHIE found that cost sharing decreased health utilization by children and that poor children were especially vulnerable. They were the least likely to see a physician for OM and they were also the least likely to use antibiotics. Another study found that prescribing of low-cost antibiotics increased with an increase in cost sharing.

Therefore, it was decided to examine the impact of the increase in cost sharing in the STD population, as a result of the changes to the SPDP, on the fill rates of necessary prescription antibiotics in children with OM and the effects of certain demographic variables, such as marital status and location, on that impact. The study hypotheses stated in the null were: 1) the SPDP changes in cost sharing would have no impact on prescription antibiotic fill rates in either population (STD or SAP), and 2) stratification on selected variables would not demonstrate an impact in either group.

3.0 The Present Investigation

3.1 Objectives and Hypotheses

This study evaluated the impact of two successive changes to the Saskatchewan Prescription Drug Plan on prescription antibiotic fill rates in children aged 0 to 14 years, with an OM diagnosis on MCIB billing claims. The plan changes under study were: 1) the July 1, 1987 change from a fixed copayment to a deductible plus coinsurance plan and 2) the January 1, 1989 change from a nonassignment to an assignment reimbursement format. Because the program changes did not affect children covered by the SAP, the study considered this population separately as a nonequivalent control group. This group retained first dollar coverage throughout the study years.

Since an antibiotic prescription was considered the treatment of choice in North America for AOM (Bluestone, 1988; Giebink et al., 1991; Paradise, 1980; Wright, 1984) and increased patient cost sharing has been shown to decrease utilization, even for medically necessary prescriptions (Foxman et al., 1987; Harris et al., 1990; Lohr et al., 1986; Reeder & Nelson, 1985; Soumerai et al., 1987), the present investigation examined the effects of SPDP changes on prescription antibiotic fill rates in children with a diagnosis of OM on MCIB claims, and the relative effects by type of

coverage and other socio-demographic variables. Explicitly, the hypotheses, stated in the null, were:

· using interrupted time series analysis, there would be no statistically significant difference between the pre-change and post-change levels, that is, the SPDP changes to STD benefits would have no impact on prescription antibiotic fill rates in either group, and

· stratification of the time series on selected variables would not produce a statistically significant impact in the variables' strata in either group over time.

The study goal was to provide a clearer picture of the impact of cost sharing on patient prescription purchase behaviour in the study population. In addition, within this diagnostic category, the impact of several socio-demographic variables on patient prescription drug purchase behaviour were examined. The importance and relevance of this study rested in health policy implications, since Canadian policy has been grounded in equal access regardless of financial resources. Also, changes in trends in antibiotic usage for otitis media may have an impact on health status and overall health care costs. The potential impact on health status and overall health costs were beyond the scope of this investigation.

3.2 Methodology

3.2.1 Study Design

The study was population-based and quasi-experimental, multiple time series by design. Quasi-experimental is a term used to describe studies that examine an intervention's impact in a natural social setting (Campbell & Stanley, 1966). It is referred to as *experimental*, in that there is a pre-test, an experimental treatment or intervention, and a post-test; and *quasi*, in that the researcher has no control over the introduction of the intervention or treatment, or whom it would affect. The assignment of subjects, random or otherwise, to treatment or control groups, is beyond the influence of the researcher. What the researcher does control is the *when* and *to whom* of measurement.

Campbell and Stanley (1966) described several quasi-experimental designs. The one which applied to this study is termed the multiple time series design. It is a merger of two other quasi-experimental designs: the time series experiment and the nonequivalent control group design.

The time series experiment is a series of periodic measurements on a group or an individual, during which an intervention is introduced. It may be illustrated (Campbell & Stanley, 1966; McDowall, McCleary, Meidinger, & Hay, 1980) as:

. . . O O O O O X O O O O O . . .

Each O denotes an observation within the time series and the X represents the intervention.

The nonequivalent control group is similar to the random controlled design. However, rather than subjects being randomly assigned to experimental and control groups, the two groups are naturally predefined, for example classrooms or neighbourhoods. Campbell and Stanley (1966) maintained that the addition of even a nonequivalent control group is an improvement over no control group at all. Of course, the more similar the two groups, especially on pretest measurement, the more suitable the control group is.

The multiple time series design, as stated above, is a combination of these two designs and may be illustrated (Campbell & Stanley, 1966; McDowall et al., 1980) in the following manner:

. . . O O O O O X O O O O O . . .

. . . O O O O O O O O O O . . .

Here, two series of measurements were taken, one on a group experiencing the intervention X, and another on a group that does not. As Campbell and Stanley (1966) explained, the intervention is tested twice, once against the nonequivalent control group and a second time against the pre-intervention values of its own series.

