Pediatric Dentists' Attitudes and Behaviors toward Protective Stabilization Devices

BY

DUSTIN DAVIS
B.S., Brigham Young University, 2008
D.D.S. Virginia Commonwealth University, 2012

THESIS

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Defense Committee:

Shahrbanoo Fadavi, Chair and Advisor, Department of Pediatric Dentistry
Linda M. Kaste, Department of Pediatric Dentistry and, Division of Epidemiology and Biostatistics, UIC School of Public Health
Rodney Vergotine, Department of Pediatric Dentistry
Robert Rada, Department of Oral Medicine and Diagnostic Service

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LIST OF ABBREVIATIONS

AAPD	American Academy of Pediatric Dentistry
ABPD	American Board of Pediatric Dentistry
BMT	Behavior Management Technique
HOM	Hand-Over-Mouth
SES	Socio-Economic Status
PS	Protective Stabilization
PSD	Protective Stabilization Device

SUMMARY

The purpose of this study is to assess the attitudes and behaviors of pediatric dentists towards protective stabilization devices (PSD). Although there exist various studies that have analyzed the range of behavior management modalities on a surface level and many that examine parental acceptance of PSDs, there are very few that attempt to investigate the different variables that might influence provider acceptance and use of PSDs.

This study was a cross-sectional survey of the 2922 American Board of Pediatric Dentistry's College of Diplomates. The survey was electronically mailed using UIC's Redcap system. The adjusted response rate was 29% and 805 of the 826 responses were used in the statistical analysis.

Bivariate and multivariate statistical analysis revealed the following:

- Providers with a lower SES patient base were more likely to be accepting of PSD, and to report use of PSD, than providers with a higher SES patient base.
- Providers who perceived their patients' parents to be more accepting of PSD were also found to be more accepting of PSD, and were more likely to report use of PSD than providers who perceived their patients' parents to be less accepting of PSD.
- Providers with low patient volume were more accepting of PSD, and more likely to report use of PSD, than providers that reported a moderate or high patient volume.
- Protective Stabilization Device use or non-use during residency was not found to be associated with current use or non-use of PSD provider acceptance of PSD.

- Provider “Age” (Board Cohort) was not associated with acceptance of PSD or use of PSD.
- Female Providers were more likely than males to be accepting of PSD and also more likely to report PSD use.
- Providers practicing not solely practicing in private practice, were more likely to be accepting of PSD use, and more likely to report use of PSD, than providers that practice solely in private practice.
- Providers from the North Central region were more likely to be accepting of PSD, and more likely to report use of PSD than collective of other AAPD districts.
- No variables were found to be retained in the multivariate model for provider acceptance of PSD
- Providers with a lower SES patient base, Low Patient Volume, Female Gender, Providers that work solely in Private Practice, and the North Central AAPD Region were all retained in the multivariate model.

1. INTRODUCTION

1.1 Background Information

The AAPD defines protective stabilization as “any manual method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a patient to move his arms, legs, body, or head freely.”(AAPD Guidelines 2013) “The restriction may involve another human(s) [“active”], a patient stabilization device [“passive”], or a combination thereof. The objectives are to reduce or eliminate untoward movement, protect the patient, staff, dentist or parent and to facilitate delivery of quality dental treatment.” (AAPD Guidelines 2011).

Indications for the use of protective stabilization devices have evolved since the AAPD first began publishing guidelines. In 2013 the AAPD issued more detailed guidance on the use of PSD, partly in response to media reports of misapplication of aversive behavior techniques (Strange 2014). In addition the US Senate published a report chastising corporate entities treating high percentages of Medicaid children, shedding more light on the topic of incorrect application of PSD (Strange 2014).

“Indications for PSD use include: a patient that requires immediate diagnosis and or urgent limited treatment and cannot cooperate due to lack of maturity or mental and physical disability; emergent care is needed and uncontrolled movements risk the safety of the patient, staff, dentist, or parent would be at risk without the use of protective stabilization; a cooperative patient quickly becomes uncooperative during the appointment and in order to protect patient safety and help expedite completion of treatment; a sedated patient may become uncooperative during treatment; and a patient

with special healthcare needs may have uncontrolled movements that would be harmful or significantly interfere with the quality of care." (AAPD Guidelines 2013)

"Contraindications to PSD use include: Cooperative non-sedated patients; Patients who cannot be immobilized safely due to associated medical or physical conditions; Patients who have experienced previous physical or psychological trauma from protective stabilization (unless no other alternatives are available); Non-sedated patients with non-emergent treatment needs to accomplish full mouth or multiple quadrant dental rehabilitation." (AAPD Guidelines 2013)

The existing body of Protective Stabilization research has mostly focused on the parental attitudes and opinions regarding these devices. These studies have demonstrated that PSD's are consistently found at the bottom of parental acceptability scales when comparing different methods of behavior management (Murphy, Fields, and Machen 1984a; Fields, Machen, and Murphy 1984; Lawrence et al. 1991; Eaton et al. 2005a). Although it is valuable to understand the viewpoint of the parent, it is arguably more important to explore the attitudes of those with experience and first-hand knowledge about these devices, since research has demonstrated an unfounded negative initial bias from parents to these devices. (Peretz and Zadik 1999; Havelka et al. 1992a; Kupietzky and Ram 2005)

There are some studies that have explored the use of PSD among pediatric dentists. Unfortunately, almost none of the existing studies attempt to comprehensively investigate provider use of PSD, or provider attitudes toward PSD. Most of the existing studies that attempt to delve into the topic of provider use and attitude are broad

overviews of a wide range of behavior management modalities with an extremely small focus on PSDs. Without a more focused approach it is difficult to come to a clear understanding about what factors shape the attitudes of providers and what the existing PSD use data truly means. The existing data is very sparse with regards to the different societal and economic factors that might play a role in a practitioner's decision to employ use of such devices. The majority of PSD literature does not distinguish between the use of PSD during sedation or for a solely uncooperative patient which scenarios come with might be viewed with different ethical viewpoints. Without this supporting data and information, the existing PSD data is clouded since these issues are more complex than they might initially seem.

It seems reasonable to hypothesize that differences would exist between the attitudes of dentists confronted by different social and financial scenarios, not to mention the cost and efficiency differences between behavior management modalities. Factors such as patient socioeconomic status, perceived parental acceptance, provider patient volume, training, age, gender, and practice type are all factors that could potentially create differences in the attitudes and behaviors of dentists towards protective stabilization devices, and should be explored in more depth than in past studies. (Casamassimo, Wilson, and Gross 2002; Peretz and Gluck 2002; Carr et al. 1999)

1.2 Purpose of the Study

The purpose of this study is to assess the attitudes and behaviors of pediatric dentists towards protective stabilization devices (PSD)

1.3 Hypotheses

1) Provider acceptance of use of PSD does not vary depending on their practice Characteristics
    a.) Lower SES patient population > higher SES population
    b.) Perceived parental acceptance > perceived non-acceptance
    c.) High patient volume > low patient volume
    d.) Increased residency experience > less residency experience
2) Provider utilization of PSD does not vary depending on their practice Characteristics
    a.) Lower SES patient population > higher SES population
    b.) Perceived parental acceptance > perceived non-acceptance
    c.) High patient volume > low patient volume
    d.) Increased residency experience > less residency experience
3) Provider acceptance of use of PSD does not vary based on personal characteristics
    a.) Young > Old
    b.) Male > Female
    c.) Other Settings > Private Practice
    d.) District IV(North Central) > Other AAPD Geographical Districts
4) Provider utilization of PSD does not vary based on personal characteristics
    a.) Young > Old
    b.) Male > Female
    c.) Other Settings > Private Practice
    d.) District IV(North Central) > Other AAPD Geographical Distric

2. REVIEW OF LITERATURE

2.1 Studies Assessing Dentists' Attitudes and Behaviors towards Protective Stabilization Devices (PSD)

In 1970, the Association of Pedodontic Diplomates surveyed their membership regarding their use of different behavior management techniques. That study found that 84% of Diplomates used some form of physical restraint to manage their patients. The survey also found that 69% of pediatric dentists used their assistant to restrain the child and that only 48% used some kind of passive restraint (a wrap or straps). The biggest reasons cited for use of a physical restraint were to deal with patient temper tantrums, patient aggression, patient resistance, and patient hysteria. That study also showed at that time 19% of Diplomates reported to never use any form of physical restraint (Association of Pedodontic Diplomates 1972).

Eleven years later in 1981, the Association of Pedodontic Diplomates again surveyed their membership regarding their attitudes and practices in behavior management. This study showed a similar result overall, with 85% of Diplomates reporting to use some form of physical restraint, and 9% reporting to never use physical restraint (Association of Pedodontic Diplomates 1981). Of those reporting use of physical restraint, 85% reported to use some form of Passive restraint (Body wrap or straps), which is a large increase from the 1970s survey (48%). Although there was a large increase in use of passive restraint reported by the 1981 survey, there were no other drastic changes in other forms of behavior management (i.e. active restraint only went from 71% to 69%).(Association of Pedodontic Diplomates 1972; Association of Pedodontic Diplomates 1981) Although it may be possible to conclude that the large

increase in use of passive restraint (from 48% to 85%) was due to some shift in treatment philosophy during this time, it seems more likely that to be a reflection of statistical weakness in the study from 1972. Most of the respondents (84%) to the 1972 survey reported use of some form of physical restraint when not broken down into detailed subcategories, versus 85% in 1981 survey, which is similar to minimal differences found in the active restraint question. In addition, 16% (19/120) of the 1972 dentists answered 'Other' when asked to specify exactly what type of restraint they used, and in the 1981 survey, this answer choice was eliminated. This statistical discrepancy likely helps account for the large differences in reported use of passive stabilization techniques in the two surveys, although it is impossible to extrapolate a trend one way or the other. (Association of Pedodontic Diplomates 1981; Association of Pedodontic Diplomates 1972)

In 1989 Nathan found that 54% of pediatric dentists say that they only use PSDs for "handicapped and sedated patients" (Nathan 1989). More recently in 1993, McKnight and Hanes surveyed 1000 Pediatric Dentists and found that 71% of Pediatric Dentists reported use of physical restraint as compared to only 3% of General Dentists (McKnight-Hanes et al. 1993).

