COST-EFFECTIVENESS ANALYSIS OF DENTAL SEALANT USING ECONOMETRIC MODELING

A DISSERTATION
SUBMITTED TO THE FACULTY OF THE GRADUATE SCHOOL
OF THE UNIVERSITY OF MINNESOTA
BY

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IN PARTIAL FULFILLMENT OF THE REQUIREMENTS
FOR THE DEGREE OF
DOCTOR OF PHILOSOPHY

JOHN A. NYMAN, PHD, ADVISOR

MAY 2009

Acknowledgements

First of all, it is my great honor to have Dr. John Nyman as my advisor and have Dr. Bryan Dowd, Dr. Karen Kuntz, Dr. D. Brad Rindal, and Dr. Xianghua Luo as my dissertation committee members.

I am profoundly thankful for Dr. John Nyman's continuing support, encouragement, guidance and assistance at every level of this research study. I would like to express my deepest gratitude to Dr. Bryan Dowd for his enormous input in helping me formulate the research questions, establish the conceptual model, construct the econometric methods, prepare defense, write and edit this dissertation. I also greatly appreciate Dr. Karen Kuntz's precious advices on study design and development. With her expertise and experience in medical decision making, her comments and suggestions are always particularly helpful in defining the research questions, analyzing data, presenting results, and discussing conclusions. I am very grateful for Dr. D. Brad Rindal's insightful suggestions and advices. As a senior dentist and an expert in dental clinical research, Dr. D. Brad Rindal has always provided me with thoughtful ideas about how prevention and treatment decisions are made in clinic, as well as how dentists think and behave in practice. My heartfelt thanks also extend to Dr. Xianghua Luo for her constructive comments and helpful advices on my dissertation research methods, especially the statistic analysis part. I also greatly appreciate her detailed suggestions for the study design, result writing, and final defense presentation.

I am grateful that the HealthPartner's Research Foundation allowed me to use their electronic datasets for this dissertation. I would like to express my special gratitude to Dr. William A. Rush for giving me the opportunity to work on their research datasets with their great research team. I have been fortunate to work with some excellent researchers and friends: Stephen E. Asche, Andrew M. Schmidt, M.S., Olga V. Godlevsky, and Craig W. Amundson. They have provided me with valuable support in data collection and study design discussion, advices on methodology, ideas to analyze results, and helps in writing and editing dissertation, over the past several years. Without them, this dissertation is impossible.

My special thanks also go to my good friend Xiang Ao, who has provided me with a strong technical support. He made a splendid effort to help me design statistical methods and program econometric models.

Finally, I would like to thank my parents and my older sister for their understanding, unconditional love and support, and sacrifice throughout my whole doctoral study period.

Dedication

This dissertation is dedicated to my parents.

Abstract

Dental sealants have been shown to be effective in reducing caries. Most believe sealants are still underused, particularly among children who need sealants the most. Because the caries prevalence continues to decline, and the disparities in children's dental heath and dental care still exist, more efficient sealant placement strategies should be implemented based on the scientific information from cost-effectiveness analysis (CEA) of dental sealant at the community level. Previous CEAs of sealant using observational datasets were unreliable because they did not address the self-selection problem. The objectives of this study are to examine the utilization of dental sealants and its determinants, evaluate the incremental effectiveness and expenditure associated with sealant placement after correcting the potential selection issue, and explore the differences in sealant's cost-effectiveness among subpopulations.

This study mainly utilized enrollment data and encounter data from a large Health Maintenance Organization in Minnesota. The study sample included 3,700 children aged 6 to 17 years during 1997 to 2001 and were continuously enrolled for 5 years. They all had a caries risk assessment (CRA), which was conducted at the beginning of the observation period, and no prior caries record for their included first permanent molars (FPMs). The CRAs were classified into three scores: low, moderate and high risk. Information on the 64 dentists who participated in the study was linked to the encounter data to identify those who conducted CRAs. Outcome variables included discounted effectiveness, as measured by the duration of caries-free state (healthy months) of a FPM, and the discounted cost associated with caries treatments, within the study period. The key independent variables included demographic variables (e.g., age,

gender, race), caries risk level, socio-economic status, sealant placement, and preventive care utilization.

Bivariate analysis and logistic analysis were performed to examine the pattern of sealant utilization and identify the determinants affecting sealant placement decision. Econometric models including classic Tobit model, selectivity-corrected Tobit model, classic two-part model, and selectivity-corrected two-part model were used to examine the selection issue and obtain unbiased marginal effects of sealant on caries-free duration and caries-related treatment cost. The working experience of the dentists who conducted the initial CRAs was used as the instrumental variable. The bootstrap method was used to obtain standard errors and confidence intervals for the incremental cost-effectiveness ratios. Sensitivity analysis and subgroup analysis were performed.

In this study, approximately 77% of the sample had one or more FPM sealed during the entry period, more than half of them had all four FPMs sealed. Children aged 6 to 8 were more likely to receive sealant than children aged 9 or older. Children at relatively high caries risk, as well as children who visited dentists for preventive care more than once a year, had greater odds of receiving sealants. Non-white children or those from families with low incomes or low education level were more likely to receive sealant. This study also identified some dentists' characteristics, such as age, gender, and working experience as the good predictors of sealant decision.

After 5 years, the sealant group had more individuals (83.9%) and more FPMs (94.3%) that stayed healthy compared with the non-sealant group in which 83.1% of the sample individuals and 91.8% of FPMs stayed healthy. A sealed FPM was associated with $56.84 expenditure (initial sealant charge was $39.00) over 5 years, and an

unsealed FPM was associated with $13.13 expenditure. The sample-average incremental cost-effectiveness ratio (ICER) was $38/caries-free month for each FPM. Based on the results from econometric models, sealants were associated with a lower probability of having any caries, longer caries-free duration, an increased probability of using any resource, and less resources consumption. The final ICER indicates that sealant cost $42.16 more than non-sealant treatment to get one more caries-free month for each FPM. The 95% CI was $22.64 to $85.40 per one more caries-free month for each FPM. Significant selection or endogeniety issue was not found in either the effectiveness or cost analysis based on the whole sample, but it existed when analyzing sealant effects among certain subgroup children. The results from subgroup analysis show that sealing children at high risk for caries appears to be highly cost effective. In contrast, sealing children at low risk for caries would be much less cost effective. Sealing the FPMs of infrequent utilizers of preventive care appears to be more cost effective than frequent utilizers of preventive care. There is no significant difference in ICERs between sealing younger children and sealing older children.

In conclusion, sealant application is not always cost effective. A uniform and fixed sealant utilization goal may not be appropriate. Sealant application should be increased among the high risk populations, such as those with previous caries or low dental care utilizers, or those directly deemed at high caries risk by dentists. The caries risk assessment procedure can improve clinical decisions on sealant application and increase efficient sealant delivery.

Table of Contents

List of Tables

List of Figures

CHAPTER 1. INTRODUCTION

1.1. The Problem

Many diseases are caused and affected by multiple factors such as biological, social and economic factors and their interactions. Those factors affect the etiology and prognosis of a disease through different paths including direct impact on outcomes and indirect impact on utilization of health care. Though regular preventive care is generally believed to improve public health, it is not distributed evenly across the populations. Despite efforts made by government and society to reduce access barriers, there still exist large disparities in people's health status and utilization of preventive health care, the causes and extent of which may differ across states and communities. Some populations face higher risks for certain diseases compared with others. Disparities in health and health care utilization generate equity problems and efficiency problems. Health care providers and policy makers face implementation and cost constraints in achieving maximum health care effectiveness in all patients. How to allocate limited resources to be more cost-effective requires health service researchers and policy makers to conduct studies based on specific situations of different areas and communities.

Tooth decay (or dental caries) is a disease with multi-factorial etiology and uneven distribution among the population. Three principal biological factors—the host (saliva and teeth), the microflora (plaque) and the substrate (diet)—interplay over time to cause dental caries. Socioeconomic factors and personal health behavioral factors also play important roles in the development of caries.[1] In the United States, overall caries has declined in recent years, but it is still the most common chronic disease in children.

More than one-fourth of U.S. children aged 2–5 and half of those aged 12–15 have decayed teeth.[2] Eighty percent of untreated caries in permanent teeth are found in about 25% of U.S. children aged 5 to 17, mostly from low-income and other vulnerable groups.[2] The disparities in dental heath and dental care are even larger than in medical health and medical care,[2] and exist across the whole country. Dental caries may cause facial pain, eating difficulty, absence from school, and poor appearance which can greatly reduce the quality of a child's life.[2] The progress of dental caries can be prevented by preventive interventions.[2] Ensuring access to preventive dental care is a key objective of oral health care policy.

Dental sealants have been proven to be effective in preventing caries by applying a plastic coating to cover the pits and fissures on a tooth's surfaces. In some cases, sealants can even stop caries in its initial stage.[2] Because nearly 90% of caries in children develop in pits and fissures on occlusal surfaces, sealants have been widely used in clinics since the 1970s for children between 6 to 18 years old. They can also be applied in a large scale through school-based programs or community-based programs. However, the effect of sealants relies on their retention and completeness. They may become broken or partly lost within a few years after application.

One of the national *Healthy People 2010* objectives is for 50% of all 8 year old children in the U.S. receive dental sealants. Currently, only about one-third of children aged 6–19 receive them.[2] Children from certain racial and ethnic groups and low-income households are less likely to have sealants.[2] Given that the incidence of tooth decay is declining, an important question to ask is whether the upfront costs of dental sealant placement are worth the reduction in dental caries. Specifically, should we advocate delivery of dental sealants to all children or target them at children at high risk of caries? Some have argued that it would be more cost-effective to provide dental sealants to children at high risk of caries.[3] It has also been suggested that the application of dental sealants (to all or only high-risk children) should be determined at state level or community level due to different prevailing disease incidence, regulatory environments and oral health care delivery structures.[3-7] Cost-effectiveness analysis (CEA) is an economic analysis. Its results can demonstrate the relationship between incremental resource consumption and outcome gain for some intervention options. It has become more and more popular in health service research, and help health decision makers or policy makers determine how to allocate limited resources in a more efficient manner. However, there have been few studies evaluating the cost-effectiveness of sealants applied in real-life situations and even fewer conducting risk-based cost-effectiveness analyses.[3, 8-10]

1.2. Specific Aims of This Study

The first aim of this study is to describe the utilization of dental sealants among children aged 6 to 18 enrolled in a dental health plan of a Minnesota HMO (Health Maintenance Organization). The socioeconomic characteristics of children with or without sealants will be examined and compared.

The second aim of this study is, based on a modified Andersen's behavioral model of dental services utilization, to evaluate the effectiveness of dental sealants measured by duration of caries-free status of children’s permanent molars and associated costs to determine the incremental cost-effectiveness ratio of sealants applied in real-life practice to children aged 6 to 17 in Minnesota. The cost-effectiveness comparison will be conducted between the sealant group and non-sealant group, with adjustments for self-selection bias.

The third aim of this study is to conduct quality-adjusted cost-effectiveness analysis of dental sealants applied to children aged 6 to 17 in Minnesota by accounting for the health status of each tooth. The quality-adjusted cost-effectiveness comparison will be conducted between the sealant group and non-sealant group, with adjustments for selection bias.

The fourth aim of this study is, based on risk assessment, to examine whether sealing teeth have different cost-effectiveness for populations at different risk levels for dental caries. Risk factors such as risk level from clinical risk assessment, previous caries experience, age, family income level, or preventive care utilization will be considered.

The data used in this analysis will consist of enrollment data, dental encounter data, and cost data from HealthPartners' dental electronic data system, as well as data about clinic settings and dental care providers.

1.3. Significance of the Study

Although delivery of sealants can reduce the number of dental caries, they are not widely used.[4] According to a report on national data, only about 23% of eight-year-old children have received a sealant on a permanent molar.[11] A major reason for the low prevalence of dental sealants may be that this preventive service is perceived to cost more than treating caries among children with low caries rates, especially since most of caries are concentrated in 25% of school-aged children.[12] Sealant cost becomes an even bigger concern as the caries incidence decreases and the possibility of over-treatment increases, as in recent years.[9] The low sealant delivery rate and non-targeted sealant placement reflect a lack of concern for risk assessment at the community level or individual level, and insufficient scientific information from high-quality cost-effectiveness analyses.[11, 13]

Federal agencies such as the Centers for Disease Control and Prevention (CDC), Division of Oral Health (DOH) need information from risk-based cost-effectiveness studies on preventive dental care. They support state- and community-based programs to prevent oral disease, promote oral health nationwide and foster applied research to evaluate prevention strategies and enhance oral disease prevention in community settings.[14] For example, in 2006, CDC allocated about $11.7 million to help states strengthen their oral health programs and expand the access of people who are hardest hit by oral diseases to the preventive dental care.[2]

This study is designed with the goal to provide useful information to federal and state government agencies as well as medical and dental insurance providers to efficiently allocate oral health care resources. The summary of its significance is as followed:

- ✧ This study will be the first study to systematically document utilization patterns of dental sealants and associated socioeconomic determinants in a population of children in Minnesota.
- ✧ This study will be the first to investigate systematically the cost-effectiveness of dental sealants based on a set of caries risk assessment criteria currently used in

dental clinics of a large HMO. The conclusions of this study will help to justify the use of the risk assessment system. They will benefit clinical decision making by identifying individual children who will benefit from sealant placement.

- ✧ The conclusions of this study will provide valuable information for insurance companies to establish recommendations for dental sealant delivery associated with different caries risk levels, design preventive dental care more efficiently, and establish more rational sealant reimbursement policies.
- ✧ The conclusions of this study will assist governmental agencies and communities in policy decision-making to design and implement dental public health interventions by targeting high risk populations. They will help the decision-makers determine how scarce resources would be best allocated to prevent dental diseases and reduce the disparities in oral health.
- ✧ This study will establish a conceptual model for displaying and analyzing decision-making processes in dental prevention care such as sealant placement, from provider preference to provider recommendation and from parents' awareness to perceived need for prevention delivery.
- ✧ This study will provide a novel path to distinguish the instrumental variables from a specific clinical decision making process, based on insurance claim dataset, which will be particularly useful for future research design.
- ✧ This study will be the first study to introduce selectivity-corrected Tobit model and selectivity-corrected two-part model, models often used in econometric studies, into dental preventive care research. It will argue that previous studies used less appropriate methods to analyze observational data from real-life practice settings.

CHAPTER 2. BACKGROUND AND LITERATURE REVIEW

2.1. Dental Caries in Children and Adolescents

2.1.1. Dental Caries and Its Incidence in Children and Adolescents

Dental caries, also called tooth decay or cavities, is a transmissible and multi-factorial disease in which *streptococci mutans* (*S. mutans*) bacteria create a primary oral infection and the structure of teeth is damaged.[2] Caries may be painless at the initial stage. If left untreated, they can cause toothache and detectable pits or holes in the teeth. They may grow very large by destroying hard tissue and the nerve and blood vessels in the tooth, ultimately causing tooth abscesses or the loss of the tooth.

Dental caries often are discovered in the early stages during routine examinations. Their progression can be stopped by treatment, which includes simple filling, crown, root canal therapy, and extraction. They can preserve the tooth tissues, restore normal function and esthetics, and prevent complications, depending on the extent of tooth destruction.[15] Early treatment is less painful and less expensive than treatment of severe and extensive caries. Caries are preventable through early and regular use of professional preventive dental services.[16] Preventive dental care such as water fluoridation, dental sealants, regular oral hygiene and dietary modifications are strongly advocated to avoid forming dental caries.[15]

Dental caries can occur at any age, but the greatest risk is faced by children. They are also the major cause of tooth loss in children.[15] Since the early 1970s, cases of dental caries in permanent teeth have been declining steadily among school-aged children.[11] This decline is the result of various preventive regimens such as water fluoridation and increased use of fluoridated toothpastes.[17] Dental caries, however, still remains the single most common chronic disease among U.S. children, occurring five to eight times as frequently as asthma, the second most common chronic childhood disease.[11, 18, 19]

In the 1930's oral epidemiologists developed the DMFS (decayed, missing, or filled permanent tooth surface) index to measure the quantity of caries in a mouth (the capital letter index, DMFS, has been used for permanent teeth, and the lower case letter index, dmfs, for deciduous teeth). [20, 21] This index commonly has been used to measure the severity and incidence of caries, as well as effectiveness of dental care.[22, 23] The mean DMFS among children and adolescents aged 6-19 years was 1.6 in 1999-2002, lower than in 1988-1994 with an absolute reduction of 0.57 surfaces.[24] Absolute reductions were larger among adolescents aged 16-19 years (1.24 surfaces), among children and adolescents from high income families (0.80 surfaces), and among non-Hispanic black children and adolescents (0.78 surfaces)[24] The same study also reported that 24.3% of DMFS were decayed surfaces, 72.5% were filled surfaces, and 3.2% were missing surfaces. The DS/DMFS (decayed permanent tooth surfaces/DMFS) ratio among non-Hispanic white children and adolescents was lower (19.3%) than among Mexican-American (33.6%) and non-Hispanic black children and adolescents (35.9%).[24]

Dental health is an essential component of a person's quality life. No one can be truly healthy if he or she is suffering from oral diseases or craniofacial disorders.[11] Poor oral health and untreated oral diseases and conditions contribute not only to eating difficulty and nutrition problems, but also affect self-esteem, the productivity, and the psychological well-being of an individual.[2, 16] More than 51 million school hours in total, or nearly 3.1 days per year for an individual child aged 5 to 17, is lost per year due to dental-related illnesses.[21] Treatment of dental diseases is costly. According to CDC, Americans made about 500 million visits to dentists in 2005, and an estimated $84 billion was spent on dental services in that year.[2] The evidence linking oral diseases and systemic diseases is also growing.[25]

Dental caries are not evenly distributed in teeth and surfaces. The teeth at highest risk are the first and second molars.[26, 27] About 90% of all dental caries in school children occur on occlusal surfaces of the molars.[26, 27] The occlusal surfaces comprise 12% of the total number of tooth surfaces, but they have much more pit and fissures, and thus are more susceptible to decay, than the smooth surfaces of the teeth.[28]

2.1.2. Disparities in Caries Prevalence in Children and Influencing Factors

Identification of caries-prone children, those who need more intensive preventive care, can benefit clinical practice and dental insurance policy decision-making, and can be useful for screening populations in government or community preventive programs.[1] Important risk factors are not only those that directly affect the development and progression of caries, but also those that indirectly affect the utilization of dental care, especially preventive care.

The risk assessment of dental caries requires consideration of factors from different categories such as biological and physical factors, demographic and socioeconomic factors, and cognitive and behavioral factors. Biological and physical factors include variations in tooth enamel, deep pits and fissures, anatomically susceptible areas, gastric reflux, and high *mutans streptococci* (*S. mutans*) count.[1] Factors related to general health status or other treatments may weaken the host defense system or increase the amount of bacteria or the reaction substrate. They include special carbohydrate diets, special health needs, frequent intake of sugared medications, reduced saliva flow from medication, or irradiation orthodontic appliances.[1] Socioeconomic factors include parents' education, occupation, poverty status, and income. The inclusion of socioeconomic factors in addition to biological variables can improve caries prediction.[29] For example, children from higher social class families generally have lower caries incidences.[30] Social class may have an indirect effect on caries risk by affecting behavioral norms such as use of preventive services, tooth brushing frequency and effectiveness, and sugar consumption. The behavior changes then can directly influence *S. mutans* levels and caries experience.[31] The cognitive and behavioral factors related to oral health include attitude to health care, oral hygiene behavior, eating habits, etc.[1, 31] Other important factors associated with caries risk also include age, gender, socio-environmental factors, and the health care system. Socio-environmental factors include water fluoridation, family oral health, a history of caries in parents or siblings, parental levels of bacteria (*S. mutans*), etc. The health care system would affect caries risk though the insurance coverage, preventive care delivery, community education programs, etc.

<u>Previous caries experience</u>

A positive correlation between past caries experience and future caries development has been reported in oral epidemiological studies.[1, 30, 32-34] For example, one study showed that 69% of the children were classified correctly into the low and high risk groups, based on their past caries experience.[35] In multivariate models incorporating biological and socioeconomic variables, prior caries experience has been found to be one of the best predictors of caries risk.[31, 36, 37] Some researchers found that prior caries experience is more sensitive for predicting future caries in children than in adults.[38, 39] Caries prevalence in primary teeth also can correctly predict future caries in permanent teeth.[38-40] Past caries experience may reflect, in part, an individual's *mutans* levels, oral hygiene status and dental health behaviors. These behaviors themselves might reflect the influence of socioeconomic status. It is generally believed that multidimensional models would have a greater ability to predict cares and provide the direction for public health intervention to reduce caries incidence.[31]

Biological factors

A correlation between the severity of carious lesions and the level of *S. mutans* in saliva has been established in children and adults.[41] Litt et al. found that baseline *mutans* is a strong predictor of dental caries, and its level is well predicted by sugar intake levels.[31] Some researchers believed that prior caries experience and the *S. mutans* level can be used together to improve prediction of caries risk.[31, 42, 43] These two variables alone could explain 15 percent of the variation in decay.[42] If caries prevalence is low, the caries-predictability of microbiological tests is also decreased.[44] Other bacteria, such as *Lactobacilli*, may be related to caries development, but they are less sensitive in predicting caries than *mutans*, especially *S. mutans*.[43]

Saliva can clear food particles from teeth. Saliva's buffering effect on acids produced by plaque micro-organisms can protect teeth from decay.[45] The buffer capacity is associated with salivary flow rate. Caries activity was found significantly higher in individuals with markedly reduced salivary function.[45] One reason for a reduced salivary flow rate in children may be the side effects of certain medications.[46]

Results from some twin studies indicated that genetic factors may be associated with dental caries incidence.[47, 48] It was found that the caries experience of monozygotic twins reared apart had a greater concordance than either dizygotic twins or unrelated controls.[49-52] The genetic factors that could contribute to dental caries experience include 1) tooth eruption time and sequence, 2) tooth morphology and contents, 3) Salivary factors and oral flora, 4) arch shape and spacing, 5) host immune response 6) propensity for diet and sugar metabolism.[53] However, the further research on specific patterns of genetic inheritance for dental caries risk is still limited, and can not provide a predictable basis for future decay rates.[53]

General medical conditions and use of medications are found related to caries development. Hobson and Fuller (1987) found that the long-term use of sugary liquid medications by children increased caries prevalence.[54] Psycho-pharmaceutical products could reduce the flow of saliva and, thus, increase the risk of caries.[55] Cytotoxic chemotherapy could disrupt the mineralization of teeth, raising the caries prevalence.[1]

Age

Caries incidence begins soon after tooth eruption in susceptible children and increases with age.[1, 56] Caries incidence has peaks at about age 7 years for coronal decay of the primary dentition and age 14 years for coronal decay of the permanent dentition.[56] Molar teeth are more susceptible to caries within three years of eruption, particularly at pit and fissure sites.[1] They are less likely to decay as the enamel matures. Decay is less likely to happen also because the cleaning function increases after the teeth reach the occlusal plane and opposing teeth are occluding.[56]

Gender

Beltrán-Aguilar et al. found that caries experience in permanent teeth was higher among females (44.5%) than males (39.5%) for children aged 6 to 19 years.[24] Similarly, in another study, higher DMFS values were found in women during childhood and adulthood than in men.[1] But the author also found that women's oral hygiene was better and they had fewer missing teeth than men. The author argued that women may seek more dental care, which is reflected in a higher filling number in the DMFS Index.[1]

Race/Ethnicity

Some surveys have shown that black and Hispanic children have higher caries risk than whites.[57] However, one study indicated that Hispanics have lower mean DMFS and a small variance in the number of lesions, and this low levels of DMFS is associated with lower levels of *mutans*.[31] Mexican-American children are another high risk population. Beltrán-Aguilar et al. reported "Mexican-American children and adolescents had higher caries experience (48.8%), compared with non-Hispanic white (39.9%) or black children and adolescents (38.8%)".[24] The DS/DMFS rate was higher among

Mexican-American (33.6%) and non-Hispanic black children and adolescents (35.9%) than among non-Hispanic white children and adolescents (19.3%).[24]

The differences in caries susceptibility among races may be determined by the utilization of dental care services varying by races. For example, the Medical Expenditure Panel Survey in 1996 reported that about 44% of the total population visited a dentist in the past year; 50% of non-Hispanic whites, 30% of Hispanics, and 27% of non-Hispanic blacks had a visit [16] About 36% of African American children and 43% of Hispanic children aged 6 to 8 years had untreated tooth decay, and this was more than for white children (26%).[16] During 1999-2002,, the level of untreated dental caries in permanent teeth among non-Hispanic black (18.1 percent) and Mexican-American (21.8 percent) children and adolescents aged 6 to 19 years was found greater than for Non-Hispanic white children (10.7 percent).[24]

The disparities in caries susceptibility and dental care utilization among races are associated with socioeconomic status and cultural factors.[31, 58] For example, the number of annual dental visits vary significantly by age, race, dental status, level of education, and family income.[16] Jones et al. found that non-Hispanic black and Mexican-American survey participants had a higher prevalence and severity of caries and lower prevalence of untreated decay compared with non-Hispanic white participants, and these non-Hispanic black and Mexican-American children and adults often have lower income and education and higher levels of dental caries.[59] This result is consistent with the reports from other two studies based on national surveys.[17, 60] When socioeconomic factors were controlled, much of the excess risk for untreated dental caries among different races was eliminated [60]

Socioeconomic factors

Socioeconomic status (education and income levels) is highly relevant to caries prevalence.[1, 61-63] Caries is less prevalent in upper than in lower social classes.[64] This may be not only due to high treatment cost, but also to a great difference in health interest between social classes.

Education is an important social factor. For children and adolescents whose health care decisions largely depend on parents, parental education level would be more relevant. It was found that the prevalence of caries inversely was related to parental education level.[65, 66] This relationship also is found for children with universal access to dental care.[67] Education may affect dental health by its impact on the utilization of dental care, especially preventive care. One CDC study indicated that the proportion of the population that has at the least one past-year dental visit is higher among those with some college education (55 percent), and lower among those with less than a high school education (24 percent).[16]

Another social factor having influence on caries prevalence is income. Edelstein found that the disparities of caries status and dental care are evident among low-income preschool children, who are twice as likely to have cavities as are higher income children.[58] According to the Third National Health and Nutrition Examination Survey 1988-1994, early childhood caries is more prevalent among children from low-income families. Moreover, a more severe form of caries is found in those children.[17] Similar results are found in other studies.[24, 59] Even the decline of the caries prevalence from 1988--1994 to 1999--2002 was larger among children and adolescents from families with incomes ≥200% of the FPL (10.5%). Poor oral health in low-income children is often associated with lack of dental care. Children from poor families are less likely to have dental sealants (3 percent), compared to the national average (23 percent).[16] Data from 1999-2002 shows that children and adolescents from high-income families had a lower level of untreated caries (8.1%), compared with those coming from families with incomes less than 200% of the FPL (19.5%).[24]

Attitudes and beliefs

People's beliefs and attitudes towards dental health have both direct and indirect influence on caries susceptibility.[1, 31] People with favorable oral-health-related beliefs would be more likely to seek preventive care and treatment. Preventive care would reduce caries susceptibility, and timely treatment would reduce the caries severity. Broadbent et al. found that individuals who held stable favorable dental beliefs about the efficacy of water fluoridation, keeping the mouth clean, avoiding sweet foods, visiting the dentist, using dental floss, and using fluoridated toothpaste had better oral hygiene, fewer teeth missing due to caries, and more restorations (the major treatment for caries).[68]

Parental attitudes towards oral hygiene, diet and indulgence, and caries-related behaviors are also associated with higher caries prevalence and experience in their children.[1, 69, 70] Parents' lack of knowledge of oral hygiene, or cultural beliefs that do not support the preservation of the primary dentition, may also contribute to a higher rate of caries in their children. Alternatively, trust in providers and satisfaction with outcomes of dental treatment can contribute to a lower rate of caries in their children.[71]

Personal health behaviors

Two personal dental health behaviors, sugar consumption and tooth brushing, have been studied with regard to their effects on dental caries among children.[31]

The role of diet in the caries development is primarily local rather than systemic, and depends on the components in food.[72] The amount of sugar intake is believed to have an effect on caries activity.[72] Several investigations have shown a significant positive association between the ingestion of sticky high-sugar foods and risk of caries.[31] The results implied that reducing sugar intake could have an effect on *mutans* levels and thereby on caries.[31] The frequency of the sugar intake also plays an important role in caries process.[73]

It is believed that regular oral hygiene, such as tooth brushing using a fluoridated dentifrice, can reduces caries incidence.[1] Thus, children with good oral hygiene are less likely to have caries, irrespective of dietary habits.[74] Caries prevalence is high only when the oral hygiene is poor.[75] Studies found that irregular tooth brushing or low tooth brushing frequency is associated with high caries experience.[61, 76, 77]

Geographic location

Oral health disparities exist among adults residing in rural and urban areas, where caries experience is greater among rural adults.[78, 79] Children living in rural areas have less access to and utilization of dental care than children living in urban areas,[80] but the reports on the difference in the sum of decayed and filled primary teeth and the sum of decayed, missing, and filled permanent teeth are not consistent. One study found the difference was not singnificant.[80] Wang et al. and Irigoyen et al. reported, based on schoolchildren in different countries, that caries levels were significantly higher in urban areas.[81, 82] Another study showed the contradictory result in which the percentages of children positive for caries, the mean DMFT values all were significantly greater in schoolchildren living in rural areas compared with those living in urban areas.[83] The difference in caries experience between rural children and urban children may be explained by the difference in eating habits, nutrition, the supply of dentists, culture and behavior among different areas. Other factors may include transportation barriers, fluoridated community water supplies, dental insurance policy, etc.[84]

Insurance coverage

Insurance coverage of dental services may influence people's behavior to seek dental care and thus influence dental health status. Studies found that dental insurance and education were important factors in determining use of dental cleanings and use of dental care,[85] and having dental insurance is associated with less untreated caries and missing teeth for persons aged 20 years or older.[86] It was found that after enrollment in dental insurance, the proportion of low-income children who had a preventive dental visit increased 50%, and the proportion of children reporting unmet need for dental services fell from 43% to 10%.[87] However, Ismail and Sohn found that "having access to a universal publicly financed dental insurance program could not eliminate all disparities in caries experience".[67] That argument is supported by the study comparing dental caries status and treatment need between children 5 to 18 years of age who were enrolled in Medicaid and who were not enrolled: caries prevalence did not differ substantially but some Medicaid-enrolled children had a significant portion of their restorative treatment needs met.[88]

Lately, some studies found that having comprehensive dental service coverage may not eliminate the disparity in the utilization of dental services. For example, though dental coverage is mostly provided by Medicaid or the State Children's Health Insurance Program (SCHIP), many low-income children do not receive adequate dental services after their enrollment in either Medicaid or SCHIP.[89] Another investigation by Edelstein reached the similar result: children in poverty or near poverty but with dental insurance coverage Medicaid and SCHIP are twice as likely to have tooth decay as are high-income children;[58] they also have twice the number of visits for pain relief but fewer total dental visits, compared to high-income children.[58] The low level of dental visits for preventive services such as sealants may contribute to the large burden of caries in low-income children.[58]

<u>Preventive dental care services</u>

The primary preventive measures in dental services includes water fluoridation, pit and fissure sealants, plaque control, and dietary analysis to control the consumption of fermentable carbohydrates.[21]

Water fluoridation is believed to be the most cost-effective way to deliver the benefits of fluoride to all residents of a community.[2] It can help to maintain optimal dental tissue development and improve dental enamel resistance against the action of acids during the entire life span of a tooth.[90] The effect of water fluoridation in reducing caries incidence has been widely studied and proved, but its contribution level was reported differently in previous studies.[2, 91-93] A study based on data in the mid-1980s showed that the mean DMFS in the permanent teeth among children residing in communities with fluoridated water was 18% lower than among those residing in communities without fluoridated water.[91] This reduction ranged 8%-37% among adolescents (mean: 26.5%) in another study based on data in 1979-1989.[92] Water fluoridation can reduce dental health disparities, because it reaches all residents in a community, and does not depend on individual behavior or socioeconomic status.[93]

Topical fluoride, including fluoride toothpaste or mouthwash, is also recommended to protect teeth from decay.[15] The local action of fluoride on the tooth surface is "at least as important as the incorporation of fluorides into dental hard tissues during tooth formation".[94] Since the effect of fluoride depends on it concentrations in the mouth, the regular exposure to fluoride is critical for caries prevention.[95-97]

Fluorides are effective in reducing carious lesions on the smooth surfaces of teeth, but deep pits and fissures on occlusal surfaces cannot be adequately brushed or protected by fluoride administration.[26] Besides, extra intake of fluoride would have side effects. Dental sealants are usually applied on the teeth of children to protect vulnerable areas, such as fissures and pits, by "sealing out" plaque and food.[26] The more detail about their effectiveness and delivery is discussed in the next section.

2.1.3. Examples of Dental Caries Risk Assessment

Over the past decade, strategies for preventing dental caries have increasingly emphasized the concept of risk assessment.[98] However, few practical tools for assessing caries risk in infants, children and adults have been well developed. Recently, some professional societies or health insurance companies have been designing and implementing some criteria for assessing caries risk for their patients.

The American Academy of Pediatric Dentistry (AAPD) developed a caries-risk assessment tool (CAT) for infants, children and adolescents,[98] which was designed to assist both dental and non-dental health care providers in assessing levels of risk for caries development in infants, children and adolescents.[98] CAT focuses on three major components of caries risk—clinical conditions, environmental characteristics and general health conditions and less on advanced technologies such as radiographic assessment and microbiologic testing. As a means of classifying dental caries risk at a point in time, CAT should be applied periodically to assess changes in an individual's risk status. As a dynamic instrument based on cumulative scientific evidences, CAT will be evaluated and revised periodically as new evidence warrants.[98]

The second example of such criteria is the caries risk assessment guideline used in HealthPartners Dental Group (HPDG), a staff model dental practice in Minnesota. This guideline has been accepted into clinical practice since 1996 and mainly used for the mixed dentition age patient population (i.e. children). This guideline has two parts: one for children aged 0-5 and another for children 6 years and older through adulthood. The primary criteria include: caries history, dietary practice, fluoride use, maternal caries, and medication/therapy. For example, high risk score would be assigned if one or more of the following is found for the evaluation recipient:

- More than 3 caries in last 3 years
- Suboptimal fluoride
- Sjogrens Syndrome

- Radiation therapy on head or neck
- Medication/xerostomia

This guideline includes recommendations for risk assessment and risk reduction strategies such as whether sealants should be applied to the pits and fissures of some teeth. The predictive validity of this guideline has been studied on adult population, but not yet on child population.[99] Over 95% of children seen by dentists have received an overall caries risk assessment score. The recommendation for low-risk children is to apply sealants only if the anatomy of the pits and fissures is deemed to be highly susceptible. This decision is left to the discretion of the dentist and child's parents.

2.2. Dental Sealants

2.2.1. How Sealants Can Prevent Dental Caries

Dental sealants are a polymerized resin developed from enamel bonding techniques and used since the mid-1970's.[26] They are a liquid at the first moment when they are applied to the surface of a tooth and can flow into the crevices of the pits and fissures of the tooth. After a sealant hardens, it forms a barrier between the tooth and the oral environment to prevent bacteria and acid from entering the vulnerable areas of the tooth.[26] Sealants can also be protective for incipient decay by eliminating the nutrient source for *S. mutans* and, thus, changing a lesion from caries-active to caries-inactive.[100-103]

During the past decade, dental caries has increasingly concentrated in children's occlusal tooth surfaces, for which dental sealants are the ideal prevention.[16] Sealant is applied without conducting anesthesia or drilling the tooth structure, causing no pain to recipients.[16] Any tooth that has an anatomically weak structure (such as deep pits or fissures) should be sealed.[16] By far the "back" teeth (premolars and molars), particularly the molars, are the most common teeth on which sealants are placed.[16] A sealant can stand certain chewing force and keep a protective function for a few years before a reapplication is needed.[28]

2.2.2. Retention of Dental Sealants

Sealants need to remain in place and intact to effectively protect the teeth. The teeth with partially or completely lost sealants have the similar caries risk as unsealed teeth.[104] The normal longevity for a well-placed sealant is three to five years, and it could be much longer in some cases.[100] The factor most likely to affect sealant retention is whether the sealant is properly applied to the tooth.[105] Complete isolation of the tooth from saliva is an important step of sealant placement.[106] Complete removal of plaque and debris from the pits and fissures prior to etching is also critical.[106] The reasons why a sealant dislodges in a short time after placement include operators' improper application or bad cooperation by young children.[106] Besides, sealant retention also depends on the eruption status of the tooth.[107] If a tooth is not entirely erupted, the retention rate is lower—likely due to difficulties maintaining a dry tooth surface during application or conducting sealant placement.[107] Finally, because sealants are susceptible to occlusal wear, the importance of continued evaluation of the sealant has to be emphasized.[106]

Sealant retention averages about 96% at one year, 82% at 5 years, 57% at 10 years, and 52% at 15 years.[11] Two long-term studies showed that 31% and 41% of the originally sealed first molars had caries or a restoration at 15 and 8 years, respectively.[108, 109] Both suggest resealing to keep sealants' protective function.

2.2.3. The Effectiveness of Dental Sealants

The effectiveness of dental sealants has been extensively studied since 1970s. Both randomized clinical trials and retrospective investigations have shown that, as long as the sealants remain intact, they are effective in preventing pits and fissure caries.[10, 23, 56, 107, 110-113] For example, a systematic review of twenty-four studies published in the early 1990s found that the preventive fraction (PF), the proportion of occlusal decay prevented, among children receiving a one-time application of sealant was 71.36%.[110] A more recent review in 2004 compared results from eight randomized or quasi-randomized controlled trials and concluded that resin sealant placement reduced caries by 86% at 12 months and 57% at 48 to 54 months in 5 to 10 year old children.[114] A 60% decay reduction on posterior teeth was documented in the *Guide to Community Preventive Services*, which examined the effectiveness of school-based sealant programs,[115, 116] Some studies suggest that sealants are more effective in high caries risk children,[10] and the caries prevalence level of both individuals and the population should be taken into account when the sealant is delivered.[114]

2.2.4. Cost and Coverage of Dental Sealants

The charges of dental sealants placement range from $20 to $45 per tooth. It is possible that a sealant breaks off or dislodges. That often requires replacement and causes extra costs.

Due to the well-cited effectiveness of dental sealants in caries prevention, many dental insurance policies provide coverage for dental sealants, but only once every few years or in the life time of a tooth. Some policies cover sealant placement only for certain teeth or the populations falling within a certain age, such as the first permanent molars in children through age eight or the second permanent molars in children through age 15.[117] Sealant benefits may or may not include the repair or replacement of a sealant within the first few yeas of its application. The state Medicaid programs started to add dental sealant benefit since the mid-1980s.[117] Currently, all state Medicaid programs include sealant placement in their covered dental services.[11]

2.2.5. Sealant Prevalence, Disparities and Influencing Factors

Sealant use has been advocated by the ADA and other oral healthcare agencies.[101] A goal set by the U.S. Public Health Service for the year 2010, outlined in their program Healthy People 2010, was for 50 percent of children aged 8 and 14 to have one or more sealed permanent molars.[118] The report in 2000 showed that only 23 percent of children in grades 2 and 3 and 20 percent of children in grades 8 and 9 had their first molars sealed.[118]

Over the past thirty years, the rate of sealant usage has been increasing. From 1988--1994 to 1999--2002, sealant prevalence increased >12% (from 19.6% to 32.2%) among children aged 6 to 19 years.[24] This increase was observed across the races and income groups.[24] The disparities in sealant use still exist, but might be decreasing.[24] This trend might be attributable to the change in sealant coverage policy in private and public insurance programs, increase in people's knowledge about sealant benefit and increases in sealant delivery programs.[24] A recent study reported that children and adolescents aged 6--19 years with at least one sealed tooth have a mean of 4.5 sealed teeth. Molars accounted for about 85% of all sealed teeth. The first and second permanent molars are more likely to be sealed than other teeth.[24]

Though sealant use has increased, it is still far too low, even at sites that have received targeted interventions.[119] The latest data from the National Oral Health Surveillance System found considerable variation in the percentages of third graders by state who have received at least one dental sealant on a permanent molar[120].[119] From a sample of 33 states, Vermont had the most with 66.1%, while South Carolina was the lowest at 20.3%. Overall, sealant use in most states is still much lower than 50%, the national health objective for 2010.[16]

The factors explaining the discrepancy in dental health sealants are similar to those that account for the variation in dental health and caries experience. Several studies found that a larger proportion of non-Hispanic white children and adolescents that have at least one sealed tooth, compared to non-Hispanic black and Mexican–American children and adolescents who may have twice as much untreated decay in their permanent teeth.[24, 116, 121] Children and adolescents from families with incomes more than 200% of the FPL are more likely to have sealed teeth than those from families with lower incomes.[2, 16, 24, 59] A report based on national surveys indicated that low-income children and adolescence paid fewer preventive visits for services such as sealants, increasing the burden of disease.[58] In Minnesota, dental sealant utilization in 1996 among children aged 6-12 ranged from 9 percent for the children enrolled in state's Medicaid program (Medical Assistance program) to 13 percent for the children enrolled in the MinnesotaCare program.[122] In 2003, about 30 percent (126,000 among 391,000) of the children and adolescents age 21 who were enrolled in Medicaid received any dental visits, and only about 20 percent of them received sealants on any permanent molar tooth.[123]

It is believed that the lack of sealant application also is associated with a low level of knowledge about sealant benefits. Cited worries include: sealants seal in existing decay; sealants are easily lost; patients prefer other restoratives; and patients do not want to incur the initial expense.[101, 124] Parental education was found to be positively correlated with the likelihood that their child had sealants.[125] Jones et al., in a study based on data from the National Health and Nutrition Examination Survey (NHANES) 1999–2000, concluded that caregivers' sealant knowledge is determined by their race/ethnicity, age, gender, marital status, education, and income.[59] They found that non-Hispanic whites have the highest caregiver knowledge (78%) and highest sealant prevalence (49%), and non-Hispanic blacks have the lowest caregiver knowledge (41%) and sealant prevalence (22%). About 71% of caregivers from high-income families have sealant knowledge, compared to about 47% of those from low-income families.

