Fluoride Varnish Application in the Primary Care Setting. A Clinical Study

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Objectives: *The study objectives were twofold: 1. To examine how an intervention to apply fluoride varnish (FV) in a primary health setting to all young, low-income children was implemented and sustained and 2. To assess the feasibility of tracking medical care utilization in this population.* ***Study Design:*** *The study included children age 1-5, insured through a government program, seen (7/1/2010- 4/30/ 2012). Data on age, race, sex, clinic encounter, eligibility for and receipt of FV was obtained. The level of data in primary care, specialty care, urgent care and hospitalizations to assess feasibility of future patient tracking was also acquired..* ***Results:*** *Of 12,067 children, 85% received FV. Differences were found by age (youngest had highest rates). Small differences by race (81%-88%, highest in Blacks.) was found. No differences were found by sex. Ability to track over time was mixed. Approximately 50% had comprehensive data. However, primary care visit and hospitalization data was available on a larger percentage.* ***Conclusions:*** *FV programs can be introduced in the primary care setting and sustained. Further, long-term follow up is possible. Future study of such cohorts capturing health and cost benefits of oral health prevention efforts is needed.*

Key words: *Fluoride varnish, caries prevention. Children. Primary care center.*

INTRODUCTION

Oral health is often overlooked despite the fact that dental decay is the most common disease in children[1-4] impacting 40% of all children age 2-11.[5] The problem for those from low-income families is even greater as this population has higher rates of caries and often has greater difficulty accessing ongoing basic dental care. The literature reports that 80% of caries within the pediatric population is experienced by 25% of children[6, 7] with children in families with low socioeconomic status (SES) three to five times more likely to experience decay that goes untreated.[8, 9] Caries progression increases with age. Edelstein reports tooth decay in 11% of two year olds, 21% in three year olds, 34% in four year olds and 55% in five year olds [5]in addition, poor oral health has been associated with both other health issues and social consequences. Berg, Coniglio, Mouradian and colleagues, have reported an association with failure to thrive in infants as well as poor school performance in children due to missed school days[10, 11] In a study assessing missed days due to dental issues for children in the Los Angeles school system in 2007, of the 7,240,000 children, an estimated 504,000 missed at least one day of school during the school year.[12] Silk, estimated 51,000,000 school hours are missed annually in our country due to oral-health related illness.[3]

To alleviate oral health problems and prevent caries progression, dental care guidelines recommend children at high risk for caries receive topical fluoride beyond that available in fluoridated water and toothpaste.[10, 13, 14] Both The America Dental Association (ADA) as well as the American Academy of Pediatric Dentists (AAPD) consider low socioeconomic status (e.g., eligible for Medicaid) one of the indicators which place children at high risk for caries.

Aware of the problem and recommended care guidelines, a large integrated health system in the Minneapolis/St Paul area instituted a policy targeting those at highest risk, children age one through five, covered by government insurance programs. Under this policy, these children were targeted to receive fluoride varnish applications in their primary care provider's office during well-child visits. The policy was implemented to ensure those at highest risk would receive quality oral health care in the setting where they are most apt to be seen, thus reducing caries and related sequelae.

We conducted a study designed to track the implementation of the initiative. The study had two aims. The first was to examine how the initiative was implemented and sustained over time. The second aim was to examine the feasibility of assessing the initiative's longer-term impact by tracking medical care utilization in this population. This second aim determined if a cohort of low- income children are able to be identified and followed over time, the data

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sources required to monitor utilization among this cohort and the completeness of prospective data capture pertaining to this cohort. The purpose of this paper is to report the rates of fluoride varnish (FV) receipt within the health system overall and by patient (age, race) and provider characteristics (credentials, specialty), and discuss findings regarding the feasibility of future patient tracking.

MATERIALS AND METHOD

This study was approved by the health plan's Institutional Review Board.