In 2004, Adair surveyed 4180 members of the American Academy of Pediatric Dentistry and found that 68% reported use of a Protective Stabilization device for the non-sedated child. While just over half (56%) reported use for their sedated patients (Adair et al. 2004)

Vargas reported (2007) that his survey of 2827 AAPD members demonstrated that 56% of pediatric dentists prefer to not use a protective stabilization device during sedations. At this time point, 45% of pediatric dentists preferred to have parents actively restrain the patient rather than use a PSD (Vargas et al. 2007).

Although there appears to be a general trend in favor of decreased use of Protective stabilization (Vargas et al. 2007; Adair et al. 2004; Nathan 1989; Association of Pedodontic Diplomates 1981; Association of Pedodontic Diplomates 1972; McKnight-Hanes et al. 1993), the literature also makes it evident that as far as behavior management philosophies are concerned, there is rarely a consensus among pediatric dentists, and there are many factors that likely play a role in a practitioners choice to use a PSD (Vargas et al. 2007; Adair et al. 2004; Nathan 1989; Association of Pedodontic Diplomates 1981; Association of Pedodontic Diplomates 1972; McKnight-Hanes et al. 1993).

2.2 Variables affecting attitudes and behaviors of dentists toward PSD

The existing body of literature has made some limited attempts at analyzing potential variables that may affect practitioner attitudes towards and use of PSD. There is a lack of standardization of terms and variables and the data is unclear and conflicted in many instances. In many cases it is difficult to differentiate between restraint types (active, passive) or between scenarios in which dentists reported use of PSDs (i.e. sedation, cooperative child, uncooperative child, special needs patient). (McKnight-Hanes et al. 1993; Association of Pedodontic Diplomates 1981; Davis and Rombom 1979; Association of Pedodontic Diplomates 1972)

2.2.1 Providers' Age

McKnight-Hanes were one of the first to report on age's connection to PSD when they reported that the 40-49 year old age group used protective stabilization devices significantly more than any other age group, and that the under 30 age group used them the least, followed closely by the over 50 age groups (McKnight-Hanes et al. 1993).

Six years later Carr similarly reported that those with over 16 years in practice were likely to report occasional use of Physical Restraint at 76.4%. The oldest age group, those with over 20 years in practice, were even more likely to report occasional use of physical restraint with 89.7% reporting as such. It was also found that those with fewer than 10 years in practice were the lowest occasional users of PSD's with only 51% reporting occasional use and 37.8% reporting no use (Carr et al. 1999).

Adair reported in 2007 that younger practitioners were more likely to report anticipated decreases in their use of PSDs (Adair et al. 2007, 403-408). This survey yielded that of 2751 AAPD members, age was not a significant factor in PSD use (Adair et al. 2007).

Yet, Wright and colleagues reported that restraint use varied depending on the age of the dentist and the dental school that the dentist attended (Wright, Giebartowski, and McMurray 1991).

Although much of the data is not perfectly comparable from a statistical viewpoint, it appears that the existing data shows that younger dentists are using less PSD than their middle aged counterparts and that there is some conflicting data regarding the oldest cohort of dentists with some studies implying increased use and

others reporting decreased use with increasing age. (Carr et al. 1999; McKnight-Hanes et al. 1993)

2.2.2 Providers' Gender

Adair's 2007 survey of 2751 AAPD members found that females, independent of age, were more likely than males to report use of a PSD for a non-sedated child (Adair et al. 2007). Wells et al. recently (2014) found supporting evidence for this conclusion when they discovered that females were more likely to report use of PSD for sedated patients and those with special healthcare needs (Wells et al. 2014)

On the other hand, Peretz's survey of 112 Israeli pediatric dentists found that males were significantly more likely to use a Protective Stabilization device (Peretz, Glaicher, and Ram 2003). The more likely use by males was also seen in an Australian survey of behavior management methods used by dentists that demonstrated that females were less likely to use restraint techniques than male dentists (Wright, Giebartowski, and McMurray 1991).

There is insufficient and conflicting data to come to a clear conclusion as to whether gender is a significant factor in PSD use, but it appears that in the United States, female dentists tend to use PSD more than males. Additional studies should be conducted.

2.2.3 Practice Setting

Havelka reported that parents of high social class were less accepting of Papoose Board and General anesthesia, but more accepting of active restraint than their lower social class counterparts (Havelka et al. 1992a). The Carr study showed

that suburban pediatric dentists were more likely to say that they never use a papoose board than their urban and rural counterparts. (Carr et al. 1999) Nathan conducted a survey of 616 dentists (166 of whom were Pediatric Diplomates) and found that practice location, caries prevalence, and educational background all played a role in the selection of treatment and behavior management strategies (Nathan 1989).

There is very limited data that addresses the effect that practice setting has on PSD acceptance. The existing data point to a relationship between lower socioeconomic type practice settings and increased use of PSD but more studies should be conducted to better understand this relationship (Havelka et al. 1992, Carr 1999, Nathan 1989).

2.2.4 Geography and PSD use

The McKnight-Hanes 1993 study explored the differences in restraint use when compared across AAPD geographic region. That study found that Southeastern dentists reported the highest use of restraint followed by the Western Dentists. The Northeastern region had the lowest reported use of restraint. Although these regional differences were found to be significant, when the data was analyzed by logistic regression based on practitioner type (GP vs. Pediatric) no statistically significant interactions were found across the different regions.(McKnight-Hanes et al. 1993)

Crossley reported that Pediatric dentists in the UK and Australia appear to use restraining methods less often than their North American counterparts and that 69% of UK dentists felt uncomfortable with the active restraint technique (parent, doctor, or assistant holding the patient) and that 61% of pediatric dentists felt uncomfortable with

the papoose board (Crossley and Joshi 2002). An Australian study showed a similar finding for Australian dentists in the state of Victoria, backing the idea that geographic location in addition to cultural differences are likely playing a role in Pediatric Dentists' attitude towards, and use of PSD (Crossley and Joshi 2002).

In summary, very few studies address the potential association between geographic location and acceptance or use of PSD. The few existing studies have shown increased use in the Southeastern United States, and decreased use and acceptance of PSD in the UK and Australia as compared to the United States (Crossley and Joshi 2002, McKnight-Hanes et al. 1993).

2.3 Dental Educators attitudes towards PSD

One of the earliest studies to survey Pediatric Dentistry program directors regarding PSDs came out in 1979. Davis found that a majority (61%) of program directors strongly felt that physical restraint induced no post-operative psychological problems (Davis and Rombom 1979). A decade later, a follow-up study demonstrated that there was a significant drop in the certainty of these program directors to 39% (Acs, Burke, and Musson 1990). Another ten years later, Acs followed up again and found an additional decrease in program director certainty to 35%, although the last decrease was not found to be statistically significant (Acs et al. 2001).

Another important finding related to these three studies is the large and statistically significant increase of scenarios (handicapped patients, very young patients, pre-medicated patients and physically resistive patients), in which program directors would recommend use of PSDs. Although this large difference was found between the

1979 and 1989 studies, no significant difference was found between the ‘89 and ‘99 studies, and the literature does not delve into the possible reasoning for this initial increase (Acs et al. 2001; Acs, Burke, and Musson 1990; Davis and Rombom 1979).

More recent studies have shown high program acceptance of both passive and active stabilization (76 - 98%), from both a didactic and clinical standpoint. Program directors have also reported a high incidence of PSD use for both sedated (81%) and non-sedated patients (63% for neurologically challenged patients) (Adair et al. 2004; Wilson and Nathan 2011).

Adair et al. reported that in the 2004 survey of program directors, that a majority reported no change in their teaching of PSD, and no likely change in this instruction in the near future (Adair et al. 2004).

Program director certainty regarding possible psychological sequelae related to PSD use has decreased since 1979, while the acceptable indications for PSD use, as deemed by these same program directors, has greatly increased. In addition, there is a high level of program acceptance of PSD use and no likely change in projected teaching of PSD (Acs et al. 2001; Acs, Burke, and Musson 1990; Davis and Rombom 1979; Adair et. al 2004; Wilson and Nathan 2011).

2.4 Parental attitudes towards PSD

A significant amount of literature addresses parental attitudes toward physical restraint. In 1984 Fields surveyed parents after they viewed videotaped segments of dentists successfully using 10 behavior management techniques. His study showed that of the ten behavior management modalities, Protective Stabilization (papoose

board) was the technique judged most unacceptable with 33% of parents deeming it unacceptable under any dental scenario. (Fields, Machen, and Murphy 1984) He also demonstrated variation in parental acceptance of papoose board depending on the perceived difficulty of the dental procedure. For example, parental acceptance of PB increased from 13% for a radiograph to 46% for an extraction (Fields, Machen, and Murphy 1984). Another study completed near the same time showed similar parental aversion towards PSDs. In this study papoose boards were rated the least acceptable of 10 behavior management techniques, followed by General Anesthesia, Sedation, and Hand-Over mouth (Murphy, Fields, and Machen 1984).

