

Management of Pediatric Urgent Dental Pain

BY

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LIST OF ABBREVIATIONS

AAPD: American Academy of Pediatric Dentistry

ASA: American Society of Anesthesiologists

COD: College of Dentistry

FDA: The Food and Drug Administration

NSAIDS: Nonsteroidal anti-inflammatory drugs

OTC: Over the Counter

IRB: Institutional Review Board

SPSS: Statistical Package for the Social Sciences

UIC: University of Illinois at Chicago

SUMMARY

Acute pain caused by a dental etiology is a common reason why over-the-counter (OTC) pain medication is used. The study examined how children's dental pain is being managed at home by parents/caregivers prior to their children seeking urgent care at the University of Illinois Chicago (UIC), College of Dentistry (COD), Post-Graduate Pediatric Dentistry Clinic. Legal guardians of patients (age 0-17) who presented to the clinic were asked to participate in this research. Consenting caregivers were asked to complete a survey with demographic information and pain management questions. A dental resident recorded pain scores using the Wong-Baker Faces pain scale¹. In addition, the dental resident completed a clinical and/or radiographic examination to determine the etiology of the dental pain. Statistical analysis was completed using SPSS. Pain medication was given to 39% of patients. Twenty-nine of the 38 children who were given medication had errors or incomplete information in the reported dosing by the caregiver. Analysis showed only an association between caregiver's race and whether the dosage of the medication was known ($P = .044$) as well as between caregiver's race and if there were errors or incomplete information in the reported dosing ($P = .044$). There were no other associations between demographic information and pain medication knowledge. There was also no association between duration of pain and whether pain medication was given. However, there was a significant association between the Wong-Baker Faces pain scale recorded and medication use.

Overall, it is hard to predict which parents have adequate knowledge on how to manage their child's dental pain. Our findings suggest a large percentage of our population experience pain and provide some form of pain management, receive information from various sources, and often have gaps in pain management knowledge. It is imperative that healthcare providers educate parents on appropriate and accurate pain management skills and that prevention efforts aim to prevent the need for pain management as tertiary care.

I. INTRODUCTION

I.1 Impact of Dental Caries/ Pain on Quality of Life

Acute and chronic pain with a dental etiology is a common reason why over-the-counter pain medication is used.² Some children visit a dentist for the first time due to emergent pain. In addition, “unrestored caries is the main factor associated with dental pain in childhood”.³

Furthermore, it is known that dental pain can have a significant impact on quality of life. A study conducted by Jackson et al, found children with dental pain are three times more likely to miss school compared to their classmates. In addition these absences, which were a product of the dental pain resulted in a lower school performance.⁴ Moreover, problems with access to care leads to more frequent urgent care dental visits.⁵

I.2 Use of Over the Counter Medications in Management of Pain

Acetaminophen and ibuprofen are the two most common OTC medications used for children for pain of any type.⁶ However dosage of OTC pain medication by caregivers may be inaccurate. Both over-dosage and under-dosage have been found in previous studies.^{6,7} A cross-sectional study in an urban academic pediatric emergency department found that 51% of patients received an inaccurate dose of medication by their caregivers.⁶ Another cross-sectional study of caregivers of children with fever in an emergency department found that 47% of the children

received the recommended dose of medication by their caregivers, while 41% were under-dosed, and 12% were overdosed.⁷ Over-dosing can lead to adverse events and safety concerns, whereas under-dosing can lead to insufficient pain management and unnecessary symptoms for patients.

A retrospective study of dental emergencies in a university-based pediatric dentistry clinic by Shaqair et al found that 34% of the children had pain for “over 30 days” and 64% were given analgesic/anti-inflammatory drugs as pre-medication before attendance.⁸ Similarly another study looked at early management of dental pain in children and adolescents. It found that 32% of patients had been in pain 1-4 weeks and 73% of patients had analgesics delivered by parents.⁹ Finally a third study which also analyzed a pediatric population with acute dental pain found that the mean duration of pain was 17.7 days and 66% of children had been treated with at least 1 dose of OTC medication.¹⁰ The literature strongly suggests that a significant portion of pediatric patients with dental emergencies are using OTC medications for pain and experience pain for a significant period of time before seeking or receiving care.

I.3 Risks associated with Over the Counter Medications

Caregivers often turn to OTC analgesics or topical anesthetics to manage their child’s acute dental pain. However, OTC medications are palliative, and most often do not treat the etiology of that pain. The primary cause of dental pain other than trauma is dental caries.³ Caries is not a self-limiting or self-resolving condition, so pain medication use alone is rarely an appropriate management strategy. In

addition, the potentially dangerous side effects and extension effects of these medications are often not known by the caregivers. “Acetaminophen (Tylenol®) toxicity is a common cause of acute liver failure in children and adolescents”.¹¹ Non-steroidal anti-inflammatory drugs (NSAIDs), such as ibuprofen, can elevate risk for kidney damage, skin reactions, and bleeding in the stomach and intestines. The risk of adverse effects increase when a child is given a higher dose of a NSAID or for an extended period of time, a situation that is possible given the characteristics of dental pain.¹² Finally, the U.S. Food and Drug Administration (FDA) has issued a warning that over-the counter oral drug productions containing benzocaine should not be used to treat infants and children younger than 2 years of age due to the risk of methemoglobinemia.¹³ The American Academy of Pediatric Dentistry (AAPD), concurs and does not recommend the use of oral benzocaine by parents for teething, and discourages other naturopathic teething remedies.¹⁴