The Setting

HealthPartners Medical Group (HPMG) is multi-specialty group practice in an integrated health system that includes a health plan, several hospitals, and a wide range of other health care services. It provides care to 400,000 active patients in the metropolitan area of Minneapolis and St. Paul, most of whom receive the majority of their primary care in 21 clinics. Approximately 60% of HPMG patients have HealthPartners insurance, and this includes large subgroups covered under Medicaid or Medicare contracts. Thus, the demographic characteristics of the patient population reflect that of the greater Minneapolis/St. Paul area. HPMG has had a paperless electronic medical record (EMR) for nine years. This EMR system integrates its primary, hospital and specialty care settings.

Determining Program Implementation

In assessing the implementation of the HPMG program, the study included children aged one through five years of age, insured through a government program, and who were seen for a well-child visit at a HPMG clinic between July 1, 2010 and April 30, 2012. Information on age (calculated based on the earliest visit that satisfied inclusion criteria), gender and race (White, Black, Asian/Hawaiian, Native American, Mixed, Other, Unknown) were obtained from the HPMG's EMR as were clinic encounter information including eligibility for fluoride varnish, receipt of fluoride varnish, service date, provider credentials (physician, nurse practitioner, physician assistant) and specialty (pediatrics, internal medicine). We examined the data to determine uptake of the initiative overall and by age, gender and race of child, by medical group clinic, and provider credentials and specialty.

Determining Feasibility of Long Term Follow-up

Recognizing that the primary interest for future study would be in determining long-term outcomes, but that insufficient time in terms of caries disease progression had elapsed to identify significant differences, we assessed the proportion of children eligible for FV treatment with comprehensive data for such an evaluation. For this aim, we followed all children under age six (ages 0-5). In addition to determining the level of data available, we also identified our ability to obtain data on all the types of encounters we would wish to track (out-patient, urgent care and hospitalizations) and determined how we would link a standardized measure of cost to encounter.

Ability to Track Children over Time

Children were included if they were less than six years of age, insured through a government program, and seen for a well-child visit at a HPMG clinic between July 1, 2010 and April 30, 2012. We excluded children with known dates of death and looked at their monthly health plan enrollment from study entry through July 31, 2012. If they were enrolled on the 15th of the month, they were classified as being enrolled for that month.

We examined data from two sources when determining our ability to track a cohort of children over time: the administrative databases and the Epic EMR system. For those enrolled, the administrative databases contain complete information on utilization, billing provider, clinic and basic patient demographics. Utilization data includes ICD-9 diagnostic codes and CPT-4 procedure codes. The Epic EMR system contains data on diagnostic and procedure codes as well as other encounter information for all care provided at an HPMG facility. Potentially, HPMG EMR data can be used to supplement gaps in coverage when needed. For purposes of the current assessment, we classified children in three groups: (1) children for whom we had comprehensive (75% coverage) administrative data, and (2) children for whom we had partial (>25% coverage) administrative data and 3. children with minimal (≤25% coverage) administrative data.

We also recognized that long term assessment would likely focus upon different types of encounter classifications including primary care visits, hospital inpatient and outpatient visits, emergency room visits, urgent care visits, and specialty care visits, representing a broad spectrum of traditional medical specialties and subspecialties as well as chiropractic, mental and chemical health and dentistry/oral surgery care. Thus, we also examined the types of data most likely to be missing.

Statistical Methods

Chi-square analyses were used to evaluate the statistical significance of differences in receiving FV by age, race, and sex. Statistical analyses were performed using SAS for Windows, version 9.2. P-values of <0.05 were considered statistically significant.