In 1991, Lawrence demonstrated a slightly increased parental acceptance of PSDs (papoose board) with a decreased acceptance of oral premedication and general anesthesia (Lawrence et al. 1991). Eaton followed up these two studies in 2005 and found that Hand-over-mouth (HOM) has now become the least parentally accepted behavior management technique with Passive restraint now in second to last place and with a significant increase in acceptability of General Anesthesia and Oral Premedication (Eaton et al. 2005a). It should be understood that although PSDs do have a lower acceptance level than all other behavior management techniques besides HOM when placed in rank order, that HOM received a much lower parental acceptability score than did PSD. (Eaton et al. 2005a)

Although the majority of these parental acceptability studies demonstrate a trend of decreasing acceptance of the more physical behavior management techniques such as hand-over-mouth and Protective Stabilization Devices, multiple studies have all demonstrated increased acceptability for behavior management techniques (including

PSDs) when treatment is preceded by a video explanation of the technique. (Lawrence 1991; Havelka 1992; Ramos 2005; Wilson 1991; Peretz 1999; Eaton 2005)

Frankel's 1991 study could be considered the most clinically relevant of all the parental acceptance studies because it surveyed mothers whose children were not able to cooperate enough to finish treatment without sedation and the use of a PSD. Instead of surveying just any parent, the survey targeted the parents who would most fully experience the difficulties associated with treating an uncooperative child and would be able to evaluate any perceived post-operative psychological damage. Of the 74 mothers surveyed, 96% said the papoose board was necessary for the treatment of their child, even though 66% of these mothers indicated that the experience was stressful for their child. Interestingly enough, 86% indicated that they would be willing to have their next child treated with the papoose board and 78% disagreed that the experience had a negative later effect on the child (Frankel 1991).

Another study that questions the accuracy and or relevance of the existing parental opinion surveys is Wilson's 1991 study. In his survey of 60 parents he showed a consistent trend for those in groups (grouping of five parents vs. parent alone), to rate various behavior management techniques as less acceptable than compared with those parents rating these techniques by themselves. In addition, another study demonstrated the difference in parental acceptability of papoose board use, based on a more positive explanation of the technique as opposed to a neutral explanation (Kupietzky 2005).

Wilson and Kupietsky's studies help shed light on the complexity of factors that may play a role in affecting parental judgment towards more aversive behavior management techniques like Protective Stabilization, and give some additional emphasis towards the importance of critically examining the methodology of the multiple studies on this topic (Wilson et. al 1991).

These studies also lessen the significance that health care professionals should give to parental acceptability ratings, at least with regards to the opinions of less-experienced parents. In addition the parental acceptability literature should help dental providers understand the value of pre-emptive and thorough explanation of behavior management techniques to help raise parental tolerance levels when more aggressive management techniques are indicated (Peretz and Zadik 1999; Wilson et al. 1991; Frankel 1991; Ramos et. al 2005; Havelka et al. 1992a; Lawrence et al. 1991).

3. MATERIALS AND METHODS

3.1 Sample Selection

The inclusion criteria for this survey were all 2922 members of the American Board of Pediatric Dentistry's College of Diplomates. This list was provided upon request to the ABPD College of Diplomates at no cost.

3.2 Study Design

This study was a cross sectional survey.

3.3 Survey Tool

A survey was generated through use of UICs Redcap system. A cover letter (Appendix A) was emailed to all members of the ABPDs' College of Diplomates through this same Redcap system. The cover letter explained the purpose of the study, the anonymity of the respondents, and identified the researchers involved in the study. The cover letter also contained a link to the study. Upon clicking upon the link respondents were directed to the survey. The Survey included 17 questions some of which would be skipped by the Redcap program if they were not applicable to the respondent (i.e. respondents that reported never using PSD were forced to skip questions that asked them in more detail about this use). This email was sent out beginning on October 21st, 2013 at 7am. A second and third electronic mailing was sent to non-respondents on November 6th, 2013 at 12:30pm and at 5pm on December 6th, 2013.

3.3 Statistical Analysis

Bivariate and multivariate (variables with *P*<.1 at bivariate) analyses contrasting "no" versus "any" PSD use, and "less accepting" or "more accepting" provider attitudes toward PSD were completed. SPSS (IBM SPSS Statistics, Version 20) was used to analyze the data.

3.4 Re-categorized variables

Due to poor distribution of responses, many of the survey responses required re-categorization to collapse some of the more poorly distributed response categories. After careful examination of response distributions, some responses were collapsed to aid in improved statistical analysis.

3.5 Provider Acceptance Score

Survey questions 7,8, and 9, regarding provider attitude towards PSD, comfort level with PSD, and comfort level with PSD use on a loved one respectively, were each found to be correlated with one another (p<.001). The PI created a summation score using these three responses, which produced a range of scores from 1 (least accepting of PSD) through 6 (most accepting of PSD). These scores did not have a good distribution and were recoded from (1 – 4 for less accepting), and from (5 – 6 for more accepting). Summation scores of 3 or 4, which could be considered neutral, were grouped with the less accepting category.

4. RESULTS

4.1 Number of Respondents and Response Rates

After data collection was completed, a gross response rate of 28% (826/2922) surveys was received. After removing 13 providers that reported no response because they were not currently practicing pediatric dentistry, 2 Incorrect Email Addresses, and 11 Diplomates that responded with automatic email responses that indicated a long-term absence, an adjusted response rate of 29% (826/2896) was calculated. Eleven Diplomates had spam filters that forced additional effort by the sender to bypass; the P.I. did not exclude these respondents after requesting bypass for all 11. It was not possible to confirm receipt of the survey to these 11 respondents it assumed that they were received. Exclusion of these 11 would not significantly affect the adjusted response rate.

4.2 Descriptive Data for Respondents (see Table I)

Seven surveys were incomplete and fourteen respondents reported in the survey that they did not see any patients. Both of these groups were excluded for data analysis leaving the number of analyzed responses at 805. The demographic characteristics of these respondents are listed in Table I. The respondents were approximately half male (52%) and female (48%) and the great majority of respondents received their board certification within the last 5 years (42%). There is a mostly even distribution of respondents from all AAPD regions with a slightly less representative sample from the Eastern region (District II - 9%). The majority of respondents report working solely in private practice (78%) and describe their patient pool as mostly being made up of patients with non-government funded insurances (83%). The majority of

respondents (64%) reported to practice in suburban areas while a sizeable minority (28%) practiced in urban areas and smaller minority in rural areas (8%).

4.3 Provider Acceptance of PSD Use (See Table II)

After creating an acceptance score from survey questions #7, #8 and #9 (see methods 3.4) it was found that 58% of respondents were considered more accepting of PSD use, whereas 42% were scored as less accepting of PSD use.

4.4 Provider Use of PSD (See Table III)

After re-categorization of the responses (see methods 3.4), it was found that 68% of Pediatric Diplomates use PSD and 32% report to never use PSD.

4.5 Practice Characteristics (see Table IV)

After re-categorization of the responses for all responses except for patient volume (see methods 3.4), it was found that the majority of respondents (83%) reported treating a higher SES patient base (Not mostly government-funded insurance), versus 17% of respondents that reported treating a lower SES patient base (Mostly government-funded insurance). Of the 83% of providers that reported treating a mostly non-government insurance patient base, only 5% reported that most of their patients were self-pay patients, while 95% reported either mostly private insurance or a mixture of insurances. A little over half of the respondents (55%) reported that they perceived the parents of their patients to be less accepting of PSD use, versus 45% that reported more accepting parents. The majority of respondents (55%) reported seeing a moderate patient volume (21-49 patients/day), 27% of respondents reported seeing a low volume (1-20 patients/day), and only 18% reported seeing a high volume of patients

(50+ patients/day). Surprisingly, 28% of respondents reported no use of PSD during their residency, whereas 72% reported use of PSD during residency.

4.6 Personal Characteristics (See Table V)

Before re-categorization of ABPD Board year certification (proxy for age) it was found that the range was 45 years, the mode with 102 respondents was at the year 2012, and the mean year was 2003 with a standard deviation of 10 years. After re-categorization (see methods 3.4), it was found that 58% of respondents were boarded before 2009, and 42% were boarded from 2009 to 2013, reflecting a preponderance of responses from recently boarded Diplomates. By gender, 52% of respondents were made by male, and 48% by females. Most (78%) of respondents reported to work solely in private practice while 22% did not. Of those 22%, 16% split their time between private practice and academia or a government funded clinic. Only 5% worked solely in either academia or a government funded clinic.

4.7 Analysis of Hypothesis #1: Practice Characteristics vs. Acceptance of PSD (See Table VI)

After completion of bivariate statistical analysis, it was found that:

a.) Providers whose patient base was mostly composed of patients with Government Insurance (Lower SES), were significantly more accepting of Protective Stabilization Devices ($p<.05$) than providers whose patient base was not mostly made up of government insurance (High SES, i.e. private insurance, a mixture of insurances, self pay). This signifies a rejection of the null hypothesis and an acceptance of the alternative hypothesis.

b.) Providers who perceived their patients' parents to be more accepting of PSD were also significantly more accepting of PSD ($p<.001$) than providers who perceived their patients' parents as less accepting of PSD. This signifies a rejection of the Null hypothesis and acceptance of the alternative.

c.) Providers with low patient volume (0-20 patients/day) were significantly more accepting of PSD ($p<.05$) than providers that reported a moderate (21-49 patients/day) or high patient volume (50+patients/day). This signifies a rejection of the null hypothesis (no significant difference between providers) and rejection of the proposed alternative hypothesis (that high volume providers would be more accepting of PSD) and acceptance of second alternative hypothesis.

d.) Protective Stabilization Device use or non-use during residency was not significantly associated with provider acceptance of PSD ($p=.255$), which signifies an acceptance of the Null Hypothesis.

4.8 Analysis of Hypothesis #2: Practice Characteristics vs. Provider use of PSD (See Table VII)

After completion of bivariate statistical analysis, it was found that:

a.) Providers whose patient base was mostly composed of patients with Government Insurance (lower SES), were significantly more likely to report PSD use ($p<.001$) than providers whose patient base was not mostly made of patients with government insurance (i.e. patients mostly have private insurance, a mixture of insurances, or self-pay, (higher SES)). This signifies a rejection of the null hypothesis and an acceptance of the alternative hypothesis.

b.) Providers who perceived their patients' parents to be more accepting of PSD were also significantly more likely to report PSD use ($p<.001$) than providers who perceived their patients' parents as less accepting of PSD. This signifies a rejection of the Null hypothesis and acceptance of the alternative.

c.) Providers with low patient volume (0-20 patients/day) were significantly more likely to report PSD use ($p<.01$) than providers that reported a moderate (21-49 patients/day) or high patient volume (50+ patients/day). This signifies a rejection of the null hypothesis (no significant difference between providers) and rejection of the proposed alternative hypothesis (that high volume providers would be more accepting of PSD) and acceptance of the alternative hypothesis.

d.) Protective Stabilization Device use or non-use during residency was not significantly associated with current provider use or non-use of PSD ($p=.395$), which signifies an acceptance of the Null Hypothesis.