A systematic review comparing safety profiles acetaminophen, NSAIDS, and opioids to manage acute nonsurgical pain in children found that Ibuprofen and acetaminophen have similar reported adverse effects and notably less adverse events than opioids. ¹⁵ In addition, opioids have greatest risk of central nervous system adverse events, particularly respiratory depression. Furthermore, children can be hypo- or hyper-responders, so the clinical effectiveness is difficult to predict. Although NSAIDS have a better safety profile than opioid options in children, they are not without adverse effects. As healthcare providers try to limit opioid prescriptions, it is important to be aware of the characteristics of the alternatives to safely and effectively provide pain control.

Over the counter pain medications can have many adverse effects when used improperly, and the usage of these medications by caregivers for the pediatric population needs to be further studied due to the lack of current research. In addition, health literacy can be a barrier to correct dosing of the OTC pain medications by caregivers. The proposed research study will collect information regarding the type and amount of pain medication that is provided to children by caregivers prior to seeking care. It will also seek to understand how long patients are in pain prior to seeking care. This information will help to identify ways in which education for caregivers on pain management techniques for children can be improved.

I.4 Study Objectives

Aim: The aim of this study is to identify how urgent dental pain is being managed at home by parents/caregivers prior to seeking urgent care at a university-based post-graduate pediatric dental clinic.

Objectives:

- To determine if caregivers accurately recalled information about the OTC pain medication given to their children for dental pain.
- To describe behaviors around OTC pain medication usage, including medication choice and sources of information.
- To determine if demographic characteristics are associated with medication choice, knowledge, and likelihood of proper use.

- To identify how long patients are in pain prior to receiving treatment.

II. MATERIALS AND METHODS

II.1 Study Approval

This study was approved for expedited review by the Institutional Review Board of the University of Illinois at Chicago (IRB # 2019-0493), Chicago, IL (Appendix B). A fluent Spanish speaker translated the approved documents into Spanish and then a different fluent Spanish speaker translated the documents back into English. The original and back-translated documents were reviewed for similarity to verify accuracy. An amendment to include documents translated in Spanish was also approved for expedited review by the Institutional Review Board of the University of Illinois at Chicago (IRB # 2019-0493), Chicago, IL (Appendix C). No funding was required for this project.

II.2 Subject Enrollment

The pediatric dental resident assigned to the urgent care clinic at the UIC College of Dentistry Pediatric Clinic between July 2019 and December 2019 identified patients who qualified for the research study based on the inclusion and exclusion criteria. The eleven senior pediatric dental residents who were approved to collect data received individualized training on data collection, dental diagnosis options and how to administer the Wong-Baker Faces Pain Scale. The pediatric dental resident assigned to urgent care asked the legal guardian of the child who presented to the UIC Pediatric Urgent Dental Clinic if they would like to participate

in the research study using a recruitment script which was available in both English (Appendix D) and Spanish (Appendix E). The resident also informed the legal guardian that their willingness will have no effect on clinical care received and participation is optional. If caregivers agreed to participate, the study was explained and informed consent was obtained electronically with Qualtrics (Provo, Utah). Informed Consent was available in both English (Appendix F) and Spanish (Appendix G). In addition, assent of the minors age 7 and over was also obtained. Assent was available in both English (Appendix H) and Spanish (Appendix I). The caregivers were asked to answer a set of screening questions to verify that the subjects meet criteria. The screening questions were available in both English (Appendix K) and Spanish (Appendix K). If the caregivers responded to a question that excluded them from the research study they were informed that they were ineligible. Participants were reminded that they have the ability to withdraw from the study at any time, and the data collected to that point would be discarded. In addition, dental residents were also asked to answer a set of screening questions to ensure eligibility based on ASA status. (Appendix L)

II.3 Study Criteria

- Inclusion Criteria
 - Patients who presented to the UIC Pediatric Urgent Care Dental Clinic (ages 0-17) with a legal guardian who is the primary caregiver of the child.
 - Children who were classified as either ASA I or ASA II.

- The child has to present with an active dental problem that had not received prior treatment.
- The child has to present with pain related to a dental diagnosis.
- The legal guardian who presented with the child had to be either English or Spanish speaking.
- Exclusion Criteria
 - Children who presented for follow-up from prior dental treatment related to a known problem.
 - Patients with a medical condition that could impact their ability to take medication or interpret and communicate their pain levels.
 - All children who were under Department of Child and Family Services.

II.4 Sample Size Determination

Prior to data collection, a power analysis was completed to determine the number of subjects needed. It was determined that a sample of 100 suggests that about 16% of the time adults fail to adhere to medication recommendations and be sufficient for our research objectives.