Other factors also partly can explain the discrepancy of sealant use. An examination of Alabama Medicaid claims from 1990 to 1997 for children 14 years and younger found that the availability of a Medicaid-accepting dentist within the county of residence and Medicaid payment/claim ratio were predictors of sealant use.[126]

Although there has been no study on sealant use and associated factors in Minnesota children, reports about predictors of dental visit utilization can provide valuable information about the factors associated with sealant use. Based on data in

2002, 87.3% of Minnesota children had at least one dental visit in the past year.[127] The same report indicated that children without dental coverage are significantly less likely to have had a dental visit in the past year, compared to children with private or public dental coverage. Children with public insurance are significantly less likely to have had a dental visit than children with private insurance. Children from households with incomes below $25,000 are less likely to utilize dental care than children from households with incomes above $25,000.[127] Children are more likely to utilize dental care if any of their parents have had a dental visit in the past year. In sum, dental care utilization is influenced by a child's dental coverage, family income, parents' health behavior, and so on.[127]

2.2.6. Application of Dental Sealants Based on Risk Assessment

The advocacy and implementation of any preventive intervention should consider targeting certain high risk patients or populations to achieve the most cost-effective results. Lately, some researchers have argued the application of sealant should be based on the risk profile performed on a number of levels: community, individual, tooth and tooth surface.[101] [56, 113] For example, Rock and Anderson indicated "sealants would be effective in preventing carious lesions in only one-third of the teeth".[128] The results of the study by Dennison et al. showed that, when sealants are delivered to the population with a low incidence of caries, about 15 first permanent molars or 10 second permanent molars should be sealed to prevent one occlusal caries.[9] While sealants would be cost-effective when placed in patients with risk factors for caries, there has been no widely accepted diagnostic predictors of caries,[26] due to the multiple-factor etiology of caries.

Tooth and surface type should be considered in sealant application. The teeth at the greatest risk for caries are molars. Initially the first molars were thought to be at greatest risk of caries attack, but researchers gradually realize that that the first and second permanent molars may be at equal risk. Both of them have a higher probability of being decayed than rest of the teeth, and they should be the main candidates for sealants.[101, 113 56] Occlusal surfaces should be the target in sealant application, because the pits and fissures concentrate on the occlusal surfaces of molars.[113]

Age should be considered in sealant application, but related evidence is incomplete and inconsistent. Some people believe that caries are more likely to happen within two to four years after tooth eruption, and the teeth remaining caries-free for four or more years after eruption may not need to be sealed.[113] Therefore, sealants for the first permanent molars should be applied to six-eight year olds, and for the second permanent molars to twelve-fourteen year olds.[129] But Rozier et al. found that "the pits and fissures of first permanent molars remain susceptible to primary decay into adolescence and beyond".[117] That suggests that age should not be the primary factor determining the sealant placement.[113]

Since low-SES children are more likely to have caries but less likely to have access to dental services, it is suggested that low-SES children be the high risk population for the application of sealants.[129] Other factors that may be important in sealant application include previous caries experience, family caries history, exposure to fluoridated drinking water, the presence of deep or stained pits and fissures, the presence of heavy plaque accumulation on the surfaces, etc.[129] If there is a general agreement on the risk factors, a patient's overall caries risk should be indexed and employed as the main criterion for sealant application.[113] Dentists usually can rely on their own experience and judgment to make a good decision about which teeth have the most pressing need for the protection that sealants provide.[129]

School-based and school-linked sealant programs generally target vulnerable populations who are unlikely to receive sealants or dental care otherwise (e.g., populations attending schools with a large proportion of students eligible for free or reduced-cost meal programs).[116, 130] They are often the integral part of a community-wide sealant delivery program.[130] A systematic review of ten studies on school-based sealant programs concluded that these programs may contribute to a relative decrease in dental caries experience of 60%.[130] In 2002, the Task Force on Community Preventive Services advocated school-based or school-linked sealant programs for the prevention of dental caries.[115] Based on CDC reports, in 2005, about 193,000 children received sealants from school-based dental sealant programs in 29 states. This number represented only about 3% of poor children who should receive sealants.[116] An expansion in the number of dental sealant programs would decrease disparities in the sealants application and caries prevalence.[131]

2.3. Cost-Effectiveness Analysis (CEA) of Dental Sealants

2.3.1. Review and Critique of Past Studies

A number of studies have been conducted to determine the cost-effectiveness of sealants. Table 2-1 provides a summery of the studies. However, most of the studies have some limitations that greatly reduce the reliability or generalizability of their results and conclusions.

(1). Most of the studies used the DMFS index as the primary outcome measurement,[4, 6, 132-136] by comparing the difference in DMFS between the start and end of the observation period. However, this measurement does not take into account the time when the caries appeared. In other words, if a caries in the intervention group appears at the start of observational period, and a caries in control group appears in the middle of observational period, the difference in DMFS would be the same. But for a patient, later caries improve quality of life. So a measurement that simultaneously can take the number and timing of caries into account would be preferable.

(2). Most of the studies had a follow-up observation of less than 5 years.[3, 6, 132, 133, 135, 136] Because sealants rarely are retained completely over the tooth's lifetime and often must be reapplied, it is important to evaluate their cost-effectiveness over a long time period. Furthermore, the potential increase in cost caused by the increase of caries due to dislodgement of sealants, as well as cost increase due to repairing sealant loss, can be observed only in a long time period.

(3). Cost estimation was biased in two studies that used sealant placement time per tooth to measure the cost of sealant application.[132, 137] The average sealing time per tooth for a patient with four teeth sealed could be less than the average sealing time per tooth for a patient with two teeth sealed due to some procedural reason.

(4). There has been no retrospective study that considered and dealt with selection problem caused by unobserved factors. Retrospective studies of secondary data frequently have some missing information that simultaneously affects the investigated outcomes and the intervention choice, which causes a selection problem because people's preference for certain interventions can be related to their outcomes. Prospective studies without randomization also can have the similar problem. The existence of a selection problem can cause biased estimation of the intervention effect. This problem has been ignored by all CEAs of dental sealants. In addition, few studies had adequate control for confounding factors including demographic factors, dental care provider factors, and clinic factors.

(5). Some studies did not take risk assessment into account.[6, 132, 134, 137, 138] Risk level of caries in a population and the progression of tooth decay influence the way to prevent the disease in the most cost-effective manner. Targeting individuals and teeth that are more likely to experience decay may increase the efficient allocation of resources in sealant programs with the least cost, thereby improving the cost-effectiveness of sealants.[3] Based on some studies with risk assessment or modeled by risk assumptions, universal delivery of sealants on low-risk population may or may not be cost-effective.[22] The inconclusive results justify the necessity of analyses based on different risk levels. In addition, those studies including risk assessment typically used low-income and past caries experience as the criteria because they are easily obtained from data sets. Such criteria are incomplete because other risk factors like family history and physical disability are not considered. Protective factors such as fluoridated drinking water are not considered either. Using appropriate risk assessment, a study is better able to make specific preventive and treatment recommendations to reduce a child's risk and improve overall oral health. Risk assessment also contributes to efficient delivery of care by eliminating unnecessary interventions.

(6). Assumptions made by some studies were very unlikely. For example, both the sealant and the restorations were assumed to be 100% effective in one study.[132] In another study, the cost of single restoration was assumed to be 2 times the cost of sealing a tooth.[134]

(7). Several studies focused only on first permanent molars.[4, 6, 22, 134, 139, 140] Their results may not necessarily be applicable to second permanent molars or premolars.

In addition, studies used different comparison designs. For example, the intervention used in one study was the combination of dental sealant, fluoride mouthrinsing, and an annual oral hygiene education session, and the control is oral hygiene education only.[135] One study compared a program comprising selective fissure sealing and application of topical fluorides (control) with a program of professional cleaning and oral health education (test).[6] Another study compared glass ionomer (GI) to resin-based (RB) sealant.[137] Sample sizes used in some studies were small.[6, 22, 132-134, 136, 137] Finally, in some of CEAs of dental sealants, effectiveness estimates were derived from previous dental literature, other clinical trials, epidemiologic studies, and national surveys. [141, 142] The above study designs may not necessarily mean weaknesses, but the results of studies could only be limited to certain program comparison, materials, or populations.

Based on the above discussion, for dental sealants, a prevention method involving a very common disease and a very large population, the quality of its cost-effectiveness analyses has been surprisingly low. The number of reliable cost-effectiveness analyses is also few. The reasons may be because of lack of adequate research training for researchers in dental care services and the difficulty obtaining long-term population level data. It seems the advocacy for the application of dental sealants by public health agencies and the decisions to cover dental sealants for enrollees made by insurance companies are based more on results of sporadic efficacy studies rather than on systematic and scientific conclusions form credible cost-effectiveness studies.

Application of dental sealants is a large scale public health prevention. Lack of reliable and sufficient scientific information for its cost-effectiveness has contributed to the low utilization of this prevention and the low efficiency of corresponding public health resource allocation.[101, 124]

Table 2-1. Cost-effectiveness Studies on Dental Sealants

Study	Design	Group	Size	Age	Follow-up year	Caries risk Considered	Teeth	Effectiveness	Cost	Conclusion
Leake and Martinello, 1976[138]	Half-mouth, Benefit/cost analysis	Sealant and control	417	6-7	4	NO.	FPMs	Difference in DMFS	Dental charge and personnel	1). Program cost/ Cost of averted disease: 4,446/1,136=$4 2). Annual effect size: 0.09 DMFS averted
Burt, 1977[132]	Clinical trial, half-mouth design	Sealant and control	118	5-12	2	NO.	Not specified	Difference in DMFS	Time on operation, salary cost	Sealing the population took 24.9% to 33.8% more time than treating the lesions in control group
Leverett, et al., 1983[133]	Half-mouth, random trial, Benefit/cost analysis	Sealant on one side, restorative care on other	292	6-9	4	Caries-active (sealant placed on a carious surface) Caries-inactive (sealant placed on a sound surface)	FPMs	Sealed surfaces 74% less caries increment than unsealed	Time on procedure and a median fee	Benefit cost ratios based on time or costs were more favorable for caries-active. Sealant should not be used unless evidence of past or current caries experience.
Simonsen, 1987[134]	Retrospective cohort study	Sealant and non-sealant	28	5-15	10	NO.	FPMs	Difference in DMFS	The cost of single restoration is assumed to be 2 times the cost for sealing a tooth	Cost for non-sealant group is 1.3 times the cost for sealant group.
Weintraub et al., 1993[22]	Retrospective cohort, life table analysis	No sealant; Any sealant; 4 molars sealant	275	7.4	5.8 – mean (up to 11 years)	Restorations on first molars prior to sealant placement on remaining	FPMs	8-year survival: sealed teeth with and without prior restoration –	ADA fee for restoration and sealant	Cost saving obtained within 4-6 years for children with prior restorations; after 8 years without prior restorations

						molars		85% and 94%; unsealed teeth – 23% and 46%		
Morgan et al., 1998[135]	Prospective nonrandom, school-based program	Intervention: dental sealant, fluoride mouthrinsing, and oral hygiene education; Control: oral hygiene education	Intervention: 256, Control: 266.	12-13	3	All from schools with high levels of dental caries experience	All second molars and appropriate FPMs	Mean differences in DMFS increments	Use average charges & assump-tions	The incremental cost-effectiveness ratio comparing intervention to control group varied between a net savings of $7.00 to a cost of $35.60 per DMFS avoided
Kervanto-Seppala et al., 2000[137]	Observational	Glass ionomer (GI) and resin-based (RB) sealant.	140 teeth	14.1		NA	Second molars	NO.	Sealant application time	GI sealants cannot be as cost-effective as RB sealants.
Arrow, 2000[6]	Decision tree	selective fissure sealing & application of topical fluorides (control); professional cleaning and oral health education (test)	200	NA	2	NO.	FPMs	Caries increment from a field trial	Labor cost + materials costs	Test program is less cost-effective, ICER=$40/year.
Weintraub et al., 2001[139]	Retrospective cohort, Medicaid	Sealed and unsealed teeth	15,438	4-7	8	Low, middle and high, based on prior	FPMs	Unsealed molars 3x more likely to	Medicaid aggregating expenditure	Medicaid expenditure savings for high risk within two years, not for low risk

	claims, Discrete time hazard model					caries-related services involving occlusal surfaces (CRSO)		get CRSO Low risk: sealant effective up to 4 y Middle risk: lower odds for 6 y High risk: reductions up to 7 y.		
Griffin et al., 2002[4]	Modeling	Seal all (SA), seal children at risk (TARGET) , and seal none (SN).	NA	6-7	9	Based on assumption	FPMs	Caries increment from literature	Based on 1999 Survey of Dental Fees	As assumption changes, TARGET may dominate SA or vice versa.
Zabos et al., 2002[136]	Prospective nonrandom, school-based program	Sealant and control	60	Mean= 10.2	5	From schools with low-SES children	Not specified	Difference in DMFS	Cost of all dental care	Sealant for low-SES children saves money,
Quinonez et al., 2005[140]	Decision tree, a Markov model	seal all (SA), risk-based (RBS), and seal none (SN)	NA	NA	10	Based on assumption	FPMs	Month gained in a cavity-free state	Based on ADA Survey of Dental Fees and Claims Data from the early 90's.	RBS has lower CE ratio than SN. SA further improved outcomes but at an small additional cost compared to RBS
Bhuridej et al., 2007[143]	Retrospective cohort, Medicaid claims,	Sealed and unsealed teeth	2132	6	4	Based on frequency of preventive visits	FPMs	4-year survivorship Utility	Medicaid aggregating expenditure	Incremental cost ranged $36.7 to $83.5 per 0.19 QATY; The ratio was lower for sealing lower utilizers and for mandibular versus maxillary molars.

2.3.2. What Make a Good Cost-effectiveness Analysis of Dental Sealant?

Based on the characteristics of the development of caries, factors affecting sealant function, and the weaknesses of past studies, a good cost-effectiveness analysis will need to address a number of key issues:

(1). an appropriate outcome measurement should be used to reflect differences between intervention and control groups in both the number of caries and the time length for caries to appear. In another words, the time pattern of caries increment should be taken into account.

(2). a study should be undertaken to extrapolate the potential costs and benefits over a relatively long time (e.g., 5-10 years).[135] Since dental caries is a slowly progressing disease, and the sealant's function depends on how long it can remain intact, a long period of observation is necessary before the true costs and benefits can be measured and definitive conclusions can be made.[6]

(3). a reliable and unbiased cost-effectiveness ratio can be estimated only after properly controlling self-selection problem and all confounding factors.

(4). cost estimation should be appropriate. Aggregating cost from real practice and real settings would reflect better the mix of different diagnostic and treatment procedures, as well as the mix of service providers. For example, dental sealants are applied in clinics more often by hygienists than by dentists, even though dentists conduct examinations and make decisions. This may reduce overall costs because of the lower wages of dental auxiliaries.

(5). a good CEA study should take populations' caries risk level into account. Risk assessment should include both risk factors and protective factors. Studies should be replicated among different age groups and populations with differing caries patterns, and in fluoridated and nonfluoridated communities.[132]

(6). a CEA study should have a large sample size and be able to control adequately for confounding factors including demographic factors, health care behavior, other dental care which may affect the oral environment, etc.

CHAPTER 3. RESEARCH DESIGN AND METHODS

3.1. Conceptual Framework for Oral Health Outcomes

The conceptual model relating dental caries, sealant application, as well as risk factors for caries, must be a multidimensional model. It should reflect not only the intervention studied, but also the patient's or the population's demographic factors, socioeconomic factors, cognitive-behavioral factors, environmental factors, and the health delivery system.[1 16, 31] However, multidimensional models, particularly those consisting of both socioeconomic and biological variables, have not been used widely in the study of oral health diseases.[31] There have been no CEAs of dental sealants establishing such a model before exploring the expected relationships among the variables. Even those studies based on risk simply consider the existence of past caries experience as their risk criterion. Use of the conceptual model would help researchers to define the variables that are of interest and that need to be controlled and to understand the analysis based on risk factors. It can also help researchers to verify the presence of selection problem, improving the estimation of outcome measures. The quality of previous studies has been hampered by the lack of theoretical or conceptual frameworks.[31]

The conceptual model used in this study is a modified version of Andersen's Behavioral Model of Health Services Utilization and its expansion for the International Collaborative Study of Oral Health Outcomes (ICS-II).[144] It is based on a "systems" perspective to understand determinants of oral health. This framework posits that personal characteristics, external environment and the dental care delivery system influence oral health behaviors and outcome.[144]

The constructs and their relationships in this model are shown in Figure 3-1. Figure 3-1 shows a conceptual model for relationships between health status of the teeth and dental sealants as the preventive care, including some external factors. The constructs are represented by the large squares. The arrows emanating from them show how they influence each other and the outcomes. For example, the primary determinants, such as personal social structure, may have direct effects but also work through oral health behaviors to influence outcomes.[144] Related measurable variables are listed under the constructs, and they should be considered for inclusion in the mathematical model (some may be eliminated later during the model reduction). The constructs include:

1). Oral health behaviors, including use of health services such as preventive care (sealants, etc.) and formal treatment care (restoration, etc.), as well as personal health practices such as tooth brushing, dental floss use, and diet.

2). Personal demographics, including age and gender.

3). Personal social structure, including ethnicity, education, family size, religion, etc.

4). Family enabling resources, including regular source of care, family income, insurance, social support, and perceived barriers to care.

5). Parental/personal health knowledge and beliefs, including knowledge about disease and health care and attitudes towards health services.

6). External environment, including region (urban/rural) and community water fluoridation.

7). Dental care system, including organization, providers, and clinic setting.

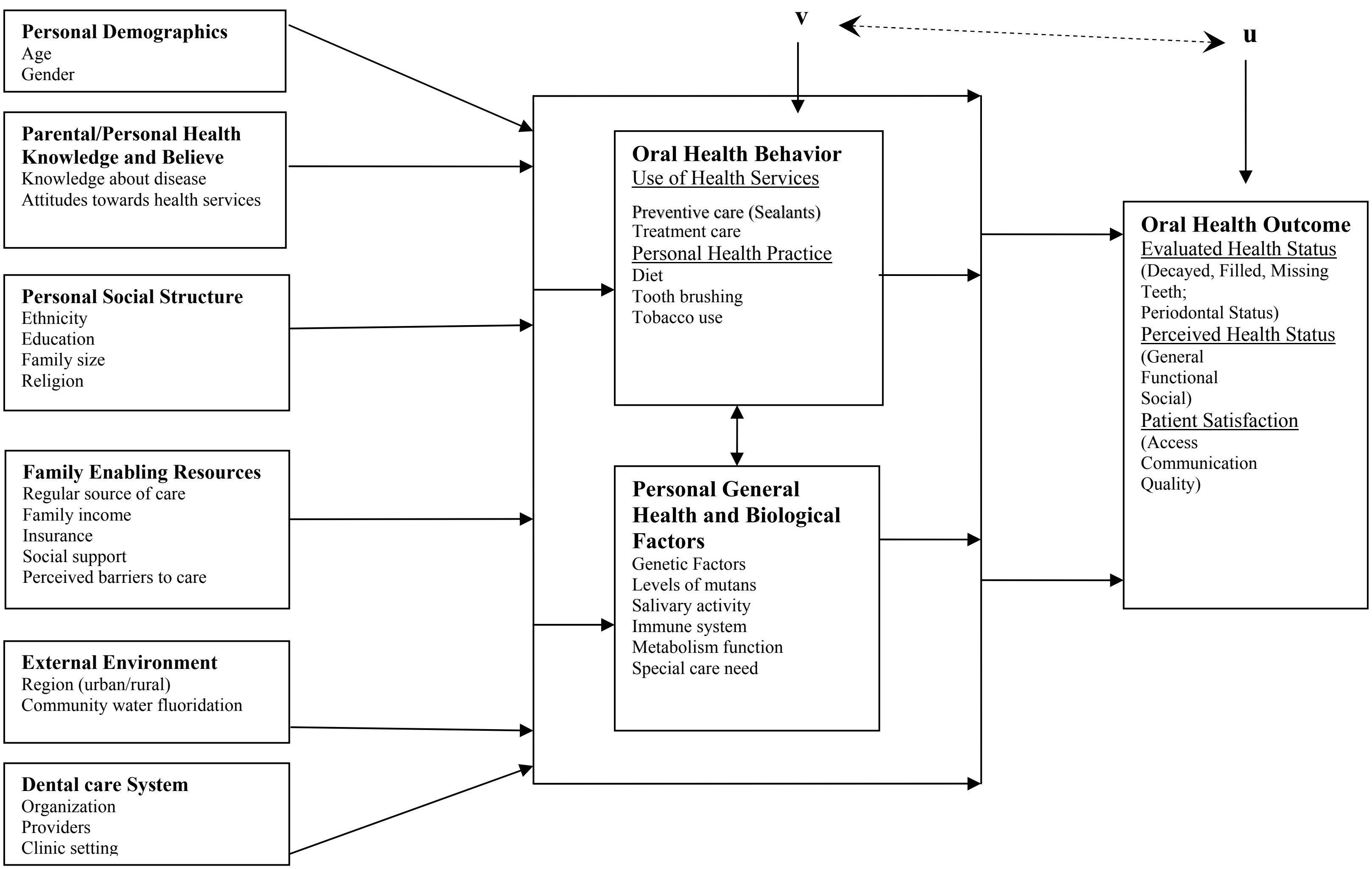
8). Personal general health and biological factors, including genetic constitution, levels of *mutans*, salivary activity, immune system, metabolism function, and special care needs.

Most of above constructs have at least one relevant variable available in the data set. "Parental/personal health knowledge and beliefs" is the only construct that is not represented. The variables that are candidates for appearing directly in the mathematical function and would directly affect cost-effectiveness of sealant use are listed in Table 3-6 and Table 3-7 for dependent and independent variables, respectively.

The Andersen's Behavioral Model includes feedback, and so does this conceptual model. In one direction, people's behavior can affect their health status or outcome. In another direction, outcome changes (in either health status or satisfaction) can also result in changes in people's health behaviors or perceived need for health care.[144] For example, if an individual is found to have caries, he/she may pay more attention to tooth brushing. Besides, risk of caries is not constant throughout life and can be changed with people's health behavior and receipt of preventive interventions.[1]

Although the conceptual model shown in Figure 3.1-1 is established for mainly studying the effectiveness (outcomes) of dental care interventions, it can also be used to demonstrate the relationship between the cost and these constructs, because the cost is associated with each intervention, treatment, and the outcome. More specifically, before any caries develops, regular checkup and preventive care generate cost. As a caries prevention, sealant placement generates cost. Once a caries appears, its treatment also generates cost. The expenditure associated with prevention and treatment of caries is the major cost of interest in this CEA. In dental care the treatment cost is largely determined by the operation procedure, and the operation is largely determined by the caries damage location and severity. Because the constructs in this model all are related to prevention, treatment, and outcome, the relationship between the cost and those constructs is very close, which may justify the assumption that the cost function shares the same explanatory variables with the effectiveness function.

Figure 3-1. Conceptual Model



Oral Health Outcome

In Anderson's model for oral health,[144] health outcomes include 'evaluated health status' based on the judgment of dental care professionals, 'perceived health status' based on the judgment and values of patients, as well as the patient satisfaction related to the care they receive. Evaluated health status is assessed by number of decayed, filled, or missing teeth and periodontal status. Perceived health status is associated with a general perspective of well-being, capturing the extent to which a person can live a functional, comfortable, and pain-free existence within society. Patient satisfaction describes how individuals feel about the access to care, communication with providers, technical care received, etc. This study uses disease-free duration to measure tooth health status and weighted tooth health status or quality-adjusted tooth health status to represent "evaluated health status" and 'perceived health status', respectively.

Oral Health Behavior

This model conceptualizes oral health behaviors (e.g., sealant use, other dental services utilization and oral hygiene practices) as intermediate constructs, which, in turn, influence oral health outcomes.[144] The use of health services is listed as an oral health behavior, parallel with personal health practices. The major aim of this study is to evaluate the cost effectiveness of sealants as applied in a general population and compare it with sealants applied according to caries risk of different children populations.

The utilization of oral health services can significantly affect the cost effectiveness of sealants. It has been shown that sealing mandibular teeth, especially among low dental care utilizers, is more cost-effective than maxillary teeth in high dental care utilizers.[3, 4, 10] The utilization of oral health services can be explained by many factors such as people's education, attitude to health care, residence location, or availability of oral health providers. The 1994 Workshop on Guidelines for Sealant Use recommended that, for each community, utilization of dental care and access to dental care should be considered when assessing caries risk and prioritizing populations for sealant delivery.[5]

Individual oral health practices affect one's oral health.[144] These behavioral variables include sugar intake, tooth brushing frequency, etc. Their roles in the caries process are primarily local rather than systemic in that they influence the *mutans* and substrate level directly and caries risk indirectly through the effects of *mutans* on the substrate.[31] For example, investigations have shown a significant positive association between increased frequency of the intake of sticky, high-sugar foods and increased risk of caries.[31, 73] Frequent and correct tooth brushing reduces caries by mechanically removing plaque from tooth surfaces.[1] Studies also have shown that caries is associated with sugar consumption only when the oral hygiene is poor.[31, 75] In sum, individual health practices may have a combined effect on individual's risk of caries, the sealant's use may be more likely to be cost-effective for children with high risk, i.e., more frequent sugar intake and less frequent tooth brushing. Individual oral health practices are not observable in the dataset of this study.

Personal General Health and Biological Factors

Anderson's model does not include biological factors and personal general health status. The reason could be that his model focuses on the effect of people's health behavior on the health outcome. However, those factors are included in this model because biological factors such as *mutans* level have been shown to be the important predictors of caries risk.[31, 41-44]

Some immune system diseases can affect saliva secretion and increase the risk of caries. For example, in spite of the more regular oral health care practices than the general population, patients with primary Sjogren syndrome (PSS) experience more dental caries, have more teeth extracted, and have more radical dental treatment and higher dental care expenses.[145]

General medical factors, like the long-term use of sugar-included medications by children, increase caries activity, because sugar consumption may increase *mutans* level.[54] Many other medications, especially psycho-pharmaceutical products, that reduce the flow of saliva may also increase caries risk.[55] Radiation therapy on head or neck also affects saliva secretion. Cytotoxic chemotherapy can disrupt the mineralization process of teeth and thus raise the caries prevalence.[1]

Tooth physiology and morphology is another critical risk factor for caries. A study showed more protective effect for second molars than for first molars: without sealant treatment, 40.1 percent of children had at least one first molar restored due to decay after five years, and 60.2 percent of children had at least one second molar restored.[9] Carlos and Gittelsohn reported that maxillary first molars had greater attack rates than mandibular first molars in schoolchildren. The onsets of caries in the same type of teeth on right and left sides of the mouth were reported to be similar by previous studies.[3]

Generally, biological factors are not available in insurance claim data, nor are they in this study, but including as many factors as possible will result in better prediction of outcomes. Sealant delivery may be more likely to be cost-effective for children with biological factors for high caries risk.

Personal Demographics

Personal demographic factors, such as age and gender, would directly influence caries risk by influencing tooth development, as well as indirectly influence caries risk through their effects on behaviors and attitudes toward oral health.[31]

In Anderson's model, aging process leads to a transition in physical, social, and psychological status.[144] But for this sealant study conducted on a child population, age would be more related to teeth's eruption time and children's cooperation with sealant providers when sealants are applied. Epidemiological surveys found that newly erupted teeth are more susceptible to caries, particularly at pit and fissure sites.[1] The reason may be because the teeth's self-cleaning is difficult before they have reached the occlusal plane and the enamel is not entirely mature for new teeth.[1] Some people argue that the occlusal surfaces of molars usually decay within 3 or 4 years of eruption or not at all.[56] In other words, the teeth and age at high risk are first permanent molars of 6-9 year olds and second permanent molars of 12-15 year olds.[129] Sealant placement may be more likely to be cost-effective for first permanent molars in children aged 6-8 year olds.

Personal Social Structure

Personal social structure of this model includes ethnicity, education, family size, religion, etc. They mainly influence oral health behaviors which in turn influence oral health status and patient satisfaction.[31, 144]

Race/ethnicity may influence dental care utilization and outcome status through its close association with culture, values, attitudes, lifestyles, education, income level, religion, etc.[31, 144] For example, Mexican-American families and non-Hispanic black families often have low education level and low family income. The level of untreated dental caries among children from these families is found greater than for white children.[16, 24] The DS/DMFS ratio among Mexican-American (33.6%) and non-Hispanic black children and adolescents (35.9%) was also found to be higher than non-Hispanic white children and adolescents (19.3%).[24]

Education would increase patients' knowledge of diseases and health, and thus change their behaviors of seeking health care. For studies based on children whose health care decisions largely depend on parents, parental education level would be more relevant. It is found that a parental education system that stressed the benefits of early dental visits resulted in an increase in children seen for preventive services.[146] It is also found that the children were more likely to obtain dental sealants if their parents were knowledgeable about dental sealants or more highly educated.[147] Therefore, parental education is a risk factor for children's caries.

Family size and religion are components of social structure which may be related to dental health behaviors and caries risk. Big family size may cause less average enabling resource for each child member. Religion is associated with culture, values, attitudes, lifestyles, education, etc., and thus may affect health behaviors and oral health experience.

It is reasonable to believe that the cost effectiveness of sealant placement would vary based on the factors discussed above. Even if those factors should not used to prioritize sealant delivery, they still could be the focus of some public policy efforts. Therefore, the ethnicity and education level are used as control variables. Family size and religion information are not available in the data source of this study.

Family Enabling Resources

Family income may affect children's risk for caries through its influence on the access to care, diet, personal health habits, etc. This influence exists for children with or without health insurance, though to a different extent. The limited income and other resources of a poor family have to be spent on things with higher priority instead of preventive care, which often causes poorer health status. According to a CDC's report, poor children have nearly 12 times more restricted-activity days due to dental-related diseases than children from high-income households.[116] Fewer than 1 in 5 Medicaid-covered children receive at least one preventive dental service in the past year.[116] In another study on Medicaid children, sealant utilization rates were found to be particularly low in the group at high risk for dental decay.[3]

In Minnesota, although the Child and Teen Checkups (C&TC) program (the Early Periodic Screening, Diagnosis and Treatment (EPSDT) program of Minnesota) has been established for recipients of Medicaid and consist of education, outreach, and preventive health care visits to address access problems, many children covered by

Medicaid (Medical Assistance and MinnesotaCare) are not getting preventive care.[148] Low utilization of dental care puts poor children at higher risk for oral diseases. Therefore, family income is a risk factor for children's caries, and sealant delivery targeted at children from low-income families may be more likely to be cost-effective.

Insurance coverage of dental services not only influences personal health behaviors to seek dental care (demand), but it also influences dentists' decisions to provide dental care (supply). High co-payment would inhibit patients' access to dental care. Low reimbursement would discourage dentists from treating patients. However, the children who are enrolled in HealthPartners and also covered by the Medicaid program are entitled to comprehensive dental services. Sealant placement has been 100% covered by the comprehensive coverage. The insurance payment type is used as a control factor in this study.

Parental/Personal Health Knowledge and Beliefs

Parental health beliefs, attitudes and knowledge of dental diseases and dental care services are often influenced by the cultural values and may have a significant impact on children's oral health outcomes.[144] This impact can be reflected in eating habits and regular oral hygiene using a fluoridated dentifrice, which changes the caries incidence.[1] Parental health knowledge and beliefs also influence children's behaviors to seek dental health services, which in turn may directly influence caries risk.[31] It is found that the children are more likely to receive dental sealants if their parents have knowledge about dental sealants.[147] These arguments are supported by the theory of planned behavior: attitudes form intentions and the intentions drive health behaviors.[149]

Since the sealant application can not be performed based on parental health beliefs alone, parental health beliefs would not be the variable of interest in this study. It may be used as a control variable. There is no direct measurement for health beliefs in the data source. Parental preventive care utilization would be used as the proxy.

External Environment

Environmental factors affect people's oral health status within the community and are often "the primary concern and responsibility of local and state public health agencies".[144]

Water fluoridation has been proven effective in preventing dental caries regardless of race/ethnicity, age, education, or socioeconomic status.[144] The prevalence of water fluoridation affects caries activity within the community. In Minnesota, public water systems provide drinking water for approximately 75% of Minnesotans, and more than 98% of the population on these water supplies receive fluoridated water.[150] The remaining 25% of the state's population live on water from private wells which may or may not have sufficient natural fluoride to prevent caries.[151] The insufficient use of fluoridated watering would cause a higher incidence of caries. Therefore, sealant delivery might be more cost-effective for children living in the communities without optimal water fluoridation. Most of the children in this study lives in urban areas, mainly the metropolitan area, and receives fluoridated water. The effectiveness of water fluoridation is not observable in this study.

In addition, geographical barriers to dental care also exist. Rural areas face a number of unique challenges that limit access to dental services for their residents.[84]

These challenges include geographic and transportation barriers, fewer fluoridated community water supplies, shortage of dental care providers and a lower rate of dental insurance.[84] Therefore, children living in rural areas have less access to and utilization of dental care services compared to children living in urban areas.[80]

Dental Care Delivery System

The dental care delivery system includes policies, resources, organization, providers and financial arrangements. It affects the individual's caries experience by influencing the accessibility, availability, acceptability, and convenience of dental care services.[144] For example, a safety net or comprehensive dental services provided by State Health Department can increase the utilization of dental care for low-income, uninsured, and Medicaid-eligible population.[144]

A dentist's academic and continuing education, specialty, working experience, knowledge of preventive measures, and the use of modern techniques can also influence the choice of prevention and treatment.[152] Parents are more likely to obtain sealants for their children if dental care providers recommended them.[147] The procedural guidelines adopted by clinics also may affect the treatment decisions made by dentists. Because patients may go to different clinics and get treatments from different providers, the effect of dental care delivery system should not be evaluated based on a specific dentist or clinic. However, the information of providers and clinics for a single dental care service such as sealant operation is available. Since clinics and providers impact patients' health outcomes only though the preventive cares or treatments received by a patient, the characteristics of those clinics and providers could be used as instrumental variables in the data analysis, and that will be discussed in the later section.

A caries is not the consequence of a single event (as is a classic infectious disease, for example) but is rather a sequel to a series of processes happening over a long period of time.[1] These processes involve multiple known and unknown risk factors related to outcomes. The parameters of conceptual models used in healthcare CEAs often are difficult to specify accurately due to the lack of outcomes-based clinical trials at the introduction of new treatments.[1] Although numerous dental health studies have been conducted to determine caries risk factors and their effects (as discussed in review section), the evidence still is incomplete or contradictory. This dearth of knowledge should be accommodated by the analytic model and methods. The model in this study allows the presence of unknown factors and relationships. For example, personal demographic and socioeconomic characteristics can influence health behavior and thus influence outcomes. But they also may affect outcomes through some unknown paths which are reflected by the arrows from these factors directly to outcomes. The v and u represent sets of unknown risk factors which could affect the choice for dental care interventions and/or dental health. These unknown factors may have correlations which are shown by dotted arrows between v and u. These unknown factors and relationships can cause selection bias. This study will try to deal with this problem in the analysis section.

3.2. Data Sources and Inclusion/Exclusion Criteria

3.2.1. Data from HealthPartners Dental Electrical Data System

The data sets which are used in this study come from a sample of children and adolescents who were aged 6 to 17 during 1997 to 2001 and had been enrolled in the Minnesota-based HealthPartners HMO between January 1997 and December 2006. HealthPartners (HP) provides dental services through a staff model dental group, and all related data for dental services are stored in their dental electronic data system, which collects dental data generated from 1994 to present. Each member, either child or adult, has a unique policy number. All services received by the same person through his enrollment period can be linked through the policy number. HealthPartners' dental group (HPDG) not only treats their own enrollees, but also treats patients who are covered by other insurance plans. It provides dental services to Medicaid enrollees under a contract with the Minnesota Department of Health and Human Services. Generally, sealant placement is 100% covered for children enrollees by both HealthPartners dental benefit and Medicaid dental benefit, but only once in the lifetime of each tooth. The data used in this study consists of three parts: (1) Healthpartners' enrollment data from 1997 to 2006, (2) HealthPartners' dental encounter (visit) data from 1994 to 2006, (3) HealthPartners' clinic and providers' information file. The Institutional Review Boards of HPRF (HealthPartners Research Foundation) approved the study.

Enrollment Data

The enrollment files are used to determine the subjects who were 6 to 17 years old during 1997 to 2001. The enrollment records have been linked to encounter data across study years by the unique HealthPartners policy number. To keep confidentiality, each policy number has been converted to a new subject identification number (SID). Only the SID will be used in data analyses. The variables in the enrollment file include the SID, birth date, gender, ethnicity, address including zip code, and the time period in which the subject is enrolled in HealthPartners plan. Children's enrollment file have been linked, using a unique policy number, to their parents' enrollment (if it depends on only the father, then the mother's information is missing).

Dental Encounter Data

Though claims data are available in HealthPartners' data system, they are not used in this study, because claims data often have missing tooth numbers or tooth numbers that are not matched with procedure codes. Instead, the dental encounter data will be used. They include the policy number, chart number, visit date, tooth number, tooth surface, dental procedure code (CPT), diagnosis code, etc. The chart number has been converted to SID which links claim data to enrollment data. The procedure codes used in HealthPartners' claim system were converted to standard procedure codes based on the 1999 American Dental Association Codes on Dental Procedures and Nomenclature. Only visits recorded between 1994 and 2006 are included in the study. Only visit records that include tooth numbers specifically used for permanent posterior teeth and corresponding procedure codes are used in analyses. Those visits with procedures delivered only to primary teeth or procedures for non-caries treatment, such as periodontal treatments (procedure code 7970 and 7971), are excluded.

HealthPartners' dental caries risk assessment records are a unique component of dental encounter data. This caries risk assessment system has been applied in HealthPartners dental group since 1996. The criteria used for the mixed dentition age patient population (i.e. children) consist of items which have been proved or accepted as predictors of future caries. For example, among these items, ‘0 caries in last 3 years’ indicates ‘low risk’; ‘1-2 caries in last 3 years’, ‘cariogenic dietary practice’ and ‘active orthodontic treatment’ indicate ‘moderate risk’; ‘3 caries in last 3 years’, ‘suboptimal fluoride’, and ‘med/physically compromised’ indicate ‘high risk’, etc.

The caries risk assessment gives recommendations for risk assessment and risk reduction strategies such as whether sealants should be applied to the pits and fissures of some teeth. The recommendation for low risk children is to apply sealants only if the anatomy of the pits and fissures is deemed to be highly susceptible. This decision is left to the discretion of the dentist and children’s parents. Over 95% of children seen by the dentist receive a caries risk assessment score.

Caries risk assessment records are available for every child in this study sample from 1997 to 2001. In previous observational studies, subjects were not assigned randomly, and dentists’ clinical criteria for selecting children for sealants or chidren’s health status were unknown, which could result in biased estimations in either direction.[3] If low-risk teeth are sealed disproportionably, cost-effectiveness could be overestimated, and if high-risk teeth are sealed, cost-effectiveness could be underestimated.[153] Unlike other studies, the clinical oral health status of a child in this study not only was known to dentists at the time the dentist made a recommendation to seal or not, it also was partially recorded as the risk level.

Clinic Setting and Provider Information

HealthPartners has information about all its dental clinic settings and dental service providers. The clinic information includes location and the number of dentists, hygienists, and dental assistants. Dentists' gender, age, specialty and working years are stored in the record. Each dentist has been assigned an identification number that appears on each encounter record. Based on this number, the amount of a specific operation such as sealant placement a dentist conducts or delegates to a hygienist or dental assistant can be calculated.

Advantages of HealthPartners' Dental Data Sets

There were a few previous studies using insurance data to assess retrospectively outcomes of sealants provided under real-life situations.[3, 8, 9, 139] Three of them used state Medicaid data[3, 9, 139] and one used private insurance data.[8] All those studies relied on claims data to generate outcome and cost information. In comparison, the advantages of HealthPartners' dental data set used in this study include:

(1). It has a relatively large sample and the long observation period.

(2). It contains dental clinic encounter data instead of claims data and, thus, includes more complete records for the tooth being treated, treatment procedure and cost information.

(3). Caries risk evaluation is conducted for enrollees on regular basis, and data are available and linkable to the encounter data. Recommendation for sealant use is recorded.

(4). The database includes services for which dentists did not submit claims, especially those that are not reimbursable (e.g., resealing a tooth).

(5). It has some information about dental care providers and clinics, offering more variables to control confounding effects and creating more instrumental variable candidates.

3.2.2. Clinical Background and Inclusion/Exclusion Criteria

This study focuses on the cost-effectiveness of sealant placement on the first permanent molars (FPMs). Age 6 is the time FPMs start to erupt.[3, 154] FPMs are exposed to risk for caries after they erupt. Based on a study, the mean eruption time of the first permanent molars for girls is 6.1 years, and it is 6.3 years for boys. The mean duration of eruption is 15.4 moths for girls and 15 months for boys.[154] Observation started with 6 years olds would capture at least 68% of all first permanent molars prior to their eruption ages.[3] Besides, one study found a temporal lag before eruption time and sealant placement.[8] Based on that study, less than 5 percent of individuals in sealant group actually received the sealant at the age of 5.[8] Therefore, age 6 can be used as the earliest start point for observation.