Therefore in the present investigation, the impact under examination was the introduction of the two changes to the SPDP in the natural social

setting of a provincial health program. The assignment of beneficiaries to the experimental and nonequivalent control groups was a direct consequence of the terms of the SPDP and the plan changes. That is, those children with STD benefits and therefore experiencing the changes formed the experimental group and those children with continuous SAP coverage which was not subject to the changes formed the nonequivalent control group.

Like any experiment, quasi-experimental designs may suffer from various threats to internal and external validity. Campbell and Stanley (1966) enumerated eight threats to internal validity (see Table 3.1) and four threats to external validity (see Table 3.2). The threats to internal validity (or sources of bias) are: history, maturation, testing, instrumentation, statistical regression, selection, experimental mortality, and interaction.

When considering the threat of history to this study design, the researcher asks: "was there any other event or process occurring during the same time period that could have influenced prescription antibiotic utilization rates, even if the study intervention had not occurred?" History, as an internal threat, was somewhat controlled by the use of a control group, albeit it nonequivalent, because both groups would experience a similar history. Therefore any differences found would then be attributable to the intervention. However, it was considered useful to entertain certain possibilities, since additional events or processes may influence groups

Table 3.1: Threats to internal validity.

Threat to Internal Validity	Description
History	other events occurring between the pre-test and post-test, in addition to the intervention, that may influence the outcome
Maturation	the effect of the passage of time on the subjects, *e.g.* growing older, increasing fatigue
Testing	if a test is taken more than once, the first test will influence the results of the second
Instrumentation	changes in calibration, observers, scorers, interviewers
Statistical Regression	if subjects selected on the basis of extreme scores
Selection	differential selection of subjects to comparison groups
Experimental Mortality	differential loss to follow-up
Selection Interaction	selection confounded by history, maturation, or testing

Adapted from Campbell, D. T. & Stanley, J. C. (1966). *Experimental and quasi-experimental designs for research.* Boston: Houghton Mifflin Company.

differently. The possibilities considered were changes in medical practice, drugs available, causative agents, and type of coverage received.

Medical practice in North America has consistently recommended antibiotic treatment for OM (Bluestone, 1988; Giebink et al., 1991; Paradise, 1980; Wright, 1984). Even if there was reason to believe practice had changed, any change should affect both groups equally and therefore effectively cancel out.

When discussing changes in drugs available or causative agents, the same argument may be applied. There was no reason to be believe the availability of drugs or a change in pathogen would differentially affect the STD and SAP groups.

To control for possible changes in type of coverage, eligible subjects were put into one of three groups: 1) standard benefits for the entire study period (STD group), 2) SAP benefits for the entire study period (SAP group), and 3) movement between coverage types at least once during the study period (MOVEMENT group). Therefore only the third group could be susceptible to bias arising from a change in coverage.

There were changes to SAP benefits and therefore eligibility in late 1987 and early 1988. In October, 1987 adult monthly training allowances increased; advances of clothing allowance were restricted and required approval of the Executive Director; travel allowance was restricted to medical treatment, attendance at sheltered workshops, and for children to attend school; and earned income exemption would not be provided to employable clients until after 3 months on assistance. In January, 1988 basic allowances were increased and shelter and utility caps were introduced.

On examination of the annual distribution of episodes for each group, it appeared that the MOVEMENT group experienced some change (see Table 3.5 - to be discussed in greater detail in Section 3.2.2). Each of the first three study years contributed 30% of the episodes, while 1989 saw only 10%. Since the unit of analysis was the episode and because of the manner in which the data were compiled, it was impossible to track individuals between the two types of coverage within this group. Did this group

experience a decrease in OM or was there less movement from one coverage to another level of coverage after 1986? The nature of the data did not allow this quandary to be reconciled. It was decided to exclude this group from the analysis and avoid a possible historical bias.

Maturation, experimental mortality, and testing were irrelevant to the present study. An episode of OM was the unit of analysis and episodes cannot age or, by study definition, be lost to follow-up. There was no administration of a test. Instrumentation or data collection was consistent throughout the study. Statistical regression and selection were not problematic, since **all** OM episodes on MCIB, for non-Native children with continuous coverage of one type or the other, entered the study.

As for interaction between selection and one or all of history, maturation, or testing, this was not a concern, since all of history, maturation, and testing, have been accounted for.

Table 3.2: Threats to external validity.

Threat to External Validity	Description
Interaction effect of testing	pretest influences post-test
Interaction of selection and experimental variable	selection contributes to outcome
Reactive arrangements of experiments	refers to inherent artificial nature of the experimental setting
Multiple treatment interference	when multiple treatments applied, *i.e.* cannot completely erase effects of prior treatment

Adapted from Campbell, D. T. & Stanley, J. C. (1966). *Experimental and quasi-experimental designs for research.* Boston: Houghton Mifflin Company.