II.5 Questionnaire

A questionnaire, which consisted of 24 questions, was developed for this study. The questionnaire was available in both English (Appendix M) and Spanish (Appendix N). The first 10 questions asked about demographic information including age, gender, and race/ethnicity of both the child and caregiver as well as

insurance information and highest degree or level of school completed by the caregiver. The parents were asked how many days the child had been in pain and if any medication was given to them for this pain. The remaining questions were designed to determine if the medication being used was over the counter or prescribed and if the caregiver had adequate knowledge of the medication being used. Additionally, the parents were asked if they had given their child any medication that was prescribed for someone else as well as where they obtained the information about how to manage their child's dental pain.

II.6 Wong Baker Faces Pain Scale

The Wong-Baker Faces Pain Scale¹ (Figure 1) was used to determine the level of pain that the child was in at that specific time. Permission to use the Wong-Baker Faces Pain Scale was granted by the Wong-Baker Faces Foundation (Appendix A). The dental resident asked all children to select by pointing to which face corresponded with the level of pain that they were in. Older children pointed to the number associated with the face instead. The dental resident then recorded the pain scale (0-10) selected. If a child was unwilling or too young to understand then it was recorded that the child was unable to answer.



Figure 1

II.7 Dental Diagnosis

After the dental resident was finished performing their clinical and/or radiographic exam of the child they were asked to determine the dental diagnosis. Previous studies were reviewed to help create a list of possible dental diagnosis for easier comparison. They were given a list of options to choose from including:

- a. Caries not affecting the pulp
- b. Caries with reversible pulpitis
- c. Caries with irreversible pulpitis
- a. Necrotic pulp due to caries
- b. Trauma
- c. Other soft tissue pathology
- d. Space maintenance or orthodontic problem

The resident selected the best option to determine a diagnosis of the child's dental pain.

II.8 Statistical Analysis

Data was recorded in Qualtrics and uploaded into SPSS for statistical analysis. The primary investigator reviewed all data to determine if there were errors in medication reporting. If a caregiver did not know the name of the medication, the dosage of the medication or the number of milligrams in one dose then it was recorded that there was an error in medication reporting. Analysis included descriptive statistics, Spearman's rho correlations, Chi square and Fisher's

exact tests. Some variables were collapsed for statistical analysis: highest level of education of the caregiver. Significance was considered a p value of < 0.05 .

III. RESULTS

III.1 Demographics

One-hundred questionnaires were received, and 98 were analyzed. One questionnaire was not analyzed because the caregiver was not a legal guardian of the child present and the other caregiver did not finish the questionnaire. Although refusal rates were not recorded it is estimated that about twenty five percent of the patients were either ineligible or the caregivers refused to participate. Therefore, this data represents about a seventy five percent response rate. Demographic data of the guardians is presented in Table 1. It appeared that some caregivers incorrectly reported their child's age as their own age. Therefore, the mean guardian age of 32 (SD = 6.6) was used to impute any caregiver age less than 14 years old, which included 22 responses in order to conduct analysis. The majority of the guardians who brought the child to the emergency clinic were female (74.5%). There was a wide distribution of races reported, but a roughly equal distribution between Hispanic/Latino (51%) and Non-Hispanic/Latino (49%) ethnicities. Most caregivers reported that their highest degree of education was high school GED or lower (57%), some reported that it was some college, vocation training, or associate degree (35%), and few reported bachelor degree or higher (8%).

TABLE 1. CAREGIVER DEMOGRAPHICS

	Mean	Standard Deviation
Age*	32	6.6
	Count (N=98)	Percentage (%)
Gender		
Male	25	25.5
Female	73	74.5
Race		
Caucasian or White	27	27.6
Black or African American	32	32.7
Native American or American Indian	4	4.1
Asian/Pacific Islander	4	4.1
Other	31	31.6
Ethnicity		
Hispanic/Latino	50	51
Non-Hispanic/Latino	48	49
Highest Degree of Education		
High School GED or Lower	56	57
Some College, Vocational Training, or Associates Degree	34	35
Bachelor's degree or Higher	8	8

*N=76 with 32 subjects imputed due to incorrect responses

Demographic data of the child is presented in Table 2. The mean child age was 6 years old (SD=2.9). There was about an equal distribution of males (49%) and females (50%), with caregiver reporting the child's gender as "other" (1%). Similar to the caregiver, there was a mixed of child's races reported with about an equal distribution between Hispanic/Latino (51%) and Non-Hispanic/Latino (49%) ethnicities. A majority of the children had public dental insurance (94%) while a few had either private dental insurance (3%) or did not have dental insurance (3%).

TABLE 2. CHILD DEMOGRAPHICS

	Mean	Standard Deviation
Age	6	2.9
	Count (N=98)	Percentage %
Gender		
Male	48	49
Female	49	50
Other	1	1
Race		
Caucasian or White	24	24.5
Black or African American	31	32
Native American or American Indian	3	3
Asian/Pacific Islander	3	3
Other	34	34.5
Multiracial	3	3
Ethnicity		
Hispanic/Latino	50	51
Non-Hispanic/Latino	48	49
Type of Dental Insurance		
Public aid/Medicaid/Medical Card	92	94
Private insurance/PPO/HMO	3	3
No dental insurance or self-pay	3	3

III.2 Relationship between Demographics and Over the Counter Medication Use

The mean duration of pain was 11.5 days (SD=28.3). Pain medication was given to 38 (39%) patients (Table 4). There was no significant association between duration of pain and whether pain medication was given (Table 3), or any of the demographic information of the child or the caregiver.