4.9 Analysis of Hypothesis #3: Personal Characteristics vs. Provider Acceptance of PSD (See Table VIII)

After completion of bivariate statistical analysis, it was found that:

a.) ABPD Board Certification Year Cohort (proxy for Age) was not significantly associated with acceptance or non-acceptance of PSD ($p=.375$). This signifies acceptance of the null hypothesis.

b.) Female Providers were significantly more likely than males to be accepting of PSD use ($p<.05$). This signifies rejection of the null hypothesis, the

proposed alternative hypothesis (males more accepting than females), and acceptance of second alternative hypothesis.

c.) Providers practicing not practicing solely in private practice were significantly more likely to accept use of PSD than providers that solely practiced in private practice ($p<.01$). This signifies rejection of the null hypothesis, and acceptance of alternative hypothesis.

d.) Providers from the North Central region (District IV) were significantly more likely to be accepting of PSD use than providers from other AAPD districts ($p<.1$). This signifies a rejection of the null hypothesis and the acceptance of the alternative.

4.10 Analysis of Hypothesis #4: Personal Characteristics vs. Provider use of PSD (See Table IX)

After completion of bivariate statistical analysis, it was found that:

a.) ABPD Board Certification Year Cohort (proxy for Age) was not significantly associated with use of PSD ($p=. 261$). This signifies acceptance of the null hypothesis.

b.) Female Providers were significantly more likely to report use of PSD than males providers ($p<.001$). This signifies rejection of the null hypothesis, the proposed alternative hypothesis (males more accepting than females), and acceptance of another alternative hypothesis.

c.) Providers practicing not practicing solely in private practice were significantly more likely to report use of PSD than providers that solely practiced in private practice ($p<.001$). This signifies rejection of the null hypothesis, and acceptance of the alternative hypothesis.

d.) Providers from the North Central region (District IV) were significantly more likely to report use of PSD use than providers from other AAPD districts ($p<.01$). This signifies a rejection of the null hypothesis and the acceptance of the alternative.

4.11 Logistic Regression-Provider Acceptance of PSD use (See Tables X and XI)

Provider perception of parental acceptance is the only variable retained in the multivariate model for provider acceptance of PSD (12.5, 95% CI 8.6-18), although Gender and North Central Region are close to being retained.

No variables are retained upon removal of Provider perception of parental acceptance, although SES, Low patient volume, Gender, and North Central Region are all close to being retained. Provider perception of parental acceptance of PSD is the strongest variable related to Provider Acceptance of PSD.

4.12 Logistic Regression - Provider Use of PSD (See Tables XII and XIII)

Gender (2.3, 95% CI 1.6-3.3), Practice Setting (0.461, 95% CI 0.277-0.765), AAPD Region (1.997, 95% CI 1.2-3.3), and Provider perception of parental acceptance (24.4, 95% CI 14.0-42.0) are retained in the multivariate model.

Upon Removal of Provider perception of parental acceptance, the following variables are retained in the multivariate model: SES (1.9, 95% CI 1.1-3.1), Low Patient Volume (1.7, 95% CI 1.0-2.7), Gender (1.8, 95% CI 1.3-2.5), Practice Setting (0.503, 95% CI 0.32-0.79), and AAPD Region (1.7, 95% CI 1.1-2.7). Moderate patient volume is also close to being retained.

TABLE I

DEMOGRAPHIC DATA FOR SURVEY RESPONDENTS

Variable	Frequency (Sample Size n=805)	Percentage
Gender		
Male	422	52%
Female	383	48%
Year of ABPD Certification(Proxy for Age)		
Before 2009	464	58%
2009-2013	340	42%
Practice Setting		
Private Practice Only	625	78%
Not Solely Private Practice	180	22%
Government Funded Clinic Only	16	2%
Academia Only	23	3%
Academia and Private Practice	94	12%
Academia and Government Funded Clinic	14	2%
Private Practice and Government Funded Clinic	33	4%
AAPD District		
District I (Northeastern)	123	15%
District II (Eastern)	76	9%
District III (Southeastern)	153	19%
District IV (North Central)	133	17%
District V (Southwestern)	162	20%
District VI (Western)	157	20%
Majority of Patients' Financial Arrangement (Proxy for SES)		
Mostly government funded dental insurance	136	17%
Not mostly government funded insurance	669	83%
Mostly private dental insurance	268	50%
Mostly Self-Pay	38	5%
A mixture of Insurance types	363	45%
Most Closely Describes Current Practice Demographic		
Rural	65	8%
Urban	226	28%
Suburban	514	64%

TABLE II

PROVIDER ACCEPTANCE OF PSD USE-DESCRIPTIVE DATA

Survey Question#		Frequency Sample Size (n=805)	Percentage
	Provider Acceptance Score		
∑(7,8,9)R	Less Accepting of PSD use	339	42%
∑(7,8,9)R	More Accepting of PSD use	464	58%
7	Which of the following would best describe your attitude towards the use of PSDs:		
	Extremely Positive	85	11%
	Positive	236	30%
	Neutral	231	29%
	Negatively	173	22%
	Extremely Negatively	79	10%
8	Describe your comfort level with Protective stabilization devices?		
	Extremely Positive	323	40%
	Positive	277	34%
	Neutral	85	11%
	Negatively	79	10%
	Extremely Negatively	41	5%
9	I would feel comfortable using a Protective Stabilization Device on my own child or a close family member		
	Strongly Agree	227	28%
	Agree	289	36%
	Neither Agree nor disagree	98	12%
	Disagree	100	12%
	Strongly Disagree	90	11%

R=Re-categorized
∑=Summation Score Created from these questions

TABLE III

PROVIDER USE OF PSD-DESCRIPTIVE DATA

Survey Question#		Frequency Total (n=805)	Percentage
1	The number of times I use Protective Stabilization Devices(PSDs) to manage patients on an average day is about:		
1R	I never use a PS Device	257	32%
1R	Provider Reports use of PSD	548	68%
	<1 time per day	371	46%
	1 time per day	65	8%
	>1 time per day	112	14%
R=Re-categorized			

TABLE IV

PRACTICE CHARACTERISTICS-DESCRIPTIVE DATA

Survey Question#		Frequency Total (n=805)	Percentage
12	Majority of Patients' Financial Arrangement (Proxy for SES)		
12R	Mostly government funded dental insurance	136	17%
12R	Not mostly government funded insurance	669	83%
	Mostly private dental insurance	268	50%
	Mostly Self-Pay	38	5%
	A mixture of Insurance types	363	45%
4	I generally feel that the parents of my patients are likely to be accepting of the suggestion to use a PSD on their child		
4R	Less Accepting Parents	446	55%
	Neither Agree nor disagree	123	15%
	Disagree	174	22%
	Strongly Disagree	149	19%
4R	More Accepting	359	45%
	Strongly Agree	65	8%
	Agree	294	37%
6	Patient Volume		
	Low (1-20 patients/day)	219	27%
	Medium (21-49 patients/day)	444	55%
	High (50+ patients/day)	142	18%
10	Residency Experience		
10R	I never used a PS Device	229	28%
10R	Provider Reports use of PSD	576	72%
	<1 time per day	16	2%
	1 time per day	106	13%
	>1 time per day	254	32%
R=Re-categorized			

TABLE V

PERSONAL CHARACTERISTICS-DESCRIPTIVE DATA

Survey Question#		Frequency Total (n=805)	Percentage
15	Year of ABPD Certification (Proxy for Age) From1964-2013	Mean 2003; S.D. 10; Mode 2012; Range 45	
15R	Before 2009	464	58%
15R	2009-2013	340	42%
14	Gender		
	Male	422	52%
	Female	383	48%
11	Practice Setting		
11R	Private Practice Only	625	78%
11R	Not Solely Private Practice	180	22%
	Government Funded Clinic Only	16	2%
	Academia Only	23	3%
	Academia and Private Practice	94	12%
	Academia and Government Funded Clinic	14	2%
	Private Practice and Government Funded Clinic	33	4%
16	AAPD District		
16R	All other AAPD Regions	671	83%
	District I (Northeastern)	123	15%
	District II(Eastern)	76	9%
	District III(Southeastern)	153	19%
	District V(Southwestern)	162	20%
	District VI(Western)	157	20%
16R	District IV(North Central)	133	17%

R=Re-categorized

TABLE VI

PROVIDER PRACTICE CHARACTERISTICS BY ACCEPTANCE OF PSD

Variable	Less Accepting N (%)	More Accepting N (%)	P-Value
Socio-Economic Status (High SES=Not mostly government dental insurance vs. Low SES=mostly government dental insurance)			
High SES Not mostly (0)	297 (44.5%)	370 (55.5%)	(FET one sided) P= .002*
Low SES Mostly (1)	42 (30.9%)	94 (69.1%)	
Perceived Parental Acceptance of PSD (Less accepting parents vs. More accepting parents)			
Less Accepting (0)	292 (65.6%)	153 (34.4%)	(FET one sided) P< .001*
More Accepting (1)	47 (13.1%)	311 (86.9%)	
Patient Volume (Low volume=1-20pts./day, moderate volume=21-49pts./day, high volume=50+pts./day)			
Low Volume (1)	75 (34.2%)	144 (65.8%)	(FET one sided) P<.05 *
Moderate Volume (2)	195 (44.1%)	247 (55.9%)	
High Volume (3)	69 (48.6%)	73 (51.4%)	
Residency Experience (No use of PSD in residency vs. Yes PSD use in residency)			
No PSD use (0)	92 (40.2%)	137 (59.8%)	(FET one sided) P=. 255
Yes PSD use (1)	247 (43.0%)	327 (57.0%)	
*Significant at p<.1			