Dental sealants represent a preventive care in dentistry. They often are used on teeth which fully erupt. Most of time, sealants are used on healthy teeth to prevent caries. In rare cases, they are used on teeth with caries in early stage. When sealants are applied on incipient caries, they often are coded differently from those on healthy teeth in HPDG. It is thus reasonable to assume in this study that there are no caries on the teeth before their first sealants.

There are a few more factors which have to be taken into consideration before setting the inclusion criteria: (1) it is believed that age 6 to 8 is a good age for sealant placement, but sealant placements often can be found in children of any age; (2) each individual has 4 FPMs and hence could have 0 to 4 FPMs sealed; (3) sealants in a mouth may not be placed on the same position, at the same day or at the same age; (4) dental encounter data should be relatively complete, including necessary information about use of dental services and expenditure within study period; (5) it is unlikely to determine whether any sealant was applied on any permanent molar in an outside clinic before a child was enrolled into the HealthPartners' dental plan. This study observed children for minimum period of five years. Considering the above factors, only children who were aged 6 to 17 years old during 1997 to 2001 and enrolled in HealthPartners' comprehensive dental plan for at the least 5 years were included.

All children should have at the least one risk assessment record at the beginning of their 5-year observational time period. Based on data from the HPDG, more than 90% of children go for a preventive visit at the least one time every two years. Therefore, this criterion is unlikely to exclude many subjects.

Table 3-1. Variables Used for Including or Excluding Subjects

Variable	Description	Sources	Variable code	Range of values
Birthday	Birthday	Enrollment data	BIRTH	Date
First day of enrollment	The first day when a subject is enrolled in HP dental benefit	Enrollment data	ENRF	Date
Enrollment length	Total number of months a subject is enrolled in HP dental benefit within the observation period	Enrollment data	ENRL	>0
Enrollment continuity	Total number of enrollment disconnections after age 6.	Enrollment data	ENRL	>0
Comp-cov	Whether a subject has comprehensive coverage within the observation period	Enrollment data	COVER	Yes or no
Tooth ID	Tooth ID	Encounter Data	TID	Integer (3,14,19,30)
Seal-apply-date	The date of sealant application	Encounter data	DATESEA	Date

3.2.3. Sample Cohorts

The original dataset included 44,250 children who were aged 6-18. One full year of continuous enrollment in HealthPartners Dental Group (HPDG) comprehensive coverage was assumed if a child had 10+ months of the coverage in any calendar year. Since the number of enrollment months was available only in the data from 1997 to 2006, the observation period has to be any 5-year period during 1997 to 2006. The entry period was from 1997 to 2001, so the start point could be any time in 1997 to 2001, and the ending point could be any time in 2002 to 2006. Any sealant or restoration procedure received in a clinic outside of HealthPartners is unknown. However, since HealthPartners' coverage requires more out-of-pocket expense for procedures done in outside clinics, and dental restorations usually are not urgent operations, it is reasonable to assume patients take all restoration procedures from HealthParners' own clinics. The final sample has 5 cohorts for each group, as shown in the following table. Each cohort includes children at age 6 to age 17. For example, if a tooth is sealed at age 7 in 1998, its observation period ends in 2003. It belongs to the cohort 2 sealant group. Similarly, if a tooth has no any restoration record, and if its earliest assessment, during 1997 to 2005, is in 1998, it belongs to the cohort 2 non-sealant group, and its observation period ends in 2003.

Table 3-2. Sampling Cohorts

Cohorts for sealant group	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006
1	AS									
2	A	S								
3		A	S							
4				AS						
5				A	S					
Cohorts for non-sealant group										
1	A									
2		A								
3			A							
4				A						
5					A					

This study used birthdays corresponding to sealant placement dates or risk assessment dates as the starting days, or the starting points, for both sealant and non-sealant groups. Sixth birthdays were used in some previous studies or designs. This study used more than just the sixth birthday. For example, for a sealant case in cohort 2 which had sealant in 1998 and entered the observation at age 9, its start point will be 9^{th} birthday. Similarly, for a non-sealant case in cohort 2 which had the early assessment in 1998 and entered the observation at age 9, its start point will be 9^{th} birthday too. If the children in sealant group and non-sealant group have the same cohort number and same age, then their starting days would be the same birthdays. The final sample included age groups from age 6 to age 17. Using more than one of the age group, this study is able to evaluate not only the cost-effectiveness difference between applying and not applying sealants on the first permanent molars in children at the same age, but also the difference between different age groups.

3.3. Data Analysis

The unit of analysis for this study is the individual person, more specifically, individual child or adolescent. Any person has four first permanent molars, but not all 4 FPMs in each child were included, based on the inclusion criteria. In other words, for some children, only one, two, or three FPMs were included. The effectiveness and cost thus are average measures on a molar basis. In this section, dependent and independent variables are described, and related calculations are formulated. The analytical models for cost and effectiveness evaluation are established, using selection-correction techniques. The methods to calculate incremental cost-effectiveness ratios and the confidence intervals are described.

3.3.1. Variable Descriptions

3.3.1.1. Outcomes Measurement (Dependent Variables)

Duration

The first effectiveness measurement for dental sealants is the duration for which a tooth stays healthy, i.e., the caries-free duration, for a FPM over the whole 5-year study period. Most of previous sealant studies used incremental number of decayed teeth or surfaces or DMFS index as the measurement of sealant effectiveness. Those measurements cannot reflect the gain due to the decrease of caries-free duration within a certain period. Obviously, the later a caries happens, the better the outcome would be for a tooth. Therefore, the duration of caries-free state of a tooth would be a more appropriate effectiveness measurement.

It is difficult to know the exact time when a carious lesion starts. Dental caries starts with demineralization of dental hard tissues and develops from initial lesions in enamel to dentinal lesions which can ultimately expose the pulp.[1] The whole process may take a long time without being noticed. There have been no universally accepted standards for caries diagnosis.[1] As matter of fact, there is no way to know when a caries initiates. Like previous studies, this study relies on restoration codes in claim data to detect when a caries appears. The resulting outcome measurement was actually the restoration-free duration. Of course, the early diagnosis may be associated with dental service utilization which is related to the patients' behavior of seeking health care. The preventive care utilization level (defined in section 3.3.1.2) was used as a control variable in the analysis. The treatment procedures used to identify caries included restorative treatments (all the one-surface amalgam and composite restorations, procedure codes 2140 and 2385, all the two-surface amalgam and composite restorations, procedure codes 2150 and 2386, and all of the three-surface amalgam and composite restorations, procedure codes 2160 and 2387), crowns (procedure codes 2931 and 2932), pulp or root canal treatments (procedure codes 3220 and 3330), and extractions (procedure codes 7110, 7120, and 7130).[3] The detailed list of the procedures can be found in Appendix A.

The maximum caries-free duration is 60 months or 5 years, because the maximum observation period in this study is 5 years. It is expected that some teeth remained healthy at the end of the whole study period. Those are called right-censored cases. They required specific methodology in data analysis.

Quality-adjusted tooth year

Another effectiveness measurement for dental sealants is quality-adjusted caries-free duration. Conceptually, it is like a measure for the tooth utility in the sense that an individual tooth also has a complete life cycle. However, unlike the quality-adjusted life years (QALY) which were widely accepted to evaluate people's well being or satisfaction in general cost-utility analyses, "quality-adjusted tooth year" (QATY) still is a term which is harder for cost-effectiveness researchers to adopt as a utility measurement, probably because of their belief that a tooth is only a very small fraction of a person's general health status. Therefore, this study only uses quality-adjusted caries-free duration to reflect both the health status (or caries severity) and the duration associated with that status for a single tooth, and uses quality-adjusted cost-effectiveness analysis instead of cost-utility analysis.

Using quality-adjusted caries-free duration to conduct the analysis could have some advantages over using other measurements such as caries-free duration. First, it can reflect the severity of caries when caries are observed for the first time, which would be unobserved otherwise. For example, if two teeth are found decayed at the same year, the one which is less harmed still can maintain the eating function, but another one which is more harmed may need to be extracted. The utility of these two teeth obviously are different. Second, using QATY can reflect more accurately the timelines with which a caries is observed and filled, as well as the timelines with which a tooth is extracted and the end point of the study. In contrast, the information about the caries severity and the tooth condition between the time it is found decayed and the end of study period would be lost in duration measurement. It is not hard to imagine that new carious lesions would be found earlier in a high service utilizer than in a low service utilizer.[3] That results in worse outcomes for high service utilizers if duration is used as the only outcome measurement. It is reasonable to assume the outcome after the initial caries treatment is related closely to the severity of the damage at the time when the caries was discovered. The duration measurement can not reflect the outcome across the whole study period, particularly at the end of the study period.

There has been no universal definition of quality of life in dental health care. A few investigators have tried to establish utility measurement for tooth health.[3, 155-157] Birch suggested that effectiveness be measured in additional years of tooth life adjusted for the quality of the tooth: a missing or extracted tooth has 0 QATY each year and a healthy tooth yields 1 QATY each year.[158] Fyffe and Kay conducted interviews on a group of dentists and a group of lay people to assess the average 'utility' values for four different tooth states of posterior teeth, using the standard gamble technique.[155] The average 'utility' values for those four tooth stages are displayed in Table 3-3. It was found that the dentists gave higher 'utility' values than lay people did. Those values have been modified or directly applied in several outcome studies or cost-effectiveness studies in oral health care.[3, 156, 157 159]

Table 3-3. Average 'Utility' Values for Four Tooth States

Tooth State	Average utility values of sample of the general public*	Average utility values of sample of dentists*
Decayed and painful posterior tooth	0.46	0.57
Decayed and non-painful posterior tooth	0.51	0.81
Filled posterior tooth, filling needs replacing	0.69	0.87
Filled posterior tooth	0.72	0.90

* Based on Fyfee and Kay, 1992

This study used the idea from Bhuridej to measure tooth quality.[3] Bhuridej used the term 'utility' and assesses tooth 'utility' in 4 intervals for 4-year observation period. For teeth entering an interval and surviving without any treatments until the end of that interval, they were assigned a tooth-year equal to 1. For teeth extracted during an interval, their tooth-year in that interval is 0. Bhuridej argued that, from a societal perspective, the tooth-years in each interval should be weighted by the average 'utilities' valued by both dentists and lay people in the study by Fyffe and Kay. Therefore a restored, crowned, or root canal treated tooth was assigned a quality-adjusted tooth-year (QATY) equal to 0.81 in the year that it was restored and before it is extracted.

Similarly, this study uses quality index 1, 0 and 0.81 for a sound tooth, an extracted tooth and a restored tooth, respectively. If the health status is changed in the middle of a year, the QATY value for that year is the sum of two separate QATY values (before and after the change) multiplied by corresponding time ratio scale, the number of months in a year divided by 12 months for a certain health status. The maximum QATY for each tooth is 5, because the observation period in this study is 5 years. Since some FPMs stayed healthy at the end of the whole study period, these right-censored cases require specific methodology in data analyses.

Cost

Total cost in this analysis is the sum of all charges generated by sealant placements, sealant repairs, and all caries-related treatments for each individual over the 5-year observation period.

Prices or charges set by medical service providers often are taken as the cost of the services even though they may not coincide with the actual resource cost. The advantage of using charge records is that the charges are well-itemized and readily available in datasets from insurance companies.[160] Gold et al. argue that, according to the economic theory, if the following assumptions hold: (1) the market is perfectly competitive for all goods and services; (2) there are no externalities and public goods in the market; (3) there are no distorting incentives such as insurance or subsidies, then "the prices in the marketplace fully reflect the opportunity cost of the marginal cost of producing the last unit of goods".[160] Even though these assumptions do not hold in the healthcare area, the prices or charges currently available in the market could be considered the best approximation of the true marginal costs of the services from a societal perspective.[3] Charges vary from place to place, or from time to time, for the same intervention or among patients for the same condition. A CEA also may yield different results depending on whether data on charge or data on payment are used.[3] Sensitivity analysis can be conducted to demonstrate the variation of cost effectiveness at various cost levels and test whether the conclusions are subject to the changes.

Discounting

Since the costs are generated in different time points during the whole 5-year period, they should be discounted. Generally, people prefer to have the goods and services now rather than some years later, considering risks associated with delay. Discounting is a technique used in CEA to adjust a future cost or benefit to be comparable to an indicated base year.[160, 161] In economic theory, the basis for discounting in CEAs is due to opportunity cost of capital. Not many dental studies reported adjustments for costs and consequences of dental interventions at different times.[162, 163] Antczak-Bouckoms et al. adopted a 5% discount rate for costs and 7% for tooth-years.[164] Morgan et al. adopted a discount rate of 0% to 10% in their CEA of a sealant program in Australia.[135] Weintraub et al. used a 5% discount rate and a 0% discount rate in their two CEAs of dental sealants, respectively.[22, 139] This study uses the first year of the observation period as the base year. The discount rate used for major comparisons and ICER calculation is 3%, and varies from 0% to 5% in sensitivity analysis.

Discounting healthcare effectiveness is more controversial than discounting costs. It has been suggested that future quality adjusted life years (QALYs) should be discounted relative to present QALYs, since the latter are generally seen more valuable by people.[160] In addition, it is reasonable to discount effectiveness if the future cost is discounted relative to the present value.[160, 164] Discount rates for effectiveness and cost can be the same or different.[160] This study uses the same base year and 3% discount rate as those for cost discounting. Zero percent and 5% are used in sensitivity analysis.

Let FE be the future effectiveness in a certain year, and BE the base year effectiveness. Let the FC be the future total cost within a certain year, and BC the cost in the base year. If the base year is the year 1 and the BE or BC are collected on the Nth year, the following formula are used to calculate the discounted effectiveness and cost for a specific year in future, respectively:

$$BE = FE * \frac{1}{(1+R)^{N-1}} \quad \text{and} \quad BC = FC * \frac{1}{(1+R)^{N-1}}$$

where R is the discount rate per year. Adding all discounted effectiveness or costs for each time interval or year can yield the total discounted effectiveness or costs for the whole study period. Table 3-4 summarizes the definitions and sources of the dependent variables.

Table 3-4. Dependent Variables Definition and Sources

Dependent Variable	Definition and/or measurement	Sources	Variable code	Range of values
Caries-free Duration	Average discounted caries-free durations over 5-year observation period per FPM for an individual.	Encounter data	Monsum	0<DUR<=60 months
QATY	Average discounted quality-adjusted caries-free durations over 5-year observation period per FPM for an individual.	Encounter data	QATY	0<QATY<=60 months
Cost	Average discounted cost generated by sealant placement/replacement and caries-related treatments over 5-year observation period per FPM for an individual.	Encounter data	COST	>=0

3.3.1.2. Independent Variables and Control Variables

Table 3-5 summarizes the definitions and sources of the independent variables. For convenience in linking variables to the corresponding methodological models, this table lists variables for sealant placement and variables for outcomes separately.

Table 3-5. Identification and Independent Variables' Definition and Sources

Independent Variable	Definition or measurement	Sources	Variable code	Range of values
Identification variables				
Person ID	Person ID	Enrollment data	StudyID	String
Tooth ID	Tooth ID	Encounter data	TID	String
Dentist ID	The ID of the dentist who placed sealant	Provider level data	DID	String

Clinic ID	The ID of the clinic where the sealant was placed	Clinic level data	CID	String
Independent variables for sealant placement				
Age	Age of a child at the beginning of study period	Enrollment data	Agestart	6-18
Gender	Gender of a child subject	Enrollment data	Gender	M, F
Race	Race	Enrollment data	Race_7	1 for White, 2 for non-White, 0 for unknown
Living area	Based on residence address of a child subject	Enrollment data & Census 2000 data	Geo_area	More urban, less urban
Income	Median family income obtained by merging geocodes with the Census 2000 data	Enrollment data & Census 2000 data	Income	>= 0
Poverty status	Families below poverty level (% of the FPL)	Enrollment data & Census 2000 data	Bpoverty1	0 – 100%
Education	Population aged >= 25 with at the least high school education (%)	Enrollment data & Census 2000 data	Sch12y1	0 – 100%
Coverage by public program	The number of months when a child's dental coverage is provided through public program, each year	Enrollment data	Pubindex	0 - 10
Caries history	The number of caries in the last 3 years	Caries risk assessment	History	0 - 5
Caries risk level	Caries risk level evaluated at the time nearest to the beginning of study period	Caries risk assessment	Risk	low=R80.1, moderate=R80.2 high=R80.3
Clinic use of fluoride	The number of clinical fluoride applications within 5-yrear observation.	Encounter data	Fluo	1 - 15

Preventive service utilization	How often a child takes preventive dental service each year	Encounter data	Uti	1 - 15
Space	Whether got treatments for space maintenance or other active orthodontics procedures	Encounter data	Space	1 for yes, 0 for no
Cohort	In which cohort in the sample an individual was included	Enrollment data	Cohort	97, 98, 99, 00, 01
Possible instrumental variables for sealant placement				
Dentist gender	Gender of provider who did risk assessments	Provider level data	Provider_gendrisk	F, M
Dentist age	The age of the dentist who did risk assessment at the beginning of study period	Provider level data	Provider_agerisk1	>0
Dentist working year	The number of the total practice years of the dentist who did risk assessment at the beginning of study period	Provider level data	Working_exprisk1	>=0
Working year in HP	The number of HP practice years of the dentist who did risk assessment at the beginning of study period	Provider level data	HP_exprisk1	>=0
Dentist propensity for sealant	The ratio of sealant recommendations made by the dentist who did risk assessment to all recommendation for	Provider level data	Provider_prrisk1,	0<PRPST<1
Distance between Residence and clinic	Estimated distance between a patient's residence and the clinic where the risk assessment was done	Enrollment and clinical level data	DIST1	>=0
Months when the risk assessment was done	Months when the risk assessment was done	Encounter data	Monriskgp	1 for month 4,5,6,11,12,1; 0 for other months

Independent variables for outcomes				
Sealant placement	Whether a sealant was placed	Encounter data	Intervention	0 for non-sealant, 1 for sealant
Gender	Gender of a child subject	Enrollment data	Gender	M, F
Race	Race	Enrollment data	Race_7	1 for White, 2 for non-White, 0 for unknown
Living area	Based on residence address of a child subject	Enrollment data & Census 2000 data	Geo_area	More urban, less urban
Income	Median family income obtained by merging geocodes with the Census 2000 data	Enrollment data & Census 2000 data	Income	>= 0
Poverty status	Families below poverty level (% of the FPL)	Enrollment data & Census 2000 data	Bpoverty1	0 – 100%
Education	Population aged >= 25 with at the least high school education (%)	Enrollment data & Census 2000 data	Sch12y1	0 – 100%
Coverage by public program	The number of months when a child's dental coverage is provided through public program in each year	Enrollment data	Pubindex	0 - 10
Caries history	The number of caries in the last 3 years	Caries risk assessment	History	0 - 5
Caries risk level	Caries risk level evaluated at the time nearest to the beginning of study period	Caries risk assessment	Risk	low=R80.1, moderate=R80.2 high=R80.3
Clinic use of fluoride	The number of clinical fluoride applications within 5-yrear observation.	Encounter data	Fluo	1 - 15
Preventive service utilization	How often a child takes preventive dental service each year	Encounter data	Uti	1 - 15

Space	Whether got treatments for space maintenance or other active orthodontics procedures	Encounter data	Space	1 for yes, 0 for no
Cohort	In which cohort in the sample an individual was included	Enrollment data	Cohort	97, 98, 99, 00, 01

Age

Age of a child in each year is determined by his/her birth date. For example, a child born on August 1, 2000 is considered to be 6 years old on August 1, 2006 for this analysis. The variable AGEG is used to indicate two age groups. One age group includes the tooth eruption year and the next two years, which is assumed to be the target ages for sealant placement. Another age group includes the ages older than the first group but younger than 18 years old. For FPMs, the molars of interest in this study, two age groups (6-8 years and 9-17 years) are used. Further analysis based on age subgroups and corresponding ICER will be reported in the results chapter.

Living area, income, education and geocodes (geographic code)

The residence of every child subject is converted into a geocode, a code used to identify a specific geographic entity, a block group in this study. The geocodes are used to identify the living location categories, such as the percentage of residents living in urban areas, by merging with the Census 2000 data. The average income family level and education level for each geographic entity are obtained using the same method. Each person's poverty status is measured as the percentage of residents living below the federal poverty line (FPL) in that person's block group. FPL is established annually by the U.S. Bureau of the Census and adjusted by family composition and the age of the family reference person.[17]

Preventive care utilization

Preventive care utilization is used to measure healthcare-seeking behavior, and it categorizes children into “high utilizer” group and “low utilizer” group of dental services. To be considered a 'high utilizer', a child should have more than one dental preventive visit every year within the study period. Children receiving one or less preventive visits per year on average are considered a “low utilizer”. In this study, a preventive visit is defined as a periodic oral evaluation (D0120) or a dental prophylaxis (D1110 or D1120). Comprehensive oral evaluation (D0150) was used by some previous studies, but it is applied more to new patients in clinics of HPDG.. Other preventive procedures listed in ADA’s CDT 2007-2008, such as topical fluoride treatment, sealant and space maintenance, are represented by separate variables in the above table.

Geocodes and the distances between residences and clinics

The location of each clinic is geocoded. The latitude and longitude of a subject’s residence and each clinic are used to estimate the ‘real-life’ distance between the residence and the clinic where the early risk assessment is conducted. Unlike the traditional method of using the clinic nearest to the residence, this study uses the clinic where the early risk assessment is conducted, not only because the latter is linked to the decision model discussed in a later section, but also because the observation and data all find that more than 90% of time the clinic where the early risk assessment is conducted and the clinic where sealant is placed are consistent. The formula used for the distance calculation is:

$$Dist=1.15*arcos(sin(lat1)*sin(lat2)+cos(lat1)*cos(lat2)*cos(long2-long1))$$

where "Dist" stands for distance in meters. "Lat1", "lat2", "long1" and "long2" are in radians. Degrees are converted into radians by multiplying degrees by cos(-1)/180.[165, 166] This formula only estimates only the distance between the two points. These two points are assumed to be on the same altitude levels. The traffic path or the real travel distance generally is longer than this estimation.

Dentist's preference to seal

Robison et al. created a variable to reflect dentist's propensity to seal, which was calculated as the percentage of the total number of dental procedures which were sealants.[153] He argued that dentist's propensity to seal affects the likelihood a patient receives sealant.[153] This study uses preference, instead of propensity, to avoid some possible conceptual confusion. Considering that some sealants are place by hygienists or dental assistants in real practice, this study calculates dentists' preference to seal as the percentage of the total number of recommended preventive procedures which were sealants. The percentage used by Robinson could be used as an alternative measure. In Robison's study, this variable, for sealant group, was calculated for the dentists who applied the sealants, and for non-sealant group, this variable was calculated for the dentists at the first dental visit within the study period.[153] In this study, this variable is calculated for all dentists who conducted the early risk assessment for the children in this study.

3.3.2. Descriptive Analysis and Univariate Analysis

Descriptive analyses and univariate analyses of sample children's characteristics, the pattern of dental service utilization including sealant placement, as well as the caries risk distribution among the sample population are conducted. To explore possible self-selection problem caused by non-randomization of sealants, t-test and Chi-square test are used to compare characteristics of children with and without sealants regarding gender, ethnicity, residential areas, family income level, and number of preventive visits, at an alpha level of 0.05. The group average cost and effectiveness for sealant group and non-sealant group and their differences are examined.

3.3.3. Cost-Effectiveness Analysis

According to Gold et al., economic evaluation techniques include cost-minimization analysis (CMA), cost-consequence analysis (CCA), cost-benefit analysis (CBA), and cost-effectiveness analysis (CEA).[160] Among them, CEA may be the most common economic evaluation in healthcare studies, because health effectiveness data are often difficult to convert to dollar value for CBA. CEA compares costs per unit of intermediate outcomes of interventions or programs.[160] To do so, the incremental cost-effective ratio (ICER) has been widely used and reported in most CEAs. The ICER is essentially the incremental cost of obtaining a unit health effect (such as one dollar per life year if the duration is used as the effectiveness) from a given health intervention when compared with an alternative.[160] It can be calculated using the following equation:

$$ICER = \frac{C_1 - C_0}{E_1 - E_0}$$

If the above ratio is below society's willingness to pay for an additional unit of effectiveness, the intervention 1, or the more costly and more effective intervention, is considered cost-effective and preferred to intervention 0. According to Gold et al., "the basic core of any CEA is an incremental comparison of an intervention with a comparison program".[160] The term "incremental", rather than "marginal", is used to indicate that the comparison could be between a few discrete alternatives, not only between continuous changing strategies.[160]

According to Gold et al. and Drummond et al.,[160, 161] some considerations need to be clarified when conducting a CEA:

1) The definition of the problem and objectives of the CEA: As a widely used preventive dental procedure, dental sealants may be under-utilized or over-utilized. This study aims to study the cost and effectiveness of dental sealants applied to the general population and to the subpopulations at different caries risks.

2). The population to whom the results may apply: This study aims to study the cost-effectiveness of sealants placed on newly-erupted permanent molars. Therefore, the results of this CEA can be applied to school-age children and adolescents.

3). The alternative interventions to be compared: Placing sealant and not placing sealant.

4). The time horizon: 5 years.

5). The cost measurement and effectiveness measurement: The cost measurement is the amount of charges to the insurance company. The effectiveness measurement includes a direct clinical outcome measure, the disease-free duration, and a quality-adjusted measure quantified as QATYs.

6). The perspective to take: Because this study measures cost though charge information from the insurance company, and this insurance company operates as both a health care provider and a service payer, this study adopts both a provider's perspective and a payer perspective. Though a societal perspective is preferred for a CEA, it could not be adopted here due to the unavailability of indirect cost incurred to children in the data from the insurance company.

3.3.3.1. Basic Model for Effectiveness Evaluation

Analytic models have been used to establish the relationships among cost, effectiveness, intervention alternatives, and the other relevant factors, in previous studies.[167, 168] There are several advantages associated with using analytic models for CEA. First, the estimated results of the models can be used to derive ICER for intervention comparison in the general population and subgroup populations.[168] The ratio of the difference of cost and effectiveness values with respect to interventions, which is evaluated from cost and effectiveness functions, is the ICER of general population studies. The ICER for any subgroup of interest can be calculated either by substituting the subgroups' values of the independent variables into the functions[168] if the coefficients are assumed to be the similar among subpopulations, or by breaking the data set into smaller sub-samples and evaluating models individually if the coefficients are assumed to be different among subpopulations. Second, some observed risk factors can be included in the models, reducing the possible bias and increasing the precision in the estimate of the ICER. Third, with non-random intervention assignment, some specific methodologies can be used to minimize the estimation bias due to the possible existence of unobserved factors which may correlated with both intervention choice and outcome measurement.[168]

This study adopts linear functions to express the relationships between outcome measurements, interventions and other relevant risk factors, because (1) they have been used in CEA before,[167, 168] and (2) the ways to deal with self-selection problem are better established for various types of liner models. Of course, other functional forms could also be employed. The overall model for the effectiveness is:

$$\begin{aligned} \text{effectiveness} = {} & \beta_0 + \beta_1\text{sealant} + \beta_2\text{age} + \beta_3\text{gender} + \beta_4\text{ethnicity} + \beta_5\text{income} + \\ & \beta_6\text{edu} + \beta_7\text{poverty} + \beta_8\text{geoarea} + \beta_9\text{publicpay} + \beta_{10}\text{riskm} + \beta_{11}\text{riskh} \\ & + \beta_{12}\text{utilization} + \beta_{13}\text{history} + \beta_{14}\text{fluo} + \beta_{15}\text{space} + \beta_{16}\text{ortho} + \\ & \beta_{17}\text{cohort98} + \beta_{18}\text{cohort99} + \beta_{19}\text{cohort00} + \beta_{20}\text{cohort01} + \varepsilon \end{aligned}$$

The primary effectiveness variable is, alternatively, the average discounted caries-free duration or the average discounted QATY per FPM for each individual over 5-year study period. The primary intervention variable is sealant indicating whether a sealant was placed on a FPM or not. The unit of analysis is individual child.

Since the data for all subjects in this study were collected from a 5-year period, the maximum caries-free duration for any tooth is 5 years or 60 months. That causes a right-censoring problem. Because all subjects had been continuously enrolled, an effectiveness value is right-censored only when no caries-related treatment was taken within the whole observation period. In this study, a Tobit model is adopted to study effectiveness.

The standard Tobit model originally was developed to accommodate censoring in the dependent variable.[169] It is a well-known econometric regression model used in the presence of subjects for whom researchers do not observe the true response or dependent variable due to some upper or lower thresholds. By incorporating the variables and thresholds in this study, the basic model can be written as:

$Y^* = \Sigma X_n'\beta_n + \varepsilon$	$\varepsilon \sim N(0,\sigma^2)$
$Y = Y^*$	if $Y^* < 60$ months
$Y = 60$ months	otherwise

where X_n represent the intervention variable and a vector of other explanatory variables; Y^* is the unobserved continuous latent dependent variable for the true average caries-free duration; Y is the observed average caries-free duration, and $Y = \min(Y^*, 60$ months$)$. The dependent variable in Tobit model for effectiveness is right-censored. Because of the 5 year observation period, the maximum average caries-free duration should be 60 months. When 3% discount rate is applied, the maximum duration is 56.6 months.

The estimates of the parameters in the above model are biased and inconsistent if ordinary least squares (OLS) is used, because the assumption of $E(\varepsilon) = 0$ in OLS does not hold.[169] Tobit model uses maximum likelihood estimation (MLE) to produce consistent estimates of the parameters, under critical assumptions of homoscedasticity and normality of the error term.

3.3.3.2. Selectivity and Instrumental Variables

It has been believed that randomized clinical trials (RCTs) can generate unbiased and precise results on outcome evaluation and have a high internal validity. However, because an RCT often enrolls subjects with restricted inclusion/exclusion criteria and follows outcomes with short time period, data from an RCT may have a low degree of external validity, which limits its usefulness for economic evaluation.[160, 161] In contrast, retrospective observational cohort studies have advantages of inexpensively providing a sufficiently large sample population and a relatively long time period of observation.[160] In addition, grouping subjects into intervention and non-intervention groups based on real clinical decision making process is more generalizable to actual dental practice. But when analyzing observational data, researchers often have to face a self-selection problem, in which subjects receive interventions in a non-random way.

Self-selection problem in sealant study

Some evidences in dental health care support the existence of a self-selection problem. Kuthy et al. found that the sealant group may have a more positive attitude toward dental prevention.[8] Weintraub et al. found that children without sealants had a larger time interval between their two dental visits and more dental prophylaxis and fluoride treatment.[22] They also found that children who visited dentists more frequently for preventive care were more likely to receive sealants. Children receiving sealants also were more likely to be white and to have a family income greater than 33% of the FPL.[3] Clinical status differences were found between children who received sealants and those who did not. Robison et al. found that a child with no past caries experience was more likely to get sealant care than a child with past caries experience.[153] That would cause the overestimation of sealant effectiveness, because fewer subsequent restorations, independent of the effect of sealants, may be found in a child with no past caries experience.[3]

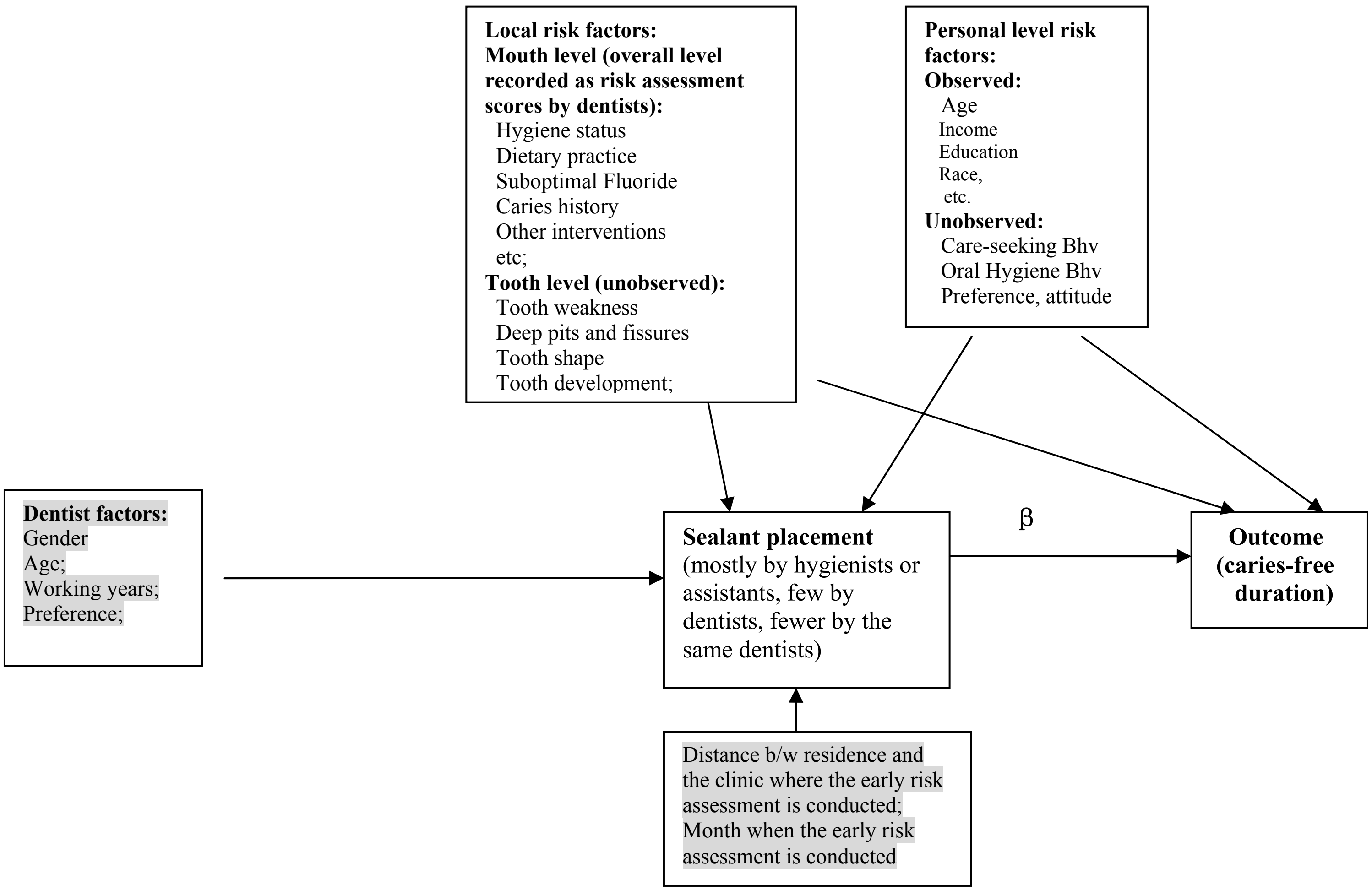
The above findings indicate an important methodological issue for CEAs of dental sealant based on observational data. Sealant possibly can be an endogenous intervention, meaning that it may be affected by many factors which also affect outcomes of sealant. A valid outcome can be derived only if all those factors or confounding variables are observed and well controlled. If there are some unobserved or missing factors that could influence or be influenced by both the intervention and the outcome, the residuals for observations with one intervention may not have the same mean as residuals for observations with another intervention. That is, the residuals are correlated with the intervention variable in the regression. This violates the usual regression assumption of independence between explanatory variables and error term. In that case the estimated coefficient for that intervention is biased.

Though many CEAs of dental sealant admitted the existence of self-selection, no one has ever tried to explore the existence of endogeneity and correct the estimation bias caused by endogeneity. This study is designed to try to overcome the self-selection problem not only through introducing additional important variables such as prior caries experience and service utilization, but also through the use of instrumental variables in statistical analysis.

Clinical decision making and a specific conceptual model for sealant placement

The instrumental variable (IV) methods have been more and more used in observational studies with large administrative datasets, such as Medicare claims data and private insurance claim data, to evaluate clinical or economic outcomes of various medical interventions.[170] However, they rarely are used in dental care studies. It is important to establish a conceptual model to display the relationships among outcome, intervention, and other influence factors, and explain the decision making process of the intervention, before an economic evaluation is conducted, especially if the economic evaluation involves self-selection and instrumental variable methodology. In section 3.1, a conceptual framework for studying dental care outcome is described. It posits that personal characteristics, external environment and the dental care delivery system influence oral health behaviors and outcome. The following figure is a simplified conceptual model which specifically displays the clinical decision making process of sealant placement. A few instrumental variable candidates are proposed.

Figure 3-2. The Simplified Conceptual Model Displaying the Possible Instrumental Variables



Dental sealant is preventive care. Generally, the decision to get a sealant is not made by either the patient side (children's parents in this study) or the dentists alone, and the sealant often is not placed on the same day when the decision is made. According to the investigation on dentists in HPDG, a sealant recommendation and placement may follow this procedure: a parent takes a child to see a dentist for a regular or periodic oral examination; the dentist performs the standard examination and caries risk assessment, and assigns a risk score to this child. At the same time, the dentist may think sealant placement would be good for this child and recommend a sealant to the parent; the recommendation may or may not be taken by the parent, and if it is taken, a sealant placement appointment needs to be made with a receptionist; then on the next visit, the child would receive one or more sealants on certain teeth from a hygienist, a dental assistant, or a dentist who may or may not be the same dentist conducting the risk assessment and recommending a sealant. It is possible that four teeth on the same position in a dental arch may get sealants at different visits. It is also possible that teeth in the same position in a dental arch may not all get sealed.

Based on the above description, an obvious fact is that sealant decision making is closely associated with risk assessment procedures, especially the one before and closest to sealant placement. Risk assessment had not been standardized and recorded in the past in HPDG until 1996. As introduced in section 2.1, the primary criteria of risk assessment include caries history, dietary practice, fluoride use, medication/therapy, etc. The guideline of risk assessment recommends that sealant be applied to the pits and fissures of teeth in children at high risk for caries. Besides assessment criteria, the form of risk assessment also includes an item for recording sealant recommendation, though such records are often not complete. Since risk assessment was adopted, the rate of sealant has increased significantly. Currently, in HPDG over 95% of children seen by dentists have received an overall caries risk assessment score. The inherent relationship between risk assessment and sealant placement can be supported further by the preliminary finding of this study which showed that more than 90% of sealants had risk assessments beforehand, and the median interval between the closest risk assessment and the sealant placement was 40 days. Generally, a child has more than one risk assessment over a few years of enrollment period. It is reasonable to believe the early risk assessments are more associated with sealant placement, because a sealant is more often recommended within 2-3 years of tooth eruption.

According to the above description of the decision making process and the connection between risk assessment and sealant placement, it is obvious that three parties are involved in sealant decision making – dentists who conduct risk assessment, children, and children's parents. Here dentists and parents are two major decision makers, and children's oral health status is the major criterion for the decision making process. A child's risk for caries can be categorized into whole mouth level risk and tooth level risk.

In the risk assessment form, the major mouth-level risk factors include previous health status (caries history), dietary practice, suboptimal fluoride, other interventions, hygiene status, etc. Mouth-level risk is mainly measured by risk score, so it is observable and recorded. The tooth-level risk factors such as deep grooves, developmental weaknesses, or occlusal malfunction, etc., are usually not considered in risk scores. So the tooth-level risk is unobservable and not recorded. As mentioned before, the clinical guideline in HPDG recommends that sealants be applied to the pits and fissures of all children at high risk for caries. But for those low risk children, a sealant is recommended if the anatomy of the pits and fissures is deemed to be highly susceptible, and this decision is left to the discretion of the dentist and the parents. In other words, even if a low risk score is given, the dentist may still recommend sealant, and children may or may not finally get the sealant.

As displayed in the conceptual model, some person-level factors not only affect health outcomes, but also affect intervention decision making. Those factors are age, gender, ethnicity, income, education level, healthcare-seeking behavior, preventive attitude, etc. It has been found that patients receiving sealant might have a preventive attitude toward dental health.[8] Though behavior or attitude could be partially reflected by the utilization of other preventive services, they are not totally observable.

The reasons for a tooth being sealed could be recent caries on other teeth, bad oral hygiene status, bad oral hygiene habit, high-sugar dietary, deep occlusal groove, developmental weakness, dentist recommendation, positive preventive attitude, etc. The reasons for a tooth not being sealed could be prior restoration, low mouth level risk, shallow occlusal groove, lack of complete eruption limiting ability to isolate the tooth when placing sealant, oversight of dentist, negative preventive attitude, etc.

In sum, for FPMs studied in this study, if they are in different persons, tooth level risk factors, mouth level risk factors, socio-economic factors, health care attitude/behavior and other factors all together explain the sealant placement decision. If, for the same person, some FPMs are sealed and some are not, tooth level risk differences may well explain sealant placement decision.

Instrumental variables

Introducing instrumental variables to correct self-selection bias has long been used in econometric studies. However, this method rarely has been used in medical outcome research, especially in dental care studies. A valid instrument should be correlated strongly with the endogenous intervention to be corrected, but be completely uncorrelated with the error term of the outcome measure. Instrumental variables should be chosen according to related theories or a conceptual model for the relationship between the intervention and the outcome studied.[170] Instruments are invalid if causality arrows run: (1) from the intervention to the instruments; (2) from the outcome to the instruments; (3) from the instruments to the outcome; or (4) from other variables to the instruments, the intervention, and the outcome.[170]

The variables in shading in Figure 3-2 are used as the candidates for the instrumental variables in this study. They include dentist characteristics, distance between a child's residence to the HP dental clinic where this child's early risk assessment is conducted, and the month when the early risk assessment is conducted. Dentist factors include age, gender, working experience, and propensity to use sealant. As discussed above, those factors are collected from the dentists who conducted risk assessments, assigned risk scores, and possibly recommended sealant placements (but sealant recommendation records were not complete).