TABLE 3. ASSOICATION BETWEEN IF PAIN MEDICAITON WAS GIVEN AND DURATION OF PAIN

Pain Medication Given (n=93)	1-6 days	7-12 days	14 or more days	P-value (Chi squared test)
Yes (n=38)	23	7	8	0.71
No (n=55)	37	10	8	

5 Subjects had incomplete data

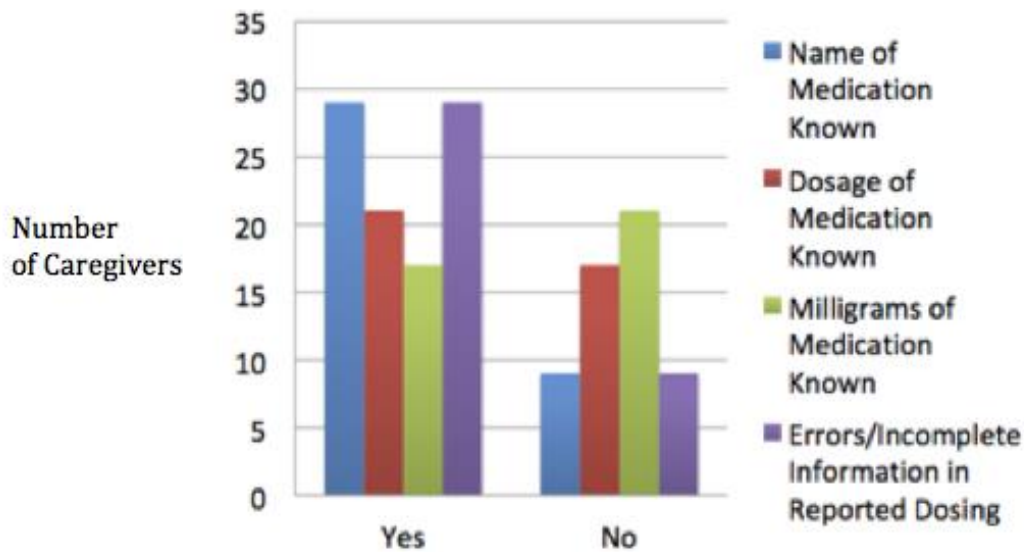
III.3 Relationship between Demographics and Over the Counter Medication Knowledge by Caregiver

Table 4 and Figure 2 summarizes the information that caregivers knew about the medication given to the child for their pain. Table 5 represents the names of “pain medication” given to their children by their caregiver. A few caregivers did report more than one medication given, thus both names are recorded in the table.

Twenty-nine of the 38 children who were given medication had errors or incomplete information in the reported dosing by the caregiver. As mentioned previously, if a caregiver did not know the name of the medication, the dosage of the medication or the number of milligrams in one dose then it was recorded that there was an error in medication reporting. In addition, if a parent/caregiver reported the usage of an antibiotic for management of pain then it was recorded as an error in medication reporting. Nine out of the 38 caregivers reported the usage of amoxicillin for management of their child’s dental pain.

TABLE 4. CAREGIVER KNOWLEDGE AND USE OF PAIN MEDICATION

	N	%
Was Pain Medication Used? (N=98)		
Yes	38	39
No	60	61
Characteristics of Dosing among Caregivers who Gave Pain Medication (N=38)		
Name of Medication Known		
Yes	29	76.3
No	9	23.7
Dosage of Medication Known		
Yes	21	55.3
No	17	44.7
Milligrams of Medication Known		
Yes	17	44.7
No	21	55.3
Errors/Incomplete Information in Reported Dosing		
Yes	29	76.3
No	9	23.7

FIGURE 2. INFORMATION ABOUT MEDICATION KNOWN**TABLE 5. “PAIN MEDICATION” REPORTED BY CAREGIVER**

Name of Medication	Count*
Tylenol®/Acetaminophen	12
Amoxicillin	9
Motrin®/Ibuprofen	6
Orajel®	4

*Caregiver could select more than one option

There was a significant association shown in Table 6 between caregiver’s race and whether the dosage of the medication was known ($P = .044$). Black caregivers were less likely to know the dosage of the medication given than expected. Figure 3 shows that black caregivers were less likely to know the dosage of the medication given compared to caregivers of other races. There was also a significant association shown in Table 7 between caregiver’s race and if there were errors or incomplete information in the

reported dosing ($P = .044$). Black caregivers were more likely to make errors or have incomplete knowledge of medication than expected. Figure 4 shows that black caregivers were more likely to have errors or incomplete knowledge of medication given compared to caregivers of other races. There was no other association's between demographic information and pain medication knowledge.