TABLE VII

PROVIDER PRACTICE CHARACTERISTICS BY USE OF PSD

Variable	Provider does not report PSD use N (%)	Provider reports PSD use N (%)	P-Value
Socio-Economic Status (High SES=Not mostly government dental insurance vs. Low SES=mostly government dental insurance)			
High SES Not mostly (0)	233 (34.8%)	436(65.2%)	(FET one sided) P<. 001*
Low SES Mostly (1)	24 (17.6%)	112 (82.4%)	
Perceived Parental Acceptance of PSD (Less accepting parents vs. More accepting parents)			
Less Accepting (0)	240 (53.8%)	206 (46.2%)	(FET one sided) P<. 001*
More Accepting (1)	17 (4.7%%)	342 (95.3%)	
Patient Volume (Low volume=1-20pts./day, moderate volume=21-49pts./day, high volume=50+pts./day)			
Low Volume (1)	50 (22.8%)	169 (77.2%)	(FET one sided) P<.01*
Moderate volume (2)	149 (33.6%)	295 (66.4%)	
High Volume (3)	58 (40.8%)	84 (59.2%%)	
Residency Experience (No use of PSD in residency vs. Yes PSD use in residency)			
No PSD use (0)	71 (31.0%)	158 (69.0%)	(FET one sided) P=. 395
Yes PSD use (1)	186 (32.3%)	390 (67.7%)	
*Significant at p<.1			

TABLE VIII

PROVIDER PERSONAL CHARACTERISTICS BY ACCEPTANCE OF PSD

Variable	Less Accepting N (%)	More Accepting N (%)	P-Value
ABPD Board Certification Year Cohort (Older Providers, before 2009 vs. Younger Providers, 2009-2013)			
Before 2009(0)	198 (42.9%)	264 (57.1%)	(FET one sided) P=. 375
From 2009-2013 (1)	141 (41.5%)	199 (58.5%)	
Gender			
Male (0)	292 (65.6%)	153 (34.4%)	(FET one sided) P< .05*
Female (1)	47 (13.1%)	311 (86.9%)	
Practice Setting (Not solely private practice (academia, government clinic, mix) vs. Solely private practice)			
Not solely private practice (0)	58 (32.2%)	122 (67.8%)	(FET one sided) P< .01*
Solely private practice (1)	281 (45.1%)	342 (54.9%)	
AAPD Region			
All other AAPD regions (0)	292 (43.6%)	378 (56.4%)	(FET one sided) P=< .1*
North Central Region (1)	47 (35.6%)	85(64.4%)	
*Significant at p<.1			

TABLE IX

PROVIDER PERSONAL CHARACTERISTICS BY PROVIDER USE OF PSD

Variable	Provider does not report PSD use N (%)	Provider reports PSD use N (%)	P-Value
ABPD Board Certification Year Cohort (Older Providers-before 2009 vs. Younger Providers,-2009-2013)			
Before 2009(0)	153 (33.0%)	311 (67.0%)	(FET one sided) P=. 261
From 2009-2013 (1)	104 (30.6%)	236 (69.4%)	
Gender			
Male (0)	163 (38.6%)	259 (61.4%)	(FET one sided) P< .001*
Female (1)	94 (24.5%)	289 (75.5%)	
Practice Setting (Not solely private practice (academia, government clinic, mix) vs. Solely private practice)			
Not solely private practice (0)	32 (17.8%)	148 (82.2%)	(FET one sided) P< .001*
Solely private practice (1)	225 (36.0%)	400 (64.0%)	
AAPD Region			
All other AAPD regions (0)	227 (33.8%)	444 (66.2%)	(FET one sided) P=<. 01*
North Central Region (1)	30 (22.6%)	103 (77.4%)	
*Significant at p<.1			

TABLE X

LOGISTIC REGRESSION - PROVIDER ACCEPTANCE OF PSD

	B	Sig.	EXP (B)	95% C.I. for EXP(B)	
				Lower	Upper
Socio-Economic Status Mostly government insurance > (Not mostly government Insurance - Reference)	-.070	.787	.933	.563	1.545
Patient Volume					
Patient Volume (High 50+/day) -Reference		.761			
Patient Volume Low (1-20/day)	.182	.501	1.20	.706	2.038
Patient Volume Moderate (21-49/day)	.154	.503	1.17	.743	1.830
Gender (Female>Male)	.313	.068	1.37	.977	1.915
Practice Setting Solely Private < (Not solely private practice-Reference)	-.330	.145	.719	.461	1.121
AAPD Region North Central > (All other regions - Reference)	.369	.111	1.45	.918	2.280
Provider Perception of Parental Acceptance* More Accepting > (Less Accepting-Reference)	2.52	.000	12.5	8.599*	18.106*
Constant	-1.03	.007	.358		
*Significant Variables					

TABLE XI

LOGISTIC REGRESSION - PROVIDER ACCEPTANCE OF PSD
(AFTER REMOVAL OF PROVIDER PERCEPTION OF PARENTAL ACCEPTANCE)

	B	Sig.	EXP (B)	95% C.I. for EXP(B)	
				Lower	Upper
Socio-Economic Status Mostly government insurance > (Not mostly government Insurance-Reference)	.399	.065	1.490	.976	2.274
Patient Volume					
Patient Volume (High 50+/day-Reference)		.197			
Patient Volume Low (1-20/day)	.409	.075	1.505	.960	2.359
Patient Volume Moderate (21-49/day)	.188	.338	1.207	.822	1.773
Gender (Female>Male)	.239	.103	1.270	.953	1.693
Practice Setting Solely Private < (Not solely private practice-Reference)	.332	.089	.717	.489	1.052
AAPD Region North Central > (All other regions-Reference)	.313	.119	1.368	.923	2.027
Constant	.133	.598	1.143		
*Significant Variables					

TABLE XII

LOGISTIC REGRESSION - PROVIDER USE OF PSD

	B	Sig.	EXP (B)	95% C.I. for EXP(B)	
				Lower	Upper
Socio-Economic Status Mostly government insurance>(Not mostly government Insurance-Reference)	.246	.414	1.28	.708	2.311
Patient Volume					
Patient Volume (High 50+/day-Reference)		.487			
Patient Volume Low (1-20/day)	.268	.365	1.31	.773	2.331
Patient Volume Moderate (21-49/day)	.288	.237	1.33	.827	2.151
Gender* (Female>Male)	.813	.000	2.25	1.558*	3.259*
Practice Setting* Solely Private< (Not solely private practice-Reference)	-.775	.003	.461	.277*	.765*
AAPD Region* North Central>All other regions-Reference)	.692	.008	2.0	1.200*	3.325*
Provider Perception of Parental Acceptance* (More Accepting>Less Accepting-Reference)	3.20	.000	24.4	14.263*	41.599*
Constant	-1.08	.010	.340		

*Significant Variables

TABLE XIII

LOGISTIC REGRESSION-PROVIDER USE OF PSD
(AFTER REMOVAL OF PROVIDER PERCEPTION OF PARENTAL ACCEPTANCE)

	B	Sig.	EXP(B)	95% C.I. for EXP(B)	
				Lower	Upper
Socio-Economic Status* (Mostly government insurance>Not mostly government Insurance)	.621	.015	1.860	1.130*	3.063*
Patient Volume					
Patient Volume High (50+/day-Reference)		.115			
Patient Volume Low * (1-20/day)>Moderate and High	.508	.039	1.663	1.025*	2.697*
Patient Volume Moderate (21-49/day)	.306	.134	1.358	.910	2.027
Gender* (Female > Male)	.591	.000	1.807	1.321*	2.471*
Practice Setting* (Solely Private < Not solely private practice)	-.687	.003	.503	.322*	.786*
AAPD Region* (North Central > All other regions)	.553	.016	1.738	1.109*	2.723*
Constant	.579	.037	1.785		

*Significant Variables

5. DISCUSSION

Although the majority of dental patients can be treated without the need for advanced behavior modalities such as protective stabilization devices, there are many patients whose behavior makes necessary the use of either a protective stabilization device, or a pharmacological method, or both, for safe completion of treatment. The purpose of this study is to assess the attitudes and behaviors of pediatric dentists towards protective stabilization devices (PSDs). This discussion will address four issues: (1) Limitations and strengths of the study, (2) Summary of findings, (3) The results and significance of this study compared to previous studies, (4) Implications for future research.

5.1 Limitations and Strengths of the Study

The lower response rate of 29% is a weakness of the study. Although past studies have demonstrated the transitive nature of Diplomate survey data to the body of Pediatric Dentists, this lower sample size makes it more difficult to generalize this inference (Association of Pedodontic Diplomates 1981).

Another limitation of this study relates to some of the proxy variables: Board Cohort (proxy for Age) and Patient Insurance (proxy for Socioeconomic status). Although Board Cohort can be considered a reasonable proxy for age, since it is highly probable that the majority of pediatric dentists taking a board certification exam would be recently graduated from residency when the academic materials would be most fresh in their minds, it is clear that this would not apply in all cases. Some pediatric dentists

will likely take the board exam later in their careers than may be assumed making a direct association between age and board cohort less clear.

And although it is likely that use of government-funded insurance is an indicator of lower socio-economic status in the majority of cases, it may not apply in all situations. Many families with children with special needs qualify for government-funded insurance plans regardless of their socio-economic status. In addition, the converse may not always hold true, and some cash-pay patients, or those with private insurance, may also be considered low SES. For example, many immigrants are not legal citizens, which may impede them from seeking out or qualifying for government-funded insurance plans despite a potential financial need. It is also possible that lower SES patients opt to purchase a private insurance plan or have an employer that purchases the plan on their behalf, making it less simple to use Insurance as a clear proxy for SES.