Since external validity addresses generalizability (*i.e.* to what population can the results be generalized), threats to external validity are moot in the present discussion. All eligible episodes for a given population were included in the investigation. The results may only be applied to that population.

3.2.2 Data Collection

Data were gathered by record linkage of three Saskatchewan Health data bases: MCIB, HIRF, and PDSB. Although these computerized data bases were developed and maintained for administrative purposes, their use as a research tool has been well established (Ernst et al., 1992; Risch & Howe, 1994; Tennis et al., 1993). Other administrative data bases such as, Medicaid (Nelson et al., 1984; Soumerai et al., 1987) and HMO (Harris et al., 1990), have been used effectively to study the impact of cost sharing.

Record linkage was a useful technique for this study because the diagnostic and prescription data may be accessed from the MCIB and PDSB data bases and limited demographic data were available on the HIRF. All three data bases used the same unique identifier allowing accurate matching. To do a similar study gathering data by manually searching physicians' and pharmacists' records for diagnostic and prescription data and questioning parents for demographic information would be a massive undertaking and likely prohibitive. Record linkage also allowed the use of historical data without the usual caveat about recall bias. Lastly,

confidentiality was more easily protected because the actual linkage was performed by an independent body and the unique identifier was replaced with a study case number.

The record linkage was performed by GDS and Associates Systems Ltd., Regina, under the direction of the Pharmacoepidemiology Unit (the Unit) of Saskatchewan Health. At the time of the study, the Unit was part of the Laboratory and Disease Control Services Branch. It is presently under the direction of the Population Health Unit of the Strategic Programs Branch and is now called Research Services.

The Unit was responsible for the coordination and supervision of all studies involving record linkage among two or more data bases of Saskatchewan Health. All studies using record linked Saskatchewan Health data were required to seek approval from Saskatchewan Health's Cross Agency Study Committee.

Contact with the Unit began the summer of 1989. Application for approval from the Cross Agency Study Committee was submitted in December, 1989. Approval was granted in February, 1990, conditional on approval by the University of Saskatchewan Advisory Committee on Ethics in Human Experimentation and resolution of any concerns expressed by the PDSB. Approval by the Advisory Committee on Ethics and Human Experimentation was granted January 8, 1990. A meeting was held with the PDSB on February 22, 1990 with a satisfactory resolution of concerns.

Applications for funding for this project were submitted to the National Health Research and Development Program (NHRDP) and the Saskatchewan Health Research Board (SHRB, currently known as the Health Services Utilization and Research Commission). The December 1989 application to NHRDP was denied. The March, 1990 application to SHRB was approved in June, 1990.

A formal contract between the Province of Saskatchewan and the Researcher was finalized on September 20, 1990. The data files were delivered on magnetic tape in November, 1991.

The MCIB administers The Medical Care Insurance Plan as set out in the *Medical Care Insurance Act*, including payment for physician services (Rawson et al., 1992). The MCIB data base has accessible files dating back to 1971. The data base is immense with the last few years recording 12 million paid physician services annually. The information captured on the data base includes: patient information (health services number [HSN], age, sex, residence, Registered Indian status), physician information (specialty, location, age, sex, place and year of graduation, practice type, referring physician), and service information (dates of service and payment, service code, type of service, primary diagnosis, location of service, billing information) (Malcolm, Downey, Strand, & West, 1993).

The MCIB data base uses the ICD-9 (WHO, 1977) for its coding guide. Although the ICD-9 codes may include up to five digits, MCIB uses

only the first three. There are two codes for OM relevant to this study, 381 - Nonsuppurative Otitis Media and Eustachian Tube Disorders and 382 - Suppurative and Unspecified Otitis Media. Both codes were used because it was uncertain how discriminatory physicians or their delegates were when coding claims. Since the objective of the study was to examine antibiotic fill rates associated with a claim on MCIB for an OM diagnosis, an absolute differentiation was not considered necessary. It would be necessary however, if there were some reason to believe that Saskatchewan physicians became more discriminatory between the two codes over the study period; no such reason is known.

The MCIB data base was searched for all claims with a diagnostic code of 381 or 382, in beneficiaries aged 0 to 14 years at date of physician visit, for the years 1984 through 1986 and 1989. The incidence of OM peaks at 6-12 months and 4-7 years of age (Bluestone, 1981; Teele et al., 1989). The age range selected comfortably included these peaks. Data for 1987 and 1988 were not included because of the break in prescription data described previously. All claims for Registered Indians were excluded. Although Registered Indians' benefits for physician and hospital care are the responsibility of the Province, their prescription benefits are provided by a federal agency and are inaccessible.