Generally, dentists vary in their use of sealants. The arrow in Figure 3-2 from dentists directly to sealant placement represents dentist's preference to apply sealant. Both risk assessment and sealant recommendation are subject to provider's age, gender, experience, etc. Some previous studies found that the dentist's academic and continuing education, knowledge of preventive measures, practice experience, and the use of modern techniques are additional factors influencing intervention choice.[152, 171, 172] For example, Weinberger and Wright found that the level of sealant placement declined the longer dentists had been in practice.[172] Siegal et al. reported that dentists' knowledge about sealants, conservative management of dental caries, number of children seen in the practice, and influence of insurance coverage for sealants al together explained 22.0 percent of the level of sealant use.[171]

In addition to the above factors, dentist preference for sealant use may be a more comprehensive factor for sealant choice. It may incorporate the above factors and other unknown dentist factors. Robison et al. found that dentists have different preferences for placing sealants. In their study, the percentage of providers with a high "propensity to seal" (> 10% of all procedures were sealants) was 57% for the sealant group and 15% for the non-sealant group.[153] Eklund et al. found that, similar to sealant placement, restoration decision was also affected by dentists' preference—"among 1,566 private dentists participating in an insurance plan, the overall propensity to place restoration was the most powerful predictor of restorative care for a group of insured children".[173]

Although it has been accepted widely that dentists' characteristics and preferences may be important in clinical decision making and the outcome of sealant cost-effectiveness studies, one potential source of confusion needs to be clarified here. The dentists in other studies are more likely to be the dentists who actually place the sealants, because they neither took risk assessment procedure into account, nor took the dentists conducting risk assessments into account. But in this study, dentists are those who assess caries risk, because sealants are often placed by hygienists or dental assistants. As clinical technology and dental practice model change, more and more sealants are placed by hygienists and dental assistants rather than by dentists, especially in HPDG. This study takes advantage of this practice model and distinguishes the intervention (sealant) *decision* procedure from the intervention (sealant) *application* procedure. Accordingly, the dentist referred to in this study is the person involved in risk assessment procedure. This practice model is supported further by the data of this study, which showed that, in about 70% of cases, dentists conducted risk assessments but hygienists/assistants applied sealants. In the rest 30% of cases, sealants were placed by dentists, but half of them were placed by the different dentists.

In the conceptual model, there is no direct arrow or relationship between dentists and outcome, which make it possible to use dentist characteristics as instrumental variables. That is because (1) sealants are often placed by hygienists or dental assistants, (2) even if a dentist places the sealant, it's unlikely to be the same dentist that does the follow-up care after the sealant is placed. Based on preliminary findings, about 20-25% of the time, the early risk assessment and the earliest caries treatment were done by the same dentists; (3) suppose that it was exactly the same dentist that did the assessment, the sealant and the follow-up care. It still could be the case that variation in dentist's characteristics could affect the decision to do sealants, but not follow-up care. In other words, there could be a professional variation in the sealant decision, but not in follow-up care; (4) there is not much that can be done in professional dental care to stop caries development between sealant placement and the time when a caries is diagnosed, besides some examination and other preventions such as fluoride use; (5) other clinical preventive care, such as fluoride treatments, more often are conducted by hygienists/assistants; (6) it is unlikely that a patient would have preventive visits to the same dentist only over a 5-year period; (7) more importantly, the major outcome is caries-free duration, and the ending point is the date when the earliest caries-fixing procedure occurred, which has little to do with how the caries is treated by a dentist.

Due to the practice model introduced before, the dentist's preference for sealants should not be measured by the percentage of patients undergoing a sealant procedure, as in Robison et al.[153] In this study, the dentist's preference for sealants is measured instead by the ratio of sealant recommendations to all caries-preventing-related recommendations. The sealant recommendations in the encounter records of HPDG are not complete. Therefore, there is no way to tell whether a child with low risk score got recommendation or not. The only information available is whether a child with a low risk score finally got any sealant or not. But, as long as the incompleteness is random, rather than systematic across dentists, dentist's preferences can be measured by the ratio.

Another instrumental variable candidate is the month when an early risk assessment was conducted. A few reasons can explain why month might affect sealant rate. First, sealant is just preventive care, and it does not have to be applied. Minnesota has very cold winters and nice summers. It is reasonable to assume sealants may be placed less often in cold months. Second, the school year calendar may affect the likelihood that a child gets preventive care. It is reasonable to assume that sealant rates may be high in vacation months and low in final examination months. For example, the preliminary study found that, sealant placement rate is the lowest in May but highest in

August. Using months as instrumental variables needs further testing. But it is a novel idea, and could be used in studies with different geographic environments or with different health care topics.

The distance from the subject's residence and the nearest clinic often has been used as an instrumental variable in previous health service research studies. One study using Medicaid claims data reported that the availability that dentists within the county of residence accept Medicaid patients was a significant predictor of dental services.[126] In a survey conducted on parents/caregivers, finding accessible dentists was a major reason for children's receiving care.[174] Since receiving a dental sealant is preventive care, it can be expected that children may be less likely to receive sealant if they live very far from the clinics. However, unlike other studies using distance from residence to the nearest clinic, this study uses the distance from residence to the clinic where the risk assessment was performed. The reason is that risk assessment often is conducted with the regular examination procedure, if a patient takes regular examinations in a clinic, this clinic could be the clinic preferred by this patient. That is probably due to transportation convenience, reputation of that clinic, patient habit, etc. As a matter of fact, the preliminary study found that 91.6% of the time sealants were placed in the same clinics as those where the patients received risk assessments prior to and the closest in time to the sealant applications. The distance from residence to the nearest clinic was calculated and tested, and no difference was found in terms of sealant rate.

There are a few variables that have the potential to be good instrumental variables but are not used in this study. One of them is specialty. Previous studies indicated that dentists' specialty may affect the decision of sealant application to children. For example, public health dentists were found to provide more preventive dental services to children.[175] Weintraub et al. found that children seeing a pediatric rather than a general dentist were more likely to receive sealants.[139] However, considering that a patient's risk for caries could affect what specialty the patient is referred to, specialty might not be a good instrumental variable for sealant study. Another potential instrument is cohort. It was found that sealant rate increased in later cohorts, and certain incentive for sealant application adopted by HPDG clinics might be able to explain that change. However, that change could be contaminated by two factors. First, this study intends to use the early risk assessments for the non-sealant group, because the early ones are assumed to be more associated with sealant decision making. Second, health care outcomes could be better in later cohorts. Therefore, cohort is not used as instrumental variable in this study. Several studies identified the insurance coverage and reimbursement rate to dental providers as the major barrier to patients receiving the service.[89, 126, 171, 176-178] Besides, other related factors such as dissatisfaction with the reimbursement procedure and difficulties in the collection of copayments may also affect dentists' use of caries control services.[3] Those are not the problems in this study, because sealants are covered 100 percent by the insurance benefit. Dentists in HPDG clinic often do not have the patient's benefit information when sealant decisions are made. Therefore, insurance type and coverage can not be used as instrumental variables in this study.

In sum, the requirement to correct self-correction problem in economic evaluation of sealant placement and the reasons to choose the above instrumental variable candidates are proposed through the clinical decision making process and the simplified conceptual model. But the strength and validity of those variables are further tested by tests such as F-test and logistic regression. The results are shown in a later section.

3.3.3.3. Selectivity-corrected Tobit Model

Dental sealant placement is preventive care which is usually applied once, and its intervention intensity is nearly constant from tooth to tooth. Failure events only cause more invasive caries-related treatments. Therefore, no condition of simultaneity needs to be treated in the model. The appropriate analytic model for effectiveness in this study is selectivity-corrected Tobit model. The functions are:

$$E = \begin{cases} E^* = \beta_s x_s + \sum \beta_n x_n + \varepsilon_i & \text{if } E^* < 60 \\ 60 & \text{if } E^* \geq 60 \end{cases}$$

$$x_s = f(\sum \alpha_v z_v + \sum \gamma_n x_n + \varepsilon_s)$$

Where:

E here is the average discounted caries-free duration across all included FPM for each individual and also the dependent variable;

X_s is for the sealants placement;

X_n is for each independent variable other than sealant in the first equation;

Z_v is for each instrumental variable[a];

$\varepsilon_i \sim N(0, \sigma_i^2)$;

[a] In this dissertation, "instrumental variables" are used only for convenience purpose. They really are "selection-identification" variables, since only MLE selection models are conducted, rather than IV estimations.

f( ) is the probit function such that:

$$\Pr(x_s = 1 \mid z_v, x_v, \varepsilon_s) = F(\sum \alpha_v z_v + \sum \gamma_n x_n)$$

where F( ) is a cumulative distribution function of the standard normal distribution.

60 is the maximum number for caries-free duration by month over 5-year period.

In this two stage model, the first equation is the main equation, and the second equation is the selection equation. Because the sealant intervention is a dichotomous variable, the selection equation can adopt a Probit regression. The following two equations show how the selectivity-corrected Tobit model incorporates independent variables and instrumental variables of this CEA to predict caries-free duration:

Main equation of interest (Tobit Regression equation)

$$\begin{aligned} Eff &= \beta_1 sealant + \beta_2 age + \beta_3 gender + \beta_4 race + \beta_5 income + \beta_6 edu \\ &+ \beta_7 poverty + \beta_8 geo + \beta_9 pubpay + \beta_{10} risk + \beta_{11} uti + \beta_{12} fluo \\ &+ \beta_{13} space + \beta_{14} ortho + \beta_{15} cohort + \omega \end{aligned}$$

Selection equation (Probit Regression equation)

$$\begin{aligned} Sealant &= f(\gamma_1 age + \gamma_2 gender + \gamma_3 race + \gamma_4 income + \gamma_5 edu + \gamma_6 poverty \\ &+ \gamma_7 geo + \gamma_8 pubpay + \gamma_9 risk + \gamma_{10} uti + \gamma_{11} fluo + \gamma_{12} space + \gamma_{13} ortho \\ &+ \gamma_{14} cohort + \gamma_{15} instrument + \varepsilon) \end{aligned}$$

$$Corr(\varepsilon, \omega) = \rho$$

Where the intervention, sealant, appears in main equation as an independent variable, and in selection equation as the dependent variable. The function f( ) is the probit function. Because little socio-demographic information was available from HealthPartners datasets during the study years, children’s residence addresses were linked to the 2000 Census to obtain block group level information for four elements which were used as proxies for socio-economic status (SES) or geographic area: median family income, percentage of individuals age 25 or older with a high school education, percentage of individuals living below poverty, and percentage of individuals living in urban area. Each of those four variables is categorized into two groups based on their medians, and represented by *income, edu, poverty,* and *geo* in the above equations. Risk has three levels, and is represented by two dummies. Five cohorts are represented by four dummies. *Instrument* represents the set of instrumental variables which are proved powerful and valid. The correlation between the error terms of the two equations is represented by ρ (rho), and the error terms are assumed to have a bivariate normal distribution. The above equation system is estimated simultaneously using full information maximum likelihood estimation technique.

The maximum likelihood estimation of classic Tobit model is sensitive to the distributional assumption about the error term of the dependent variable. With departure from censored normal assumptions, the estimators can be asymptotically biased.[179-182] A number of specification tests and alternative estimation methods have been proposed. For example, Bera et al. use either the Lagrange multiplier principle or a likelihood ratio test and usually consider the Pearson family of distributions as an alternative to the normal distribution.[183] Other tests include Hausman's test, the information matrix (IM) test of White, Fin and Schmidt's LM test, and so on.[184-186] In this study, normality of the error term was tested for both classic Tobit model and selectivity-corrected Tobit model.

The software package Stata 10 was employed for the Tobit estimation.[187] For estimating classic Tobit estimation, the standard Stata command "Tobit" was used. For selectivity-corrected Tobit model, a new estimation command "cmp", which was developed by David Roodman, was used.[188] This command can fix multi-equation models that mix probit, tobit, and "continuous" (unbounded/OLS-like) dependent variables. For example, according to the command documentation, one could regress a censored continuous variable on one binary endogenous variable which can be predicted by additional instrumental variables.[188]

The standard simultaneous estimation results include *rho* (the correlation between the error terms of the two equations), *sigma* (the standard error of the outcome regression) and *lambda* (lambda = rho*sigma). If *rho* is not significantly different from 0, there is no endogeneity or self-selection, and simple model without selectivity correction could be used. If *rho* is significantly different from 0, there is endogeneity or self-selection, and selectivity-corrected model should be used.

It is important to have valid instrumental variables for selection-corrected models. However, only a small number of studies have been able to identify appropriate instrumental variables, due to the nature of the study and data availability. It has been found that models based on poor instrumental variables also obtain biased and inconsistent estimation.[189] Most of unknown factors which correlate outcomes and interventions in dental studies are personal behavioral factors and biological factors. The dataset in this study includes children's charts and clinical risk evaluation from which an individual's clinical risk level and preventive service utilization can be derived. The former reflect the mouth health and hygiene status, and the latter may partially reflect the personal behavior and attitude to health care. It could be expected that incorporating the above variables into multivariable regressions would correct the self-selection problem to a great extent.

3.3.3.4. Two-part Model and Selectivity-corrected Two-part Model

Two-part Model

Tobit model is well known for its ability to handle censored data and evaluate the censored part and uncensored part together. Besides, the selectivity-corrected Tobit model is well established. However, in this analysis, the proportion represented by censored part of outcome is high – around 85% of observations had outcome measured as 60 months (if discount rate=0). The evaluation of censored part would be relatively important. A two-part model is often used to analyze dataset featured by many censored values. It takes the advantage of basic rule of probability.[190] For example, if maximum censoring point is 60, then:

$$E(y|x) = Pr(y<60) \times E(y|y<60) + Pr(y=60) \times E(y|y=60)$$

The whole dataset is split into two separate parts. Part one indicates whether a caries-free duration is at the maximum, i.e., if a child had no caries on 4 FPMs at all over 5 years. This part is analyzed on the full sample using probit model. Part two is analyzed on the subsample with any caries on FPMs over 5 years.[190] The following structural equations explaining effectiveness and sealant placement:

Probit regression equation

$$Eff(60) = f(\beta_1 sealant + \beta_2 age + \beta_3 gender + \beta_4 race + \beta_5 income + \beta_6 edu$$
$$+ \beta_7 poverty + \beta_8 geo + \beta_9 pubpay + \beta_{10} risk + \beta_{11} uti + \beta_{12} fluo$$
$$+ \beta_{13} space + \beta_{14} ortho + \beta_{15} cohort + e_1)$$

OLS regression equation

$$Eff(<60) = \beta_1 sealant + \beta_2 age + \beta_3 gender + \beta_4 race + \beta_5 income + \beta_6 edu$$
$$+ \beta_7 poverty + \beta_8 geo + \beta_9 pubpay + \beta_{10} risk + \beta_{11} uti + \beta_{12} fluo$$
$$+ \beta_{13} space + \beta_{14} ortho + \beta_{15} cohort + e_2$$

where eff(60) is the probability of effectiveness less than 60 months, eff(<60) is a continuous variable conditional on effectiveness is less than 60, e1 and e2 are the error terms of those two equations and they are independent. The function f( ) is the probit function.

Selectivity-corrected Two-part Model (SCTM)

The rationale for using selectivity-corrected structure model has been discussed in previous sections. Unlike the selectivity-corrected Tobit model, selectivity-corrected two-part model (SCTM) has rarely been used in literature. If selection regression with IVs is combined with each of two parts of two-part model, the final system of equations consists of four regressions: the first part of SCTM is a bivariate probit model composed of two probit models with correlated error terms, and the second part is a treatment effect model composed of a probit model and a OLS model with correlated error terms. The following bivariate probit model exemplifies how independent variables and instrumental variables are incorporated to predict whether or not an effectiveness value is at the censoring limit:

Main equation of interest (probit regression equation)

$$Eff\ (1 or 0) = f(\beta_1 sealant + \beta_2 age + \beta_3 gender + \beta_4 race + \beta_5 income + \beta_6 edu + \beta_7 poverty + \beta_8 geo + \beta_9 pubpay + \beta_{10} risk + \beta_{11} uti + \beta_{12} fluo + \beta_{13} space + \beta_{14} ortho + \beta_{15} cohort + e_1)$$

Selection equation (probit regression equation)

$$Sealant = f(\gamma_1 age + \gamma_2 gender + \gamma_3 race + \gamma_4 income + \gamma_5 edu + \gamma_6 poverty + \gamma_7 geo + \gamma_8 pubpay + \gamma_9 risk + \gamma_{10} uti + \gamma_{11} fluo + \gamma_{12} space + \gamma_{13} ortho + \gamma_{14} cohort + \gamma_{15} instrument + \varepsilon_1)$$

$$Corr(\varepsilon_1, e_1) = \rho_1$$

where the sealant appears in main equation as an independent variable, and in selection equation as the dependent variable. Caries-free duration is transformed into a binary variable *eff(1or0)* that equals one when an effectiveness value is not at the censoring limit and zero otherwise. The function f( ) is the probit function. The expectation of e_1 is not zero, if sealant is indeed endogenous, and the error terms e_1 *and* ε_1 in the structural equations should be significantly correlated. The *sealant* variable itself is a binary variable. Therefore, both regressions are probit models. The instrument used in the selection equation must be correlated with sealant decision, but at the same time must not significantly impact caries-free duration directly. For example, one of the chosen instruments is whether or not the dentist who conducted the early risk assessment had more than 25 years of working experience. The reason explaining this observation could be that dentists who received their professional education before the mid 1970's when sealant was formally accepted by ADA are less likely to recommend sealant during the regular examination and risk assessment procedure.

Maximum likelihood estimation is used to simultaneously estimate two equations, assuming the correlation between the error terms of the above two equations, ρ_1 (rho1), follows a standard bivariate normal distribution (with zero means and unit variances). This approach controls for the non-zero expectation of the error term in the main equation of interest. The possible endogeneity of the *sealant* variable is tested by the likelihood ratio test. That is equivalent to testing whether ρ_1 equals to 0. If ρ_1 is not significantly different from zero, there may be no or very little self-selection bias with regard to whether or not an effectiveness value is at the censoring limit, and a single equation (classic probit equation in this case), instead of two-stage model, can produce unbiased estimates. If ρ_1 is significantly different from zero, the *sealant* variable is likely to be endogenous, and two-stage model will produce unbiased estimates.

The following treatment-effect (TE) model evaluates the second part of SCTM. It exemplifies how independent variables and instrumental variables are incorporated to predict an effectiveness value given this value is not at the censoring limit:

Main equation of interest (OLS equation)

$$\begin{aligned} &Eff\,(<60) = \beta_1 sealant + \beta_2 age + \beta_3 gender + \beta_4 race + \beta_5 income + \beta_6 edu \\ &+ \beta_7 poverty + \beta_8 geo + \beta_9 pubpay + \beta_{10} risk + \beta_{11} uti + \beta_{12} fluo \\ &+ \beta_{13} space + \beta_{14} ortho + \beta_{15} cohort + e_2 \end{aligned}$$

Selection equation (probit regression equation)

$$\begin{aligned} &Sealant = f(\gamma_1 age + \gamma_2 gender + \gamma_3 race + \gamma_4 income + \gamma_5 edu + \gamma_6 poverty \\ &+ \gamma_7 geo + \gamma_8 pubpay + \gamma_9 risk + \gamma_{10} uti + \gamma_{11} fluo + \gamma_{12} space + \gamma_{13} ortho \\ &+ \gamma_{14} cohort + \gamma_{15} instrument + \varepsilon_2) \end{aligned}$$

$$Corr(\varepsilon_2, e_2) = \rho_2$$

Again, sealant appears in main equation as an independent variable, and in selection equation as the binary dependent variable. The function f( ) is the probit function. Effectiveness is a continuous variable if it is not at the censoring limit. Since effectiveness is observed for each individual regardless of the sealant decision, sample loss due to selection process is not an issue in this model, which is different from sample-selection model.[191]

The two regressions in this TE model are estimated simultaneously using maximum likelihood methods.[180] It is assumed that their error terms are jointly normally distributed. The possible endogeneity of the *sealant* variable also is tested by the likelihood ratio test. If ρ_2 is not significantly different from zero, there may be no or very little self-selection bias for effectiveness values which are not at the censoring limit, and a single equation or generic normal regression (OLS in this case) will produce unbiased estimates. If ρ_2 is significantly different from zero, *sealant* variable is likely to be endogenous, and the two-stage model should be used. Otherwise, the estimated sealant effect would be biased. For example, if ρ_2 is positive, the estimated sealant effect from simple OLS would generally be biased away from zero.

The estimation of all four equations together, based on two parts of SCTM, would be overwhelming. However, if the error terms between two main equations of interest are independent, which often is the assumption of simple two-part model, each part of SCTM could be estimated separately. Besides, if omitted variables and endogenous sealant are assumed to exist, correcting selectivity/endogeniety could be more important for obtaining consistent sealant's marginal effect.

Finally, the estimation results from ordinary least square, classic Tobit model, selectivity-corrected Tobit model, two-part model, and selectivity-corrected two-part model, were compared to each other. The following rule is used to determine which model would be use for ICER calculation:

(1). if self-selection is not found, non-selectivity-corrected models or generic normal regression are used, either the classic Tobit model or two-part model in this study; if self-selection is found, selectivity-corrected models are used, either the selectivity-corrected Tobit model or selectivity-corrected two-part model;

(2). if the error term distribution of effectiveness is found to be censored normal or can be retransferred to be censored normal, Tobit models are used, either the classic Tobit model or two-part mode selectivity-corrected Tobit model; if the error term distribution of effectiveness is not censored normal and is hard to retransferred to be censored normal, two-part models are used, either a simple two-part model or a selectivity-corrected two-part model;

(3). for subgroup analyses, if self-selection is not found, or instrumental variables are tested and found to be weak, non-selectivity-corrected models are used, either the classic Tobit model or two-part model; if self-selection is found, and instrumental variables are found to be strong, selectivity-corrected models are used, either the selectivity-corrected Tobit model or selectivity-corrected two-part model.

3.3.3.5. Models for Cost Estimation

Basic model for cost estimation

Similar to effectiveness estimation, the overall analytic model for the cost is:

$$\text{cost} = \beta_0 + \beta_1\text{sealant} + \beta_2\text{age} + \beta_3\text{gender} + \beta_4\text{ethnicity} + \beta_5\text{income} + \beta_6\text{edu} + \beta_7\text{poverty} + \beta_8\text{geoarea} + \beta_9\text{publicpay} + \beta_{10}\text{riskm} + \beta_{11}\text{riskh} + \beta_{12}\text{utilization} + \beta_{13}\text{history} + \beta_{14}\text{fluo} + \beta_{15}\text{space} + \beta_{16}\text{ortho} + \beta_{17}\text{cohort98} + \beta_{18}\text{cohort99} + \beta_{19}\text{cohort00} + \beta_{20}\text{cohort01} + \varepsilon$$

The primary intervention variable still is *sealant* indicating whether or not any sealant was placed. The unit of analysis is the individual child. The primary cost variable is the average discounted cost per FPM for an individual over 5-year study period. Only sealant/resealant cost and cost of treatment of caries are included because (1) costs generated by other procedures such as periodontal or orthodontic treatments are irrelevant; (2) costs generated by regular or comprehensive examinations and radiograph are insignificant in term of amount; (3) dentists pay more attention to the costs associated with the subsequent caries treatment procedure; and (4) utilization of dental care and clinical fluoride application are controlled by corresponding variables. The procedures for which the costs are calculated are listed in appendix A.

Tobit Model and Selectivity-corrected Tobit Model

In general health care cost studies, the Tobit model or two-part model often has been used to deal with the cases in which a large proportion of subjects have $0 expenditure during the whole study period. This study is not an exception.

During the five-year observation period, most individuals did not have any caries or take any caries treatment. If they are in a sealant group, their cost could be just the one-time sealant cost if no resealant or any caries treatment procedure was received. Because the first sealant on each FPM was placed in the first year, no discount is needed. In other words, for sealant group individuals, their minimum cost must be one-time sealant cost which is a constant. For non-sealant group individuals, their minimum cost must be \$0. For convenience of analysis, the cost of one sealant was removed temporarily from the final cost, the average cost per FPM, for each sealant individual. That resulted in a large proportion of subjects having \$0 expenditure, causing a left-censoring problem. In this study, the Tobit model is adopted to analyze cost with \$0 threshold, the basic model can be written as:

$$Y^* = \Sigma X_n'\beta_n + \varepsilon \qquad \varepsilon \sim N(0,\sigma^2)$$

$$Y = Y^* \qquad \text{if } Y^* > \$0$$

$$Y = \$0 \qquad \text{otherwise}$$

where X_n represent the intervention variable and a vector of other explanatory variables; Y^* is the unobserved continuous latent dependent variable for the true average cost for each included FPM in an individual; Y is the observed average cost, and $Y = \max(Y^*, \$0)$. The dependent variable in Tobit model for cost is left-censored. Maximum likelihood estimation (MLE) is used to produce consistent estimates of the parameters in Tobit model, under critical assumptions of homoscedasticity and normality of the error terms.

Similar to effectiveness estimation, the cost regression also needs to correct a possible self-selection problem, the same instrumental variables as those used in effectiveness regression are used here. The analytic model for cost analysis is the selectivity-corrected Tobit model (SCTM). The functions are:

$$C = \begin{cases} C^* = \beta_s x_s + \sum \beta_n x_n + \varepsilon_i & \text{if } C^* > 0 \\ 0 & \text{if } C^* \le 0 \end{cases}$$

$$x_s = f(\sum \alpha_v z_v + \sum \gamma_n x_n + \varepsilon_s)$$

Where:

C here is the average discounted expenditure per FPM for each child and also the dependent variable;

X_s is for the sealants placement;

X_n is for each independent variable other than sealant in the first equation;

Z_v is for each instrumental variable;

$\varepsilon_i \sim N(0, \sigma_i^2)$;

f( ) is the probit function.

In this two stage model, the first equation is the main equation, and the second equation is the selection equation. Because the sealant intervention is a dichotomous variable, the selection equation can adopt a Probit regression. The following two equations show how the selectivity-corrected Tobit model incorporates independent variables and instrumental variables of this CEA to predict cost:

Main equation of interest (Tobit Regression equation)

$$\begin{aligned} Cost &= \beta_1 sealant + \beta_2 age + \beta_3 gender + \beta_4 race + \beta_5 income + \beta_6 edu \\ &+ \beta_7 poverty + \beta_8 geo + \beta_9 pubpay + \beta_{10} risk + \beta_{11} uti + \beta_{12} fluo \\ &+ \beta_{13} space + \beta_{14} ortho + \beta_{15} cohort + \omega \end{aligned}$$

Selection equation (Probit Regression equation)

$$Sealant = f(\gamma_1 age + \gamma_2 gender + \gamma_3 race + \gamma_4 income + \gamma_5 edu + \gamma_6 poverty + \gamma_7 geo + \gamma_8 pubpay + \gamma_9 risk + \gamma_{10} uti + \gamma_{11} fluo + \gamma_{12} space + \gamma_{13} ortho + \gamma_{14} cohort + \gamma_{15} instrument + \varepsilon)$$

$$Corr(\varepsilon, \omega) = \rho$$

Where the intervention, sealant, appears in main equation as an independent variable, and in selection equation as the dependent variable. The function f( ) is the probit function. The discussion about relevant variables, estimation of SCTM, and test of selectivity can be found in section 3.3.3.3.

In health care cost studies, the distribution of cost often does not follow a normal distribution. A skewed cost distribution can cause the residual to have unequal variance and raise estimation issues. After costs in different intervals are discounted and summed, the natural log is taken to have the final cost normalized. Other transformations and the resulted distributions of the error term of the above models are examined. Any transformed cost which can greatly improve the behavior of the residuals, or increase the normality of the error term, is used.

The arithmetic difference of this cost function with respect to sealant placement variable is the marginal effect of sealant on the total cost. It will be the numerator of the ICER.

Two-part model and Selectivity-corrected Two-part model

Although the Tobit model and SCTM are better established, there are two problems associated with using Tobit model and SCTM to estimate cost regressions.

One problem is there are too many cost values at the censoring point. In these data, around 85% of individuals never incur any expense, and their final costs were measured at \$0 (if the cost of the first sealant was removed from the final cost for sealant group). In such as situation, evaluation of whether or not a cost value is at the censoring limit may be more important than evaluation of cost values which are not at the censoring limit. Another problem is the distribution of cost values which are not at censoring point is not completely normal, even after cost variable is transformed.

A two-part model is another model often used to analyze cost data characterized by a large proportion of individuals having \$0 expenditure. The whole dataset is split into two separate parts. Part one indicates whether or not a final cost value is positive, i.e., whether or not a child received any caries treatment on any FPM over 5 years. If the minimum censoring point is \$0, then:

$$E(y|x) = Pr(y=0) \times E(y|y=0) + Pr(y>0) \times E(y|y>0)$$

The first part of the right-hand side equation is analyzed on the full sample using probit model. The second part is analyzed on a subset of the sample with positive average cost per FPM. Similar to effectiveness estimation, the following structural equations explaining cost and sealant placement:

Probit regression equation

$$\begin{aligned} Cost(0) = f(&\beta_1 sealant + \beta_2 age + \beta_3 gender + \beta_4 race + \beta_5 income + \beta_6 edu \\ &+ \beta_7 poverty + \beta_8 geo + \beta_9 pubpay + \beta_{10} risk + \beta_{11} uti + \beta_{12} fluo \\ &+ \beta_{13} space + \beta_{14} ortho + \beta_{15} cohort + e_1) \end{aligned}$$

OLS regression equation

$$Cost\ (>0) = \beta_1 sealant + \beta_2 age + \beta_3 gender + \beta_4 race + \beta_5 income + \beta_6 edu + \beta_7 poverty + \beta_8 geo + \beta_9 pubpay + \beta_{10} risk + \beta_{11} uti + \beta_{12} fluo + \beta_{13} space + \beta_{14} ortho + \beta_{15} cohort + e_2$$

Where cost(0) is a binary variable indicating whether or not a cost value is positive, cost(>0) is a continuous variable given that its value is bigger than 0, e1 and e2 are the error terms of those two equations and they are independent. The function f( ) is the probit function. The cost model controls for the same variables as in the effectiveness model. Service charges are assigned to sealant/resealant and caries treatment procedures by the HPDG 2005 fee schedule.

The two-part model is different from the sample selection model in its assumptions. The two-part model assumes two statistically independent decision-making processes: the initial decision of whether or not to use health care services is made first, and then how much services are used,[192] while sample selection model assumes that two decisions are statistically related. The two-part model assumes that all utilization data are observed and zero cases are the actual ones. The sample selection model assumes that the potential utilization is observed conditional on some endogenous dummy variable and zero cases include some unobservable negative outcomes.[179] The two-part model has no assumption about the joint distribution of the error terms of the two equations. The sample selection model requires an assumption about the joint distribution of the two error terms.

Because of the highly skewed positive health service utilization and expenditure data, the second part of two-part model often needs to be log transformed to reduce skewness.[139, 192, 193] Preliminary findings of this study showed that the log scale residuals of the second part are homoscedastic.

Since the marginal effect of sealant on cost is in terms of dollars, rather than log dollars, retransformation of the estimated coefficients is necessary to interpret model results. The process of retransformation and the way to calculate marginal effects are discussed in detail in Section 3.3.3.6.

Similar to effectiveness estimation, because there is self-selection bias caused by unobserved variables or omitted variables which are correlated with sealant choice, if the estimation model does not correct self-selection, the results of both parts of two-part model would be biased. The SCTM with four equations is used for cost evaluation using IV method: the first part of the SCTM is a bivariate probit model composed of two probit models with correlated error terms, and the second part is a treatment effect model composed of a probit model and an OLS model with correlated error terms. The following bivariate probit model exemplifies how independent variables and instrumental variables are incorporated to predict whether or not a cost value is at the censoring limit:

Main equation of interest (probit regression equation)

$$
\begin{aligned}
&Cost\ (0 or 1) = f(\beta_1 sealant + \beta_2 age + \beta_3 gender + \beta_4 race + \beta_5 income + \beta_6 edu \\
&+ \beta_7 poverty + \beta_8 geo + \beta_9 pubpay + \beta_{10} risk + \beta_{11} uti + \beta_{12} fluo \\
&+ \beta_{13} space + \beta_{14} ortho + \beta_{15} cohort + e_1)
\end{aligned}
$$

Selection equation (probit regression equation)

$$
\begin{aligned}
&Sealant = f(\gamma_1 age + \gamma_2 gender + \gamma_3 race + \gamma_4 income + \gamma_5 edu + \gamma_6 poverty \\
&+ \gamma_7 geo + \gamma_8 pubpay + \gamma_9 risk + \gamma_{10} uti + \gamma_{11} fluo + \gamma_{12} space + \gamma_{13} ortho \\
&+ \gamma_{14} cohort + \gamma_{15} instrument + \varepsilon_1)
\end{aligned}
$$

$Corr(\varepsilon_1, e_1) = \rho_1$

Where the *sealant* appears in main equation as an independent variable, and in selection equation as the dependent variable, cost(0) is a binary variable that equals one when a cost value is positive and zero otherwise. The expectation of e_1 is not zero, if sealant is indeed endogenous, and the error terms e_1 *and* ε_1 in the structural equations should be significantly correlated. The *sealant* variable itself is a binary variable. Therefore, both regressions are probit models.

The following treatment-effect (TE) model evaluates the second part of SCTM. It exemplifies how independent variables and instrumental variables are incorporated to predict a cost value given this value is not zero:

Main equation of interest (OLS equation)

$$Cost\ (>0) = \beta_1 sealant + \beta_2 age + \beta_3 gender + \beta_4 race + \beta_5 income + \beta_6 edu$$
$$+ \beta_7 poverty + \beta_8 geo + \beta_9 pubpay + \beta_{10} risk + \beta_{11} uti + \beta_{12} fluo$$
$$+ \beta_{13} space + \beta_{14} ortho + \beta_{15} cohort + e_2$$

Selection equation (probit regression equation)

$$Sealant = f(\gamma_1 age + \gamma_2 gender + \gamma_3 race + \gamma_4 income + \gamma_5 edu + \gamma_6 poverty$$
$$+ \gamma_7 geo + \gamma_8 pubpay + \gamma_9 risk + \gamma_{10} uti + \gamma_{11} fluo + \gamma_{12} space + \gamma_{13} ortho$$
$$+ \gamma_{14} cohort + \gamma_{15} instrument + \varepsilon_2)$$

$Corr(\varepsilon_2, e_2) = \rho_2$

Again, *sealant* appears in main equation as an independent variable, and in selection equation as the binary dependent variable. The function f( ) is the probit function. Cost is a continuous variable if it is positive. The log transformation is used to reduce skewness. The detailed discussion about instrumental variables, estimation of SCTM, and test of selectivity can be found in section 3.3.3.4. Similar rules are applied when determining which model would be appropriate for calculating the marginal effect of sealant on cost, which is also discussed in detail in section 3.3.3.4.

3.3.3.6. Marginal Effects and ICER Calculation

The sample-average CER

The sample-average CER will be calculated by dividing the difference between sample-average costs by the difference between sample-average effectivenesses.[168] There will be no need for model fitting or regression. The equation will be:

$$\text{sample-average CER} = (C_s - C_0)/(E_s - E_0)$$

where C_s is the average cost per FPM for an individual in the sealant group, E_s is the average effectiveness per FPM for an individual in the sealant group, C_0 is the average cost per FPM for an individual in the non-sealant group, E_0 is the average effectiveness per FPM for an individual in the non-sealant group. The sample-average ICER will be calculated to compare with previous studies reporting average estimates.

Marginal Effects of Effectiveness

Three marginal effects of explanatory variables can be obtained from the Tobit model or selectivity-corrected Tobit model. If the data beyond the censored limit have characteristics similar to those within the censored limit, and they also are the outcome of interest, then the marginal effect focusing on the latent variable y* should be used. If only those uncensored observations are the outcome of interest, the marginal effect focusing on data which are uncensored should be used. If data always are censored and the observed effect is the effect of interest, both censored and uncensored cases should be considered when calculating the marginal effect, and this marginal effect generally is the most useful one.[179, 191] Which one should be used by a study largely depends on the particular purpose of the analysis.[191]

The effectiveness and cost associated with dental sealant may change with time. The normal longevity for a well-placed sealant is about five years.[100] The characteristics of a sealant placed less than 5 years may be different from those placed more than 5 years, and the relationships between effectiveness or cost and explanatory variables also can be different, depending on how well a sealant remains in place and intact, and how often a tooth is resealed. This study assumes the sealant's retention changes over time, and so does its effectiveness. In other words, sealant effectiveness beyond 5 years is not the same as or even similar to its effectiveness within 5 years since placement. It suggests that the most commonly used marginal effect, which considers both censored and uncensored cases, should be adopted for this analysis. For the effectiveness variable with the upper censoring point of 60 months (if 0% discount is applied), the expected value of y is:

$$E[y|x] = P(y^* < 60|x) * E(y| x, y^* < 60) + P(y^* >= 60|x) * 60$$

For a binary independent variable, such as sealant placement in this study, its marginal effect on the effectiveness is:

$$\partial E[y|x_j]/\partial x_j = F((60-x_i\beta)/\sigma)|_{xj=1}(x_i\beta - \sigma\lambda_i)|_{xj=1} + (1- F((60-x_i\beta)/\sigma)|_{xj=1})*60$$
$$- (F((60-x_i\beta)/\sigma)|_{xj=0}(x_i\beta - \sigma\lambda_i)|_{xj=0} + (1- F((60-x_i\beta)/\sigma)|_{xj=0})*60)$$

where $\lambda_i = f((60-x'\beta)/\sigma)/F((60-x'\beta)/\sigma)$, x′ here is a vector consisting of all the independent variables, but with xj=1 or 0 as appropriate, x_i is a vector consisting of all the independent variables except for the sealant variable, and x_j represents the sealant variable. This equation generates a single value for one case. The mean of those values for all case in the sample would be the final marginal effect.

When calculating the marginal effects based on two-part model or selectivity-corrected two-part model, the similar rule of probability applies.[190] For the effectiveness variable with the upper censoring point of 60 months, the expected value of y is:

$$E[y|x] = P(y^*<60)E(y|y<60) + P(y^*>=60)E(y|y^*>=60)$$

which is:

$$E[y|x] = P(y^*<60)E(y|y<60) + P(y^*>=60)*60$$

Then the incremental effect or marginal effect of the binary sealant prevention based on two-part models is:

$$E(y|x_s=1)-E(y|x_s=0)=[(P(y^*<60|x_s=1)*E(y|y<60|x_s=1)]+P(y^*>=60|x_s=1)*60$$
$$– ([P(y^*<60| x_s=0)*(E(y|y<60|x_s= 0)]+P(y^*>=60|x_s=0)*60)$$

where x_s represents the sealant variable. This equation generates a single value for one case. This equation generates a single value for each case. The mean of those values for all cases in the sample would be the final marginal effect.

Marginal Effects of Costs

If, based on model selection rules mentioned in section 3.3.3.4., the Tobit model or selectivity-corrected Tobit model is adopted for the cost analysis. The commonly used marginal effect, which considers both censored and uncensored cases, should be calculated for this analysis. For the cost variable with the lower censoring point $0, the expected value of y is[191]:

$$\begin{aligned} E[y|x] &= P(y > 0|x) * E(y|\, x, y^* > 0) + P(y = 0|x) * 0 \\ &= P(y > 0|x) * E(y|\, x, y^* > 0) \end{aligned}$$

For a continuous independent variable x, its marginal effect on the cost is:

$$\partial E[y|x_k]/\partial x_k = F(x'\beta/\sigma)\beta_k$$

where k indicates the variable of interest, and $F(\Sigma_k x_{ik}'\beta/\sigma)\beta_k$ will be calculated for each person. In this study, the marginal effects will be calculated as the averages of individual marginal effects, rather than at the means of the explanatory variables. The former is more accurate.

For a binary independent variable x, such as sealant placement in this study, its marginal effect on the cost is:

$$\partial E[y|x_j]/\partial x_j = F(x_i\beta/\sigma)|_{xj=1}(x_i\beta + \sigma\lambda_i)|_{xj=1} - F(x_i\beta/\sigma)|_{xj=0}(x_i\beta + \sigma\lambda_i)|_{xj=0}$$

where $\lambda_i = f(x'\beta/\sigma)/F(x'\beta/\sigma)$, x′ here is a vector consisting of all the independent variables, but with xj=1 or 0 as appropriate, x_i is a vector consisting of all the independent variables except for the sealant variable, and x_j represents the sealant variable. This equation generates a single value for one case. The mean of those values for all cases in the sample would be the final marginal effect.

When calculating the marginal effects of explanatory variables on the cost based on two-part model or selectivity-corrected two-part model, the expected cost value depends on both parts of the model.[190] Because the cost variable has the lower censoring point $0, the expected value of y is the product of the probability of being positive cost and the expected conditional mean[192, 193]:

$$E(y|x)=P(y>0) \times E(y|y>0)$$

Marginal effect of a continuous variable x_c in two-part model or SCTM is:

$$\partial E[y|x_c]/\partial x_c = pr(y>0)*\partial E(y|y>0)/\partial x_c + E(y|y>0)*\partial pr(y>0)/\partial x_c$$

where x_c is the variable of interest. Incremental effect or marginal effect of a binary variable x_s in two-part model or SCTM is:

$$E(y|x_s=1)-E(y|x_s=0) = [(P(y>0|x_s=1)*E(y|y>0|x_s=1)] - [P(y>0|x_s=0)*(E(y|y>0|x_s=0)]$$

where x_s could be any binary variable of interest, but it is for the sealant variable in this study. Still, the marginal effects will be calculated as the averages of individual marginal effects, rather than at the means of the explanatory variables.

In the second part of either two-part model or SCTM, the ordinary least squares (OLS) or the treatment effect model will be estimated on a log-transformed cost variable so that the error term could be approximately normal. After estimation, retransformation will be needed to obtain actual marginal effects.