A strength of this study is that, despite its lower response rate, it did receive a high number of gross respondents (n=826), giving the study statistical power. Another strength of the study is the good geographic distribution of respondents. This study's finding regarding use and acceptance of PSD in the North Central Region (District IV) would be less meaningful had the majority of respondents been from that region.

Another strength of this study is that it looked at variables previously not studied and yielded multiple statistically significant results not found in the previous literature (see results-specifically regarding SES, Perceived Parental Acceptance, Patient Volume, Residency Experience, Practice Setting, AAPD Region). This current study

corroborates findings of the existing literature for Age(Board Cohort) and Gender (compare with Adair 2007, McKnight-Hanes 1993, Carr 1999).

5.2 Summary of Findings

It was hypothesized that there would be no difference between provider acceptance of PSD across the following variables (Practice Characteristics): SES, Perception of Parental Acceptance, Provider Patient Volume, and Residency Experience with PSD.

It was found that providers with a lower SES patient base were more accepting of PSD use. Providers who perceived their patients' parents to be less accepting of PSD were also found to be less accepting of PSD. Providers with low patient volume (0-20 patients /day) were significantly more accepting of PSD than providers that reported a moderate (21-49 patients/day) or high patient volume (50+ patients/day). Protective Stabilization Device use or non-use during residency was not found to affect provider acceptance of PSD.

It was hypothesized that there would be no difference between provider use of PSD across the following variables (Practice Characteristics): SES, Perception of Parental Acceptance, Provider Patient Volume, and Residency Experience with PSD.

It was found that providers whose patient base was mostly composed of low SES patients, were more likely to report PSD use than providers who treated a higher SES patient base. Providers who perceived their patients' parents to be less accepting of PSD were also found to be less likely to report PSD use. Providers with low patient volume (0-20 patients/day) were more likely to report PSD use than providers that

reported a moderate (21-49 patients/day) or high patient volume (50+ patients/day). It was also found that Protective Stabilization Device use or non-use during residency made no difference in current provider use or non-use of PSD.

It was hypothesized that there would be no difference between provider acceptance of PSD across the following variables (Personal Characteristics): Age (Board Cohort), Gender, Practice Setting, and AAPD Region.

It was found that Age (Board Cohort) was not associated with acceptance or non-acceptance of PSD. Female Providers were more likely than males to be accepting of PSD use ($p<.05$). Providers practicing solely in private practice were less likely to accept use of PSD than providers that did not practice solely in private practice. Lastly, providers from the North Central region were significantly more likely to be accepting of PSD use than providers collectively from other AAPD districts.

It was hypothesized that there would be no difference between provider use of PSD across the following variables (Practice Characteristics): SES, Perception of Parental Acceptance, Provider Patient Volume, and Residency Experience with PSD

It was found that Age (Board Cohort) was not associated with use or non-use of PSD. Female Providers were significantly more likely than males to report use of PSD. Providers practicing solely in private practice were less likely to report PSD use than providers that did not practice solely in private practice. Lastly, providers from the North Central region were significantly more likely to report use of PSD use than providers from the collective of other AAPD districts.

5.3 Results and significance of this study compared to previous studies

Although many of the findings in this study are novel and do not have direct comparisons in the literature, a few of the findings are comparable to past studies, and there exist some tangentially related studies.

5.4 Socioeconomic Status

The present study found that lower SES providers accept use of, and use PSD, more than higher SES providers. This increased acceptance and use of PSD among lower SES providers might be linked to the higher caries disease burden that is found in lower SES populations (AAPD Guidelines, 2012). A higher caries risk population is more likely to have patients with urgent needs such as abscesses, swellings, or pain, which are more likely to be clear indications for PSD use. It might seem logical to point at patient cost for dental treatment as a barrier to more acceptable treatment options to deal with behaviorally difficult patients found in this low SES population, but patient cost is unlikely to be the source of this discrepancy since government-funded insurances typically cover all of the costs for general anesthesia or sedation for children. When taking this into consideration, it is logical to conclude that general anesthesia or sedation is more likely to be financial impediment for the higher SES group, since in many cases, private insurance companies will not cover, or only partially cover such services.

Other factors besides a higher disease burden in low SES patients, such as increased parental acceptance of PSD among lower SES populations and lower reimbursement rates of government insurance plans might also play roles in this SES discrepancy (Havelka 2002). The combination of these two factors might make it that

much easier for providers to justify use of PSD out of convenience. The question still stands that since these providers not only use PSD more than higher SES providers, but also are more accepting of PSDs, did one influence the other, and if so in which direction? Does the increased use of PSD by low SES providers lead them to justify their actions or does increased use lead to increased enlightenment about PSD use? Or do lower SES providers choose to work in a higher caries risk in part because they are more accepting of more aversive behavior management techniques like PSD that are likely to be used more often?

5.5 Provider perception of Parental Acceptance of PSD

The present study found that providers who perceived their patients' parents to be less accepting of PSD, were also found to be less accepting of PSD, and were less likely to report use of PSD, than providers who perceived their patients' parents to be more accepting of PSD. Although no studies were found directly investigating provider perception of parental acceptance of PSD, there are multiple studies that show that parents tend to have an initial negative bias towards PSDs (Peretz and Zadik 1999; Wilson, Antalis, and McTigue 1991; Frankel 1991; Ramos, Carrara, and Gomide 2005; Havelka et al. 1992a; Lawrence et al. 1991). There are also multiple studies that demonstrate that PSDs are found near the bottom of most parental acceptability scales when comparing different behavior management techniques (Murphy, 1984; Lawrence, 1991; Eaton, 2005). This finding begs the question whether some pediatric dentists are catering to, and having their opinions about PSD shaped by parental desires, as opposed to relying on their own expertise in behavior management modality selection. Casamassimo's 2002 study backs this assertion when he found that board certified

pediatric dentists reported using less assertive behavior management techniques than in the past due to changes in parenting styles (Casamassimo, 2002).

A factor that might dampen the significance of this finding-that pediatric dentistry Diplomates tend to use more PSD if they perceive that their patients' parents are more accepting of PSD is the inherent bias that exists from asking such a subjective question. It is likely that those that think the parents are more accepting of PSDs are influenced by their own personal bias for PSD use. Some providers might more carefully explain and justify their use of PSD, knowing that a more thorough explanation of PSD leads to increased parental acceptance for PSD (Peretz and Zadik 1999; Wilson, Antalis, and McTigue 1991; Frankel 1991; Ramos, Carrara, and Gomide 2005; Havelka et al. 1992a; Lawrence et al. 1991). This parental acceptance might reinforce the providers' perception of how parents feel about PSD, essentially creating a positive feedback loop. The reverse scenario is also a possibility.

5.6 Patient Volume

There are no existing studies on how patient volume might affect provider acceptance of PSD or use of PSD. The present studies' finding that providers with low patient volume (0-20 patients/day) were more accepting of PSD, and more likely to report use of PSD, than moderate or high volume providers is of some significance considering the recent increase in corporate dentistry. This finding goes against the studies proposed alternative hypothesis, which surmised that increased volume would likely be associated with increased PSD use and increased PSD acceptance. This study confirms that at least as far as these Pediatric Dentistry Diplomates are concerned, PSD use and acceptance does not appear to be tied to moderate or high

patient volume providers, and that in fact the opposite is true. This finding might be explained the hypothesis that low volume providers are less likely to practice solely in private practice due to the difficulty task in affording overhead with so few patients. We learn from the current study that those that do not practice solely in private practice are more likely to use and accept PSD, so this connection may help explain the low volume provider acceptance and use. Another explanation is that low volume providers might be seeing a disproportionate quantity of behaviorally challenging patients that require a greater time commitment limiting the patient volume that these providers can treat.

5.7 Residency Experience

Wright reported that restraint use varied depending on the age of the dentist and the dental school that the dentist attended (Wright, Giebartowski, and McMurray 1991). This study found no significant difference between those that did or did not use PSD in residency, which finding backs the idea that experience with PSD may not make any difference in how a highly trained pediatric dentist feels about PSD. This finding also shows the lack of influence a specific residency program might have when it comes to PSD.

5.8 Age

McKnight-Hanes (1993) showed that the 40-49 year olds were the age group most likely to use of PSD and that the younger practitioners (<30), were the least likely group to use PSD, with those over 50 as second least likely. Carr (1999) found a similar finding, that middle aged dentists, those with >16 years in practice were high occasional users of PSD at 76.4%. But unlike McKnight-Hanes' study, Carr found that those with > 20 years were the most likely occasional users at 89.7% (Carr, 1999).

Adair found the youngest providers to be the most likely to anticipate decreased PSD use in the future, but he found no significant difference in PSD use between age groups (Adair, 2007). Although some of the current literature seems to point to younger providers using less PSD, this study backed Adair's study and found no significant difference in use or acceptance between the two Board cohorts. This finding is not an ideal comparison to past studies since the present study used Board Cohort as a proxy for age instead of age ranges, and consolidated all Diplomates from before 2009 into one group, which muddies the comparison for older and middle aged dentists. It is useful to learn that the youngest group of Diplomates is not significantly different from older Diplomates as far as their acceptance and use of PSD, based on their Board certification date. It is important to note that there was a recent push for older practitioners to gain Board Certification, which may also lessen the correlation between Board Cohort and age.

5.9 Gender

Gender is another topic that shows some conflicting results in the literature. Adair's survey of 2751 AAPD members found that females were more likely to use PSD on a non-sedated child, whereas in two separate studies Peretz and Wright both found Males more likely to use PSD than females (Adair 2007, Peretz 2003, Wright 1991). Wells very recently surveyed a select group of 511 Pediatric dentists and found that females were more likely to report use of PSD for sedated patients and those with special healthcare needs (Wells 2014).