TABLE 6. ASSOCIATION BETWEEN RACE AND DOSE KNOWLEDGE

Caregiver Race (N=38)	Yes (N=17)	No (N=21)	<i>p</i> -value*
White (N=13)	7	6	.044
Black (N=15)	3	12	
Other (N=10)	7	3	

**Fisher's Exact Test (2-sided)*

FIGURE 3. CAREGIVER RACE AND DOSE KNOWLEDGE

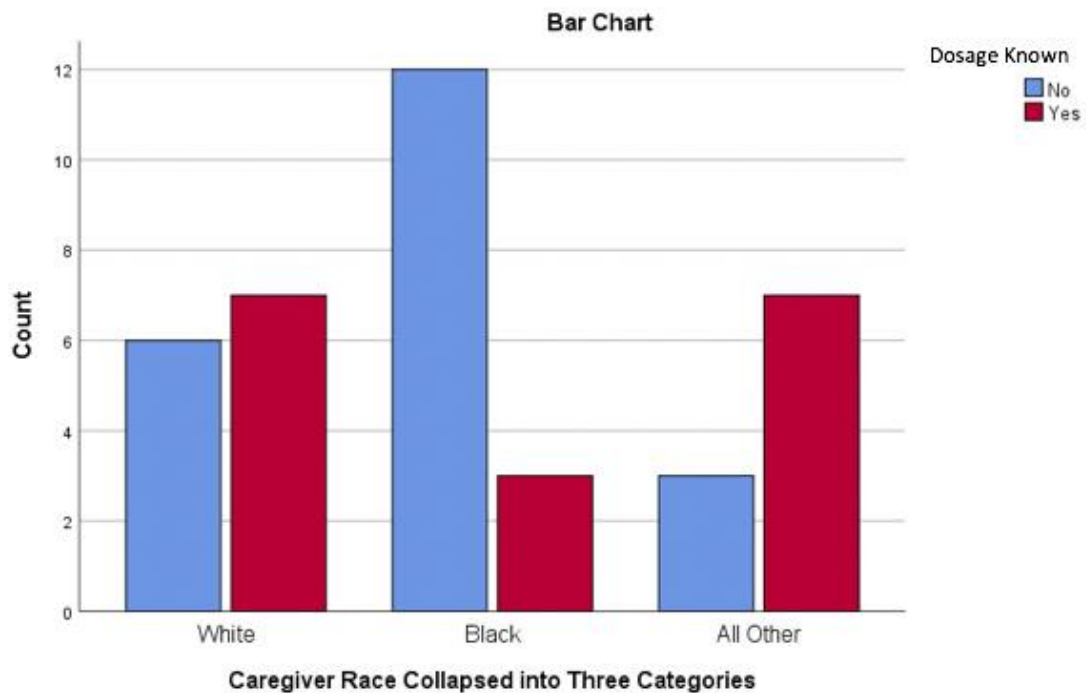
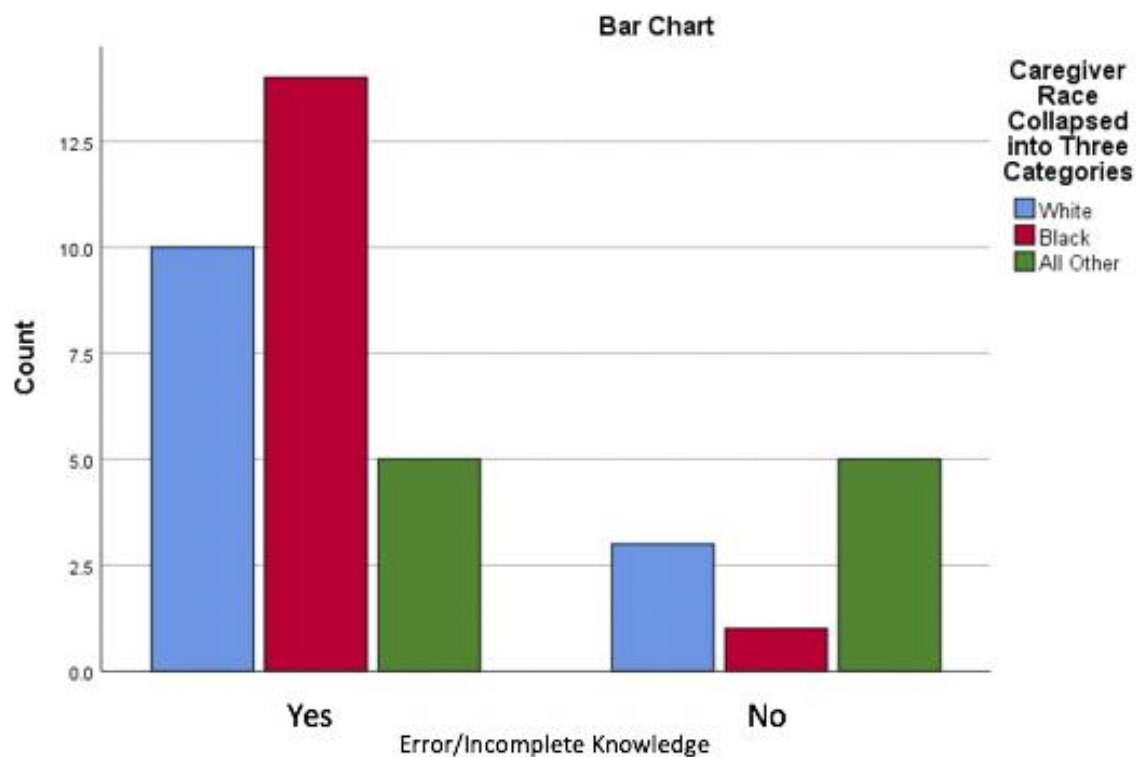