The way to calculate the predicted unlogged cost variable E[y] depends on the characteristics of the error term.[194] If the log-scale error term is approximately normal and homoskedastic:

$$E[y] = \exp(x\beta + .5\sigma^2)$$

If the log-scale error term is approximately homoskedastic but not normal:

$$E[y] = \exp(x\beta)S.$$

where S is the smearing estimator developed by Duan (1983) to estimate the retransformed dependent variable without imposing the normality assumption. The smearing estimator is the average of the exponentiated residual from OLS in two-part model or SCTM[195]:

$$S = \frac{1}{N}\sum_{i=1}^{N}\exp(\hat{\varepsilon}).$$

Since the preliminary results showed that the log-scale error terms from either two-part model or SCTM of this study is homoskedastic, this study will use smearing estimator to retransform the results. It is believed that OLS with a homoskedastic retransformation works well with data with heavy-tailed distributions.[194] If the log-scale error term is heteroskedastic, a heteroskedastic retransformation should be adopted,[194] but it is unnecessary for this study.

ICER and confidence interval

Incremental cost-effective ratio (ICER) probably is the most important result reported by a CEA study. ICER is essentially the incremental cost of obtaining a unit health effect (such as one dollar per life year or one dollar per quality-adjusted life year) from a given health intervention when compared with an alternative.[160] It can be calculated using the following equation:

$$ICER = \frac{C_1 - C_0}{E_1 - E_0}$$

where C_1 is the cost associated with sealant prevention, C_0 is the cost associated with non-sealant alternative, E_1 is the effectiveness associated with sealant prevention, E_0 is the effectiveness associated with non-sealant alternative, the numerator C_1-C_0 is the incremental or marginal effect of sealant on the cost, and the denominator E_1-E_0 is the incremental or marginal effect of sealant on the effectiveness. Before calculating ICER, the cost of the first sealants which was once removed for convenience of analysis will be put back into the final cost of sealant group.

There are four possible situations regarding the statistical significance of the marginal effects of sealant: (1). C_1-C_0 is significantly different from 0, and E_1-E_0 is not significantly different from 0; (2). C_1-C_0 is not significantly different from 0, and E_1-E_0 is significantly different from 0; (3). both C_1-C_0 and E_1-E_0 are not significantly different from 0; (4). both C_1-C_0 and E_1-E_0 are significantly different from 0. The situation (1) shows that either sealant is cost-saving or non-sealant is cost-saving. The situation (2) shows that either sealant is more protective or non-sealant is more protective. The situation (3) shows that sealant is quite similar to non-sealant on both cost and effectiveness. The situation (4) would be a little complicated. It may either show that sealant is cost-effective or not cost-effective, depending on the signs of numerator and denominator and confidence interval (CI) of ICER. Only situation (4) would require the confidence interval of ICER.

Traditionally sensitivity analysis often has been used to reflect the uncertainty of ICER. In recent years, CIs have been increasingly reported in CEA studies.[168] However, CIs have never been reported for an ICER of dental sealant vs. non-sealant. The data of this study show a large proportion of cost or effectiveness values on the censoring limits, and a highly skewed distribution of dental care expenditure. That may cause the problems with the use of normal theory statistical methods to construct CIs. Even if the cost or the effectiveness variable is normally distributed, the ratio of two marginal effects or numerator/denominator may not be normally distributed.[168] The distribution of ICER is often unknown.[196] Therefore, this study will use bootstrap method to generate CI for ICER. Up to 1,000 bootstraps will be performed until a stable and robust CI is obtained. Each bootstrap iteration will consist of sampling the dataset with replacement. The models for effectiveness and cost will be estimated on each sample and marginal effects will be calculated. Standard errors will then be calculated based upon the distribution of the 1,000 ICER estimates.

3.3.3.7. Subgroup Analysis

As discussed before, caries prevalence varies among the populations. In general, cost-effectiveness results would favor the intervention applied to the populations with higher disease prevalence.[197] It can be expected that sealant delivery is more cost-effective when it targets the population at high risk of developing occlusal caries.[9] The low risk populations would be overtreated with the sealant. Risk-based ICERs from subgroup analyses would be important to optimize the allocation of limited resources.

There are two ways to conduct the subgroup analysis. One way is to incorporate the variables of interest into the interaction terms of the models and focus on analyzing those terms based on all individuals in the sample. That assumes the relationships or coefficients between other variables and outcomes remain the similar across subgroups. Another way is to focus on analyzing the coefficients associated with the variables of interest based on those individuals in the subgroup sample. It assumes that people are different in real life on many characteristics, and the relationships or coefficients between other variables and outcomes vary across subgroups. It does not require focusing on interaction terms of the models. This study adopts the second way to conduct subgroup analysis, since its assumption and findings may more likely reflect real life situation.

Finally, non-parametric bootstrap method will be used to calculate confidence intervals for different ICERs. This method is believed to have much better coverage accuracy than parametric methods when medical costs or the ratio estimators have a skewed distribution.[168, 196]

3.3.4. Quality-adjusted Cost-effectiveness Analysis

According to Gold et al. (1996), CEA compares the cost per unit of a single effect of the various programs. Cost utility analysis, moreover, has often been used to compare programs' costs with multiple effects.[160] This study adopts QATY as another effectiveness measurement which is similar to utility measurement QALY. Since QATY can reflect both the duration and severity of tooth health status, it has the potential to be a more accurate dental care outcome measurement after further development of the severity index system.

The way to calculate QATY is described in section 3.3.1.1. This quality-adjusted CEA shares the same characteristics of variables and models as those for CEA, such as the censoring limits of the dependent variables, the self-selection of the intervention, and so on. Therefore, the same estimation methods are used for this analysis, and they are skipped in this section.

3.3.5. Sensitivity Analysis

Sensitivity analysis is a method used to assess whether the cost-effectiveness ratios are robust to changes of certain important parameters.[161, 198] Some critical assumptions for outcome measurements also can be addressed.

The one-way sensitivity analysis can be used to test the effect of the change of each parameter at a time.[160] This study conducts one-way sensitivity analysis on two major parameters: a set of dental service charges and discount rates.[3] In addition to the charges used in HP, the total cost incurred by each tooth is also evaluated using charges from the American Dental Association (ADA) 2005 Survey of Dentists Fees. These fees are selected because they reflect the current average dental fees across the United States. For discount rate, 0% and 5% are used, in addition to 3%, to recalculate the costs and caries-free duration and QATYs for sealed and non-sealed teeth. For all those one-way parameter changes, ICERs and associated CIs are recalculated.

CHAPTER 4. RESULTS

This retrospective observational study evaluates the effectiveness and costs associated with dental sealants placed on first permanent molars (FPMs) of children and adolescents aged 6 to 17 years. The data sets come from a sample that had been continuously enrolled for at the least five years in the Minneapolis-based HealthPartners HMO, between January 1997 and December 2006. This sample consisted of 5624 children and adolescents receiving preventive dental care or treatments from dentists, hygienists, and dental assistants in HealthPartners Dental Group (HPDG). The HealthPartners' enrollment files were used to collect subjects' demographic information and socio-economic characteristics based on their residence at block-group level. The dentists' information such as age, gender, and working experience were collected from company's records. The dental encounter and claim data for the sample across the whole observation period were available for identifying encounter dates, treatment services and costs. Data management and univariate analyses were conducted in SAS Version 9.1.3.[199] Econometric analyses were conducted in Stata Version 10.[187] The significant levels for all statistical tests will be set at 0.05.

This results chapter consists of several sections: descriptive statistics displaying sample characteristics; intervention selection comparison and instrumental variables analyses; effectiveness and cost analyses; subgroup analyses and sensitivity analyses.

4.1. Descriptive Statistics and Sample Characteristics

The initial dataset contained 44,250 individuals who were age 6 to 18 with at the least 10 months of HPDG comprehensive coverage. A total number of 1,973,118 encounter records were associated with these children. The dental encounter and claim records were collected from 1991 to 2006. This study sample was restricted to children and adolescents who were age 6 to 17 years during any year from 1997 to 2001. They had to be enrolled continuously for at the least 5 years and had at least one caries risk assessment (CRA) at any time during 1997 to 2001. A total of 4,624 children with 13,365 FPMs initially were included into the sample population of this study. Any individual subject can have from one to four FPMs that were qualified for the study purpose. Those molars should have no prior record of receiving a restoration or any other caries-related treatment at the start of the observation period. Among these subjects, 27 subjects have missing residence information and were removed, because all the socio-economic information for this study had to be based on geocodes and census data. When clinic and provider data were examined, about 3% of the sample was deleted because of wrong records. For example, the provider's employment might end before the risk assessment. Moreover, 795 (16%) had a dentist identification number that did not link to the database of providers containing information (e.g., provider age, gender, or graduation year) for these dentists. Of 18 clinics included in the study, 17 clinics had geocodes and latitude and longitude information. Only one clinic, PD, where 1781 assessments and 690 sealants were conducted, had a missing geocode.

The final sample population is further restricted to 3,700 children with a CRA visit that had a dentist linkable to the provider information file. They were seen by 64 dentists, of whom 62 were in general dentistry, and 2 in pediatric dentistry. About 31% (n=20) of dentists were female. The median provider age was 41.6 years old. Dentists worked at the dental group for a median of 6.4 years and had a median of 16 years experience since graduation. The distribution of subjects based on the number of their FPMs that were qualified is shown in Table 4-1.

Table 4-1. The Distribution of Children and Their FPMs Qualified and Included in the Study (n = 3,700)

	Sealant group # of children and percentage	**Non-sealant group** # of children and percentage	**Whole sample** # of children and percentage
# of children with all 4 FPMs in study	1601 (55.94%)	638 (76.13%)	2239 (60.51%)
# of children with 3 FPMs in study	344 (12.02%)	91 (10.86%)	435 (11.76%)
# of children with 2 FPMs in study	423 (14.78%)	55 (6.56%)	478 (12.92%)
# of children with 1 FPMs in study	494 (17.26%)	54 (6.44%)	548 (14.81%)
Total # of children studied	2862	838	3700
Total # of FPMs studied	8776	2989	11765

Table 4-1 lists the number of children included in sealant group and non-sealant group, as well as the number of FPMs in each individual included in both groups. For both groups, more than half of individuals (55.94% for sealant group, 76.13% for non-sealant group) had all four FPMs included. They are denoted as S4 for sealant group and N4 for non-sealant group. The rest of the individuals had at the least one but less than four FPMs included in the sample. They are denoted as S1 for sealant group and N1 for non-sealant group. The reasons for the children being included in S1 group are that some of their FPMs were treated before the start of the observational period or never got sealed over the whole observation period. The reasons for the children in N1 group are that some of their FPMs were treated previously or got sealed sometime during the whole observation period. Children in S4 and S1 groups together constituted 77% of the whole sample, and this combined group (S4+S1) can be designated as 'any sealant' group (S). Among these children, having one, two, three, or four FPMs sealed are 17%, 15%, 12%, 56%, respectively. Since most of children are in the S4 group or N4 group, the cost and effectiveness difference between these two groups is the major comparison of interest. The comparison between 'any sealant' group and N4 group also was conducted. Since the number of children in N1 is small, and some of them may have received sealants during the observation period, N1 group was ignored in the analysis.

Table 4-2. Characteristics of the Study Sample

Patient Attributes	Number, Percentage or Mean (SD)
Socio-demographics	
Total	3,700
Age	
6 -- 8	1,751
9 -- 17	1,949
Gender	
Female	50.3%
Race*:	
White	43.2%
Non-White	12.0%
Unknown	44.9%
Median family income**:	
Less than $55,528	25.0%
$55,528 to less than $67,368	25.0%
$67,368 to less than $82,100	25.0%
$82,100 and greater	25.0%
Median of percentage of population with high school education**	93.3%

Median of percentage of population below poverty level**	3%
Median of percentage of population living in urban area**	100%
Mean # of years paid by public program during observation period	mean=0.6 (sd=1.6)
Baseline health conditions	
Caries risk assessment score: Low Medium High	 66.4% 17.9% 15.6%
Any caries in last 3 years: 0 1 to 2 more than 2	 66.7% 17.9% 15.5%
Dental care utilization	
# of regular examinations and prophylaxis visits per enrollment year: <=1 >1	 44.1% 55.9%
# of fluoride treatment visits during observation	mean=3.0 (sd=2.2)
Took any orthodontics treatment during observation period? Yes No	 13.0% 87.0%
Took any space maintenance treatment during observation period? Yes No	 1.7% 98.3%

Age 6-17 with a caries risk assessment during 1997 to 2001, and continuously enrolled for 5 years (n = 3,700)

*Race data available for 55% of the sample, n=1989.

**Census variables summarize information about the census block group in which the person lives. They do not describe the individual.

The socio-demographic information, baseline oral health condition, and dental care utilization of the study sample are summarized in Table 4-2. There are 3,700 children aged 6 to 17 during 1997 to 2001 who were continuously enrolled in the HealthPartners' comprehensive dental coverage for at least 5 years in the sample. Two age groups are used in analysis: age 6 to 8 group (n = 1,751) and age 9 to 17 group (n = 1,949). There are equal percentages of male and female. Forty-three percent are white, 12% are non-White such as African-American and Hispanic, and 45% of the sample have no ethnicity information. Univariate analyses, based on the 2000 census information on the neighborhoods in which the sample children lived, found that the 25th percentile the median family income in the block-group level was $55,528, the 50th percentile was $67,368, and the 75th percentile was $82,100. Most of the study sample was living in urban areas with relatively high income and education level. The median of percentage of population below poverty level was only 3%, and the median of the neighborhood rates of high school education attainment for those 25 years of age or older was 93.3%.

As shown in 4-2, the distribution of initial caries risk assessment (CRA) scores found 66.4% with low risk, 18% with moderate and 15.6% at high risk. This distribution is very similar to that of the past caries history, implying that the past caries history is the major criterion for risk assessment. The mean number of regular examinations and prophylaxis visits per enrollment year is 6. It was based on the number of encounters rather than the number of procedures. Besides, some children in the sample also received some fluoride treatments during the observation period (mean=3.0, sd=2.2), which may decrease the caries risk. A small number of children took other dental treatments such as orthodontics treatments or space maintenance treatments, which may increase the caries risk.

In sum, the children in the study sample were characterized as being more likely from the families or neighborhoods with relatively high SES. They had their teeth checked on a frequent basis. Two thirds of them were assessed as low caries risk at the beginning of the study.

Table 4-3. Association of Child Attributes with First Caries Risk Assessment Score

Patient Attributes	Low risk (n=2453)	Moderate risk (n=663)	High risk (n=584)	P-value***
Socio-demographics				
Age	Age 6-8: 46.93%	Age 6-8: 41.58%	Age 6-8: 57.80%	<0.0001
Gender	Female: 50.48%	Female: 52.24%	Female: 47.16%	0.199
Race**	White: 83.37%	White: 75.64%	White: 61.96%	<0.0001
Mean of family income* (SD)	70,851 (20,871)	67,160 (19,896)	64,360 (19,694)	<0.0001
Mean of percentage of population with high school education* (SD)	92.1% (6.9%)	91.0% (6.8%)	89.4% (8.9%)	<0.0001
Mean of percentage of population below poverty level* (SD)	5.0% (6.6%)	5.74% (7.14%)	6.79% (8.83%)	<0.0001
Mean of percentage of population living in urban area* (SD)	90.82% (26.1%)	90.05% (27.0%)	87.85% (30.1%)	0.06
Mean # of years paid by public program (SD)	0.08 (0.27)	0.16 (0.36)	0.24 (0.42)	<0.0001
Baseline health conditions				
Any caries in last 3 years:	Yes: 3%	Yes: 89%	Yes: 98.4%	<0.0001
Dental care utilization				
# of regular examinations and prophylaxis visits per enrollment year: <=1 compared to >1	40.88%	51.62%	49.11%	<0.0001
# of fluoride treatment visits during observation	2.88 (2.21)	3.01 (2.23)	3.37 (2.37)	<0.0001
Took any orthodontics treatment during observation period?	Yes: 13.35%	Yes: 14.84%	Yes: 9.57%	0.018
Took any space maintenance treatment during observation?	Yes: 0.67%	Yes: 2.01%	Yes: 5.50%	<0.0001
Sealant placement rate compared to non-sealant	77.47%	87.94%	85.46%	<0.0001

*Census variables summarize information about the census block group in which the person lives. They do not describe the individual.
**Race comparison only based on 55% of the sample with available information, n=1989.
***P values determined by ANOVA for comparison of means or chi-square test for comparison of proportions.

Caries risk assessment (CRA) score is an important variable in this study. It is a comprehensive measurement of general oral health status of an individual. CRAs were classified into three scores; low, moderate and high, and all analyses were made relative to the first caries risk assessment for each age cohort group. More than 90% of CRAs in this study were conducted by general dentists. Even if some CRAs were conducted by hygienists or assistants, they often needed be confirmed by dentists. The CRA score can affect both the sealant placement decision and sealant cost-effectiveness. The associations of the child attributes with first CRA scores are displayed in Table 4-3. The distribution of initial CRAs found 66% with low risk, 18% with moderate and 16% at high risk. This table shows a similar distribution of the gender among different risk levels ($p=0.199$). However, children in age 6 to 8 group were more likely to be assigned a high risk score than children in age 9 to 17 group ($p<0.001$). One reason could be that age 6 to 8 is the beginning of the mixed dentition stage when primary teeth have relatively more decay problems, and newly erupted teeth have more weaknesses. Another reason could be that FPMs in children at high caries risk were more likely to get sealed at young age, and those who had never gotten sealants at age 6 to 8 had low caries risk.

Table 4-3 shows that white children who were from families with relatively higher income, lower poverty level, and better education were more likely to have low caries risk ($p<0.001$), which is consistent with previous studies.[1, 31, 57, 58, 61-63] In the high risk category, children had a little longer dental coverage through public programs verses those in the low risk group ($p<0.001$). The distributions of the risk scores in rural children and urban children were similar ($p=0.06$). Of the children at low risk only 3% had any caries in past 3 years, while among the children with moderate or high risk 89% and 98% had any caries in past 3 years ($p <.0001$). High caries risk assessment scores were associated with low preventive care utilization ($p<0.001$) and more fluoride treatments ($p<0.001$). Sealant placement rate was generally high in this study sample due to the sampling method, but sealant placement was obviously associated with higher risk scores ($p<0.0001$).

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4.2. Sealant Application and Instrumental Variables Analyses

The analyses of sealant application factors and selection bias were based on the whole study sample of 3,700 individual children who had been enrolled continuously for 5 years in HealthPartners' comprehensive dental coverage. The associations of child attributes such as socio-demographics and health conditions, with sealant application are revealed. The relationships between proposed IVs and sealant placement are analyzed, and the relevant assumptions about IV are validated. Sealant placement is not limited to FPMs. However, since an individual generally has sealants on FPMs if he received any sealant, this study can make an argument that "non-sealant on FPMs" is the similar to "non-sealant", and the later term is used in this section for convenience.

4.2.1. Evidence of Selection Bias

Approximately 77% of the sample received at the least one sealant. Table 4-4 compares the characteristics of patients who did and did not receive any sealant on the FPMs.

Table 4-4. Characteristics of Children with and without Sealed FPMs

Child Attributes	Sealant group (with at the least one sealed FPM) (n=2862)	Non-sealant group (n=838)	P-value***
Socio-demographics			
Age	Age 6-8: 51.4%	Age 6-8: 32.3%	<0.0001
Gender	Female: 50.7%	Female: 48.6%	0.315
Race**	White: 77.1%	White: 83.4%	0.009
Mean of median family income* (SD)	68,676 (20,186)	71,246 (22,442)	0.003
Mean of percentage of population with high school education* (SD)	91.4% (7.3%)	92.1% (7.1%)	0.02
Mean of percentage of population below poverty level* (SD)	5.4% (7.1%)	5.3% (7.1%)	0.537
Mean of percentage of population living in urban area* (SD)	89.9% (27.5%)	91.7% (24.3%)	0.072
Mean # of years paid by public program (SD)	0.13 (0.33)	0.07 (0.25)	<0.0001
Baseline health conditions			
Caries risk assessment score: low vs. medium and high	Low: 63.9%	Low: 77.1%	<0.0001
Any caries in last 3 years:	Yes: 36.0%	Yes: 22.1%	<0.0001
Dental care utilization			
# of regular examinations and prophylaxis visits per enrollment year: <=1 compared to >1	42.2%	52.0%	<0.0001

*Census variables summarize information about the census block group in which the person lives. They do not describe the individual.

**Race comparison only based on 55% of the sample with available information, n=1989.
***P values determined by Student t-test for comparison of means or chi-square test for comparison of proportions.

As shown in Table 4-4, sealants were delivered more often to the children in the age 6 to 8 group. No significant difference in sealant rates was found between the boys and girls (p=0.315). There were significant differences between children who did and who did not receive at least one sealant on their FPMs by race, socioeconomic status, and baseline health condition. However, contrary to some previous studies which found that non-Hispanic white children and adolescents from families with relatively high incomes or high education level were more likely to have sealed teeth than those from families with lower incomes,[2, 16, 24, 58, 59, 116, 121, 125] this study found that children who received at least one sealant were significantly more likely to be non-white (p=0.009) and from families with relatively low incomes (p=0.003) or low education level (p=0.02). Poverty level and living area were not found to be associated with sealant rate. In the sealant group, children had a little longer dental coverage through public programs verses those in the non-sealant group (p<0.0001). Approximately 64% of children in sealant group were at low risk for caries, which was significantly lower than the percentage in non-sealant group (p<0.0001). Similarly, children with previous caries history were found to have a higher sealant rate (p<0.0001). So while making sealants more cost effective, the results might be biased against sealant effectiveness. Table 4-4 also compares the preventive care utilization between the two groups, and found that sealants were more likely to be placed on FPMs of children who had more than one preventive visit per year of enrollment (p<0.0001).

As noted earlier, based on the conceptual model and literature review, there is a concern that sealant intervention is endogenously determined. Some empirical evidence appears to confirm this hypothesis. As shown in Table 4-4, children receiving sealants are more likely to be non-white, come from families with lower incomes and less education, and use more dental care. Yet in some previous studies, caries prevalence was found higher among minorities.[136] Moreover, as shown in Table 4-4, among the children in the sealant group, the percentage of low risk children were lower and the percentage of children with recent caries history were higher. Those observed differences indicate that high risk individuals may have self-selected themselves into the sealant group. Another possible reason for those differences is that dentists may be more likely to place sealants in children who they perceive are at greater risk of caries.[22]

Another important bias could be related to the difference in the utilization of dental care. Both in previous studies and in this study, the more frequent users of preventive dental exams and services were more likely to receive sealants.[3, 8, 10, 22] There could be two different reasons to explain this finding. One is that children's parents in sealant group had a more interest in preventive dental care, which could positively affect the sealant effect. This reason is supported by previous studies that found more low risk children in sealant group.[2, 16, 24, 59] Another reason, in contrast, could be that children with more problems or high caries risk tended to use more preventive dental care, particularly if under the same insurance scheme, which hence could negatively affect the sealant effect. This reason is supported by the findings in this study where more high risk children were in sealant group.

In summary, the results, whether in previous studies or in this study, suggest a significant selection into the sealant intervention on the basis of observables and perhaps some unobservables. The unobserved factors could include attitude toward to health care, oral hygiene behavior and status, diet habit, tooth level weakness, etc. This kind of selection needs to be addressed explicitly to obtain consistent estimators of the sealant effect. Models that include confounding variables and use IV methods are necessary and appropriate.

4.2.2. Findings Supporting IVs

Section 3.3.3.2 established the connection between the initial risk assessment for each individual in each age cohort and sealant decision making. It is found that over 95% of time a sealant placement followed an overall caries risk assessment. The median interval between the closest risk assessment and the sealant placement was 38 days, the average was 92 days, and standard deviation was 160.52 days. Section 3.3.3.2 also proposed some predictors of sealant decision, including dentist age, dentist gender, dentist working experience, dentist preference for sealant, the distance between children's residence to clinics, and the month when the risk assessment was taken. This section presents how these possible IVs were related to sealant placement.

Table 4-5. Relationships between Sealant Placement and Possible Instrumental Variables.

Instrumental variables to be tested	Sealant group (with at the least one sealed FPM) (n=2862)	Non-sealant group (n=838)	P-value*
Dentist age <=50 compared to >50	69.12%	53.29%	<0.0001
Dentist gender	Female: 20.53%	Female: 14.86%	<0.0007
Dentist working years <=25 compared to >25	76.27%	58.71%	<0.0001
Dentist working years in HealthPartners (SD)	11.48 (7.37)	12.50 (7.62)	0.001
Dentist preference for sealant (SD)	5.38 (1.90)	4.96 (1.86)	<0.0001
Distance b/w residence and clinic <=11.8 mile compared to >11.8 mile	80.49%	76.86%	0.032
January	7.26%	7.71%	0.676
February	8.29%	10.00%	0.147
March	8.63%	8.14%	0.678
April	8.25%	8.29%	0.978
May	5.67%	7.86%	0.03
June	8.60%	8.43%	0.886
July	8.36%	9.43%	0.363
August	11.93%	9.86%	0.123
September	7.53%	8.43%	0.424
October	10.04%	6.71%	0.007
November	8.18%	8.86%	0.563
December	7.26%	6.29%	0.369

*P values determined by Student t-test for comparison of means or chi-square test for comparison of proportions.

The sample was treated by 64 dentists, the majority of whom were male and general dentists. The median dentist age was 41.6 years old. Dentists worked at their dental group for a median of 6.4 years and had a median of 16 years experience since graduation. As shown in Table 4-5, age and gender are significantly associated with sealant placement. Children seeing younger dentists or female dentists for risk assessment were more likely to receive sealant. That is perhaps because female and younger dentists are more cautious and prevention/intervention orientated. More importantly, as noted in section 3.3.3.2, older dentists may receive their professional education before the mid 1970's when sealant was formally accepted by ADA, and hence they don't tend to use as much or recommend as much sealant during the regular examination and risk assessment procedure. Similarly, this difference is also found in dentist's working years in HealthPartners. Dentist preference for sealant is a comprehensive measurement, and it may, somehow, be able to represent other dentist factors. It is measured by the ratio of sealant recommendations to all caries-preventing-related recommendations. Although sealant recommendations in the encounter records are not complete, as long as the incompleteness could be assumed to be random, rather than systematic, across dentists, dentist preference measurement can be used. The Table 4-5 shows that the sealant placement was associated with higher dentist preference for sealant ($p<0.0001$).

As discussed in section 3.3.3.2, conceptually, the distance between a residence and the clinic that was associated with initial risk assessment could be another useful IV. The distance was converted into a binary variable based on the differential distance: <11.8 miles (75% quartile), and >11.8 miles. The proportions of the sample who were associated with the shorter distance were 80.5% and 76.9% for sealant group and non-sealant group, respectively. The difference is significant ($p=0.032$), and it may affect the receipt of sealant. The sealant placement pattern was also investigated to examine if there was any difference by months. A few reasons for how the month variable could affect sealant rate are discussed in section 3.3.3.2. However, contrary to expectation, most of months did not have significant relationships with sealant rate. The only months which might be associated with sealant rate were May and October. Risk assessments conducted in May seem more related to lower sealant rate (p=0.03), which may be due to the relatively busy schedule at the end of the school year. Risk assessments conducted in October was more related to higher sealant rate (p=0.007), which seems reasonable if considering the school year schedule, the dentists' working schedule, weather, coverage, etc.

Based on the above simple statistics, the majority of proposed instruments seem to discriminate between sealant and non-sealant interventions. Those findings are preliminary. The next section carries a logistic regression analysis and produces more conclusive evidence.

4.2.3. Prediction of Sealant Placement and Validation of IVs

In this section, logistic regression was employed to examine the effects of observed variables, such as individual attributes and dental care utilization, on the likelihood of sealant placement, as well as how well the proposed IVs predicted sealant placement controlling for all other variables. The regression results are displayed in Table 4-6.

Table 4-6. Results from Logistic Model Predicting Sealant Rates Based on Patient Attributes and IV Characteristics.

Variables	Odds Ratio	Std. Err.	P>|Z|
Socio-demographics			
Age 9-17 vs 6-8	0.586	0.059	0.000
Gender M vs F	0.935	0.087	0.471
Race White Non-White Unknown	 Reference 1.201 0.983	 0.256 0.117	 0.391 0.887
Median family income* High vs. low	0.988	0.116	0.921
Percentage of population* below poverty level High vs. low	1.025	0.237	0.875
High school education* High vs. low	0.828	0.097	0.110
Geo_area* More urban vs. less urban	0.947	0.121	0.669
Mean # of years paid by public program	1.262	0.226	0.193
Baseline health conditions			
Caries risk assessment score: low medium high	 Reference 1.799 1.113	 0.258 0.160	 0.000 0.455
Dental care utilization			
# of regular examinations and prophylaxis visits per enrollment year: >1 compared to <=1	1.822	0.177	0.000
Cohorts			
Cohort 1997	Reference		
Cohort 1998	3.681	0.467	0.000
Cohort 1999	6.789	1.065	0.000
Cohort 2000	7.993	1.339	0.000
Cohort 2001	5.361	0.806	0.000
Instrumental variable candidates			

Dentist gender M vs F	1.122	0.155	0.401
Dentist working years >25 compared to <=25	0.393	0.041	0.000
Dentist preference for sealant	1.063	0.027	0.017
Distance b/w residence and clinic, >11.8 mile compared to <=11.8 mile	0.863	0.098	0.194
January	Reference		
February	1.035	0.233	0.878
March	1.182	0.276	0.474
April	1.487	0.348	0.090
May	1.084	0.264	0.741
June	1.647	0.388	0.034
July	1.278	0.296	0.289
August	1.708	0.382	0.017
September	1.338	0.316	0.218
October	1.931	0.466	0.006
November	1.188	0.273	0.453
December	1.788	0.447	0.020

*Census variables summarize information about the census tract in which the person lives. They do not describe the individual.

Table 4-6 shows that age was associated with sealant application (OR 0.59, p<0.001). Children aged 6 to 8 were more likely to receive sealant than children aged 9 or older. That probably is because some FPMs at high risk may already have received sealants during age 6 to 8. Moreover, it may be related to the sealant delivery pattern in the clinic. It long has been suggested that sealant should be placed on FPMs during age 6 to 8. The results from the logistic model shows no difference in sealant application rates by gender (p=0.47) or race (p>0.05) over the entire sample. Since there was no economic disincentive relative to cost, i.e., sealants were reimbursed 100 percent, all racial groups are as likely to receive sealants. Different from the significant bivariate associations in section 4.2.1., the results of the logistic model indicate that sealant application rates did not differ significantly among children residing in regions with different education and median family income levels. Living area and poverty level remained insignificant in the logistic model. The median family income, poverty level, and education were converted into binary variables based on their medians.

As shown in Table 4-6, compared to children at low caries risk, children at moderate risk had 80% greater odds of receiving sealants (OR 1.799, $p<0.001$). Contrary to expectations, high risk children were not more likely to receive sealants than low risk children ($p=0.455$). Further analysis, not shown in the Table, divided the sample into two age groups and conducted the regression separately. The same trend was found in both groups, and it was even more significant in age group 9 to 17. The reason perhaps is because dentists tend not to place sealants on questionable occlusal surfaces, especially in high risk children beyond the recommended sealant age range. Since caries history was highly correlated with CRA score, it was removed from the model. The Table 4-6 shows that the number of preventive visits was significantly associated with sealant rates. Children who visited dentists for preventive care more than once a year had 82% greater odds of receiving sealants (OR 1.822, $p<0.001$). For children included in different cohorts, their sealant rates were significantly different (all Ps<0.001).

The ability to predict sealant placement was not as expected for all proposed IVs. Provider gender was significant in bivariate analysis, but not significant ($p=.47$) in the logistic model. Dentists with working years more than 25 years were less likely to apply sealants (OR 0.393, $p<0.001$). Dentist age and dentist working experience in HealthPartners were highly correlated with dentist working year ($r=0.94$ and 0.77, respectively), and they were removed from the model. As a comprehensive measurement, dentists preference for sealant was found associated with sealant rates, but was not highly significant (p=0.017). It could be a weak IV and needs further validation. In addition, distance and month indicators which were proposed as IVs in the conceptual model turned out not to be good predictors of sealant placement.

In sum, only the dentist's working years would be a valid IV. It was a strong predictor of sealant placement after adjusting for child attributes, and more importantly, the prediction was in the proposed direction. To test further if the dentist's working years significantly affect the sealant application decision, an F-statistic from the ordinary least square regression of the sealant intervention variable on dentist's working years was calculated.[200] F-statistics can reflect the total variation explained by the IV relative to the total unexplained variation. It was suggested that an F-statistic of 10 or greater indicates a strong IV.[201] If an F-test value is less than 10, the IV would be weak and there is no advantage using IVs to conduct analysis. Since the F-value was 79.39 based on the regression on the whole sample, dentist's working years would be a strong IV and have substantial explanatory power.

Another condition for a valid IV is that this IV does not have a direct effect on the outcome except through an indirect effect on the likelihood of receiving the intervention. If this assumption does not hold, the estimates from the IV analysis would be biased.[170] This assumption is impossible to test for the first instrument, and often it needs to be taken on faith.[170] This study examined the consistency of dental care providers from risk assessment to sealant to the first caries treatment. About 75% of sealants were placed by dental assistants or hygienists, rather than by dentists. Also only 16.41% of assessments and sealants were conducted by the same dentists. For those cases, since the dentists' working experience may affect the outcome through the operation skills rather than through the decision making, little contamination of the validity of the IV may exist. Moreover, this study found that, after 3 to 5 years, less than 22% of the time children would be able to see the same dentists. It is reasonable to believe that a dentist who treated a sample child generally was not the dentist who did the initial risk assessment for the same child. The assumption that the working year of a dentist who conducted the initial CRA for a child does not have a direct effect on the outcome except through an indirect effect on the likelihood of receiving sealant further was confirmed by interviewing dentists in clinic.

4.3. Analyses of Main Effectiveness

As mentioned in at the beginning of this chapter, both sealant and non-sealant groups had more than half of individuals (55.94% for sealant group, 76.13% for non-sealant group) either with all four FPMs sealed within one year or with all unsealed FPMs during 5 years in the sample. They were marked as S4 for sealant group and N4 for non-sealant group. The groups of individuals with at least one but less than four FPMs included in the sample were marked as S1 for sealant group and N1 for non-sealant group. The combined group of S4 and S1 are referred to as 'any sealant' group and represented simply by S group. Since more than 60% of the sample were in either S4 group or N4 group, the comparison between them is the major comparison of interest for this study. The comparison between group S and group N4 is conducted using modeling and the whole sample only. Since the number of children in N1 is small, and some of them may have received sealants during the observation period, N1 group was ignored in the analysis. The sample-based average effectiveness difference and the modeling-based results are reported in this section.

4.3.1. General Outcome Comparison

During 5 year follow-up period, some FPMs received caries-treating procedures, such as restorations and crowns. The more such procedures are found in a group, the worse the effectiveness can be for this group. Before running analytic models, Table 4-7 summarizes the numbers and proportions of the relevant procedures found at the end of the fifth year of observation for the sample of individuals in the S4 group and N4 group.

Table 4-7. Effectiveness Comparison based on Caries-treating Procedures Delivered to Individuals with ALL 4 FPMs Sealed or ALL 4 FPMs Unsealed, over 5 Years

Major caries treatments and their frequency over 5 years	**Sealant group (S4)**		**Non-sealant group (N4)**	
	Earliest procedures in records	Total number of procedures over 5 years	Earliest procedures in records	Total number of procedures over 5 years
Total number of subjects	1601		638	
Number of subjects without any new caries	1343 (83.9%)		530 (83.1)	
Total number of FPMs	6404		2552	
Number of FPMs without any new caries	6041 (94.3)		2344 (91.8)	
1-surface restoration	293 (80.7%)	321 (79.1%)	119 (57.2%)	136 (51.5%)
2-surface restoration	57 (15.7%)	66 (16.3%)	64 (30.8)	84 (31.8%)
3+-surface restoration	10 (2.8%)	13 (3.2%)	7 (3.4%)	9 (3.4%)
Crown	3 (0.8%)	3 (0.7%)	15 (7.2%)	20 (7.6%)
Pulp or root canal treatment	0 (0%)	3 (0.7%)	1 (0.5%)	12 (4.6%)
Extraction	0 (0%)	0 (0%)	2 (1%)	3 (1.1%)

Mean of restoration-free months per FPM*	58.64 months	57.49 months
Mean of net cost per FPM*	$56.84	$13.13
Incremental cost-effectiveness ratio*	$38/caries-free month	

Results are based on 0% discount rate.
*Caries-free or restoration-free months per FPM, as well as net cost per FPM, are average measures across all included FPMs for each individual.

Table 4-7 shows that, at the end of the fifth year of observation, 83.9% of the sample in S4 group and 94.3% of FPMs in S4 group stayed healthy or received no caries treatment. In contrast, 83.1% of the sample individuals and 91.8% of FPMs stayed healthy in N4 group. The differences between two groups were not great. A protective effect of only 2.5 (94.3% minus 91.8%) percent was found associated with sealant placement. Table 4-7 also compares the difference in the frequency of each type of treatment received by the two groups. Among all first or earliest caries treatments, 80.7% were one-surface restorations in S4 group, and 57.2% were one-surface restorations in N4 group. Similarly, 18.5% were restorations involving two or more surfaces in S4 group, and 57.2% were restorations involving two or more surface in N4 group. Moreover, children in S4 group had smaller proportion of extensive restorative treatments, such as crowns, endodontic therapies, and extractions (0.8% vs. 8.7%). Since some FPMs could get more than one procedure over the follow-up period, Table 4-7 compares the total frequency of each type of treatment over 5 years. It is found that children group N4 experienced fewer one-surface restorations (51.5%) but more multiple-surface restorations and relatively extensive treatments, compared to group S4. All these findings indicate that group without sealant experienced worse effectiveness. A sealant effectiveness analysis which can take caries severity into account may be more able to reflect real life differences.

In addition to procedure summary, Table 4-7 demonstrated that there was a difference in sealant effectiveness between S4 group and N4 group (58.64 months vs. 57.49 months). For convenience of illustration, the sample-based mean expenditures for S4 group and N4 group were displayed also. Their difference was relatively big ($56.84 vs. $13.13). Accordingly, the incremental cost-effectiveness ratio, based on sample average, would be $38/caries-free months if discount rate is zero.

4.3.2. Sealant Effectiveness Based on Analytical Modeling

This section focuses on studying the sealant effectiveness using several models: OLS model, classic Tobit model without selectivity-correction, selectivity-corrected Tobit model, classic two-part model, and selectivity-corrected two-part model. Two comparisons are conducted: S4 group vs. N4 group, and S group vs. N4 group. Three percent of discount rate is applied in this section, while 0% and 5% of discount rates are applied in sensitivity analysis. The marginal effects of sealant on average caries-free duration from various models are calculated and contrasted in section 6.5.

S4 Group vs. N4 Group

Since a large number of children did not have any caries on FPMs over 5 year follow-up, the distribution of the effectiveness variable has a mass of observations with

56.6 months which is the maximum average caries-free duration after being discounted by 3%. That justifies the use of Tobit model and two-part model. Table 4-8 displays the estimation results from OLS, classic Tobit Model, and selectivity-corrected Tobit model, and Table 4-9 displays the estimation results from two-part model and selectivity-corrected two-part model. The results are shown separately due to the page limit, but are discussed together. The comparison groups are the S4 group and N4 group.