The present study found that females were not only more likely to use PSD, but were also more likely to be accepting of PSD use, which finding supports Adair and

Wells' studies. Peretz and Wrights studies were surveys of Israeli and Australian dentists, which may provide insight into the differences in the studies as compared to a survey of North American dentists found in both Wells and Adairs' studies. It is possible that international male pediatric dentists are more authoritative behavior managers or it could be possible that other cultural or even economic factors might play a role in the differences between the studies. Future studies should be done in North America and internationally to build a stronger evidence base.

5.10 Practice Setting

There are no studies that directly address our finding that providers whose practice includes activities outside of private practice (i.e. academia or government funded clinics) are more likely to report use and acceptance of PSD. Three studies are tangentially related as they address one of the central issues that differentiates working solely in private practice versus working in academia, or a government funded clinic: the lower socioeconomic status of the patients found in academia or government funded clinics. One study reported that parents of high social class were less accepting of Papoose Boards than their lower social class counterparts (Havelka 1992a). Carr found that suburban pediatric dentists were more likely to say that they never used a papoose board than their urban and rural counterparts (Carr 1999). Nathan found that practice location and caries prevalence seemed to play a role in the selection of treatment and behavior management strategies (Nathan 1989).

It is possible that the increased acceptance and use of PSD in the non-solely private practice Diplomates is related to the lower SES and higher caries risk populations, with whom these providers are likely to have more interaction (AAPD

Guidelines, 2012, Havelka, 1992). It is also possible that the increase in acceptance and use of PSD are a function of a more flexible schedule that Academia or a government funded clinic could provide. A clinic that is less financially motivated might be more likely to spend the extra time and effort to use a PSD on a behaviorally challenging or medically complex patient, whereas those in private practice might be more likely to save time by sending the patient to be treated under general anesthesia.

Other contributing factors could play a role in explaining this finding is the public relations image and financial impact that might be related to visible use of PSD on less cooperative or very vocal patients especially due to the low acceptability of PSD found in multiple studies ((Murphy, 1984, Lawrence, 1991, Eaton, 2005). Academic settings and government-funded clinics typically are set up as public safety nets and as such are able to focus less on how public perception of PSD might effect the finances of their practice, and more on how to most effective methods for treatment.

5.11 AAPD Region

It is no simple task to explain the various cultural, geographical, and financial factors that might play a role in describing these findings.

The only study that the PI found that related to PSD use across AAPD regions was the study by McKnight-Hanes that reported that the southeast had the highest reported use of PSD followed by the Western region (McKnight-Hanes, 1993). The current study found that providers from the North Central region were significantly more likely to be accepting of PSD ($p<.1$), and less likely to report use of PSD ($p<.01$) than providers from other AAPD districts.

The data in the present paper show differences in residency training regarding PSD use (28% of Diplomates reported no use of PSD in their residency). Wright found in Australia, that restraint use varied depending on the dental school that the dentist attended (Wright, Giebartowski, and McMurray 1991). The present study reported that PSD use or non-use in Residency did not play a role in a providers' current use or acceptance of PSD, making it difficult to conclude that differences in PSD use/acceptance by region can be blamed solely on residency training or experience. More studies should be done to replicate or disprove these findings.

Reimbursement rates vary by state and by individual insurance plans, and these differences likely play a role in dentist-parent decision to use PSD on a child, or to opt for a more parentally accepted behavior management technique such as sedation or general anesthesia (Eaton, 2005). In states where sedation reimbursement is too low to make it financially worthwhile for the provider, it is likely that providers will be less willing to offer sedation, and will encourage the parents of poorly behaved or medically compromised patients to either attempt treatment in the papoose, under general anesthesia, or refer them to providers that are still willing to sedate such as the local dental school.

Another factor that likely plays a role is regional culture. The PI was not able to explain why the North Central region has higher use and acceptance of PSD, but it is suspected that culture plays a role.

5.12 Multivariate Analysis-Provider Acceptance of PSD

The only variable found to be retained in the multivariate model for Provider Acceptance of PSD was Provider perception of parental acceptance of PSD (More Accepting > Less Accepting), although Gender (Female > Male) and AAPD Region (North Central > Others) were both very close to being retained. This finding shows that the parents of patients are a big influence on how Pediatric Dentistry Diplomates come to feel about PSD. Further studies need to be completed to better understand why Provider perception of parental acceptance of PSD is so strongly driving the model for Provider Acceptance of PSD. Even when the strongest variable is removed (Provider perception of parental acceptance as seen in Table XI), no other variables are retained in the multivariate model which further solidifies this finding that the way Diplomates feel about PSD truly has a connection with the community where they practice the parents with whom they associate.

5.13 Multivariate Analysis-Reported use of PSD

The variables that were found to be significant for provider use of PSD in the multivariate model were the following were SES (Low > High), Patient Volume (Low > Moderate or High), Gender (Female > Male), Practice Setting (Not solely private Practice > Solely private practice), and AAPD Region (North Central > All Others), and Provider Perception of Parental Acceptance (More Accepting > Less Accepting). Yet again the strongest driver of the regression model was Provider Perception of Parental Acceptance, which reinforces this idea that not only do the parents that Diplomates associate with influence their feelings about PSD (acceptance), they also influence how they use PSD.

6. CONCLUSIONS

- Diplomate perception of parental acceptance of PSD was the most important factor related to Diplomate Acceptance of PSD.
- Female Gender, Practice Setting (Diplomate works in a setting besides solely private practice), AAPD District IV (North Central), and Diplomate perception of parental acceptance, are all important factors related to Diplomate Use of PSD.
- Use, or non-use of PSD in residency, was not associated with provider Acceptance or current Use of PSD.
- Multivariate models yielded differences from bivariate significance
- Further study is needed

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APPENDICES

APPENDIX A

Cover Letter

Dear Colleague,

Please allow me to introduce myself. My name is Dustin Davis, and I am a second year Pediatric Dentistry resident at the University of Illinois at Chicago. Under the guidance of my research committee lead by Dr. S. Fadavi, I am conducting a study with the purpose to investigate what Pediatric Dentists' thoughts and practices are regarding protective stabilization devices (i.e. papoose board, pedi-wrap).

This topic has become increasingly controversial as society has become generally less trusting of health care professionals, and unfortunately more litigious. Behavior management techniques that were deemed acceptable for years have recently come under more scrutiny. It is in this environment that it is crucial that good science, led by the experts in the field, guide the public conversation.

Although you may have participated in studies in the past that have questioned your use of these devices, little data exists to clarify the different factors that shape your viewpoint and help you make the difficult decision to forcibly restrain a patient, or to not do so.

You are being contacted because you are a Diplomate of the American Board of Pediatric Dentistry and are truly the best source for information on this topic. The enclosed questionnaire will take less than 5 minutes to complete and your participation is completely voluntary. Please help us reveal an accurate viewpoint on this topic by participating!

APPENDIX A (CONTINUED)

All information you provide will be anonymous.

If you have any questions or concerns about the research study, please contact me at davisdm@uic.edu. My research advisor is Dr. Shahrbanoo Fadavi, sfadavi@uic.edu. If you have any questions about your rights as a research subject, please contact the UIC Office for the Protection of Research Subjects (OPRS) at 1-866-789-6215 (toll free) or email OPRS at uicirb@uic.edu.

Thank you for your participation!

Dustin Davis, DDS
2nd Year Pediatric Dentistry Resident
University of Illinois at Chicago, College of Dentistry

Shahrbanoo Fadavi, DDS, MS
Professor, Department of Pediatric Dentistry
UIC College of Dentistry

APPENDIX B

Survey:

(1) The number of times I use Protective Stabilization Devices (PSD's) to manage patients on an average day is about:

a.) <1 time per day

b.) 1 time per day

c.) >1 time per day

d.) I never use a PS device *[Skip ahead to question 4]*

(2) I use Protective stabilization devices (PSD) for the following scenarios: [Mark all that apply]

a.) Sedations

b.) Special Needs Patients

c.) Emergency Patients

d.) Un-cooperative Patients

e.) Pre-cooperative Patients

(3) Rank the scenarios in which you use a PSD device from the most(1) to the least(5): [Mark with a (0) any scenarios where you would not use a PSD]

___ Sedations

___ Special Needs

___ Emergency Patients

___ Un-cooperative Patients

___ Pre-Cooperative Patients

(4) I generally feel that the parents of my patients are likely to be accepting of the suggestion to use a PSD on their child.

a.) Strongly Agree

b.) Agree

c.) Neither agree nor disagree

d.) Disagree

e.) Strongly Disagree

(5) I use PSD's more often when I feel that parents perceive them positively.

a.) Strongly agree

b.) Agree

c.) Neither agree nor disagree

d.) Disagree

e.) Strongly disagree

(6) Following is the average number of patients I see on a daily basis when I am practicing:

a.) 1-5

b.) 6-20

c.) 21-49

d.) 50+

e.) I don't see patients

APPENDIX B (CONTINUED)

(7) Which of the following would best describe your attitude towards the use of PSD's:

a.) I feel extremely positive towards the use of PSD's

b.) I feel positive toward the use of PSD's

c.) I feel neutral towards the use of PSD's

d.) I feel negative towards the use of PSD's

e.) I feel extremely negative towards the use of PSD's

(8) Describe your comfort level with Protective Stabilization Devices (PSD's):

a.) Extremely comfortable

b.) Comfortable

c.) Neutral

d.) Uncomfortable

e.) Extremely uncomfortable

(9) I would feel comfortable using a Protective Stabilizing device (PSD) on my own child or a close family member.

a.) Strongly agree

b.) Agree

c.) Neither agree nor disagree

d.) Disagree

e.) Strongly disagree

APPENDIX B (CONTINUED)