TABLE 7. ASSOCIATION BETWEEN RACE AND ERRORS/INCOMPLETE KNOWLEDGE

Caregiver Race (N=38)	Error (N=29)	No Error (N=9)	p-value*
White (N=13)	10	3	.044
Black (N=15)	14	1	
Other (N=10)	5	5	

*Fisher's Exact Test (2-sided)

FIGURE 4. CAREGIVER RACE AND ERRORS/INCOMPLETE KNOWLEDGE

III.4 Other Medication Used and Source of Information

One question was if caregivers were using any other methods to help with their child's dental pain. A mix of responses were recording including brushing more often, hot towels to the cheek, ice packs, rinsing with warm water, and using Orajel® summarized in Table 8. The most common answer was Orajel®. Nine out of the 38

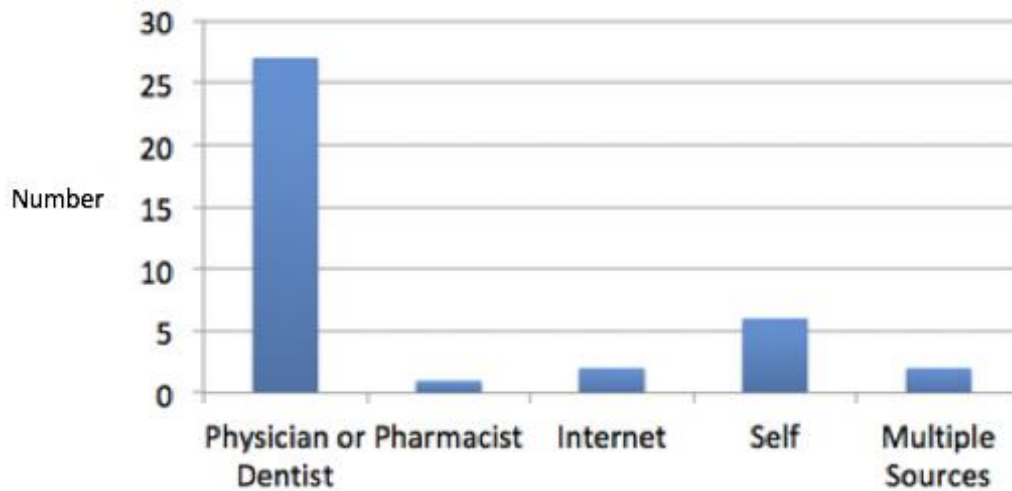
caregivers reported giving it to their child for their dental pain as either the main pain medication or as another method to manage dental pain. Additionally, only 1 of the 38 caregivers reported giving their child a medication that was prescribed for another person and not their child. Most caregivers (27 out of the 38) reported that they received information about how to manage their child's dental pain from their physician or dentist. (Figure 5)

TABLE 8. OTHER METHODS USED TO MANAGE DENTAL PAIN

Product or Technique	Count*
Orajel ®	5
Brushing teeth	2
Hot Towels	1
Ice Packs	1
Motrin®/Ibuprofen	2
Warm water rinses	1
Tylenol®/Acetaminophen	2

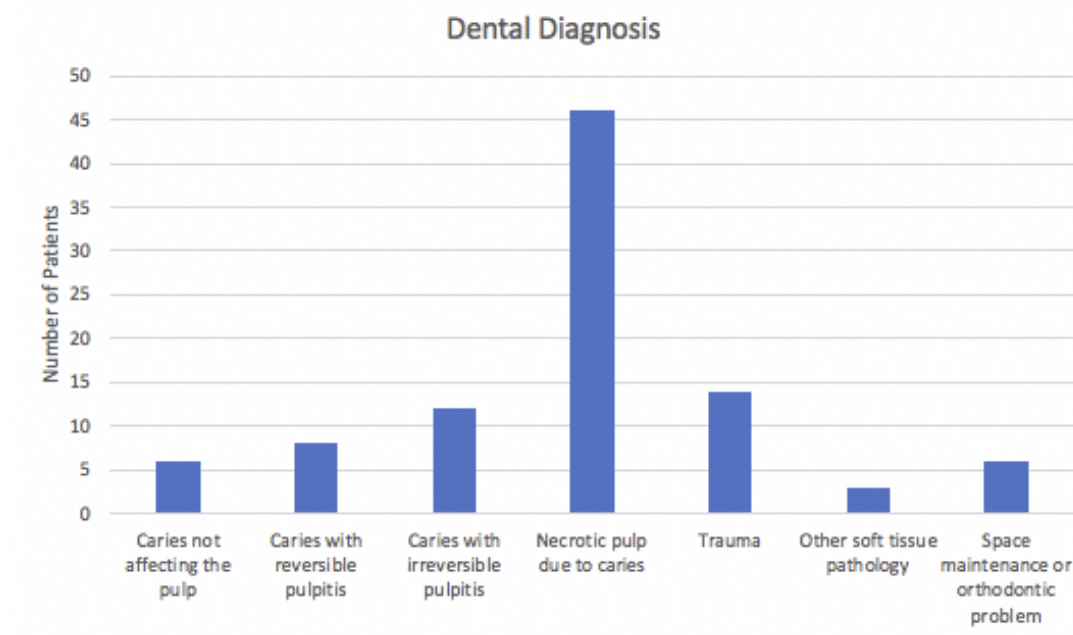
**Caregivers could select more than one option*