RESULTS

Program Implementation

There were 12,067 children identified who met eligibility criteria for the assessment of program implementation. Overall, 85% of children received FV. Table 1 provides a breakdown of FV receipt by age. The percentage of eligible children receiving FV was the highest (94%) for the youngest children and dropped to 65% for those age five. This resulted in a statistically significant difference in FV receipt by age (P<0.001). Although there was a significant difference found by race (P<0.001), over 80% of children of all races received FV: 88% of Black, 86% of mixed race, 85% of those where race was categorized as "other," 84% of Asian/Hawaiian, 83% of White children and 81% of Native American children. No differences were found by sex, approximately 85% of both females and males received the application

Of the providers who saw the eligible children (n=12,067), 97% were physicians, 3% nurse practitioners, and <1% physician assistants. For 10 cases the credentials of the provider were unknown. The majority (81%) of these providers specialized in pediatrics.

Administration of FV by medical group clinic was variable ranging between 68-94% of eligible children receiving the FV application. Examination of FV administration over time indicated that between 80% to 90% of eligible children received FV within all medical group clinics each month since the FV initiative began.

Feasibility to Track a Patients over Time

For the feasibility assessment we broadened our age range to also include children aged 0-1 with a well-child visit at HPMG. Our goal was to determine how an identified HPMG patient cohort fell across our three categories: comprehensive data, partial data and minimal data. We examined the availability of administrative data over two time intervals. The first interval was for a four month window, beginning with the month of study qualification. The second time interval was 12 months.

We found 15,298 children who met our expanded age (0-5) criteria with coverage that was state subsidized and did not have a known date of death. For the four month window (April 2012 through July 2012) all 15298 were included. Fifty-four percent (n=8301) had 3-4 months of coverage and administrative data available (Table 2). When examining the 12-month follow-up window we needed to exclude 3248 identified after August 2011, leaving a cohort of 12, 050. Of these, 6714 (56%), had 10-12 months of coverage (comprehensive data), 1186 (10%) had 4-9 months of coverage (partial data) and the remainder had 0-3 months of data (minimal data). For those with limited coverage, we assessed the ability of HPMG EMR to supplement missing data regarding utilization. For those with less than complete administrative data, we were able to capture hospital inpatient data, urgent care and primary care encounters using the HPMG EMR records. For example, for the 4150 with 0 months of coverage, we found that 14% had a data on a hospital inpatient stay. This percentage was relatively close to the 22% who had a hospital stay from the group with 10-12 months of coverage.

We then examined the type of data most likely to be available from the EMR if minimal data was available from administration billing systems. We found that data was reasonably available from the EMR for primary care encounters, hospital inpatient visits and for urgent care. Encounters for specialty visits, outpatient hospital visits same day surgery, and emergency rooms were more likely to be missed.

DISCUSSION

National reports reiterate the poor condition of oral health in young (age 5 and under) minority and low income children.[5, 10, 11] NHANES survey results also report poorer oral health in minorities and those with lower SES. Whereas 76% of white parents reported their children's teeth were in "good to excellent" condition, the percentage fell to 61% for blacks and 47% of Hispanics. Reporting teeth in good to excellent condition was found in only 49% of poor parents compared to 60% of low income, 75% of middle income and 83% of high-income parents.[5]

With all the data indicating both the prevalence of dental health problems[1-4] and the disparities faced by those at highest risk,[6, 7] HPMG systematized FV application by making it part of their Care Model Process for children age one through five who are enrolled in government programs. The initiative was initially piloted among three clinics in 2007, then all pediatric providers received training in early 2010. The program was fully implemented in all clinics by July 2010. We assessed how the program was being implemented and found that it has been successfully adopted by the clinics and appears to be sustaining. At least 85% of children targeted to receive FV have been obtaining the applications. This is true across clinics, sex, race and age (except for 5 year olds). In the latter group, the application rate was down to 65%. In discussion of possible reasons, some pediatricians commented that for some, the pre-school visits require a variety of assessments so that FV application may become less of a priority. In addition, some children may now be seeing dentists outside the health system. It is possible that some received FV in other settings by this point. Still, reminders for fluoride application are now embedded into EMR and a risk factors assessment for future caries is supposed to be included in each visit.