(10) During my residency I used a Protective Stabilization (PS) device approximately:

a.) <1 per day

b.) 1 time/day

c.) >1 time/day

d.) I rarely used a PS device during my residency

e.) I never used a PS device during my residency

(11) Which most closely describes your practice setting:

a.) Private Practice only

b.) Government funded Clinic only

c.) Academia only

d.) Academia & Private Practice

e.) Academia & Government Funded Clinic

f.) Private Practice & Government Funded Clinic

(12) Which most closely describes the majority of your patients' financial arrangement: [If you work in multiple practice types, please refer to the setting that best represents how you personally practice]

a.) Mostly Government funded dental Insurance (i.e. Medicaid or Similar)

b.) Mostly Private dental insurance

c.) Mostly Self-Pay

d.) A mixture of insurance types

APPENDIX B (CONTINUED)

(13) Which most closely describes your current practice demographic:

a.) Rural

b.) Urban

c.) Suburban

d.) Other

(14) Your gender is: __ Male __ Female

(15) In what year did you became Board Certified by the ABPD: _____

(16) In which AAPD region do you practice:

a.) District I (Northeastern)

b.) District II (Eastern)

c.) District III (Southeastern)

d.) District IV (North Central)

e.) District V (Southwestern)

f.) District VI (Western)

APPENDIX C

UNIVERSITY OF ILLINOIS
AT CHICAGO

Office for the Protection of Research Subjects (OPRS)
Office of the Vice Chancellor for Research (MC 672)
203 Administrative Office Building
1737 West Polk Street
Chicago, Illinois 60612-7227

Exemption Granted

August 13, 2013

Dustin Davis, DDS

Pediatric Dentistry

801 S Paulina St

M/C 850

Chicago, IL 60612

Phone: (312) 996-7530 / Fax: (312) 413-8006

RE: Research Protocol # 2013-0777
"Pediatric Dentists' Attitudes and Behaviors Towards Protective Stabilization Devices"

Sponsors: None

APPENDIX C (CONTINUED)

Dear Mr. Davis:

Your Claim of Exemption was reviewed on August 12, 2013 and it was determined that your research protocol meets the criteria for exemption as defined in the U. S. Department of Health and Human Services Regulations for the Protection of Human Subjects [(45 CFR 46.101(b)]. You may now begin your research.

Exemption Period: August 12, 2013 – August 12, 2016

Performance Site(s): UIC

Recruitment: Via American Board of Pediatric Dentistry email list

Subject Population: Adult (18+ years) subjects only

Number of Subjects: 1200

The specific exemption category under 45 CFR 46.101(b) is:

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably

place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

You are reminded that investigators whose research involving human subjects is determined to be exempt from the federal regulations for the protection of human subjects still have responsibilities for the ethical conduct of the research under state law and UIC policy. Please be aware of the following UIC policies and responsibilities for investigators:

1. Amendments You are responsible for reporting any amendments to your research protocol that may affect the determination of the exemption and may result in your research no longer being eligible for the exemption that has been granted.

2. Record Keeping You are responsible for maintaining a copy all research related records in a secure location in the event future verification is necessary, at a minimum these documents include: the research protocol, the claim of exemption application, all questionnaires, survey instruments, interview questions and/or data collection instruments associated with this research protocol, recruiting or advertising materials, any consent forms or information sheets given to subjects, or any other pertinent documents.

3. Final Report When you have completed work on your research protocol, you should submit a final report to the Office for Protection of Research Subjects (OPRS).

APPENDIX C (CONTINUED)

4. Information for Human Subjects UIC Policy requires investigators to provide information about the research protocol to subjects and to obtain their permission prior to their participating in the research. The information about the research protocol should be presented to subjects in writing or orally from a written script. When appropriate, the following information must be provided to all research subjects participating in exempt studies:

a. The researchers affiliation; UIC, JBVMAC or other institutions,

b. The purpose of the research,

c. The extent of the subject's involvement and an explanation of the procedures to be followed,

d. Whether the information being collected will be used for any purposes other than the proposed research,

e. A description of the procedures to protect the privacy of subjects and the confidentiality of the research information and data,

f. Description of any reasonable foreseeable risks,

g. Description of anticipated benefit,

h. A statement that participation is voluntary and subjects can refuse to participate or can stop at any time,

i. A statement that the researcher is available to answer any questions that the subject may have and which includes the name and phone number of the investigator(s).
j. A statement that the UIC IRB/OPRS or JBVMAC Patient Advocate Office is available if there are questions about subject's rights, which includes the appropriate phone numbers.

Please be sure to:

→Use your research protocol number (listed above) on any documents or correspondence with the IRB concerning your research protocol.

APPENDIX C (CONTINUED)

We wish you the best as you conduct your research. If you have any questions or need further help, please contact me at (312) 355-2908 or the OPRS office at (312) 996-1711. Please send any correspondence about this protocol to OPRS at 203 AOB, M/C 672.

Sincerely,

Charles W. Hoehne
Assistant Director

Office for the Protection of Research Subjects

cc: Indru C. Punwani, Pediatric Dentistry, M/C 850

Shahrbanoo Fadavi, Pediatric Dentistry, M/C 850

APPENDIX D

UNIVERSITY OF ILLINOIS
AT CHICAGO

Office for the Protection of Research Subjects (OPRS)
Office of the Vice Chancellor for Research (MC 672)
203 Administrative Office Building
1737 West Polk Street
Chicago, Illinois 60612-7227

Exemption Determination

Amendment to Research Protocol – Exempt Review

UIC Amendment # 1

September 20, 2013

Dustin Davis, DDS

Pediatric Dentistry

801 S Paulina St

M/C 850

Chicago, IL 60612

Phone: (312) 996-7530 / Fax: (312) 413-8006

RE: Protocol # 2013-0777

“Pediatric Dentists' Attitudes and Behaviors Towards Protective Stabilization Devices”

Dear Dr. Davis:

The OPRS staff/members of Institutional Review Board (IRB) #2 have reviewed this amendment to your research, and have determined that your research protocol continues to meet the criteria for exemption as defined in the U. S. Department of Health and Human Services Regulations for the Protection of Human Subjects [(45 CFR 46.101(b)].

APPENDIX D (CONTINUED)

The specific exemption category under 45 CFR 46.101(b) is:

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

You may now implement the amendment in your research.

Please note the following information about your approved amendment:

Exemption Period: September 18, 2013 – September 18, 2016

Amendment Approval Date: September 18, 2013

Amendment:

Summary: UIC Amendment #1 dated August 1, 2013 and submitted to OPRS on September 9, 2013 is an investigator-initiated amendment increasing the anticipated number of subjects from 1200 to 3500.

You are reminded that investigators whose research involving human subjects is determined to be exempt from the federal regulations for the protection of human subjects still have responsibilities for the ethical conduct of the research under state law and UIC policy. Please be aware of the following UIC policies and responsibilities for investigators:

Amendments You are responsible for reporting any amendments to your research protocol that may affect the determination of the exemption and may result in your research no longer being eligible for the exemption that has been granted.

APPENDIX D (CONTINUED)

Record Keeping You are responsible for maintaining a copy all research related records in a secure location in the event future verification is necessary, at a minimum these documents include: the research protocol, the claim of exemption application, all

questionnaires, survey instruments, interview questions and/or data collection instruments associated with this research protocol, recruiting or advertising materials, any consent forms or information sheets given to subjects, or any other pertinent documents.

Final Report When you have completed work on your research protocol, you should submit a final report to the Office for Protection of Research Subjects (OPRS).

Information for Human Subjects UIC Policy requires investigators to provide information about the research protocol to subjects and to obtain their permission prior to their participating in the research. The information about the research protocol should be presented to subjects in writing or orally from a written script. When appropriate, the following information must be provided to all research subjects participating in exempt studies:

a. The researchers affiliation; UIC, JB VAMC or other institutions,

b. The purpose of the research,

c. The extent of the subject's involvement and an explanation of the procedures to be followed,

d. Whether the information being collected will be used for any purposes other than the proposed research,

e. A description of the procedures to protect the privacy of subjects and the confidentiality of the research information and data,

f. Description of any reasonable foreseeable risks,

g. Description of anticipated benefit,

h. A statement that participation is voluntary and subjects can refuse to participate or can stop at any time,

i. A statement that the researcher is available to answer any questions that the subject may have and which includes the name and phone number of the investigator(s).

APPENDIX D (CONTINUED)

j. A statement that the UIC IRB/OPRS or JB VAMC Patient Advocate Office is available if there are questions about subject's rights, which includes the appropriate phone numbers.

Please be sure to:

→Use your research protocol number (2013-0777) on any documents or correspondence with the IRB concerning your research protocol.

We wish you the best as you conduct your research. If you have any questions or need further help, please contact me at (312) 355-2908 or the OPRS office at (312) 996-1711. Please send any correspondence about this protocol to OPRS at 203 AOB, M/C 672.

Sincerely,

Charles W. Hoehne
Assistant Director

Office for the Protection of Research Subjects

cc: Marcio Da. Fonseca, Pediatric Dentistry, M/C 850

Shahrbanoo Fadavi, Pediatric Dentistry, M/C 850

VITA

Dustin Davis, D.D.S

EDUCATION:	University of Illinois at Chicago, Chicago, IL. MS Oral Sciences 2014-Current Candidate
	University of Illinois at Chicago, Chicago, IL. Specialty Certificate, Pediatric Dentistry 2012-Current Candidate
	Virginia Commonwealth Univ., Richmond, Va. Doctor of Dental Surgery 2008-2012
	Brigham Young University, Provo, UT. Bachelor of Science Biology 2003-2008
EXPERIENCE:	Teaching Assistant Department of Pediatric Dentistry, University of Illinois at Chicago, 2012-2014
	Pediatric Dental Associate 3020 Dental Associates, Chicago, IL
	Pediatric Dental Associate Children's Dentistry, Chicago, IL
CERTIFICATION:	Basic Life Support Pediatric Advanced Life Support
PROFESSIONAL MEMBERSHIPS:	American Academy of Pediatric Dentistry American Dental Association Illinois Society of Pediatric Dentistry