FIGURE 5. SOURCE OF INFORMATION ON HOW TO MANAGE CHILD'S PAIN



III.5 Dental Diagnosis and Wong Baker Faces Pain Scale

Figure 6 summarizes the dental diagnoses that were recorded by the dental resident. The primary etiology of the dental pain was recorded by the dental resident thus only one selection was made per patient. Table 9 summarizes the Wong Baker Faces Pain Scores¹ that were recorded by the dental resident. There was a significant association between the pain scale recorded and medication use (Table 10).

FIGURE 6. DENTAL DIAGNOSIS AT URGENT CARE APPOINTMENT**TABLE 9. WONG-BAKER FACES PAIN SCORES**

Pain Score	Count (N=98)	Percentage (%)
0-2	10	10.2
3-4	20	20.4
5-6	14	14.3
7-8	20	20.4
9-10	22	22.4
Child unable to answer	12	12.3

TABLE 10. ASSOICATION BETWEEN IF PAIN MEDICATION WAS GIVEN AND PAIN SCORE

Pain Medication Given (n=88)	0-3 (none or low)	4-7 (moderate)	8-10 (high)	P-value (Chi squared test)
Yes (n=31)	3	7	21	> 0.01*
No (n=57)	12	32	13	

10 Subjects had incomplete WBFS

IV. DISCUSSION

IV.1 Pain Medication Use

This study found that a majority of caregivers (61%) did not give their child any pain medication prior to bringing them to the dentist. This differs from previously reported studies such as Thikkurissy et al¹⁰, and we do have concern that patients may have self-selected for more mild cases. The sample at our university dental clinic may have impacted this result. Thikkurissy et al¹⁰ conducted a study at a hospital based pediatric dental program, which may have attracted patients in greater pain and thus were more likely to have taken pain medication. Pain medication usage will vary by region depending on access to care. In addition, patients in greater pain and more likely to be taking medication may have been unwilling to participate. Finally, it has been shown that caregivers, children and practitioners do not always agree on the level of pain that a child may be experiencing.^{16,17} Therefore caregivers may underestimate their child's dental pain and therefore not managing it correctly.¹⁸

Furthermore, this study did find a significant association between the Wong Baker Faces pain scores and medication use. It is expected that patients in greater pain are more likely to be taking medication. The ability to prevent emergencies or access emergent dental care that treats the etiology of the problem could reduce the risk of adverse events associated with these medications. Unfortunately, emergency dental care is often accessed through hospital emergency rooms, and the treatment is typically palliative and often involves recommendation or prescription of OTC analgesics.

IV.2 Predictions about which Caregivers use Pain Medication Properly

In this study an association between caregiver's race and whether the dosage of the medication was known ($P = .044$) was found as well as between caregiver's race and if there were errors or incomplete information in the reported dosing ($P = .044$). No other demographic information showed a predictive relationship with pain medication use. Therefore, this study indicated that it may be difficult to determine which caregivers have accurate knowledge of pain medication use and its proper use based on demographic characteristics. Although we found that Black/African American caregivers were more likely to have missing knowledge about medication usage it is important to not overgeneralize and best to provide detailed instruction to anyone, regardless of race. In addition, there can be cultural and societal expectations around pain and pain management, which may certainly have an impact on our results.¹⁹

Furthermore, caregivers often cannot identify weight as the correct method of determining dosage of medication for pediatric patients.¹⁰ This could easily lead to over or under dosing, even for those that have properly selected a medication. Medication labels can be complicated and caregivers with lower health literacy are more susceptible to make errors when giving their child pain medication.²⁰ Thus it is important for dentists and physicians to educate caregivers of all their patients about pain management strategies, as well as proper pain medication use, even for OTC medications.

IV.3 Access to Care

The mean duration of pain of the children was 11.5 days. It appears that caregivers are often waiting a significant amount of time before seeking professional care for their child. Many factors can contribute to this finding such as barriers to

accessing care, social or life stressors and underestimation of children's pain by caregiver. The University of Illinois Department of Pediatric Dentistry population consists of about 95% Medicaid patients. Due to the low number of Medicaid providers in the state it is possible that our clinic sees children who are in pain for longer due to the time it takes to find a provider who will treat them. Additionally, it can be difficult to make an appointment at our clinic due to the high volume thus adding to the delay in care. The delay in care is a failure of the system, as patients should not be waiting until they are in pain to receive dental care. If more providers were available and accepted Public Aid Insurance perhaps these patients would have an increase in access to care and thus seek treatment for dental caries prior to developing pain. However due to the lack of providers most families unfortunately don't seek care until their child is in pain leading to progression of dental caries and thus more extensive dental work needed.