We also examined our ability to capture data over time and were encouraged that it could be done on this population. While not all children could provide comprehensive data, we believe the proportion that could, would be representative of the underlying population. Further, we found we were able to capture some information even on those with minimal interaction with the system. The types of encounters that were not found (specialty visits, outpatient hospital visits same day surgery, and emergency room) may be due to the fact that children are going outside the owned facilities to receive those types of care. Therefore, for the children without comprehensive data available, we would still have some available primary care, hospital inpatient, and urgent care data.

We considered how we would approach future analyses in long term assessments and drafted an initial analysis plan. We have created operational definitions for the variables of interest and identified strategies of analyses. We would operationally define Primary Care Visits to include total visits to a primary care physician (general practice, family practice, pediatrics, nurse practitioner, physician assistant). Emergency Department Visits would be the total number of visits to an emergency department leading to either discharge or inpatient admission. Total Medical Costs: would include all medical costs incurred during the year. Inpatient Medical Costs would include: emergency care, unscheduled procedures, unscheduled inpatient stays. Ambulatory Medical Costs would include: primary care, specialty care, outpatient pharmacy, and scheduled procedures that are part of routine care. Both Primary Care visits and Emergency Department visits would be reported as count outcomes.

We would analyze using a count data model with Poisson distributed errors. The three cost outcomes (total, in patient and ambulatory) could be analyzed in two ways, first focusing on a comparison of patients receiving FV to those who did not. The second analysis would focus upon cost trends over time using data across several years. This analysis could determine whether the overall trend in costs significantly differ between those who did and did not receive FV.

As healthcare resource use data is generally skewed, thus, we would perform diagnostic tests to determine the best final specification for analytic models (e.g. a log-transformed ordinary least squares or a generalized linear model with gamma distributed error) using established methods. Further, as there are significant differences between clinics not fully accounted for by the available patient-level demographic data, we would suggest a robust covariance estimator to adjust for potential heteroskedasticity. Finally, previous studies by this team indicate a significant percentage of patients can be anticipated to have a zero value for one or more of the medical resource use measures. Thus, we would employ a two-stage hurdle model to account for the zero-mass problem.

Medical cost data due to coverage design, pre-negotiated discounts, payment methodologies, and contracted amounts data

could be examined in two ways. First, cost outcomes would be based on the health plan's Total Cost Relative Resource Value units (TCRRVs). TCRRVs are based upon Centers for Medicare and Medicaid Services (CMS) relative value units (RVUs) but extend RVU measures to include inpatient, outpatient surgery, emergency room services, scheduled outpatient, professional, and pharmacy services. Where a CMS weight does not exist, TCRRVs use the average billed amount from claims. This can be done because TCRRVs value services similarly to RVUs, are convertible to dollars using the Medicare cost factor for the study year. Second, multivariate regression models could incorporate a random clinic effect to account for variation in billed amounts across clinics not directly attributable to observed patient or clinic factors.

Models might examine variation at the clinic level using a likelihood ratio test at the 5% level. Additionally, baseline patient-level demographic models could be developed. Covariates significant at the 10% level in univariate models could be screened for confounding and multicolinearity and appropriate adjustments taken prior to introduction into a multivariate framework. Interactions significant at the 10% could be retained in the final model.

Study Limitations

This study was conducted in a single health care system that may not be reflective of all health care systems. The capacities to capture data on health care utilization would not be found in all systems. Further, providers within this system may be more compliant with FV application as they are employed by the health system and are required to follow initiatives. The system is highly focused on preventive care. This may not be the focus of all providers. Even with these limitations, however, the results are encouraging.

CONCLUSIONS

This study has demonstrated that FV programs can be introduced, that long term follow-up, while challenging, is possible and a workable analysis plan can be implemented. Future research should provide such follow-up capturing the health and cost benefits of oral health prevention efforts for those most vulnerable. With additional evidence, it would be possible to increase outreach interventions and improve the oral health of our children.

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