Table 4-8. Estimation Results from OLS, Classic Tobit Model, and Selectivity-corrected Tobit model on Effectiveness, Comparison between S4 Group and N4 Group, (Discount Rate=3%)

Variables	**OLS Regression** Coef.	Std. Err.	P-value	**Tobit Regression** Coef.	Std. Err.	P-value	**Selectivity-corrected Tobit Regression** Coef.	Std. Err.	P-value
Socio-demographic									
Age									
6-8	Ref			Ref			Ref		
9-17	-0.385	0.242	0.112	-2.753	1.281	**0.032**	-0.412	0.268	0.124
Gender									
Female	Ref			Ref			Ref		
Male	0.025	0.207	0.905	1.045	1.097	0.341	0.025	0.206	0.904
Race									
White	Ref			Ref			Ref		
Non-White	1.308	0.380	**0.001**	5.203	2.054	**0.011**	1.312	0.379	**0.001**
Unkown	-0.004	0.224	0.987	0.452	1.186	0.703	-0.002	0.223	0.993
Median family income*									
< $67,000 (median)	Ref			Ref			Ref		
>= $67,000	-0.186	0.268	0.489	-0.734	1.422	0.606	-0.188	0.267	0.483
High school education*									
< 93% (median)	Ref			Ref			Ref		
>= 93%	0.241	0.260	0.354	1.542	1.363	0.258	0.237	0.259	0.360
Percentage of population below poverty level*									
< 3% (median)	Ref			Ref			Ref		
>= 3%	-0.153	0.225	0.498	-0.768	1.186	0.517	-0.157	0.225	0.486
Geo_area*									
< 100% (median)	Ref			Ref			Ref		
= 100%	-0.090	0.275	0.744	-0.807	1.458	0.580	-0.090	0.274	0.744
Mean # of years paid by public program	-0.259	0.392	0.509	-2.152	1.993	0.280	-0.257	0.391	0.511

Table 4-8. Estimation Results from OLS, Classic Tobit Model, and Selectivity-corrected Tobit model on Effectiveness, Comparison between S4 Group and N4 Group, (Discount Rate=3%), (continued)

	OLS Regression			**Tobit Regression**			**Selectivity-corrected Tobit Regression**		
Variables	**Coef.**	**Std. Err.**	**P-value**	**Coef.**	**Std. Err.**	**P-value**	**Coef.**	**Std. Err.**	**P-value**
Baseline health condition									
Caries risk assessment score:									
Low	Ref			Ref			Ref		
Medium	-1.497	0.309	**0.000**	-8.318	1.527	**0.000**	-1.486	0.311	**0.000**
High	-4.184	0.336	**0.000**	-14.999	1.601	**0.000**	-4.186	0.335	**0.000**
Dental care utilization									
Sealant placement	1.295	0.261	**0.000**	2.711	1.381	0.050	1.166	0.614	0.058
# of preventive visits per enrollment year:									
<=1	Ref			Ref			Ref		
> 1	-0.029	0.250	0.906	-0.309	1.333	0.817	-0.017	0.254	0.947
# of fluoride treatment visits during observation	-0.101	0.065	0.122	-0.847	0.330	0.010	-0.101	0.065	0.121
Orthodontics treatment?									
No	Ref			Ref			Ref		
Yes	0.672	0.353	0.057	3.859	1.942	0.047	0.673	0.351	0.055
Space maintenance treatment?									
No	Ref			Ref			Ref		
Yes	-1.147	0.810	0.157	-2.949	3.609	0.414	-1.145	0.807	0.156
Cohort									
Cohort 1997	Ref			Ref			Ref		
Cohort 1998	-0.291	0.325	0.370	-0.064	1.679	0.969	-0.256	0.357	0.474
Cohort 1999	-0.574	0.359	0.110	-0.786	1.836	0.669	-0.530	0.404	0.189
Cohort 2000	0.216	0.387	0.576	3.222	2.096	0.124	0.264	0.436	0.545
Cohort 2001	-0.404	0.402	0.316	-0.157	2.046	0.939	-0.365	0.434	0.400

Table 4-9. Estimation Results from Two-part Model and Selectivity-corrected Two-part Model on Effectiveness, Comparison between S4 Group and N4 Group, (Discount Rate=3%)

	Two part model						**Selectivity-corrected Two part model**					
	Probit Regression			**OLS Regression**			**Biprobit Model**			**Treatment-effect Model**		
Variables	**Coef.**	**Std. Err.**	**P-value**	**Coef.**	**Std. Err.**	**P-value**	**Coef.**	**Std. Err.**	**P-value**	**Coef.**	**Std. Err.**	**P-value**
Socio-demographic												
Age												
6-8	Ref			Ref			Ref			Ref		
9-17	0.170	0.077	**0.027**	0.305	1.040	0.769	0.251	0.118	0.034	0.755	1.179	0.522
Gender												
Female	Ref			Ref			Ref			Ref		
Male	-0.089	0.066	0.175	-1.599	0.903	0.078	-0.088	0.065	0.175	-1.695	0.888	0.056
Race												
White	Ref			Ref			Ref			Ref		
Non-White	-0.237	0.128	0.064	3.846	1.632	**0.019**	-0.244	0.126	0.052	3.683	1.603	**0.022**
Unkown	-0.033	0.071	0.641	0.413	0.962	0.668	-0.038	0.071	0.595	0.464	0.939	0.621
Median family income*												
< $67,000 (median)	Ref			Ref			Ref			Ref		
>= $67,000	0.031	0.086	0.720	-0.326	1.144	0.776	0.034	0.086	0.688	-0.166	1.134	0.883
High school education*												
< 93% (median)	Ref			Ref			Ref			Ref		
>= 93%	-0.097	0.084	0.248	-0.441	1.074	0.682	-0.084	0.086	0.328	-0.515	1.050	0.624
Percentage of population below poverty level*												
< 3% (median)	Ref			Ref			Ref			Ref		
>= 3%	0.032	0.073	0.655	-0.934	0.945	0.324	0.043	0.073	0.555	-0.890	0.921	0.334
Geo_area*												
< 100% (median)	Ref			Ref			Ref			Ref		
= 100%	0.054	0.088	0.539	-0.813	1.167	0.487	0.053	0.089	0.548	-1.005	1.165	0.388
Mean # of yrs paid by public program	0.146	0.122	0.232	0.636	1.508	0.673	0.136	0.123	0.267	0.731	1.472	0.619

Table 4-9. Estimation Results from Two-part Model and Selectivity-corrected Two-part Model on Effectiveness, Comparison between S4 Group and N4 Group, (Discount Rate=3%), (continued)

	Two part model						**Selectivity-corrected Two part model**					
	Probit Regression			**OLS Regression**			**Biprobit Model**			**Treatment-effect Model**		
Variables	**Coef.**	**Std. Err.**	**P-value**	**Coef.**	**Std. Err.**	**P-value**	**Coef.**	**Std. Err.**	**P-value**	**Coef.**	**Std. Err.**	**P-value**
Baseline health condition												
Caries risk assessment score:												
Low	Ref			Ref			Ref			Ref		
Medium	0.468	0.091	**0.000**	-2.664	1.163	**0.023**	0.427	0.107	**0.000**	-2.783	1.142	**0.015**
High	0.728	0.096	**0.000**	-7.668	1.151	**0.000**	0.724	0.099	**0.000**	-7.402	1.175	**0.000**
Dental care utilization												
Sealant placement	-0.019	0.081	0.814	6.370	1.178	**0.000**	0.363	0.440	0.409	7.938	2.403	**0.001**
# of preventive visits per year:												
<=1	Ref			Ref			Ref			Ref		
> 1	0.019	0.081	0.819	-0.034	1.078	0.975	-0.021	0.093	0.821	-0.318	1.117	0.776
# of fluoride treatment visits during observation	0.058	0.020	**0.005**	0.138	0.250	0.580	0.056	0.020	**0.006**	0.128	0.243	0.598
Took any orthodontics treatment during observation period?												
No	Ref			Ref			Ref			Ref		
Yes	-0.219	0.119	0.065	0.848	1.590	0.594	-0.220	0.117	0.061	0.869	1.543	0.573
Space maintenance treatment												
No	Ref			Ref			Ref			Ref		
Yes	0.125	0.221	0.572	-1.037	2.598	0.690	0.115	0.217	0.594	-1.086	2.520	0.666
Cohort												
Cohort 1997	Ref			Ref			Ref			Ref		
Cohort 1998	-0.048	0.101	0.635	-1.964	1.337	0.143	-0.152	0.159	0.342	-2.370	1.411	0.093
Cohort 1999	-0.019	0.113	0.866	-2.031	1.410	0.151	-0.151	0.190	0.427	-2.415	1.465	0.099
Cohort 2000	-0.214	0.127	0.092	-0.564	1.690	0.739	-0.351	0.210	0.095	-1.226	1.869	0.512
Cohort 2001	-0.038	0.126	0.761	-2.422	1.544	0.118	-0.152	0.183	0.404	-2.985	1.680	0.076

Tables 4-8 and 4-9 display the estimation results from five different models for comparison between S4 group and N4 group. These models have different assumptions, specifications and coefficient interpretations. For example, the estimated coefficients of the linear OLS regression are the marginal effects of one unit change in covariates on the outcome. The coefficients of the Tobit models are changes in the latent outcome variable due to one unit change in covariates. The coefficients of the probit regressions from two-part models are related to probability of having any caries on any FPM in a child. Therefore, comparing the absolute values of the coefficients from these models is not meaningful. The signs and significant levels of the corresponding coefficients from these models would be still useful for policy implication. For example, a positive sign could mean the increase of the covariate of interest also increases the aggregated caries-free duration or the likelihood of having any caries, at certain statistical significant level. The marginal effects associated with sealant placement were calculated based on the formula provided in methodology chapter. They reflect the changes in the effectiveness due to the sealant application status. They are comparable and presented in section 4.5.

Firstly, Table 4-8 presents the estimated effects of observed variables on the effectiveness based on a simple OLS model. Only 3 factors had significant effects on effectiveness -- race, caries risk score, and sealant placement. Compared to white children, non-white children had longer caries-free duration ($p=0.001$). Children who had higher risk scores had shorter caries-free duration ($p<0.001$). Children receiving sealant on all 4 FPMs had an average 1.3 more healthy tooth months than the children who did not receive any sealant on any FPM ($p<0.01$).

From the same table, it is easy to see that the coefficients estimated from classic Tobit model were generally larger in absolute value and in the same direction as those from OLS. Because of the massive observations were at the censoring point, this difference is expected. Like the results of OLS, non-white children were found to have longer caries-free duration (p=0.011). Children with moderate and high caries risk scores were found to have shorter caries-free duration (p<0.001). Children receiving sealant were likely to have longer caries-free duration for each FPM (p=0.05). Other covariates were not statistically significant.

Table 4-8 also presents the estimated coefficients of observed variables on the effectiveness based on the selectivity-corrected Tobit model. This model used IV to account for the non-random assignment of sealant placement. One important test, which is not displayed in the Table but is reported in the text, is for the correlation between the error terms in the selection equation and main equation of interest. This correlation is represented by ρ. If the test shows ρ is statistically significant, that indicates that selection bias due to the unobserved factors may significantly affect the results and the correction was needed. Based on the conceptual model and the context for sealant delivery, if favorable sealant selection occurs, the selectivity-corrected sealant effect should be greater than the uncorrected sealant effects. When adverse sealant selection occurs, the selectivity-corrected sealant effect should be less than the uncorrected sealant effect. However, the results of this selectivity-corrected Tobit model showed that the correlation ρ was small in magnitude in the effectiveness model for S4 vs. N4 group, and not statistically significant (Z value=0.23, p=0.817). Since the selection bias was not detected, the models without selectivity correction could be accepted, and unobserved factors may not generate significant estimation bias. As shown in Table 4-8, race, risk level, and sealant were statistically significant factors and they maintained same direction as well in the selectivity-corrected model. Like the non-selectivity corrected model, other coefficients were not statistically significant.

Table 4-9 shows the estimated coefficients of two-part model and selectivity-corrected two-part model. They reflect how those observed factors affect the probability of having any caries over 5 years as well as the average caries-free duration. Among all covariates, the higher risk level was found related to higher probability of having any caries. The number of fluoride treatments was also positively associated with the probability of having any caries ($p<0.05$). It may be because children who received more fluoride treatments were those with more tooth problems. The results of the bivariate probit model were similar. Both models do not show that sealant placement and other factors have any statistically significant effect on the probability of developing any caries. The correlation ρ was small in magnitude in the bivariate probit model and not statistically significant (Z value=-0.85, p=0.397).

Like the results of OLS and Tobit models, race, risk level, and sealant placement were factors associated with the average caries-free duration given any caries was developed, based on two-part models. For example, non-white children had longer caries-free duration than white children. Compared to low risk children, those with moderate and high caries risk scores were found to have shorter caries-free duration. Children in the sealant group were likely to have longer caries-free duration. Other covariates were not statistically significant. Similar to the selectivity-corrected Tobit model and bivariate probit model, the correlation ρ in the treatment effect model was also small in magnitude and not statistically significant (Z value=-0.74, p=0.460).

In sum, the directions and significant levels of the coefficients of the above fitted models were consistent. No selectivity problem was found for the comparison between S4 group and N4 group. The models without selectivity correction can be accepted.

S group vs. N4 group

S group not only included children with all 4 FPMs sealed, but also included children with one , two or three FPMs sealed. That implies that sealant placement for S group may be more selective or risk-based, since the unsealed FPMs could be those that had previous restorations or those that were less likely to develop caries. The effectiveness, average caries-free duration, was discounted by 3%. Table 4-10 displays the estimation results from OLS, classic Tobit model, and selectivity-corrected Tobit model, and Table 4-11 displays the estimation results from two-part model and selectivity-corrected two-part model.

Table 4-10. Estimation Results from OLS, Classic Tobit Model, and Selectivity-corrected Tobit model on Effectiveness, Comparison between S Group and N4 Group, (Discount Rate=3%)

	OLS Regression			**Tobit Regression**			**Selectivity-corrected Tobit Regression**		
Variables	**Coef.**	**Std. Err.**	**P-value**	**Coef.**	**Std. Err.**	**P-value**	**Coef.**	**Std. Err.**	**P-value**
Socio-demographic									
Age									
6-8	Ref			Ref			Ref		
9-17	-0.899	0.250	**0.000**	-3.363	1.218	**0.006**	-0.915	0.252	**0.000**
Gender									
Female	Ref			Ref			Ref		
Male	-0.223	0.226	0.325	0.354	1.102	0.748	-0.224	0.226	0.322
Race									
White	Ref			Ref			Ref		
Non-White	0.677	0.408	0.097	3.020	1.931	0.118	0.684	0.407	0.093
Unkown	0.157	0.247	0.524	1.351	1.210	0.264	0.156	0.246	0.527
Median family income*									
< $67,000 (median)	Ref			Ref			Ref		
>= $67,000	-0.137	0.292	0.639	0.051	1.416	0.971	-0.136	0.291	0.641
High school education*									
< 93% (median)	Ref			Ref			Ref		
>= 93%	0.163	0.283	0.565	0.584	1.361	0.668	0.154	0.283	0.585
Percentage of population below poverty level*									
< 3% (median)	Ref			Ref			Ref		
>= 3%	-0.115	0.250	0.646	-0.149	1.212	0.902	-0.117	0.249	0.639
Geo_area*									
< 100% (median)	Ref			Ref			Ref		
= 100%	-0.226	0.302	0.454	-1.245	1.471	0.398	-0.226	0.301	0.452
Mean # of years paid by public program	-0.634	0.420	0.131	-3.807	1.911	0.046	-0.629	0.419	0.133

Table 4-10. Estimation Results from OLS, Classic Tobit Model, and Selectivity-corrected Tobit model on Effectiveness, Comparison between S Group and N4 Group, (Discount Rate=3%), (continued)

	OLS Regression			**Tobit Regression**			**Selectivity-corrected Tobit Regression**		
Variables	**Coef.**	**Std. Err.**	**P-value**	**Coef.**	**Std. Err.**	**P-value**	**Coef.**	**Std. Err.**	**P-value**
Baseline health condition									
Caries risk assessment score:									
Low	Ref			Ref			Ref		
Medium	-1.765	0.307	**0.000**	-10.215	1.443	**0.000**	-1.740	0.311	**0.000**
High	-3.924	0.339	**0.000**	-15.687	1.530	**0.000**	-3.924	0.339	**0.000**
Dental care utilization									
Sealant placement	2.121	0.293	**0.000**	8.158	1.387	**0.000**	1.835	0.695	**0.008**
# of preventive visits per enrollment year:									
<=1	Ref			Ref			Ref		
> 1	-0.133	0.270	0.621	-0.304	1.316	0.817	-0.112	0.273	0.681
# of fluoride treatment visits during observation	-0.209	0.068	**0.002**	-1.466	0.323	**0.000**	-0.209	0.068	**0.002**
Orthodontics treatment?									
No	Ref			Ref			Ref		
Yes	0.599	0.353	0.090	4.534	1.781	0.011	0.601	0.353	0.088
Space maintenance treatment?									
No	Ref			Ref			Ref		
Yes	-1.124	0.883	0.203	-2.113	3.794	0.578	-1.120	0.881	0.203
Cohort									
Cohort 1997	Ref			Ref			Ref		
Cohort 1998	-0.636	0.355	0.073	-1.822	1.718	0.289	-0.557	0.394	0.158
Cohort 1999	-0.670	0.385	0.082	-1.636	1.883	0.385	-0.572	0.440	0.194
Cohort 2000	-0.813	0.409	0.047	-2.638	1.986	0.184	-0.710	0.467	0.128
Cohort 2001	-1.053	0.429	**0.014**	-3.717	2.046	0.069	-0.958	0.476	**0.044**
Constant	55.545	0.594	0.000	84.704	3.026	0.000	55.690	0.673	0.000

Table 4-11. Estimation Results from Two-part Model and Selectivity-corrected Two-part Model on Effectiveness, Comparison between S Group and N4 Group, (Discount Rate=3%)

	Two part model						**Selectivity-corrected Two part model**					
	Probit Regression			**OLS Regression**			**Biprobit Model**			**Treatment-effect Model**		
Variables	**Coef.**	**Std. Err.**	**P-value**	**Coef.**	**Std. Err.**	**P-value**	**Coef.**	**Std. Err.**	**P-value**	**Coef.**	**Std. Err.**	**P-value**
Socio-demographic												
Age												
6-8	Ref			Ref			Ref			Ref		
9-17	0.098	0.056	0.078	-3.325	0.991	**0.001**	0.104	0.060	0.083	-3.294	1.036	**0.001**
Gender												
Female	Ref			Ref			Ref			Ref		
Male	-0.060	0.050	0.228	-2.599	0.904	**0.004**	-0.060	0.050	0.231	-2.620	0.919	**0.004**
Race												
White	Ref			Ref			Ref			Ref		
Non-White	-0.152	0.092	0.100	-0.255	1.501	0.865	-0.154	0.093	0.096	-0.265	1.482	0.858
Unkown	-0.070	0.054	0.195	-0.176	0.992	0.859	-0.070	0.055	0.200	-0.168	0.980	0.864
Median family income*												
< $67,000 (median)	Ref			Ref			Ref			Ref		
>= $67,000	-0.028	0.065	0.671	-1.427	1.135	0.209	-0.028	0.065	0.663	-1.419	1.120	0.205
High school education*												
< 93% (median)	Ref			Ref			Ref			Ref		
>= 93%	-0.022	0.064	0.732	0.106	1.064	0.921	-0.019	0.065	0.773	0.092	1.058	0.930
Percentage of population below poverty level*												
< 3% (median)	Ref			Ref			Ref			Ref		
>= 3%	-0.014	0.055	0.807	-1.186	0.984	0.228	-0.013	0.056	0.817	-1.187	0.968	0.220
Geo_area*												
< 100% (median)	Ref			Ref			Ref			Ref		
= 100%	0.047	0.067	0.479	-1.168	1.183	0.324	0.047	0.067	0.479	-1.186	1.182	0.316
Mean # of yrs paid by public program	0.196	0.089	0.027	0.197	1.431	0.891	0.194	0.089	0.029	0.198	1.408	0.888

Table 4-11. Estimation Results from Two-part Model and Selectivity-corrected Two-part Model on Effectiveness, Comparison between S Group and N4 Group, (Discount Rate=3%), (continued)

	Two part model						Selectivity-corrected Two part model					
	Probit Regression			OLS Regression			Biprobit Model			Treatment-effect Model		
Variables	**Coef.**	**Std. Err.**	**P-value**	**Coef.**	**Std. Err.**	**P-value**	**Coef.**	**Std. Err.**	**P-value**	**Coef.**	**Std. Err.**	**P-value**
Baseline health condition												
Caries risk assessment score:												
Low	Ref			Ref			Ref			Ref		
Medium	0.449	0.065	**0.000**	-2.309	1.127	**0.041**	0.439	0.075	**0.000**	-2.334	1.142	**0.041**
High	0.629	0.069	**0.000**	-6.017	1.135	**0.000**	0.628	0.070	**0.000**	-5.992	1.149	**0.000**
Dental care utilization												
Sealant placement	-0.291	0.061	**0.000**	5.260	1.115	**0.000**	-0.191	0.391	0.625	5.521	3.087	0.074
# of preventive visits per year:												
<=1	Ref			Ref			Ref			Ref		
> 1	-0.006	0.061	0.923	-0.992	1.050	0.345	-0.013	0.068	0.845	-1.027	1.103	0.352
# of fluoride treatment visits	0.073	0.015	**0.000**	0.065	0.252	0.796	0.073	0.015	**0.000**	0.064	0.248	0.798
Took any orthodontics treatment during observation period?												
No	Ref			Ref			Ref			Ref		
Yes	-0.224	0.082	**0.006**	-0.241	1.481	0.871	-0.224	0.082	**0.006**	-0.244	1.458	0.867
Space maintenance treatment?												
No	Ref			Ref			Ref			Ref		
Yes	0.051	0.169	0.763	-2.693	2.779	0.333	0.049	0.169	0.772	-2.708	2.739	0.323
Cohort												
Cohort 1997	Ref			Ref			Ref			Ref		
Cohort 1998	0.037	0.078	0.637	-2.502	1.383	0.071	0.009	0.134	0.947	-2.578	1.599	0.107
Cohort 1999	0.031	0.085	0.715	-2.384	1.513	0.115	-0.003	0.160	0.983	-2.465	1.734	0.155
Cohort 2000	0.077	0.091	0.396	-2.750	1.570	0.080	0.041	0.169	0.808	-2.861	1.973	0.147
Cohort 2001	0.125	0.094	0.184	-2.907	1.590	0.068	0.092	0.160	0.568	-3.009	1.927	0.118
Constant	-1.170	0.130	0.000	49.683	2.300	0.000	-1.219	0.231	0.000	49.598	2.450	0.000

Tables 4-10 and 4-11 display the estimation results from five different models for comparison between S group and N4 group. The estimation result based on a simple OLS model shows that four factors had significant effects on effectiveness -- age, caries risk score, sealant placement and fluoride treatment. Compared to children aged 6 to 8, children aged 9 to 17 had shorter average caries-free duration ($p<0.001$). Children who had higher risk scores had shorter caries-free duration ($p<0.001$). Children receiving sealant on at the least one FPM had an average 2.1 more tooth months than the children who did not receive any sealant on any FPM ($p<0.001$). The higher number of fluoride treatments was associated with shorter caries-free duration ($p=0.002$). Fluoride treatments were recorded at person level instead of at tooth level, and they could be another variable reflecting a relatively high caries risk. Other covariates were not statistically significant. The same factors were also found from the classic Tobit model in the same table. The coefficients estimated from the classic Tobit model were generally larger in absolute value and in the same direction as those from OLS. Younger children with low caries risk scores and sealant placement were more likely to have longer caries-free duration for each FPM (all p values less than 0.01).

Table 4-10 also presents the estimated coefficients of observed variables on the effectiveness based on the selectivity-corrected Tobit model. The correlation between the error terms in the selection equation and main equation of interest, which is represented by ρ was found small in magnitude and not statistically significant (Z value=0.45, p=0.65). Therefore, the classic Tobit model without selectivity correction could be accepted, and some unobserved factors may not generate significant estimation bias. Similar to the result of the classic Tobit model, age, risk level, sealant and fluoride treatment number were statistically significant factors and they maintained same direction as well in the selectivity-corrected model. Other coefficients were not statistically significant.

Table 4-11 shows the estimated coefficients of two-part model and selectivity-corrected two-part model. In both models, age and gender were found to affect the average caries-free duration given any caries was developed, but not the probability of having any caries. Older and male children are more likely to have shorter caries-free duration (all p values less than 0.01). In both models, the higher risk level was found not only related to higher probability of having any caries, but also to shorter caries-free duration. The sealant effect was shown differently in two models. In simple two-part model, sealant was found associated with lower probability of having any caries and shorter caries-free duration. But in selectivity-corrected two-part model, the sealant coefficients had similar values but were not statistically significant. That may be because the selectivity-corrected model needs a bigger sample to show statistical difference. Moreover, in both models, the number of fluoride treatments and taking any orthodontics treatment were found to affect the probability of having any caries, but not the average caries-free duration given any caries was developed. Similar to the findings for the comparison between S4 group and N4 group, the ρ values were small in magnitude and not statistically significant in both the bivariate probit mode (Z value=-0.26, p=0.795) and in the treatment effect model (Z value=-0.09, p=0.928).

In sum, the directions and significant levels of the coefficients for some important factors such as caries risk scores and sealant placement are basically consistent across models. They are also consistent across two types of comparisons, S4 vs. N4 and S vs. N4 comparisons. No selectivity problem was found in either comparison.

4.4. Analyses of Main Cost

This section focuses on studying the cost associated with sealant application using several models: OLS model, classic Tobit model without selectivity-correction, selectivity-corrected Tobit model, classic two-part model, and selectivity-corrected two-part model. Two comparisons are conducted: S4 group vs. N4 group, and S group vs. N4 group. A three percent discount rate is applied in this section, while 0% and 5% of discount rates are applied in the sensitivity analysis. The marginal effects of sealant on cost from various models are calculated and contrasted in section 6.5.

S4 Group vs. N4 Group

Since a large number of children did not have any caries on FPMs over 5 year follow-up, the distribution of the cost variable has a mass of observations with $0 which is the minimum average cost per FPM, no matter before or after being discounted by 3%. That justifies the use of Tobit model and two-part model. Table 4-12 displays the estimation results from OLS, classic Tobit model, and selectivity-corrected Tobit model, and Table 4-13 displays the estimation results from two-part model and selectivity-corrected two-part model. The comparison groups are the S4 group and N4 group.

Table 4-12. Estimation Results from OLS, Classic Tobit Model, and Selectivity-corrected Tobit model on Cost, Comparison between S4 Group and N4 Group, (Discount Rate=3%)

	OLS Regression			**Tobit Regression**			**Selectivity-corrected Tobit Regression**		
Variables	**Coef.**	**Std. Err.**	**P-value**	**Coef.**	**Std. Err.**	**P-value**	**Coef.**	**Std. Err.**	**P-value**
Socio-demographic									
Age									
6-8	Ref			Ref			Ref		
9-17	-7.864	3.706	**0.034**	-7.865	3.701	**0.034**	-7.366	4.320	0.088
Gender									
Female	Ref			Ref			Ref		
Male	-9.465	3.132	**0.003**	-9.450	3.127	**0.003**	-9.450	3.128	**0.003**
Race									
White	Ref			Ref			Ref		
Non-White	-13.771	5.711	**0.016**	-13.751	5.703	**0.016**	-13.815	5.711	**0.016**
Unkown	-0.720	3.390	0.832	-0.709	3.385	0.834	-0.735	3.387	0.828
Median family income*									
< $67,000 (median)	Ref			Ref			Ref		
>= $67,000	-3.306	4.020	0.411	-3.307	4.014	0.410	-3.276	4.016	0.415
High school education*									
< 93% (median)	Ref			Ref			Ref		
>= 93%	0.084	3.888	0.983	0.086	3.882	0.982	0.157	3.896	0.968
Percentage of population below poverty level*									
< 3% (median)	Ref			Ref			Ref		
>= 3%	0.702	3.407	0.837	0.711	3.402	0.834	0.782	3.417	0.819
Geo_area*									
< 100% (median)	Ref			Ref			Ref		
= 100%	-0.621	4.096	0.880	-0.621	4.090	0.879	-0.627	4.090	0.878
Mean # of years paid by public program	6.985	5.718	0.222	6.982	5.710	0.221	6.935	5.714	0.225

Table 4-12. Estimation Results from OLS, Classic Tobit Model, and Selectivity-corrected Tobit model on Cost, Comparison between S4 Group and N4 Group, (Discount Rate=3%)

Variables	OLS Regression Coef.	Std. Err.	P-value	Tobit Regression Coef.	Std. Err.	P-value	Selectivity-corrected Tobit Regression Coef.	Std. Err.	P-value
Baseline health condition									
Caries risk assessment score:									
Low	Ref			Ref			Ref		
Medium	19.601	4.479	**0.000**	19.574	4.472	**0.000**	19.375	4.559	**0.000**
High	44.396	4.726	**0.000**	44.321	4.719	**0.000**	44.352	4.721	**0.000**
Dental care utilization									
Sealant placement	26.813	4.399	**0.000**	26.777	4.392	**0.000**	29.209	11.707	**0.013**
# of preventive visits per enrollment year:									
<=1	Ref			Ref			Ref		
> 1	8.688	3.798	**0.022**	8.652	3.792	**0.023**	8.424	3.927	**0.032**
# of fluoride treatment visits during observation	2.938	0.958	**0.002**	2.943	0.956	**0.002**	2.935	0.957	**0.002**
Took any orthodontics treatment during observation period?									
No	Ref			Ref			Ref		
Yes	-17.930	5.564	**0.001**	-17.907	5.556	**0.001**	-17.929	5.558	**0.001**
Space maintenance treatment?									
No	Ref			Ref			Ref		
Yes	16.397	10.939	0.134	16.402	10.923	0.133	16.347	10.926	0.135
Cohort									
Cohort 1997	Ref			Ref			Ref		
Cohort 1998	-1.564	4.935	0.751	-1.541	4.928	0.755	-2.190	5.716	0.702
Cohort 1999	0.549	5.336	0.918	0.580	5.329	0.913	-0.227	6.433	0.972
Cohort 2000	-8.943	5.847	0.126	-8.903	5.839	0.127	-9.756	6.972	0.162
Cohort 2001	-2.860	6.012	0.634	-2.817	6.003	0.639	-3.521	6.777	0.603
Constant	-50.261	8.406	0.000	-50.205	8.394	0.000	-51.456	10.084	0.000

Table 4-13. Estimation Results from Two-part Model and Selectivity-corrected Two-part Model on Cost, Comparison between S4 Group and N4 Group, (Discount Rate=3%)

	Two part model						Selectivity-corrected Two part model					
	Probit Regression			OLS Regression			Biprobit Model			Treatment-effect Model		
Variables	**Coef.**	**Std. Err.**	**P-value**	**Coef.**	**Std. Err.**	**P-value**	**Coef.**	**Std. Err.**	**P-value**	**Coef.**	**Std. Err.**	**P-value**
Socio-demographic												
Age												
6-8	Ref			Ref			Ref			Ref		
9-17	-0.135	0.065	**0.039**	-0.073	0.063	0.246	-0.101	0.123	0.412	-0.138	0.107	0.198
Gender												
Female	Ref			Ref			Ref			Ref		
Male	-0.171	0.057	**0.003**	-0.056	0.051	0.274	-0.171	0.057	**0.003**	-0.052	0.051	0.310
Race												
White	Ref			Ref			Ref			Ref		
Non-White	-0.194	0.105	0.064	-0.009	0.091	0.922	-0.197	0.105	0.059	0.010	0.094	0.913
Unkown	-0.011	0.062	0.858	0.027	0.055	0.625	-0.013	0.062	0.834	0.029	0.055	0.602
Median family income*												
< $67,000 (median)	Ref			Ref			Ref			Ref		
>= $67,000	-0.034	0.074	0.647	-0.083	0.064	0.197	-0.032	0.074	0.671	-0.091	0.065	0.160
High school education*												
< 93% (median)	Ref			Ref			Ref			Ref		
>= 93%	-0.075	0.072	0.300	0.083	0.062	0.179	-0.069	0.073	0.344	0.085	0.062	0.168
Percentage of population below poverty level*												
< 3% (median)	Ref			Ref			Ref			Ref		
>= 3%	-0.034	0.062	0.585	0.099	0.055	0.073	-0.029	0.064	0.649	0.098	0.055	0.074
Geo_area*												
< 100% (median)	Ref			Ref			Ref			Ref		
= 100%	-0.051	0.077	0.508	0.041	0.065	0.525	-0.051	0.077	0.507	0.058	0.068	0.398
Mean # of yrs paid by public program	0.139	0.106	0.192	-0.062	0.088	0.480	0.135	0.107	0.207	-0.065	0.088	0.461

Table 4-13. Estimation Results from Two-part Model and Selectivity-Corrected Two-part Model on Cost, Comparison between S4 Group and N4 Group, (Discount Rate=3%), (continued)

	Two part model						Selectivity-corrected Two part model					
	Probit Regression			OLS Regression			Biprobit Model			Treatment-effect Model		
Variables	**Coef.**	**Std. Err.**	**P-value**	**Coef.**	**Std. Err.**	**P-value**	**Coef.**	**Std. Err.**	**P-value**	**Coef.**	**Std. Err.**	**P-value**
Baseline health condition												
Caries risk assessment score:												
Low	Ref			Ref			Ref			Ref		
Medium	0.314	0.084	**0.000**	0.110	0.070	0.113	0.300	0.095	**0.002**	0.111	0.069	0.110
High	0.575	0.094	**0.000**	0.386	0.071	**0.000**	0.576	0.095	**0.000**	0.345	0.089	**0.000**
Dental care utilization												
Sealant placement	0.752	0.073	**0.000**	-0.655	0.089	**0.000**	0.917	0.493	**0.063**	-0.930	0.382	**0.015**
# of preventive visits per year:												
<=1	Ref			Ref			Ref			Ref		
> 1	0.206	0.069	**0.003**	-0.007	0.062	0.914	0.190	0.085	**0.026**	0.018	0.070	0.797
# of fluoride treatment visits	0.073	0.018	**0.000**	0.016	0.015	0.261	0.072	0.018	**0.000**	0.020	0.015	0.192
Took any orthodontics treatment during observation period?												
No	Ref			Ref			Ref			Ref		
Yes	-0.314	0.098	**0.001**	-0.105	0.093	0.260	-0.315	0.098	**0.001**	-0.105	0.092	0.251
Space maintenance treatment?												
No	Ref			Ref			Ref			Ref		
Yes	0.149	0.222	0.502	0.126	0.160	0.431	0.146	0.221	0.511	0.134	0.158	0.395
Cohort												
Cohort 1997	Ref			Ref			Ref			Ref		
Cohort 1998	-0.047	0.091	0.609	0.086	0.080	0.283	-0.092	0.165	0.578	0.135	0.103	0.192
Cohort 1999	-0.031	0.101	0.758	0.074	0.085	0.379	-0.087	0.194	0.655	0.129	0.111	0.248
Cohort 2000	-0.110	0.107	0.303	0.011	0.094	0.904	-0.169	0.209	0.419	0.091	0.142	0.523
Cohort 2001	0.011	0.111	0.918	0.046	0.095	0.626	-0.038	0.186	0.840	0.119	0.136	0.381
Constant	-1.021	0.153	0.000	3.755	0.137	0.000	-1.104	0.284	0.000	3.930	0.272	0.000

Tables 4-12 and 4-13 display the estimation results from five different models for comparison between S4 group and N4 group. Based on the result of the simple OLS model, eight factors had significant effects on cost – age, gender, race, caries risk score, sealant placement, preventive care utilization, number of fluoride treatment and orthodontics treatment. For example, older age and male seemed to be associated with lower tooth level cost. Compared to white children, non-white children incurred lower cost ($p<0.05$). Higher risk scores were found to be associated with higher cost ($p<0.001$). Sealing all 4 FPMs was likely to increase average expenditure per FPM ($p<0.001$). Besides, children with greater preventive visit utilization and more fluoride treatments were likely to incur more cost, and children with any orthodontics treatment during observation period may incur less cost.

As shown in Table 4-12, the coefficients estimated from the classic Tobit model were generally similar in absolute value and in the same direction as those from OLS. However, because of the massive observations were at the censoring point $0, some differences in the coefficients between two models should be expected. Considering the fact that cost data had very skew distribution, and the residuals of the Tobit model were not normally distributed no matter what transformation was performed, the coefficients estimated from the classic Tobit model might be biased.

Table 4-12 also presents the estimated coefficients of observed variables on the effectiveness based on the selectivity-corrected Tobit model. The test shows that ρ, the correlation between the error terms in the selection equation and main equation of interest, was small in magnitude in the effectiveness model for S4 vs. N4 group, and not statistically significant (Z value=-0.22, p=0.823). Since the selection bias was not detected, the models without selectivity correction could be accepted, and some unobserved factors may not generate significant estimation bias for the sealant effect on cost. Due to the skew distribution problem mentioned above, the coefficients estimated from the selectivity-corrected Tobit model might be biased

Table 4-13 shows the estimated coefficients of the two-part model and selectivity-corrected two-part model. They reflect how those observed factors affect the probability of using any resource over 5 years for each FPM, as well as the average expenditure on each FPM. Both models show the similar factors affecting the probability of using any resource. Among all covariates, male seemed to be associated an increase of this probability. The higher risk level was found to be related to higher probability of incurring cost. Sealant placement increases this probability. More preventive visit and fluoride treatments were positively associated with this probability. It may be because children receive more fluoride treatments were those with more tooth problems. Children with any orthodontics treatment were likely to had lower probability of incurring any cost. One reason for that might be that orthodontics treatment was likely to be applied in relatively healthy mouth. Another reason might be related to insurance type. Though all sample individuals had comprehensive dental coverage, the coverage for orthodontics treatment generally was more restricted. Those children who were from the wealthy families and had better private insurance coverage for orthodontics treatment might have lower caries risk. The result of the bivariate probit model shows that the correlation ρ was small in magnitude and not statistically significant (Z value=-0.34, p=0.737).

As shown in Table 4-13, caries risk score and sealant placement were only two factors affecting cost if the cost value was not \$0. It turned out that higher risk level was likely to increase expenditure for each FPM, but sealing FPMs would decrease the expenditure. Similar to the selectivity-corrected Tobit model and bivariate probit model, the correlation ρ in the treatment effect model was also small in magnitude and not statistically significant (Z value=0.73, p=0.468). In two part models, natural log transformation of cost was used in the second part regressions, which helped improve the behavior of the residuals. Therefore, the estimated results would be less biased. But the calculation of the marginal effect of sealant placement needs retransformation of the coefficients, which is discussed in the methods section.

In sum, the directions and significant levels of the coefficients of the above fitted models were basically consistent. No selectivity problem was found for the comparison between S4 group and N4 group. The models without selectivity correction can be accepted.

Table 4-14. Estimation Results from OLS, Classic Tobit Model, and Selectivity-Corrected Tobit model on Cost, Comparison between S Group and N4 Group, (Discount Rate=3%)

Variables	OLS Regression Coef.	Std. Err.	P-value	Tobit Regression Coef.	Std. Err.	P-value	Selectivity-corrected Tobit Regression Coef.	Std. Err.	P-value
Socio-demographic									
Age									
6-8	Ref			Ref			Ref		
9-17	-13.517	5.219	**0.010**	-13.504	5.218	**0.010**	-13.824	5.267	**0.009**
Gender									
Female	Ref			Ref			Ref		
Male	-8.030	4.731	0.090	-8.016	4.743	0.091	-8.034	4.743	0.090
Race									
White	Ref			Ref			Ref		
Non-White	-7.909	8.203	0.335	-7.949	8.346	0.341	-7.809	8.353	0.350
Unkown	-6.557	5.194	0.207	-6.551	5.192	0.207	-6.584	5.193	0.205
Median family income*									
< $67,000 (median)	Ref			Ref			Ref		
>= $67,000	-6.655	6.092	0.275	-6.649	6.088	0.275	-6.609	6.090	0.278
High school education*									
< 93% (median)	Ref			Ref			Ref		
>= 93%	-0.567	5.889	0.923	-0.558	5.892	0.925	-0.741	5.906	0.900
Percentage of population below poverty level*									
< 3% (median)	Ref			Ref			Ref		
>= 3%	-0.617	5.242	0.906	-0.618	5.237	0.906	-0.667	5.239	0.899
Geo_area*									
< 100% (median)	Ref			Ref			Ref		
= 100%	3.185	6.295	0.613	3.184	6.289	0.613	3.178	6.290	0.613
Mean # of years paid by public program	22.325	8.372	**0.008**	22.337	8.390	**0.008**	22.430	8.395	**0.008**

Table 4-14 Estimation Results from OLS, Classic Tobit Model, and Selectivity-Corrected Tobit model on Cost, Comparison between S Group and N4 Group, (Discount Rate=3%), (continued)

Variables	**OLS Regression** Coef.	Std. Err.	P-value	**Tobit Regression** Coef.	Std. Err.	P-value	**Selectivity-corrected Tobit Regression** Coef.	Std. Err.	P-value
Baseline health condition									
Caries risk assessment score:									
Low	Ref			Ref			Ref		
Medium	23.173	6.340	**0.000**	23.159	6.338	**0.000**	23.663	6.435	**0.000**
High	53.913	6.709	**0.000**	53.886	6.721	**0.000**	53.900	6.722	**0.000**
Dental care utilization									
Sealant placement	18.217	6.525	**0.005**	18.204	6.519	**0.005**	12.081	14.957	0.419
# of preventive visits per enrollment year:									
<=1	Ref			Ref			Ref		
> 1	15.211	5.617	**0.007**	15.181	5.683	**0.008**	15.611	5.762	**0.007**
# of fluoride treatment visits during observation	7.874	1.395	**0.000**	7.871	1.394	**0.000**	7.887	1.394	**0.000**
Took any orthodontics treatment?									
No	Ref			Ref			Ref		
Yes	-28.327	7.601	**0.000**	-28.303	7.618	**0.000**	-28.266	7.618	**0.000**
Took any space maintenance treatment?									
No	Ref			Ref			Ref		
Yes	10.690	16.763	0.524	10.686	16.747	0.523	10.815	16.749	0.518
Cohort									
Cohort 1997	Ref			Ref			Ref		
Cohort 1998	6.200	7.450	0.405	6.211	7.458	0.405	7.856	8.286	0.343
Cohort 1999	5.325	8.038	0.508	5.340	8.050	0.507	7.370	9.198	0.423
Cohort 2000	4.884	8.592	0.570	4.898	8.600	0.569	7.018	9.774	0.473
Cohort 2001	13.158	8.909	0.140	13.169	8.915	0.140	15.116	9.884	0.126
Constant	-102.427	12.785	0.000	-102.342	12.827	0.000	-99.186	14.578	0.000

Table 4-15. Estimation Results from Two-part Model and Selectivity-Corrected Two-part Model on Cost, Comparison between S Group and N4 Group, (Discount Rate=3%)

	Two part model						Selectivity-corrected Two part model					
	Probit Regression			OLS Regression			Biprobit Model			Treatment-effect Model		
Variables	Coef.	Std. Err.	P-value	Coef.	Std. Err.	P-value	Coef.	Std. Err.	P-value	Coef.	Std. Err.	P-value
Socio-demographic												
Age												
6-8	Ref			Ref			Ref			Ref		
9-17	-0.292	0.048	**0.000**	0.224	0.048	**0.000**	-0.299	0.050	**0.000**	0.234	0.055	**0.000**
Gender												
Female	Ref			Ref			Ref			Ref		
Male	-0.106	0.044	**0.016**	-0.015	0.043	0.735	-0.107	0.044	**0.015**	-0.017	0.043	0.694
Race												
White	Ref			Ref			Ref			Ref		
Non-White	-0.091	0.079	0.246	-0.006	0.073	0.936	-0.088	0.079	0.264	-0.010	0.073	0.895
Unkown	-0.030	0.048	0.527	-0.011	0.047	0.818	-0.031	0.048	0.518	-0.011	0.047	0.818
Median family income*												
< $67,000 (median)	Ref			Ref			Ref			Ref		
>= $67,000	-0.042	0.057	0.461	-0.049	0.055	0.372	-0.041	0.057	0.471	-0.048	0.054	0.377
High school education*												
< 93% (median)	Ref			Ref			Ref			Ref		
>= 93%	-0.019	0.055	0.727	0.091	0.052	0.085	-0.024	0.056	0.673	0.089	0.052	0.088
Percentage of population below poverty level*												
< 3% (median)	Ref			Ref			Ref			Ref		
>= 3%	-0.053	0.048	0.270	0.089	0.048	0.062	-0.055	0.048	0.261	0.089	0.047	0.061
Geo_area*												
< 100% (median)	Ref			Ref			Ref			Ref		
= 100%	0.030	0.059	0.618	0.011	0.056	0.839	0.030	0.059	0.617	0.008	0.057	0.889
Mean # of yrs paid by public program	0.215	0.079	**0.007**	0.028	0.072	0.697	0.217	0.079	**0.006**	0.028	0.071	0.694

Table 4-15. Estimation Results from Two-part Model and Selectivity-Corrected Two-part Model on Cost, Comparison between S Group and N4 Group, (Discount Rate=3%), (continued)

	Two part model						Selectivity-corrected Two part model					
	Probit Regression			OLS Regression			Biprobit Model			Treatment-effect Model		
Variables	**Coef.**	**Std. Err.**	**P-value**	**Coef.**	**Std. Err.**	**P-value**	**Coef.**	**Std. Err.**	**P-value**	**Coef.**	**Std. Err.**	**P-value**
Baseline health condition												
Caries risk assessment score:												
Low	Ref			Ref			Ref			Ref		
Medium	0.235	0.059	**0.000**	0.152	0.057	**0.007**	0.247	0.063	**0.000**	0.152	0.056	**0.007**
High	0.484	0.065	**0.000**	0.380	0.057	**0.000**	0.483	0.065	**0.000**	0.389	0.062	**0.000**
Dental care utilization												
Sealant placement	0.436	0.058	**0.000**	-0.635	0.068	**0.000**	0.290	0.296	0.328	-0.549	0.231	**0.017**
# of preventive visits per year:												
<=1	Ref			Ref			Ref			Ref		
> 1	0.189	0.053	**0.000**	-0.037	0.052	0.469	0.200	0.056	**0.000**	-0.045	0.055	0.412
# of fluoride treatment visits	0.094	0.013	**0.000**	0.028	0.012	**0.019**	0.094	0.013	**0.000**	0.027	0.012	**0.022**
Took any orthodontics treatment during observation period?												
No	Ref			Ref			Ref			Ref		
Yes	-0.278	0.070	**0.000**	-0.086	0.071	0.225	-0.277	0.070	**0.000**	-0.087	0.070	0.215
Space maintenance treatment?												
No	Ref			Ref			Ref			Ref		
Yes	0.164	0.168	0.328	0.076	0.133	0.567	0.166	0.168	0.321	0.074	0.132	0.574
Cohort												
Cohort 1997	Ref			Ref			Ref			Ref		
Cohort 1998	0.067	0.070	0.337	0.050	0.068	0.462	0.106	0.104	0.305	0.032	0.081	0.692
Cohort 1999	0.016	0.075	0.835	0.058	0.073	0.426	0.064	0.120	0.593	0.039	0.087	0.659
Cohort 2000	0.023	0.080	0.776	0.120	0.078	0.125	0.073	0.127	0.563	0.095	0.099	0.338
Cohort 2001	0.133	0.083	0.109	0.133	0.079	0.095	0.179	0.123	0.145	0.109	0.099	0.267
Constant	-0.959	0.119	0.000	3.775	0.116	0.000	-0.883	0.200	0.000	3.722	0.176	0.000

Tables 4-14 and 4-15 display the estimation results from five different models for comparison between S group and N4 group. The estimation result based on a simple OLS model shows that 7 factors had significant effects on cost -- age, number of years paid by public program, caries risk score, sealant placement, preventive care utilization, fluoride treatment and orthodontics treatment. Compared to children aged 6 to 8, children aged 9 to 17 incurred less cost ($p<0.05$). Children with longer public program enrollment were more likely to use resources ($p<0.01$). Higher risk scores were associated with higher expenditure ($p<0.001$). Children receiving sealant on at the least one FPM incurred more tooth level cost than the children who didn't receive any sealant on any FPM ($p<0.01$). Besides, more preventive care utilization and more fluoride treatment were associated with more cost, and orthodontics treatment was associated with less caries-related cost. The same factors were also found from the classic Tobit model in the same table. The coefficients estimated from the classic Tobit model were similar in magnitude and in the same direction as those from OLS. Again, because the very skew distribution of cost data, the residuals of the Tobit model were not normally distributed no matter what transformation was performed, hence the coefficients estimated from the classic Tobit model might be biased.