When a claim for OM was identified, a search for additional claims for OM in the following fourteen days was performed. If additional claims

were found in the following fourteen days, these were considered to be follow-up visits to the first visit and not retrieved for the study data. While Hornbrook et al. (1988) maintained that an arbitrary time period may be used, there were reasons for selecting 14 days as the limit.

It was considered to be good practice for a physician to examine a child with a diagnosis of OM after a prescribed course of antibiotics (usually of 10 to 14 days duration) (Bluestone, 1988). Since it was difficult to predict whether or not a follow-up visit would also include an antibiotic prescription for OM, these physician visit claims were excluded from the study and considered part of the index visit and thereby constituted an episode. This was similar to the Lohr et al. (1986) study which considered all visits and services within 14 days to constitute a single episode for acute conditions. From here on in this report, a MCIB claim for one of the two diagnostic codes for OM meeting the above criteria is referred to as an *episode* of OM.

Because AOM, ROM, COME, and CSOM may differ in treatment regime and MCIB's three-digit diagnostic code did not differentiate among the types, and because of uncertainty about Saskatchewan physician discrimination between the two codes, each episode was also coded as *acute* or *not acute*, depending on the number of episodes experienced by the child within a given time period, based upon the MCIB data. If the episode was the third or more frequent within in a six month period, it was coded as *not acute*. This was based on the definition of ROM (Lisby-Sutch et al., 1990).

However, it was not labelled as recurrent because without further information, it could just as easily have been CSOM. What was more certain was what it is not, that is, it was not acute. Otherwise the episode was coded as *acute*. This variable was called TYPEOM.

Additional information retrieved from the MCIB data base included the date of the episode (*i.e.* initial visit for that episode), age of the child at time of visit (in years), sex of the child, and whether the source of care was a GP or a medical specialist. Also each episode for a single individual was assigned a sequential episode number in chronological order.

The HIRF contains the identification and demographic details of all Saskatchewan residents eligible for health benefits, including name, HSN, sex, marital status, date of birth, date of death, mailing address, five-digit residence code, Registered Indian status, SAP coverage, and health-services coverage eligibility dates (Saskatchewan Health, 1991; Rawson et al., 1992). Approximately 1% of the population are ineligible for these benefits because their health care is provided and administered through federal funding (members of the Royal Canadian Mounted Police, members of the Canadian Forces, and inmates of federal penitentiaries) (Malcolm et al., 1993).

Each Saskatchewan Health beneficiary is assigned an HSN. Prior to 1991, the number was an eight-digit number, with the first six digits identifying the family unit and the last two identifying the individual family member. Beneficiaries' numbers could change in their life time, for

example, if they left the province, when they turned 18, or when a woman married. There is a mechanism in place for tracking changes for any single individual and linking their historical data. In 1991 each beneficiary was assigned a life-time unique HSN.

Linking the identified episodes with the HIRF data base was the second step in the record linkage. Some inconsistencies in the data were encountered at this stage in the linkage. They were: a) a single member family, b) an episode outside eligible coverage dates according to HIRF, c) no match on the HIRF, and d) a family match but no child match on HIRF. The first, a single member family, means that the HIRF data base indicated that a family, for which there had been a claim, had only one member. One possible explanation for such an instance was that the child might have been a ward of the court.

The second idiosyncracy was that episodes identified from claims on MCIB were outside the HIRF's coverage dates for those individuals (*i.e.* according to the HIRF they were ineligible for Saskatchewan Health benefits). This can happen if the Department is notified of a lapse in coverage after the fact. Upon notification the HIRF is updated historically to reflect actual coverage dates. However, if a service was provided, claimed, and processed, it remained on the appropriate service data base and thereby showed up as outside coverage dates. The third inconsistency was a failure to find a match on the HIRF.

The fourth inconsistency occurred when a family match could be found, but the child was not. In other words, the first six digits of the HSN were found on the HIRF but there was no match for the last two digits that identify the individual family member.

These episodes with idiosyncracies were retained in the study's data files for later evaluation. A variable called ERROR was created to identify those episodes which were problematic. The variable had four categories, one for each type of inconsistency described above.

Screening for SAP coverage was part of the HIRF match. The data were divided into three files at this point. Episodes under continuous SAP coverage for the entire study period, 1984-1986 and 1989, became the SAP file; episodes under continuous STD coverage for the entire study period became the STD file; and those episodes in which the beneficiary moved between SAP and STD coverages became the MOVEMENT file.

The HIRF match also provided the following data: mother's age, father's age, family size, and location. Location was based on the last two digits of the five-digit HIRF residence code. The first three digits identify the municipality and the last two indicate city, town, village, rural, north, or reservation. The definitions for city, town, and village are based on *The Urban Municipality Act, 1984*, where a city contains 5000 or more residents, a town 500 to 4999 residents, and a village less than 500 residents. However, a community is recorded at the level at which it is incorporated