Table 4-14 also presents the estimated coefficients of observed variables on the cost based on the selectivity-corrected Tobit model. The correlation between the error terms in the selection equation and main equation of interest was found small in magnitude and not statistically significant (Z value=0.46, p=0.649). Similar to the result of the classic Tobit model, age, number of years paid by public program, caries risk score, sealant placement, preventive care utilization, fluoride treatment and orthodontics treatment were statistically significant factors and they maintained same direction as well in the selectivity-corrected model. However, sealant effect was not statistically significant ($p=0.419$).

Table 4-15 shows the estimated coefficients of two-part model and selectivity-corrected tow-part model. In both models, age was found to affect both the probability of incurring any cost and the amount of cost, but in different directions. Children aged 9 to 17 were less likely to use any resource, but more likely to incur more cost once they started to use resources. In both models, male was found to be associated with lower probability of using any resource ($p<0.05$). The length of public program enrollment was associated with higher probability of using any resource ($p<0.01$). In both models, the higher risk level was found not only related to higher probability of using any resource, but also related to more resources consumed.

The sealant effect was different in two models. In simple two-part model, sealant was found associated with higher probability of using any resource and less amount of resources consumed. But in selectivity-corrected two-part model, the sealant effect on the probability was not statistically significant. That may be because the selectivity-corrected model needs bigger sample to show statistical difference. Moreover, in both models, the preventive care utilization and the number of fluoride treatments were positively associated with the probability of incurring any cost, but taking any orthodontics treatment was negatively associated with the probability of incurring any cost. Similar to the findings for the comparison between S4 group and N4 group, the ρ values were small in magnitude and not statistically significant in both the bivariate probit mode (Z value=0.52, p=0.606) and in the treatment effect model (Z value=-0.39, p=0.695).

In sum, the directions and significant levels of the coefficients for some important factors such as caries risk scores and sealant placement are basically consistent across models. They are also consistent across two types of comparisons, S4 vs. N4 and S vs. N4 comparisons. No selectivity problem was found in either comparison.

4.5. Marginal Effects of Sealant and ICERs for Major Comparisons

The major results for a cost-effectiveness analysis are often ICERs. Before the ICERs of this analysis are presented, the marginal effects of sealant placement on effectiveness and cost need to be calculated based on the estimated coefficients from the models in the above sections. The ways to calculate marginal effects from different models are discussed in the methods section. In addition, the standard errors and significant levels for those marginal effects should be obtained. If either marginal effect of sealant on effectiveness or cost is insignificantly different from zero, the interpretation of corresponding ICER would not be clear. If both marginal effects of sealant on effectiveness and cost are significantly different from zero, the corresponding ICERs can and should be presented. Table 4-16 lists the marginal effects of sealant on effectiveness and cost from five different models. The discount rate was 3%.

Table 4-16. Marginal Effects of Sealant on Effectiveness and Cost from Different Models (Discount=3%)

	Marginal Effects on Effectiveness	Std. Err.	Marginal Effects on Cost	Std. Err.
S4 vs. N4 (all 4 fist molars sealed vs. all 4 first molars unsealed)				
OLS	1.30**	0.26	65.81***	4.40
Classic Tobit Model	0.42	0.22	47.45***	1.23
Selectivity-corrected Tobit Model	0.75	0.41	48.14***	3.28
Simple two-part model	1.07***	0.31	40.84***	1.73
Selectivity-corrected Two-part Model	0.35	1.53	39.67***	11.70
S vs. N4 (at least one fist molars sealed vs. all 4 first molars unsealed)				
OLS	2.12***	0.29	57.22***	6.53
Classic Tobit Model	1.55***	0.30	44.58***	1.90
Selectivity-corrected Tobit Model	1.21*	0.48	42.76***	4.51
Simple two-part model	2.11***	0.39	34.24***	2.29
Selectivity-corrected Two-part Model	1.74	2.05	32.61***	12.32

* p<0.05; ** p<0.01; *** p<0.001.

The first part of the Table 4-16 shows the marginal effect comparisons between children with all 4 FPMs sealed and children without any FPM sealed. The marginal effects of sealant on caries-free duration of each FPM ranged from 0.35 to 1.30 months, showing a small increase in effectiveness caused by sealant placement. The increases were similar in absolute values across five models. Two of five marginal effects, the one from OLS and the one from two-part model, were statistically significant. Those from Tobit models were not but close to statistically significant at the 5% level. The marginal effect of sealant on cost of each FPM ranged from $39.67 to $65.81, showing an increase in dental care expenditure caused by sealant placement. The increases were similar in absolute values across five models. As mentioned in the method section, for convenience of modeling, the constant initial sealant charge was not included in modeling. But the final marginal effect on cost, as shown in Table 4-16, is the sum of the marginal effects from models and the constant initial sealant charge of $39.00 in HealthPartners. Therefore, those numbers were easily different from $0, and became statistically significant. If the total expenditure associated with sealant intervention was higher than $39.00, it did not necessarily mean that the sealant group had more cost on caries treatment. It was more likely to be caused by the re-sealants. Within the 5-year observation period, about 13.5% of all sealed FPMs received one re-sealant, about 3% of them received 2 to 4 re-sealants, and nearly 83.7% of sealed FPMs did not receive any re-sealant.

In addition to the mean marginal effects, the corresponding standard errors are presented in Table 4-16. The standard errors based on two-part models were obtained using a bootstrapping method. Since multicollinearity did not appear to be a problem in the full model, no model reduction was necessary. The bootstrapping was repeated 1000 times. The same seed numbers were used for the standard errors based on the same models. All pairs of the marginal effects of sealant on effectiveness and cost from 1000 bootstrapped samples were saved. The standard errors based on simple two-part models were similar to those based on OLS and Tobit models, but those based on selectivity-corrected two-part models seemed to be inflated by the two-stage estimation, and had relatively bigger absolute values compared with other standard errors, especially for cost analysis.

The second part of Table 4-16 shows the marginal effect comparisons between children with at the least one FPM sealed and children without any FPM sealed. The marginal effect of sealant on caries-free duration of each FPM ranged from 1.21 to 2.12 months, representing a small increase in effectiveness caused by sealant placement. Four out of five marginal effects were statistically significant, and only the one from selectivity-corrected two-part model was not statistically significant. That may be due to its relatively large standard error. The marginal effects of sealant on cost of each FPM ranged from $32.61 to $57.22, representing an increase in dental care expenditure caused by sealant placement. Considering that the initial sealant charge per FPM was $39.00, the marginal effects less than $39.00 could mean that certain cost saving on caries treatment was obtained by sealant placement. Again, the standard errors are presented in the Table. Those based on selectivity-corrected two-part models had relatively bigger absolute values, and the corresponding marginal effects were less likely to be statistically significant.

Generally speaking, the marginal effects shown in Table 4-16 did not vary substantially across five models for both sets of comparisons. However, only one model should be used to obtain each marginal effect which was used for calculating the ICERs. According to the criteria set up in the method section, the simple two-part models were picked for both effectiveness and cost analyses. Because no substantial selectivity was found after controlling observed confounding factors, the selectivity-corrected models would not be necessary for the CEA on the whole sample. Moreover, since a large proportion of dependent values, either caries-free duration or cost, were at the censoring points, and Tobit models generally have stricter requirements for data distribution, the simple two-part model seem to be more appropriate for the CEA on the whole sample. Accordingly, sealant placement was likely to be associated with 1.07 more caries-free months per FPM and with $40.84 increase in total cost per FPM over 5 years than non-sealant intervention, if the sample consists of the children with all 4 FPMs sealed and children without any FPM sealed. If the sample consists of the children with at the least one FPM sealed and children without any FPM sealed, sealant placement was likely to be associated with 2.11 more caries-free months per FPM and with $34.24 increase in total cost per FPM over 5 years than non-sealant intervention. Both sets of numbers showed that sealant was more effective and more costly.

After the marginal effects of sealant on effectiveness and cost are known, ICERs are easily calculated. The uncertainty of ICERs can be reflected by the ICERs' confidence intervals (CIs). Since ICERs generally do not follow any certain distribution, their standard errors and 95% CIs were also obtained using a bootstrapping method in this study. The bootstrapping was repeated 1000 times. Due to the lack of the information about willingness to pay for extra caries-free duration in dental health research, rather than directly determine whether sealant should be applied, the ICERs and their CIs of this study are used to provide some reference values, ranges, and comparisons with each other.

Because both numerators and denominators of ICERs are marginal effects which come from modeling, and have their own ranges and distributions, it causes some difficulty interpreting ICERs and their CIs. For example, a positive ICER can come from both positive numerators and denominators or both negative numerators and denominators. A negative ICER can come from a positive numerator and a negative denominator, which means good investment, or from a negative numerator and a positive denominator, which, on the other hand, means a bad investment. Their CIs no longer have a one-dimension meaning, but a two-dimension meaning. A cost-effectiveness plane, shown in Figure 4-1, can often be used to show the distributions of the numerators and denominators of bootstrapped ICERs and help interpret the associated CIs.

Figure 4-1. Cost-effectiveness Plane with Four Quadrants

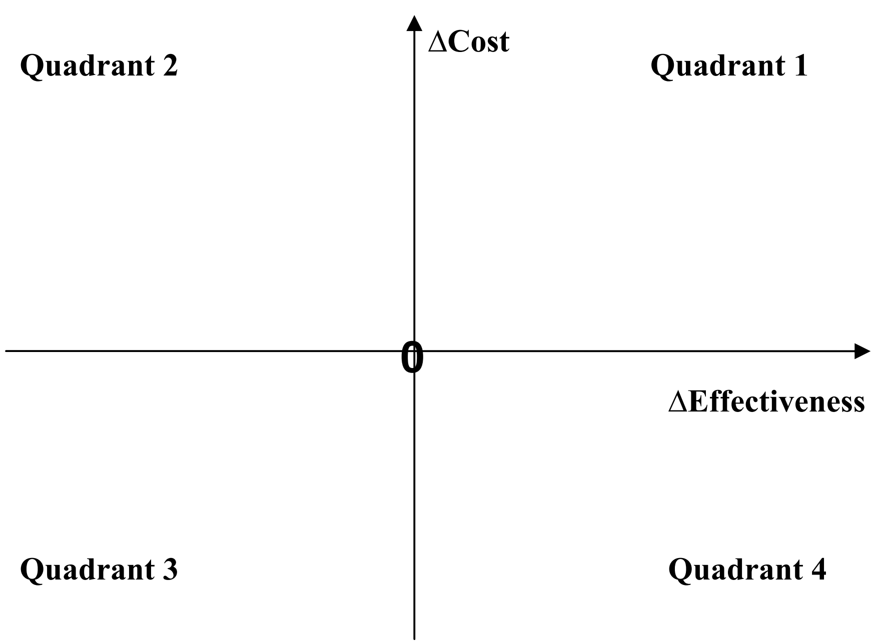

Figure 4-1 is a cost-effectiveness plane with four quadrants. The horizontal axis represents the effectiveness change, or marginal effect, of one intervention vs. an alternative intervention (for this study, sealant intervention vs. non-sealant intervention), and the vertical axis represents the cost change of one intervention vs. an alternative intervention. The four quadrants have the following interpretation for this study:

Q1: $\Delta C > 0$, $\Delta E > 0$, sealant had greater effectiveness and greater cost;

Q2: $\Delta C > 0$, $\Delta E < 0$, sealant had less effectiveness but greater cost, non-sealant is dominant;

Q3: $\Delta C < 0$, $\Delta E < 0$, sealant had less effectiveness and less cost;

Q4: $\Delta C < 0$, $\Delta E < 0$, sealant had greater effectiveness but less cost, sealant is dominant;

Since the ICER here is a two-dimension measure, the statistical meaning for one-dimension measure would not be very appropriate. For example, a 95% CI including the value 0 does not necessarily mean an intervention is similar to its alternative. It could mean this intervention costs nothing but generates great effectiveness. A 95% CI for an ICER could be interpreted like a one-dimensional confidence bound only if the ICER falls into a single quadrant with the same signs on two axes, such as Q1 or Q3. If an ICER falls into more quadrants or quadrants with different signs on the axes, the mix of interpretations associated with the same sign of the ICER makes it difficult to understand the relative preferences among intervention alternatives. To help understand ICERs and their CIs, two steps were adopted in the result analysis. First, since the marginal effects were one-dimension measure and could be interpreted by direct statistical significance, as long as a marginal effect was not statistically different from 0, the conclusion was made without the ICER being calculated. Second, if an ICER was presented, its distribution among four quadrants was also presented in percentage. Table 4-17 compares the ICERs and CIs of sealant vs. non-sealant based on two sets of samples. The discount rate was 3%.

Table 4-17. ICERs Sealant vs. Non-sealant (Based on S4 vs. N4 and S vs. N4)

	ICER (95% Conf. Interval)	Distribution of Resampled ICERs	Conclusion
Based on S4 vs. N4	42.2 (22.6, 85.4)	Q1: 100% Q2: 0% Q3: 0% Q4: 0%	Sealant costs $42.2 more than non-sealant treatment to get one more caries-free month for each FPM. (100% chance more costly and more effective)
Based on S vs. N4	16.0 (10.1, 28.2)	Q1: 100% Q2: 0% Q3: 0% Q4: 0%	Sealant costs $16.0 more than non-sealant treatment to get one more caries-free month for each FPM. (100% chance more costly and more effective)

Discount rate: 3%.
Unit for ICER: dollar per caries-free month of a single FPM.

As shown in Table 4-17, the ICER of sealant was 42.2. It means that, after 5 years, based on the sample with all the children with four FPMs sealed and children without any FPM sealant, the incremental CE ratio was $42.2 per additional well-tooth month. The distribution of resampled ICERs showed that, of the 1000 estimates of the ICERs, all ICERs were positive values and all of them were Q1 observations. This means that in all cases sealant was more expensive than non-sealant and, at the same time, more effective than non-sealant. Similarly, the ICER, based on the sample with all the children with at the least one FPM sealed and children without any FPM sealant, was

$16.0 per additional well-tooth month. Since their bootstrapped ICERs were also 100% in quadrant 1, sealant still appeared to be more costly and more effective than non-sealant. The CIs shown in the table were obtained from the estimates at the 0.025th and .975th percentiles of the bootstrapped distribution. Since the ICERs falls into one quadrant only in both cases, and their CIs did not include value 0, it was safe to believe two ICERs were different from 0. Moreover, because two CIs had some overlap values, the ICERs may not be different from each other. Therefore, both analyses appeared to have consistent results.

4.6. Sensitivity Analysis

Sensitivity analysis is often required by a CEA study to evaluate the stability of its results. A one-way sensitivity analysis was used in this study to explore how the results can be affected by changing values of some parameters one at a time. As described in the method section, the parameters which were adjusted included discount rate, treatment charges, and effectiveness measure. Two more discount rates, 0% and 5%, were used, and the results were compared to the results based on 3% discount rate. The treatment charges were changed from the charges recorded in HealthPartners' claim data to the 2005 ADA average fees, and the total caries-related cost was recalculated for each FPM. The effectiveness measure was changed from the caries-free duration to the quality-adjusted caries-free duration which reflected the different status between restored teeth and extracted teeth. Table 4-18 shows the results of the one-way sensitivity analysis.

Table 4-18. Sensitivity Analysis of Sealant Effectiveness and Cost (Based on S4 vs. N4)

	Marginal Effects on Effectiveness (Std. Err.)	**Marginal Effects on Cost (Std. Err.)**	**ICER (95% Conf. Interval)**	**Distribution of Resampled ICERs**	**Conclusion**
Applying Discount: 3%	1.071*** (0.307)	40.838*** (1.726)	42.2 (22.6, 85.4)	Q1: 100% Q2: 0% Q3: 0% Q4: 0%	Sealant costs $42.2 more than non-sealant treatment to get one more caries-free month for each FPM. (100% chance more costly and more effective)
Applying Discount: 0%	1.153*** (0.320)	41.037*** (1.836)	39.4 (21.1, 80.5)	Q1: 100% Q2: 0% Q3: 0% Q4: 0%	Sealant costs $39.4 more than non-sealant treatment to get one more caries-free month for each FPM. (100% chance more costly and more effective)
Applying Discount: 5%	1.024*** (0.283)	40.712*** (1.647)	43.9 (23.6, 89.1)	Q1: 100% Q2: 0% Q3: 0% Q4: 0%	Sealant costs $43.9 more than non-sealant treatment to get one more caries-free month for each FPM. (100% chance more costly and more effective)
Applying ADA Average Fees	1.071*** (0.296)	45.346*** (1.696)	46.8 (25.2, 94.5)	Q1: 100% Q2: 0% Q3: 0% Q4: 0%	Sealant costs $46.8 more than non-sealant treatment to get one more caries-free month for each FPM. (100% chance more costly and more effective)
Applying Quality-Adjusted Measures	0.234*** (0.063)	40.838*** (1.718)	191.7 (104.3, 382.9)	Q1: 100% Q2: 0% Q3: 0% Q4: 0%	Sealant costs $191.7 more than non-sealant treatment to get one more quality-adjusted caries-free month for each FPM. (100% chance more costly and more effective)

* p<0.05; ** p<0.01; *** p<0.001.
Unit for ICER: dollar per caries-free month of a single FPM.

Since no selectivity was found in any results in one-way sensitivity analysis, the marginal effects in Table 4-18 were estimated by simple two-part models, and their standard errors were obtained by bootstrap method. The whole sensitivity analysis was based on the sample with all 4 FPMs sealed and children without any FPM sealed, which was the main sample for this study.

First, Table 4-18 compares the results of the effectiveness and cost analyses when the discount rate was changed from 3% (for the main analysis) to 0% and 5%. Because both the effectiveness measure and cost measure were discounted in this study, all their estimated marginal effects changed. The higher discount rate was associated with a smaller marginal effect on effectiveness and cost. Generally, none of the changes caused significant difference in the overall cost-effectiveness of sealing FPMs. For example, after 5 years, the ICER was $39.4 per additional well-tooth month if no discounting was used, and the ICER was $40.7 per additional well-tooth month if 5% discount rate was used. All their distributions of bootstrapped ICERs showed that sealant was more expensive and more effective than non-sealant. Since their bootstrapped ICERs all fall in quadrant one, their confidence interval can be compared. The overlap in their confidence intervals also indicated that there was no significant difference across the ICERs after adjusting discount rates.

Second, the charges for sealant and caries treatments in HealthPartners' were replaced by the average charges published in 2005 ADA Survey of Dentists Fees. This change only affected the marginal effect of sealant on cost. The latter was increased by a small amount. The resulting ICER was distributed in quadrant 1 only, indicating that sealant was more expensive and more effective than non-sealant. This ICER showed the similar overall cost-effectiveness of sealing FPMs as other ICERs.

Finally, the effectiveness measure, caries-free duration, was replaced by the quality-adjusted caries-free duration which differentiated healthy, restored, and extracted teeth by assigning weights of 1, 0.8, and 0, respectively. This change affected the marginal effect on effectiveness only but caused the most significant change in the ICER. The large value of the ICER, 191.7, was caused by its small but statistically significant denominator, 0.23. One reason for the small difference in effectiveness may be due to the imperfect quality-adjusted weights. The weights used in this analysis did not differentiate procedures like multiple-surface restoration, crown, or root canal treatment, so they could not reflect the true difference in tooth health status. Another reason is that both sealant and non-sealant groups had few FPMs with severe cases. For example, as shown in that Table 4-7, both groups had very few extraction cases. Although children in group N4 experienced less one-surface restorations (51.5%) but more multiple-surface restorations and relatively extensive treatments, compared to group S4, those differences were not reflected by the relatively simple quality-adjusted weights.

The third reason for the small marginal effect on effectiveness associated with the quality-adjusted effectiveness measure may be that this measure also included the duration from caries occurrence to the end of the observation period, but other effectiveness measure simply included the duration from the beginning of observation to the caries occurrence. Due to the above discussion, this ICER should be interpreted cautiously.

In sum, the ICERs of sealant vs. non-sealant were 'insensitive' to the changes in some major parameters. The results of this CEA should be able to provide some reliable information for the decision making process related to dental sealant delivery.

4.7. Subgroup Analysis

In addition to the overall study population, sealant intervention effects were also examined for 5 pairs of subgroups of interest: 1) high caries risk subgroup and low caries risk subgroup; 2) high preventive care utilizers and low preventive care utilizers; 3) children aged 6-8 and children aged 9-17; 4) children from areas with a relatively high median family income and children from areas with a relatively low median family income; 5) children from areas with a relatively high proportion of urban residents and children from areas with a relatively low proportion of urban residents. There subsamples came from the main study sample which consisted of the children with all 4 FPMs sealed and the children without any FPM sealed. This analysis used 3% discount rate.

Although selectivity was not found in the main analysis on the whole study sample, it may exit in the cost or effectiveness evaluations on some subgroups. However, since the subsamples have small sizes, the theoretical justification for the IV's ability to predict sealant placement may not be the same for all subgroups and was re-checked. The Table 4-19 summarized the size, the IV's power or ability to predict sealant placement, and the probabilities of selectivity tests for various subgroups of interest. The IV's power was evaluated based on F-statistics: the IV's power is strong if F value is bigger than 15.0, and the IV's power is weak if F value is less than 15.0. The probabilities of selectivity tests were from Z-tests for the correlation between the error terms in the selection equation and main equations of interest from the selectivity-corrected models.

Table 4-19. Selectivity Test in Subgroup Analysis (Based on S4 vs. N4)

		Selectivity-corrected Tobit Model			**Selectivity-corrected Two-part Model**					
					Bivariate Probit			**Treatment Effect Model**		
		size	IV's power	Z-test for selectivity	size	IV's power	Z-test for selectivity	size	IV's power	Z-test for selectivity
High Risk	E	588	W	0.77	588	W	0.55	162	W	0.20
	C	588	W	0.81	588	W	0.75	304	W	0.31
Low Risk	E	1651	S	**0.001**	1651	S	0.74	196	W	0.99
	C	1651	S	0.40	1651	S	0.50	542	W	0.50
High Utiliza-tion	E	1298	S	0.07	1298	S	0.20	214	W	0.80
	C	1298	S	**0.00**	1298	S	0.30	568	W	**0.00**
Low Utiliza-tion	E	941	S	0.30	941	S	**0.02**	144	W	0.20
	C	941	S	0.10	941	S	**0.00**	278	S	**0.004**
Age <=8	E	1360	S	0.88	1360	S	0.58	209	W	0.66
	C	1360	S	0.73	1360	S	0.20	608	W	**0.03**
Age >8	E	879	S	0.50	879	S	0.60	149	W	0.50
	C	879	S	0.50	879	S	0.70	238	W	**0.0**
High Income	E	1137	S	0.86	1137	S	0.03	174	W	0.41
	C	1137	S	**0.00**	1137	S	0.69	413	S	**0.005**
Low Income	E	1102	S	0.55	1102	S	0.90	184	W	0.60
	C	1102	S	0.80	1102	S	0.80	433	S	0.15
More Urban	E	1846	S	0.43	1846	S	0.38	297	W	0.38
	C	1846	S	0.69	1846	S	0.80	683	S	0.45
Less Urban	E	393	W	0.56	393	W	0.21	61	W	-
	C	393	W	0.28	393	W	**0.00**	163	W	-

IV's power was evaluated based on F-statistics: S-strong: F>=15.0; W-weak: F<15.0.
Z-test for selectivity testing the correlation between the error terms in the selection equation and main equation of interest, selectivity exists if p-value<0.05.
E for effectiveness analysis; C for cost anaylsis.

The first pair of subgroups presented in Table 4-19 is high caries risk subgroup and low caries risk subgroup. This high caries risk subgroup included the children at moderate risk and high risk so that the sample size was large enough for analysis. Besides, these children generally had at the least one caries in the past three years. As shown in Table 4-19, the sample size of the high risk subgroup (n=588) was smaller than the low risk subgroup (n=1,651). The IV's power associated with the high risk subgroup was weak, and no selectivity was found from both selectivity-corrected models. For the low risk subgroup, the IV's power was weak for the treatment effect model for both effectiveness analysis and cost analysis. Selectivity was found by the selectivity-corrected Tobit model (p=0.001) but not by any part of the selectivity-corrected two-part model, which might be due to the weak IV.

The second pair of subgroups presented in Table 4-19 is high preventive care utilizers and low preventive care utilizers. Those with >1 preventive visit per year were called 'high' utilizers (n=1,298), while those <=1 preventive visits per year were classified as 'low' utilizers (n=941). As shown in Table 4-19, no selectivity was found from both selectivity-corrected models for effectiveness analysis for the high preventive care utilizers. Selectivity was found by the selectivity-corrected Tobit model (p<0.01) and treatment effect model for cost analysis for the high preventive care utilizers. The correlations between the error terms from the above two models were all negative (not shown in the table), indicating that some missing or unobserved factors decreased the cost associated with sealant placement. The IV's power associated with the treatment effect model was weak. If the IVs are weak and can not well predict the endogenous variable, the results from IV method would be even worse than those from OLS, because the predicted value of the endogenous variable would have very little variance. Therefore, there is no advantage to conducting the IV analysis or selectivity-corrected models for either effectiveness or cost analysis for high preventive care utilizers. In contrast, for the low preventive care utilizers, selectivity was found by both the bivariate probit model and the treatment effect model. The correlations between the error terms from the bivariate probit model and the treatment effect model were all positive (not shown in the table), indicating that some missing or unobserved factors increased the cost associated with sealant placement. Since the IV's power associated with both models for the cost analysis was strong, the selectivity-corrected two-part model was used to estimate the marginal effects and the final ICER.

The third pair of subgroups presented in Table 4-19 is the subgroup aged 6 to 8 and the subgroup aged 9-17. Selectivity was only found by the treatment effect models for cost analysis, and the associated IV's power was weak.

The fourth pair of subgroups presented in Table 4-19 is the relatively high income subgroup and the relatively low income subgroup. Those from the areas with >$67,368 median family income was classified as high income subgroup (n=1,137), while from the areas with <=$67,368 median family income was classified as low income subgroup (n=1,102). Selectivity was found by the selectivity-corrected Tobit model and the treatment effect model for cost analysis for the high income subgroup, but not found by the bivariate probit model. No selectivity was found from both effectiveness analysis and cost analysis for the low income subgroup.

The last pair of subgroups presented in Table 4-19 is the relatively 'more urban' subgroup and the relatively 'less urban' subgroup. Those from the areas with 100%

urban residents were classified as 'more urban' subgroup (n=1,846), while those from the areas with <100% urban residents were classified as 'less urban' subgroup (n=393). Selectivity was not found most of time. The IV's power was particularly weak for the 'less urban' subgroup.

In general, the results from subgroup analysis were consistent with those from the main CEA in term of selectivity presence. One reason may be because the confounding factors were well controlled, especially by the risk scores and utilization measure. Another reason may be due to the small sample size in subgroup analysis. Based on the above results, simple two-part models was selected to evaluate marginal effects and ICERs for the subgroups listed in Table 4-19, except for the cost analysis for the low preventive care utilizers. The marginal effects and ICERs, as well as corresponding conclusions are presented in Table 4-20.

Table 4-20. Subgroup Analysis of Sealant Effectiveness and Cost (Based on S4 vs. N4)

	Marginal Effects on Effectiveness (Std. Err.)	Marginal Effects on Cost (Std. Err.)	ICER (95% Conf. Interval)	Distribution of Resampled ICERs	Conclusion
Moderate and High risk Subgroups	5.72*** (1.40)	15.57 (8.01)	N.A	Q1: 96.7% Q2: 0% Q3: 0% Q4: 3.3%	Sealant obtains 5.72 more caries-free month for each FPM than non-sealant treatment without significant additional cost
Low risk Subgroup	0.10 (0.20)	44.94*** (1.32)	N.A	Q1: 81.0% Q2: 19.0% Q3: 0% Q4: 0%	Sealant costs $44.9 more than non-sealant intervention but obtains insignificant caries-free duration increase.
High Utilization Subgroup	0.12 (0.35)	47.82*** (1.95)	N.A	Q1: 64.1% Q2: 35.9% Q3: 0% Q4: 0%	Sealant costs $47.8 more than non-sealant intervention but obtains insignificant caries-free duration increase.
Low Utilization Subgroup	1.92*** (0.48)	34.58*** (2.75)	19.36 (10.35, 35.29)	Q1: 100% Q2: 0% Q3: 0% Q4: 0%	Sealant costs $19.36 more than non-sealant treatment to get one more caries-free month for each FPM. (100% chance more costly and more effective)
Subgroup at Age 6-8	1.11* (0.51)	43.34*** (2.93)	57.47 (17.61, 221.13)	Q1: 99.2% Q2: 0.8% Q3: 0% Q4: 0%	Sealant costs $57.5 more than non-sealant treatment to get one more caries-free month for each FPM. (99.2% chance more costly and more effective)
Subgroup at Age 9-17	1.41* (0.59)	38.68*** (2.24)	14.92 (12.93, 102.58)	Q1: 99.2% Q2: 0.8% Q3: 0% Q4: 0%	Sealant costs $14.9 more than non-sealant treatment to get one more caries-free month for each FPM. (99.2% chance more costly and more effective)
High Income Subgroup	1.37** (0.49)	38.37*** (2.65)	35.27 (14.31, 95.98)	Q1: 100% Q2: 0% Q3: 0% Q4: 0%	Sealant costs $35.3 more than non-sealant treatment to get one more caries-free month for each FPM. (100% chance more costly

					and more effective)
Low Income Subgroup	1.07* (0.46)	42.22*** (2.54)	44.89 (18.47, 170.60)	Q1: 99.6% Q2: 0.4% Q3: 0% Q4: 0%	Sealant costs $44.9 more than non-sealant treatment to get one more caries-free month for each FPM. (99.6% chance more costly and more effective)
More Urban Subgroup	0.89** (0.32)	42.10*** (1.92)	58.03 (24.73, 168.18)	Q1: 99.8% Q2: 0.2% Q3: 0% Q4: 0%	Sealant costs $58.0 more than non-sealant treatment to get one more caries-free month for each FPM. (99.8% chance more costly and more effective)
Less Urban Subgroup	2.39 (1.33)	33.18*** (5.22)	N.A.	Q1: 92.3% Q2: 7.7% Q3: 0% Q4: 0%	Sealant costs $33.2 more than non-sealant intervention but obtains insignificant caries-free duration increase.

Discount Rate: 3%

The Table 4-20 demonstrates that sealants significantly increased the caries-free duration by 5.72 months per FPM for high risk children, after 5 years. But the difference between expenditures for sealed and unsealed teeth was not statistically significant during the same period. The standard error for the marginal effect on cost was relatively large, and it may be caused by the small size of the high risk subgroup and even smaller size for the treatment effect model. Considering the initial sealant cost is $39.0, it still appears that some subsequent expenditure was saved by sealant placement. As mentioned earlier, the marginal effects may have a more direct statistical meaning than the ICERs. If any marginal effect is not statistically different from 0, the associated ICER is obtained directly, either as 0 or infinity, and no bootstrap or calculation of CI is necessary. For the high caries risk subgroup, the ICER was 0, meaning that sealant placement improved the effectiveness by 5.72 caries-free month for each FPM compared to non-sealant, without causing extra expenditure. In contrast, for the low caries risk subgroup, sealants significantly increased the expenditures by $44.9 (then could not offset the cost of placing sealants), but the difference between effectiveness for sealed and for unsealed teeth was not statistically significant, after 5 years. Since the marginal effect on effectiveness is the denominator of the ICER, the ICER was actually infinity, meaning that sealant placement was a bad investment for the low caries risk subgroup. In sum, sealant effect on effectiveness improvement and cost saving was much greater for the high risk subgroup, and much less for the low risk group. That indicated a higher efficiency of sealant application in high risk children.

Table 4-20 demonstrates that sealant effect on improving caries-free duration was not statistically significant for high preventive care utilizers but statistically significant for low preventive care utilizers, after 5 years. Higher cost associated with sealant was found in both groups, but the difference was greater for high preventive care utilizers. Based on those marginal effects, the ICER was lower for sealing lower preventive care utilizers, meaning that sealing FPMs in relative low preventive care utilizers appeared to be more cost-effective than in relative high preventive care utilizers.

It is recommended more often to place sealants on FPMs in children aged 6 to 8. However, Table 4-20 shows that sealant had a positive effect on caries-free duration in both subgroups at age 6-8 and at age 9-17, after 5 years. Sealant caused greater cost in both groups, but the difference was smaller for subgroup aged 9-17. Their bootstrapped ICERs were almost all in quadrant one, and hence can be compared. Since there was some overlap between the ICERs for two age subgroups, sealing FPMs in children aged 9 and above may be equally cost-effective as sealing FPMs in children aged 6 to 8.

Two income-based subgroups were analyzed to explore how SES factors may affect cost-effectiveness of sealant. Table 4-20 shows that sealing FPMs had a positive effect on caries-free duration in both high income and low income subgroups, after 5 years. Sealant caused more cost in both groups, too. Their bootstrapped ICERs were almost all in quadrant one, and some overlap existed between the two ICERs. Therefore, sealing FPMs in high income group appeared to be equally cost-effective as sealing FPMs in low income group. One reason for this result may be that the data variation is not sufficient in income – only 25% of the sample came from the areas with the median family income less than $55,528. Another reason may be that all individuals in the sample had 100% coverage for sealing FPMs.

People's living area is often associated with their access to health care services and their socio-economic status. At the end of Table 4-20, the CEA results based on 'more urban' group and 'less urban' group were presented. Sealing FPMs was likely to improve caries-free duration by 0.89 month per FPM, after 5 years, for 'more urban' group. But sealant effect on caries-free duration was not found in 'less urban' group. Sealant caused more expenditure in both groups, but the difference was smaller for 'less urban' group. It appeared that the ICER for 'more urban' group was smaller than the ICER for 'less urban' group and could be a better investment. However, those ICERs should be interpreted cautiously. The first reason is that the study sample had a small variation in urbanization degree – most of individuals came from areas with 100% urban residents. The second reason is that there were very few children (n=61) involved in the second part analysis of the two-part model for the effectiveness analysis for 'less urban' group, and the standard error for the marginal effect on effectiveness hence might become relatively large. If more samples were included, the marginal effect on the effectiveness for 'less urban' group would have been statistically significant, and their ICER would have been smaller than that for 'more urban' group.

In sum, although with small variation, the ICERs for each subgroup were similar in range to those for the overall study sample as shown in Table 4-17 and Table 4-18. That further confirmed that the results estimated in this study were reliable and consistent. When conclusions are drawn from the results of subgroup analysis, factors such as sample size, estimation model, ICER range, and distribution of bootstrapped ICERs all should be taken into account. From policy perspective, the conclusions from subgroup analysis should be used to help decision making about sealant application in certain populations and communities, rather than support sealant use in one population over another population.

CHAPTER 5. DISCUSSION

Dental caries is the most common chronic disease among U.S. children. It can cause facial pain, eating difficulty, poor appearance, absence from school, and even a reduction of a child's life quality. Nearly 90% of caries in children develop in pits and fissures on occlusal surfaces, especially those on the first and second permanent molars. Dental sealants have been widely used in clinics since the 1970s and have been proven to be effective in preventing caries by applying a plastic coating to cover the pits and fissures on a tooth's surfaces. One of the national *Healthy People 2010* objectives is for 50% of all U.S. children aged 8 to have dental sealants.[2] However, the current sealant prevalence has been much lower than 50%. Only about one-third of children aged 6–19 receive sealants.[2] Disparity in sealant use also has existed. On the other hand, the incidence of caries has been declining in the last decades, but the prices of sealant placement and dental treatments keep rising. It has been argued that sealants should be only applied in children at high risk of caries, rather than the whole population. While clinical trials have shown the protective effect of sealants, there is a lack of substantive evidence showing that the upfront costs of dental sealant placement has sufficient value to justify the reduction in dental caries. There were only a few studies evaluating the cost-effectiveness of sealants applied in real-life situations, and none of them explored the typical selection issue caused by missing or unobserved factors in observation studies.

This study used the administrative data from a dental health plan of a Minnesota HMO (Health Maintenance Organization) to examine the utilization of dental sealants among children aged 6 to 17. With the application of an instrumental variable analysis, this study modeled effectiveness and cost associated with sealant application by controlling for both observed and some potentially unobserved variables. The final incremental cost-effectiveness ratios (ICERs) for the main sample and subgroups were generated and compared. This chapter first summarizes the key study findings and compares them with results of other studies. Second, this chapter discusses some major strengths and limitations of this study and their possible effect on the main conclusions. Third, it presents the clinical and policy implications based on the study findings. Finally, this chapter concludes with future research recommendations for sealant application.

5.1. Main Findings and Discussion

5.1.1. Sealant Utilization, Caries risk and Other Relevant Factors

<u>Caries Risk</u>

In order to better predict caries risk of an individual and utilize the proper strategies to prevent future caries, the HealthPartners Dental Group (HPDG), a staff model dental practice in Minnesota, implemented a caries risk assessment guideline in their dental clinical settings in 1996. This guideline uses caries history as the major criterion, as well as dietary practice, fluoride use, maternal caries, medication/therapy, etc., to determine caries risk scores, and has been validated on adult patients.[99] About 95% of children seen by HPDG dentists have been classified as being at high, moderate, or low caries risk. This guideline also includes recommendations for risk reduction strategies such as sealant placement and fluoride application.

In this study, all the children included had received a risk assessment at the beginning of their observation period. Among them, 66% of children were found at low risk, 18% at moderate and 16% at high risk. Male and female had similar risk distribution. Children in age 6 to 8 group were more likely to be in high risk category than those in age 9 to 17 group, which might be due to the caries history of primary teeth around age 6 to 8. In this study, white children and those with high SES were more likely to have low caries risk, which is consistent with previous studies.[1, 31, 57, 58, 61-63] The comparison between risk scores and caries history records showed that these two factors had a close relationship, which was why the latter did not appear in the later analysis models. In this study, children seeing dentists less frequently were more likely to be assigned a moderate or high risk level. Children at high caries risk were more likely to take fluoride treatments. In general, the main findings that the children from families with low SES and being from a minority population were more likely to be the low dental care utilizers and have high caries risk are expected and consistent with the literature. Low SES children often had more gaps in enrollment, but this study required 5-year continuous enrollment, the number of children from low SES families or with moderate or high caries risk was smaller than that of children with high SES or low caries risk.

Sealant Utilization and Relevant Factors

The data of this study included enrollment information, risk assessment and provider information from a large private group practice, which provided a unique opportunity to examine sealant utilization patterns and related determinants for Minnesota's children population. Since the first permanent molars are generally the main teeth receiving sealants, the results of this study, which focuses on FPMs, can well reflect the general sealant utilization among individuals.

In this study, approximately 77% of the sample received at the least one sealant during the entry period. This proportion is much higher than other studies have shown.[3, 9, 118, 139] For example, one study examined a sample of children insured by a preferred provider organization with a 70% sealant coverage in 1990 and 1991, and found only 16.3 percent use rate for the sealant benefit.[9] A report in 2000 showed that only 23 percent of children in grades 2 and 3 and 20 percent of children in grades 8 and 9 had their first molars sealed.[118] A Medicaid study by Bhuridej reported an overall 40% sealant rate among their routine utilizers. A few reasons may explain the relatively high sealant utilization in this study.[3] First, the sample of this study was collected around 2000, later than other study samples. Sealant rate in more recent years was higher than in early years. Second, the study sample was from a private insurance company, and the sample characteristics showed that those children were more from families with higher SES and received preventive care on a frequent basis. Third, the HPDG implemented a caries risk assessment guideline which focuses on preventive care such as sealant in late 1990s. Forth, this study required at the least 5-years continuous enrollment for each subject, and the long enrollment increased the chance of getting sealant. Fifth, this study sample had a wider age range and included some children who received sealants between age 9 to 17. Therefore, the sealant rate of this study should not be directly compared to other studies or the objective proposed by the national *Healthy People 2010* which is to have 50% of all U.S. children aged 8 to have dental sealants.[2] Similar to what was found in another study,[3] among all children with sealant, most had all four FPMs sealed, justifying the use of children with all 4 sealed FPMs to be the major intervention cohort in analysis.

For this study sample, gender was not found associated with sealant application. Both bivariate analysis and logistical model demonstrated that children aged 6 to 8 years were more likely to receive sealant than children aged 9 years or older. That is understandable because sealant use has been recommended for children aged 6 to 8 years. Bivariate analysis showed a higher sealant rate in non-white individuals. That was similar to the result from the study by Zabos et al.,[136], but opposite to the result from the study by Weintraub et al.[139] However, the results from logistic model, after controlling other factors, shows no race difference in sealant application rates over the entire sample. That indicated that, in some areas or communities, minority groups might still have problems of accessing sealant intervention, possibly due to low insurance coverage or lack of sealant application guideline. In HPDG, since there were no economic disincentives relative to cost, and sealant placement is a 100% covered procedure, all racial groups are as likely to receive sealants.

As described in chapter two, disparity in sealant use has existed, but might be decreasing in recent years.[24] Many previous studies found that sealant placement was related to some SES factors, and affluent children from families with high education level were more likely to receive sealants.[2, 16, 24, 58, 59, 116, 121, 125, 202, 203] Bivariate association of this study showed the opposite direction—children receiving sealants were more likely to come from families with relatively low incomes or low education level. Although this relationship was not supported by the logistic model, this study did not find significant disparity caused by SES difference. This result implies that sealant coverage policy of HPDG may lessen the financial barriers to poorer children, or dentists may make sealant application decision by taking SES factors into account.

Unlike previous studies which used caries history or dental service utilization to measure risk for caries, this study utilized a population with unique risk assessment records for each individual. This risk record was closely related to caries experience but also considered other factors. According to the 2008 report of the American Dental Association Council on Scientific Affairs, sealants are underutilized in high caries risk populations which include children in low SES families or in certain racial groups.[204] However, in this study, sealant placement rate was generally high in children at higher risk levels, which implies that, in HPDG, children at high caries risk may have few barriers to getting sealant, or dentists select patients for sealant largely based on individual's caries risk level.

The frequency of preventive visits has been used as another risk measure in sealant related studies. Some studies found that children in the sealant group often had more preventive visits,[3, 8, 22, 139] which could due to a more preventive attitude toward dental health.[8] The findings of this study also show that the number of preventive visits was significantly associated with sealant rates. Children who visited dentists for preventive care more than once a year had 82% greater odds of receiving sealants. Combined with the above discussion, this finding implies that sealant placement in HPDG was less affected by SES factors but more affected by patient care-seeking behavior or patient attitude toward to healthcare which may not be fully observed.

This study sample included 5 cohorts which were observed from 1997, 1998, 1999, 2000, and 2001, respectively. These cohorts were significantly different in terms of sealant utilization rate. Sealant rate increased over the years. Specifically, children belonging to cohort 1997 were more likely to be in non-sealant group, but children in 1999 or later were more likely to be in sealant group. This trend might be in part because the risk assessment guideline implemented since 1996 improved the sealant use. It might be also caused by the sampling method which utilized the earliest or initial caries risk assessment records for the non-sealant group.

Sealant application is associated with dentist/provider's behavior or preference. Before coming to see a dentist, general patients may have little knowledge about their risk for caries. They may also lack the knowledge about a sealant effect. Dentists not only select children for sealants based on their perceived risk level, but also recommend or apply sealants based on their own preferences.[22, 147, 153, 204-206] This study created a comprehensive measurement, the dentist's preference, and found it was associated with sealant rate. Dentist preference for caries may be related to age, gender, specialty, working experience, continuing education, etc. Among those factors, dentist's age and working experience were found to be more significant determinants for sealant placement in this study. This relationship was confirmed by logistic model after controlling individual's risk level. Moreover, this finding was supported by some previous studies. For example, Weinberger and Wright found that the level of sealant placement declined the longer dentists had been in practice.[172] Badner and Rosenberg reported that dentists who used sealants more frequently were those recent graduates who received training related to new procedures,[207] As explained in Chapter 3, older dentists may have received their professional education before sealant was formally accepted by the ADA, and hence they do not tend to use or recommend sealant during the regular examination and risk assessment. They could be less convinced of sealant effectiveness, or they may think that sealant could not stay intact for a long time or that amalgam restorations were more economical.[133, 208] Some have argued that dentist' behavior could introduce bias or methodological issues into the results.[22, 153] In contrast, this study, through a conceptual model and analysis of the specific practice pattern in HPDG, established selectivity-corrected econometric models by using dentist's working experience as the instrumental variable. The advantage of this technique is discussed in detail in a later section.

Finally, a traditional IV candidate, distance, and a creative IV candidate in this study, month, was found to have only weak relationship with sealant utilization. Theoretically, they could affect people's motivation to get preventive intervention through their effect on transportation time and cost, weather, schedule, coverage transition, etc. The weakness of their effect found in this study might be related to a small variation in living areas or high stability in enrollment status. They could still be strong determinants on sealant utilization in a different community or for a different study sample.

5.1.2. Sealant Effect on Cost and Effectiveness

Selectivity

Before summarizing sealant effects on caries-free duration and caries-related expenditure, the selectivity or endogeniety issue should be addressed. As discussed in Chapter 3, previous evidence showed the existence of a selection problem in sealant studies using observational datasets.[3, 8, 22, 153] However, neither of them mentioned or explored the possible selectivity issue caused by missing or unobserved factors which is a common problem in observational studies and can bias the final results. As the first effort to address such issue, this study used an instrumental variable method and econometric models to analyze sealant effect on effectiveness and cost. Two selectivity-corrected models—a selectivity-corrected Tobit model and a selectivity-corrected two-part model—were used to test the selectivity issue for the sample as a whole and for the two parts of the sample separately, one part on the censoring point and another part not on the censoring point. The results did not show significant selectivity or endogeniety in either the effectiveness models or cost models. Two main reasons may explain this finding. First, the analytic models used in this study had better control over confounding factors, and the effect of possible missing or unobserved variables were well represented in the models. For example, this study used caries risk scores assigned directly by dentists, and those scores could be a more comprehensive measure of caries risk. Besides, this study included many factors in the models such as SES factors, preventive care utilization, public payment index, fluoride treatment number, and orthodontics treatment record. Second, there might be fewer barriers for access to sealant for this study sample, and hence fewer unobserved factors affecting both outcome and sealant intervention. For example, all children in this study sample had full sealant coverage. They generally came from urban areas and affluent families. Although selection was not a problem for the main analysis based on the whole sample, it may have been a problem for subgroup analysis, which is discussed in the next section. For any specific practice environment or community, selectivity or endogeniety issue could exist and should be examined.

<u>Effectiveness</u>

The results from the descriptive analysis show that, after a 5-year follow-up period, the majority of FPMs in both groups did not receive any restoration or other caries-related treatment. The sealant group had more individuals (83.9%) and more FPMs (94.3%) that stayed healthy than the non-sealant group, in which 83.1% of the sample individuals and 91.8% of FPMs stayed healthy. A protective effect of only 2.5 percent (94.3% minus 91.8%) was found associated with sealant placement. When caries-related treatment type and frequency were compared, children in the non-sealant group experienced less one-surface restorations but more multiple-surface restorations and relatively extensive treatments than children in the sealant group. Without controlling for other factors, the sample average caries-free duration for each FPM in the sealant and non-sealant groups was 58.64 months and 57.49 months, respectively. All these findings indicate a positive but moderate sealant effect on caries-free duration. If caries severity is considered, this effect could be stronger. These findings were consistent with previous evidence from private insurance claim data or Medicaid databases which indicated that placement of sealants on FPMs was associated with a reduction in the subsequent provision of restorative services.[9, 139, 209] For example, one study reported that, during a 5-year follow-up, 12.5% of non-sealant teeth became carious, and 8% of sealant teeth became carious, indicating a protective sealant effect of only 4.5 percent.[210] A 4-year study based on a Medicaid sample found that sealed molars were less likely to receive subsequent restoration than non-sealed molars (13% vs. 29%), and sealed molars had fewer extensive restorative treatments and greater median caries-free duration.[209]

This study used a two-part model to evaluate sealant effect on caries-free duration by controlling for confounding factors. Children with all 4 FPMs sealed and children with at the least one FPM sealed (including 4) were used as the sealant group in separate analyses. Their results were generally consistent. Among all variables, a higher risk level was found associated with a higher probability of having any caries and shorter caries-free duration. Children in the sealant group were likely to have a lower probability of having any caries and longer caries-free duration. The marginal effect of sealant on effectiveness showed that sealant placement was likely to be associated with 1.07 more caries-free months per FPM over 5 years than non-sealant intervention, if the sample with all 4 FPMs sealed was used as the sealant group. If the sample with at the least one FPM sealed was used as the sealant group, sealant placement was likely to be associated with 2.11 more caries-free months per FPM than non-sealant intervention. The above two marginal effects were found not significantly different from each other, and all showed sealant was effective. Compared to some previous studies,[9, 22, 209] this study found a lower restoration rate both at the individual and tooth levels, and a smaller positive sealant effect. This could be expected, because the sample of this study had a higher SES, longer continuous enrollment and more frequent preventive care utilization. Most of the sample also had low caries risk level. Those characteristics determined that caries prevalence among this sample was low. If both sealant and non-sealant groups have a low restoration rate during the 5-year follow-up, their difference would be small. In addition, all previous studies did not test for the existence of selectivity/endogeniety problems due to possible exclusion of some factors that could affect both outcome and the sealant decision, their results could be biased or overestimated.

Cost

The results from the descriptive analysis show that, after the 5-year follow-up period, the majority of FPMs in both groups did not incur any restoration cost or other caries-related treatment cost. Without controlling for any confounding factors, on average, a sealed FPM was associated with a $56.84 expenditure during 5-year observation, and this amount included sealant, resealant, and any caries-related treatment cost. Within the same time period, an unsealed FPM was associated with a $13.13 expenditure, and that amount included only caries-related treatment cost. Like the result for effectiveness difference, considering the initial sealant charge and each resealant charge was $39.00 in HealthPartners, the difference in caries-related cost between sealant and non-sealant was small. Though the non-sealant group involved more extensive treatments than the sealant group, the cost difference was not obvious because only a small number of FPMs in both groups had caries and generated cost.

The further analysis, based on a two-part model, evaluated sealant effects on caries-related treatment costs by controlling for confounding factors. The higher risk level was found to be associated not only with increased probability of incurring any cost, but also with greater consumption of resources. Sealant was found to be associated with an increased probability of using any resource but less resource consumption. Besides, preventive visit utilization and fluoride treatments were positively associated with probability of incurring any cost. It may be because children seeing dentists more often had a greater chance of having their caries located. The marginal effect of sealant on cost showed that sealant placement was likely to be associated with a $40.84 increase in total cost per FPM over 5 years than non-sealant intervention, when the sample with all 4 FPMs sealed was used as the sealant group. When the sample with at the least one FPM sealed was used as the sealant group, sealant placement was associated with a $34.24 increase in total cost per FPM over 5 years than the non-sealant intervention. Those numbers were not significantly different from each other, but both showed that sealant was costly. Given that the initial sealant charge and each resealant charge was $39.00 in this study, little difference was found between sealant and non-sealant strategies.

Previous studies were less likely to report a single number for marginal effect of sealant on cost. They more often incorporated that information into the final ICERs. One reason might be that the charges or expenditures for sealant and other caries-related treatments, not like effectiveness or caries-free duration, have changed over time, especially the relative charge of sealant to the charge for a restoration. In 1985, according to the American Dental Association median fee schedule, the sealant charge was $12, and a one-surface amalgam charge was $25.[22] Another study listed sealant mean charges: $16.26 in 1986, $17.00 in 1987, and $17.80 in 1988. The charges for one-surface restorations were $36.40 in 1986, $37.95 in 1987, and $41.00 in 1988.[211] A more recent study used $31.89 for the sealant charge in conducting a CEA of sealant among Medicaid children in Iowa.[209] In contrast, this study used $39.00 as the sealant charge and $90.00 for a one-surface amalgam restoration based on claims data from HPDG. They were similar to the amounts from the ADA 2005 Survey of Dentists Fees: $41.41 for the sealant charge and $99.13 for a one-surface amalgam restoration. Based on different costs for sealants and restorations, the ICERs would be different. If the charge of sealant is relatively higher than the charge for a restoration, the sealant effect is less likely to be cost-saving. Therefore, the final ICERs should more likely reflect actual cost information.

ICER

The ICER based on the sample average was calculated without controlling for confounding factors. It was $38 per caries-free month, meaning that, after 5years, sealant cost $38 more than non-sealant treatment to get one more caries-free month for each FPM. This amount of money is almost the same as the charge for one sealant which was $39.00. The second ICER, a more accurate one, was obtained from econometric modeling based on the sample including all children with 4 sealed FPMs as the sealant group. This ICER was $42.2 per caries-free month, meaning that, after 5years, sealant cost $42.2 more than non-sealant treatment to get one more caries-free month for each FPM. Moreover, for ICERs from econometric modeling, this study also provided bootstrapped CIs for those ICERs, as well as the distribution of bootstrapped CIs on the cost-effectiveness plane (CE plane), in order to reflect ranges and uncertainty of those ICERs. The distribution of bootstrapped ICERs showed that, of the 1000 estimates of the ICERs, 100% had positive values and appeared in Q1 on CE plane. This means that sealant was more effective but more expensive than non-sealant intervention. The final 95% CI for the second ICER was $22.6 to $85.4. The third ICER was obtained from econometric modeling based on the sample including all children with at the least one sealed FPM as the sealant group. This ICER was $16.0 with 95% CI from $10.1 to $28.2 per caries-free month, meaning that, after 5years, sealant cost $16.0 more than non-sealant treatment to get one more caries-free month for each FPM. Both ICERs were different from 0, and were not significantly different from each other due to their overlapped CIs.

Some previous studies found smaller ICERs, and some obtained larger ICERs. One study, based on a much smaller sample, found that after 4 years the ICER was $28.86 per restoration-free year when the group of children with all 4 sealed FPMs was used as the sealant group, and the ICER was $10.26 per additional restoration-free year when the group of children with any sealed FPM was used as the sealant group.[22] Another study observed a Medicaid sample for 4 years and found that sealed FPMs had less subsequent treatment and greater survivorship but incurred more cost than non-sealed FPMs. Its ICER ranged from $193 to $440 per quality-adjusted tooth year.[143] Kuthy et al. used a sample from a large private dental insurance company and found that, after 3 years, children with sealants had longer caries-free duration but higher aggregate costs, and corresponding cost-effectiveness ratios was $532.70 versus $385.40 per 2 restoration-free months.[8]

Compared to previous observational studies, especially those studies on Medicaid samples, the ICERs obtained in this study were relatively high. Because other studies did not correct for selection or the endogeneity problem, if there are some unobserved factors positively affecting the outcome and sealant decisions, sealant' effect would be over-estimated. Of course, if dentists selectively seal teeth in higher-risk children, and that is not well controlled by modeling, the results would be underestimated.(Weintraub et al., 1993) This study included risk and other confounding factors in the analytical models, and used IV methods to correct the selectivity problem. Its ICERs, therefore, should be more accurate estimations.

In this study, both the sealant and non-sealant groups had more than 80% individuals and more than 90% FPMs that stayed healthy during the whole follow-up period. The relatively low caries rate may have affected the ICER's calculation and made it harder to distinguish the difference between sealant and non-sealant. In addition, the sample's characteristics can affect study results. The sample of this study was from a big HMO. Its SES was relatively high and the preventive visit utilization was relatively high. More than two thirds of this sample was confirmed to have low caries risk by risk assessment. It would be expected the ICERs based on this sample were more likely to be higher. Although this sample may not represent a general or a high risk population well, the results of this study can be a good complement to previous findings that were based on Medicaid population or higher risk population.[10, 143] Moreover, separate analyses on the high risk and low risk subgroups of this sample still can show a significant difference in their ICERs, which is discussed in the next section.

One of the unexpected findings in this study is that income, poverty level, geographic area, and education had little effect on effectiveness and cost. This is different from the common belief that SES may be able to accurately and inexpensively indicate caries risk and predict tooth survivorship and related expenditure.[3] The finding could be caused by (1). small variation in SES factors, (2). possible inclusion SES factors into risk assessment scores by dentists, (3). practice and behavior pattern specific to the community.

One-way sensitivity analysis was conducted in this study to examine how sensitive the results were to the changes of some important parameters one at a time. To adjust for time preferences, this study calculated aggregate effectiveness and cost using 3% discount rate which was close to the "social rate of time preference".[3] Two alternative discount rates, 0% and 5%, were used in the sensitivity analysis, and the results were compared to the results based on 3% discount rate. None of the discount rate changes caused significant difference in the overall cost-effectiveness of sealing FPMs. In addition, the charges for sealant and caries treatments in HealthPatners' were replaced by the average charges published in 2005 ADA Survey of Dentists Fees. This change did not affect the ICERs obtained in this study, either. Finally, the effectiveness measure, caries-free duration, was replaced by the quality-adjusted caries-free duration which differentiated healthy, restored, and extracted teeth by assigning weights of 1, 0.8, and 0, respectively. There have been very few studies which conducted a similar analysis.[143, 155] This change in effectiveness measure caused a very large ICER. That may be due to the relatively low rate of severe caries after 5 years and the over-simplified weights. One reason for the small difference in effectiveness may be due to the imperfect quality-adjusted weights. The weights used in this analysis did not differentiate procedures like multiple-surface restoration, crown, or root canal treatment, so they could not reflect the true difference in tooth health status. A set of well-developed and accepted quality weights for dental health status is needed for this type of analysis.

5.1.3. Subgroup Analyses

Cost-effectiveness relationships among alternative interventions are often not the same for all subgroups of patients. Subgroup analysis has been more and more included into a CEA, and its results are important to optimize benefit of medical care and to minimize healthcare costs.[168] Previous studies on cost-effectiveness of sealant have done subgroup analysis based on factors such as prior caries experience,[22, 139] preventive care utilization[143] and tooth position[143], etc. However, very few studies did such analysis. This study examined cost-effectiveness of sealant in 5 pairs of subgroups of interest: (1) high caries risk subgroup and low caries risk subgroup; (2) high preventive care utilizers and low preventive care utilizers; (3) children in the 6-8 age group and children in the 9-17 age group; (4) children from areas with relatively high median family income and children from areas with relatively low median family income; (5) children from areas with relatively high proportion of urban residents and children from areas with relatively low proportion of urban residents.

High and Low Caries Risk Groups

Before models were conducted, the presence of selectivity was checked for effectiveness and costs separately, for each subgroup, in order to determine whether the selectivity-corrected model should be used. The power of the IV was also tested. When the IV's power is weak, selectivity issue may exist but is less likely to be found. For the high risk and low risk subgroups, the IV's power was weak, and no selectivity issue was found for both effectiveness and cost analysis.

The results demonstrate that, for the high risk subgroup, sealants significantly increased the caries-free duration by 5.72 months per FPM, after 5 years. But the difference between expenditures for sealed and unsealed teeth was not statistically significant. In this case, sealing children at high risk for caries would be highly cost-effective, and it should be a good investment. In contrast, for the low caries risk subgroup, sealants significantly increased the expenditures by $44.9, but the difference between effectiveness for sealed and for unsealed teeth was not statistically significant. In this case, sealing children at low risk for caries would be much less cost-effective, and it would be a bad investment.

These findings are consistent to the findings from other studies. For example, Griffin et al. conducted a simulation study to compare universal sealant delivery with risk-based sealant delivery to children. Their results showed that targeting only high-risk children dominated sealing all or sealing none of the children.[4] Two sealant studies which used a Medicaid sample and caries experience as the risk factor found that the lower a community's caries incidence becomes, the less cost-effective sealants are likely to be with regular use.[22, 139] It was argued that the Medicaid children might not be at high caries risk, and sealants would be applied based on past caries and restorative treatment rate in a population.[139]

The results of this subgroup analysis demonstrated that the risk assessment scores used in HPDG are sufficient to help clinical decision-making about preventive dental care delivery. Caries experience, as the major criterion of risk assessment, could be a sufficient caries predictor for sealant decision-making. The guideline used in HPDG with the suggestion that sealant should be used in children with high risk scores is justifiable and should be advocated.

High and Low Preventive Care Utilization Groups

People's preventive care utilization is related to their knowledge, behavior, attitude towards to health care, and so on. Some factors associated with preventive care utilization may be missing or unobservable in observational studies. This study found that, for the effectiveness analysis, the IV's power was weak, and no obvious selectivity issue was found for both high and low utilization subgroups. However, for the cost analysis, selectivity problem was found by for both high and low utilization subgroups. The correlation between the error terms in sealant equation and cost equation was negative for the high utilization subgroup, indicating a possibility of underestimating the sealant effect on cost if the selection/endogeneity is not corrected. In contrast, for the low preventive care utilizers, the correlation between the error terms was positive, indicating a possibility of overestimating the sealant effect on cost.

The results demonstrated that sealant did not significantly improve caries-free duration but increased cost, for high preventive care utilizers. In contrast, sealant significantly improved caries-free duration and increased cost, for low preventive care utilizers, after 5 years. The increased cost was less in low preventive care utilizers than in high preventive care utilizers. The conclusion is that sealing FPMs in relative low preventive care utilizers appeared to be more cost-effective than in relative high preventive care utilizers.

A similar conclusion was obtained in another study which used Medicaid children as the sample and $31.89 for sealant charge.[143] It reported that the ICER for sealing FPMs of high utilizers ($204.7 to $510.3 per tooth year) was greater than the ICER for low utilizers ($171.1 to $329.2 per tooth year).[143] It argued that dental care utilization patterns of children may be the most appropriate factor to identify high-risk groups, and sealant application in lower dental care utilizers is the most cost-effective strategy.

Age Groups

This study had two age subgroups: the subgroup at age 6 to 8 and the subgroup at age 9 to 17. No obvious selection problem was found for both effectiveness and cost analysis, and for both subgroups. The associated IV's power was weak.

The results demonstrated that sealant had a positive effect on caries-free duration in both age subgroups after 5 years. Sealant caused increased cost in both age subgroups, but the increase was smaller for subgroup at age 9-17. The findings based on bootstrapped ICERs showed that sealing FPMs in children aged 9 and above can be as cost-effective as sealing FPMs in children aged 6 to 8.

It has been believed that the time period after tooth eruption is the most caries-prone period, and sealants for FPMs should be placed in children aged 6 to 8. Evidence showed that more restorations were conducted when the children were 8 to 10 years old, and few were rendered to 6- and 7-year-olds.[3] However, some data indicated that teenagers may be as susceptible to occlusal caries as children.[212] Almost all previous studies on sealing FPMs started observation at age 6 or before age 8. The evidence for a sealant effect in older children has been lacking. This study argues that age may not be an appropriate factor for sealant placement. Even younger children may have high risk for caries, the older children's cooperation in clinics may improve the sealant effect and, hence, the sealant cost-effectiveness.[213]

High and Low Income Groups

This study did not find obvious selection problem for both effectiveness and cost analysis, and for both high and low income subgroups. The IV's power was relatively strong. The results showed that sealing FPMs had positive effect on caries-free duration and increased cost in both high income and low income subgroups, after 5 years. The ICER of sealing FPMs of high income subgroup was similar to the ICER for low income subgroup ($35.27 to $44.89 per caries-free month).

Although there is some evidence indicating that children from low-income families are at a greater caries risk than other children,[117] almost no sealant studies have conducted subgroup analysis based on family income. A few previous studies used a sample of Medicaid children which could be assumed to be at high risk, and did not find that sealants were cost-saving.[3, 139] In those studies, the differences in sealant's cost-effectiveness were only found when prior caries history or preventive care utilization was used to classify subpopulations.

The similar cost-effectiveness of sealant between high and low income subgroups found in this analysis may be because the data variation is not sufficient in income or poorer children had fewer barriers to receive sealants. However, it could also imply that income may not be a good risk factor to identify target population for dental care, no matter of whether from a practice perspective or policy perspective.

'More Urban' and 'Less Urban' Groups

Most of the children in this study sample were from urban areas. The 'less urban' subgroup had a very small sample size (n=393). As expected, the IV's power was weak for the 'less urban' subgroup but strong for 'more urban' subgroup. A selectivity problem was not found most of time. The results showed that sealing FPMs was likely to improve caries-free duration by 0.89 month per FPM over 5 years for 'more urban' group. But sealant effect on caries-free duration was not significant in 'less urban' group. Sealant caused more expenditure in both groups, but the difference was smaller for 'less urban' group. People's living area is often associated with their access to health care services and their socio-economic status. None of previous sealant studies have explored sealant's cost-effectiveness in different geographic areas. This study was the first attempt. But due to the small variation in urbanization degree in this study sample, those results should be interpreted cautiously.

5.2. Strengths and Limitations

Study Strengths

This study has a number of strengths. First, this study collected a relative large dataset including more complete and unique information. The children in this study sample had been enrolled in the Minnesota-based HealthPartners HMO. The data sources were enrollment data and encounter data from the electronic data system for HealthPartners' dental group (HPDG), as well as the provider's information. The final sample population included 3,700 children, and 2,239 children were included in main analysis. A relative large sample is often required for conducting econometric models using an IV method and subgroup analysis. A few previous studies either required continuous enrollment as a inclusion criterion but used a small sample for analysis, or had a large sample but used incomplete claim information caused by discontinued enrollment.[3, 8, 139] This study collected the sample from a large local HMO and used multiple-cohort design to increase the sample size. The final sample not only included children with 5-year continuous enrollment, but had sufficient size for econometric evaluation and subgroup analysis. In addition, this dataset had some unique information. For example, it contained dental clinic encounter data instead of general claims data which recorded caries risk assessment scores for each patient, risk factors such as caries history, and some services not appearing in general claims (e.g., resealing a tooth). The risk assessment scores were a more comprehensive risk measure directly assigned by dentists. They have never been used by other sealant studies. Moreover, this dataset had some information about dental care providers and clinics, offering more variables to control for confounding effects and creating more instrumental variable candidates.

Second, this study is the first attempt to establish a conceptual model which demonstrated the relationships among outcomes, socio-demographic factors, health care behavior, risk factors, and sealant determinants, ensuring that the results were robust and reliable. This study was a retrospective study, with aim to evaluate the effectiveness and costs of sealants in a real-life situation. Due to its non-randomized nature, selectivity would be a problem causing biased estimation. Previous studies tried to include many confounding factors into their regressions to control that problem. But very few of them realized that unobserved factors such as attitude toward to health care, oral hygiene behavior and status, salivary fluoride levels, diet habit, occlusal anatomy, and so on, could still bias the estimation results.[139] This study addressed the issue of selectivity using an instrumental variable approach which has been commonly used in econometric analyses. Although selection was not found to be a problem for the main analysis based on the whole sample, it was found in high and low preventive care utilizers in the subgroup analysis. The same methodology can and should be used to examine selectivity or endogeniety issue which could exist in any different practice environment or any different community.

Third, this study presented a unique approach to identify possible instrumental variables from a complicated clinical decision-making process. Generally, it is difficult to find instrumental variables from an observational study based on claim data due to limited information in the data sources. Traditionally, the distance between patients' residence to clinics has been used as an IV. Unfortunately, this variable did not work for this study. Through investigation into sealant placement procedures in HPDG and establishment of a conceptual model, this study explicitly built the connection between regular examination with risk assessment and sealant placement. Not just in theory, this study also found evidence supporting such connection. For example, in HPDG, over 95% of time a sealant placement followed an overall caries risk assessment. The median interval between the closest risk assessment and the sealant placement was 38 days. Such connection was not enough for identifying IVs. This study also found a specific practice pattern existing in sealant delivery: most of time, the decision makers, dentists, do not place sealant by themselves. Sealant placement is often delegated to hygienists or assistants. Given the presence of this practice pattern, the decision makers' or dentists' characteristics, such as working experience, age, gender, and even preferences could be used as IVs. One thing worth mentioning is that this practice pattern is also close to the optimal sealant delivery that is supported by some studies.[214] Finally, when the time for sealant's being accepted by ADA was considered, the decision makers' working experience became a good IV for this study. The idea presented by this study about how to distinguish the instrumental variables from a specific clinical decision making progress will be particularly useful for future research design.

Forth, two types of selectivity-corrected models were used to estimate sealant effect on effectiveness and cost in addition to classic Tobit model and two-part model: selectivity-corrected Tobit model and selectivity-corrected two-part model, which consists of a bivariate probit model and a treatment effect model. Due to the highly skewed distribution of effectiveness and cost measures, results based on one model may be not reliable. The use of those two selectivity-corrected models can not only explore the possible selectivity issue for the whole sample, but also can explore the selectivity issues associated with the probability of receiving any treatment and how many treatments were done (given any treatment). The results from these models were compared and similar marginal effects were found. Thus the findings of this study were reliable.

Fifth, this study conducted a series of analyses based on various real-life situations. For example, most of sealant recipients have all 4 FPMs sealed, but some have one to three FPMs sealed. This study used the former group and the combined group as the sealant group in separate analyses. The similar results ensured reliable conclusions. Moreover, this study conducted subgroup analysis on several pairs of subgroups, assuming that the sealant effects on effectiveness and cost were different. Those analyses have rarely been done by previous studies. The results of this study examined the presence of selectivity among each subgroup, and further confirmed the assumption. Besides, the results of the analysis on high risk and low risk subgroups further supported the risk assessment score as an appropriate caries risk predictor. The results of the analysis on younger and older groups of children implied that sealant delivery was equally cost effective for both groups.

Sixth, previous sealant studies only used one-way sensitivity analysis to test the reliability of their estimation results. Though more recent CEA studies use confidence intervals to examine the uncertainty for their results, it has not been done by any CEA on dental sealant. This study provides an opportunity to address this gap. By using bootstrapping technique, this study presented CIs for the ICERs and reported possible distribution of ICERs in each quadrant on cost-effectiveness plane.

Study Limitations

There are a series of limitations existing in this study's data and measurements, and result generalization. First, there are some limitations related to the nature of the secondary data used in this study. For example, HP started to collect enrollees' ethnicity information in 2005 on voluntary basis. Ethnicity information may not be available for every included subject in the data set of this study. Although encounter data used in this study are more complete than claim data used by previous studies, there will still be some cases with missing tooth number or incorrectly coded procedures. It can be assumed that those cases are uniformly distributed across the whole data set and between sealant and non-sealant group. In this study dataset, some re-sealant placements were wrongly coded as sealant placements, but they were corrected by checking all procedure records for the whole sample. Moreover, this study used dentists' characteristics in the analysis. Although such information in this dataset was more complete than in another study which had only 25-30% of provider information,[8], about 3% of sample was still deleted because of wrong dentist records, and another 16% had dentist identification numbers with incomplete information.

Second, there are some limitations related to the outcome measures. This study used caries-free duration and quality adjusted caries-free duration as the effectiveness measures. There has been no uniform definition of utility or quality of life in dental health care. The quality weights used in this study have rarely been used in dental care studies.[143] More developed and widely accepted quality weights for dental care should be used in future studies. Costs associated with interventions were collected from encounter data in this study. In addition to sealant and re-sealant cost, only caries treatment cost were included. Some treatments and indirect costs were not available, which may underestimate reductions in total costs from sealant use. For example, the expenditure related to pharmacy and emergency visits were not available. Costs associated with travel time, absence of school, parents' absence of work, and so on, were not available in the data set. Claim charges were used in this study to calculate aggregate cost. They may reflect the plan's best attempt at reflecting resource consumption, but not true resource assumption from societal perspective.

Third, some limitations may be associated with the use of geocodes or zip codes. Since no family income or education information could be collected directly from individual HP enrollees, this study relied on linking geocodes or zip codes to Census 2000 data to collect area-based average income and education information for each subject. Those census data do not accurately reflect the income or education level of individual families or subjects. However, considering that the results of this study will be used to guide sealant delivery which is on a community level, the area-based measures might be acceptable.

Forth, some limitations may be associated with the generalizability of the conclusions. For example, the children included in this study had been enrolled in a private insurance company for at the least 5 years. Most of them were from urban areas with relatively high median family income and education level. The variation in SES factors was not large. Two third of them were evaluated at low risk for caries. They may not be able to represent a population which should be targeted by sealant delivery. However, the results of this study still provided valuable information about sealant's cost-effectiveness, especially for children living in Minnesota. Considering that a few sealant studies in last two decades used Medicaid population which was assumed to be high risk population,[22, 139, 143] this study is a good complement to those studies. In addition, the results and conclusions of this study may be limited to 5 years after sealant application. Sealants need to stay intact on tooth surfaces to play preventive function. However, evidence shows that sealant's effectiveness declines over time. One study found that 82.0% of sealants were completely retained and 10.9% was partially retained after 5 years since placement; after 10 years, only 56.7% of sealants were completely retained and 20.8% was partially retained.[134] More studies with longer follow-up period would be needed for examining sealant's effectiveness in a longer term.

5.3. Implications for Public Health Policy

Sealant Utilization Level and Decision-making Strategy

Sealant use has been advocated by the ADA and other oral healthcare agencies.[101] The national oral health objectives for dental sealants, outlined by both the U.S. Public Health Service Healthy People 2000 and the U.S. Department of Health and Human Services initiative Healthy People 2010, were for 50 percent of children aged 8 and 14 to have one or more sealed permanent molars.[9, 118] Compared to this goal, the current sealant utilization level might still be low. One report in 2000 showed that only 23 percent of children in grades 2 and 3 and 20 percent of children in grades 8 and 9 had their first molars sealed.[118] Two other reports showed that sealant prevalence was around 30%.[204, 215] Most of researchers and professionals believe pit-and-fissure sealants are still underused, particularly among children at high risk of experiencing caries or coming from lower-income families or certain ethnic groups.[204, 215] A few researchers argued that some populations at low caries risk may be overtreated with sealants, especially considering that the cost for sealant continues to increase, but the caries prevalence continues to decline.[9, 197, 210]

The primary aim for conducting sealant's cost-effectiveness analysis is to explore the most efficient way to deliver sealants. The results of this study imply that the current sealant delivery is not very efficient. Sealants have been overused in some low risk populations, and underused in some high risk populations. Sealant application should be improved among the high risk populations, and those populations could be the children with previous caries, low dental care utilizers or those directly deemed at high caries risk by dentists. Among the low risk populations, probably targeting individuals rather than the whole populations would be a more efficient strategy to deliver sealants. The results of this study also imply that a uniform and fixed sealant utilization goal may not be appropriate. Currently, caries prevalence is relatively low in some areas. For example, among the sample population of this study, caries rate ranged from 16.1% to 16.9% of the sample over 5 years. This rate was even smaller in terms of first molars. More than 2 thirds of the sample were deemed to be at low caries risk. The uniform 50% goal would be a little too high for such population.

This study provided some incremental cost-effectiveness ratios to dental health policy makers, showings that sealant is more effective but also more costly. Because no willingness to pay (WTP) is associated with caries-free duration, there may be no straight answers for the decision makers about weather sealant is an efficient preventive care in a community or among a population, based on the ICERs obtained from this study. However, those ICERs and their ranges can still help the decision makers to allocate resources accordingly. Although sealant has long been a covered benefit in many health plans or by many health programs, the policy makers could set up specific incentive structures or put certain restrictions in place to increase sealant utilization in high risk populations and control sealant utilization in low risk populations.

Improving Sealant Utilization

As discussed above, sealants are still underutilized in high caries risk populations.[204] Related policy strategies should be taken to improve sealant utilization in those populations. The findings of this study imply that the decision making for sealant is an interactive process among dentists and patients or children's parents. Some educational efforts, therefore, should be directed toward both dentists and patients. Patients and the public should have access to the knowledge about preventive dental care including sealant. The access could include books, media, radio, TV program or public health program. In clinic, dentists and other professionals should inform patients or children's parents about the availability and effectiveness of sealants. Education should also address patients' healthcare behavior. On the other hand, the findings of this study imply that dentists play an important role in sealant decision-making process. Their knowledge and preference greatly affect sealant's utilization. It can be expected that the more information about cost-effectiveness of sealants are available to dentists, the more likely dentists will deliver sealants to the children who need sealants the most.

In addition, to improve sealant utilization, some outreach programs should be provided to children who, otherwise, are less likely visit dentists.[143] Other strategies to improve sealant utilization or sealant effect include adjusting reimbursement for sealant and re-sealant, delegating sealant placement to hygienists or assistants, organizing school-based and school-linked sealant delivery programs, etc.[135, 141, 216]

Assessing Sealant Effect on Community Level

The results of this study imply that studies on preventive dental care such as sealant should be encouraged or supported in order to provide more information about risk-based or community-based cost-effectiveness to dental care professionals and public health agencies. Although most of dental preventive interventions or public health programs are implemented on a state or community basis, there have been few studies evaluating the cost-effectiveness of sealants applied in real-life situations and even fewer conducting community-based or risk-based cost-effectiveness analyses.[3, 8-10] More importantly, the results of this study and previous studies show that sealant's cost-effectiveness could vary significantly among different communities or populations. The relative cost and effectiveness of sealant depends on many factors such as the caries disease profile, water fluoridation, socio-economic status, delivery techniques, reimbursement polices, dental care utilization patterns, and so on. Therefore, related applied studies should be encouraged to evaluate prevention strategies and enhance oral disease prevention in community settings.[14] Those studies would be able to help the ADA, CDC, or other federal or state public health agencies develop more detailed recommendations for use of pit-and-fissure sealants and allocate limited resources more efficiently.

Developing Guidelines for Sealant Delivery

The disparity in sealant application has existed and has been reported by many studies. Some reports showed that children with more prior caries experience or children from low income families were less likely to receive sealants.[88, 204] In other words, sealants are underused in high risk populations but overused in low risk populations. The results of this study and a few previous studies show a little different pattern for sealant utilization. Sealant placement was found more associated with high caries risk, and less associated with SES or race factors.[22] One possible explanation for that difference is that dentists' criteria or decisions to apply sealant or sealant delivery procedures vary by area and by organization. In some areas, risk evaluation was conducted before sealant placement, but in other areas, patients' risk level was not conducted or no explicit criteria were used for sealant placement. The dataset used in this study came from HPDG where a caries risk assessment guideline was designed to encourage the appropriate use of preventive interventions such as sealant on patients with the greatest potential for benefiting from them. This study found that after this risk assessment guideline was implemented in 1996, the sealant rate increased significantly in HPDG. In addition, partly because of this guideline, children assigned with higher caries risk scores were more likely to receive sealants.

Only with enough scientific information can dental care providers identify children with high risk and deliver preventive care in a most cost-effective manner.

Dental professional organizations and public health agencies for oral health should be responsible for developing or updating guidelines or recommendations to provide such as information to health professionals and the public, based on critical review of published scientific evidence. These guidelines should include standard criteria for risk evaluation and cost-effectiveness information on a state or community basis.

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