IV.4 Use of Orajel® and Antibiotics to Manage Pain

Orajel® was used as an additional medicament for management of dental pain by several caregivers. Orajel® is available over the counter and therefore caregivers may be unaware of the potential severe adverse effects. Benzocaine is the active ingredient in Orajel® and can lead to significant adverse reactions such as methemoglobinemia.²¹ Tooth pain should not be managed with topical benzocaine such as Orajel® and education of caregivers needs to occur in order for this cease. There may be a belief that due to its marketing and delivery mechanism, Orajel® may be safer or more suitable for young children than systemic medication. However,

this is known to be false and education of caregivers needs to include this information.

Nine of the caregivers reported that an antibiotic was given as pain medication to their children. An analgesic is a drug given to aid in the relief of pain whereas an antibiotic is a medication given to inhibit or destroy bacteria. It has been shown that misconceptions about antibiotic use are prominent especially in the socioeconomically disadvantaged populations.²² The lack of understanding between an antibiotic and an analgesic is likely a healthy literacy issue. Low oral health literacy is a barrier to proper medication taking and dosing and therefore there needs to be further education in the difference between pain medication and antibiotics as well as their purposes.

Although with the use of an antibiotic, pain may dissipate, it is not a true analgesic and unless treatment is performed the pain is likely to recur. In addition, the overuse of antibiotics is a major health concern. Antibiotics are often overprescribed by dentists leading to antibiotic resistance.²³ Although this study did not look specifically at antibiotic stewardship, it is our job as pediatric dentists to follow guidelines to avoid over usage of antibiotics by providers.

IV.5 Proper Medication Usage

This study indicated that it may be difficult to determine which caregivers have accurate knowledge about pain medication and its proper use based on demographic characteristics. Medication labels can be complicated and caregivers with lower health literacy are more susceptible to make errors when giving their

child pain medication. It is important for dentists and physicians to educate caregivers of all their patients about pain management strategies, as well as proper pain medication use, even for OTC medications.

IV.6 Study Limitations

Several limitations were noted in this study. Patient recruitment in emergency clinics can be challenging as the patients may be in pain, under stress, or pre-occupied with treatment needs. The recruitment of subjects for this study came from a generally busy walk-in emergency clinic, which may have decreased the chances of fully engaged participation. In addition, if the practitioners did not have sufficient time when managing treatment, the survey was not conducted. We were limited to self-reported data, which may have been more indicative of errors in memory or communication than actual medication administration. The survey asked questions about a potentially sensitive area such as improper prescription use. Despite assurances of anonymity, some caregivers may not have answered all questions accurately or completely.

Another limitation of this study was the sample size. Although there were an adequate number of patients surveyed, only 39% of the patients were given pain medication. Thus, statistical analysis was limited due to this variable. Additionally, patients were only recruited from our urgent dental care clinic. This prevented patients who presented with pain at their initial visits from being approached and were thus missed. Therefore, this study did not have the opportunity to collect data from all patients in pain at our clinic. Furthermore, although dental residents received individualized

training there was likely inconsistency with the Wong Baker Faces Pain Scale scoring due to the multiple providers.

Finally, although our population showed racial and ethnic diversity, it primarily consisted of caregivers with less education currently using Medicaid/State Insurance for their child. In addition, this study was conducted in Chicago, IL and thus the results of this study may not be generalizable to all populations in all geographic areas.

IV.7 Future Studies

This study did have several strengths such as a diverse population and was able to capture a majority of our clinic population since more than 90% of our sampling frame consists of English and/or Spanish speakers. However future studies could be expanded to include additional populations. It would be interesting to see if caregivers of a different socioeconomic status would have similar rates of incorrect medication usage and if any predictive relationships could be established. Multiple caregivers in our study reported using antibiotics as a method of pain control. Further investigation into the understanding of medication purposes by caregivers could provide valuable insight.

IV.8 Implications for the Profession

As pediatric dentists it is important that we not only educate families about oral hygiene but also about how to manage dental pain if it should occur. Children rely on management of their dental pain by their caregivers and thus better parental education is imperative. It is our job as pediatric dentists to provide anticipatory guidance and management of dental pain should be included in discussions with

families. This study also highlights that many children experience pain secondary to caries. Prevention efforts can reduce caries and the effects of caries, such as pain, to avoid the need for pain management. Unfortunately, this study also highlights that pain is prevalent in this primarily Medicaid population, and this may highlight subjects inability to properly access care at earlier stages of the disease, or social determinants of health that lead these families to avoid care until pain is a cue to action.

V. CONCLUSION

Our findings suggest that it is difficult to predict which caregivers are likely to use medication improperly. The safest approach is to assume that any caregiver has the potential to use medication improperly. Therefore, it is imperative that healthcare providers educate parents on appropriate and accurate pain management skills. Systemic changes to improve access to dental emergency services may reduce the risks of improper medication usage.

APPENDICES

APPENDIX A



*Our Foundation Exists to Provide
Global Access to our Scale and
to Promote Optimal Pain
Assessment, Pain Management,
and Atraumatic Care.*

Dear Dr. Frankel,

Thank you for completing our web form. I apologize for the delay in getting back to you.

You are welcome to use the Wong-Baker FACES® Pain Rating Scale in your publishing project with no licensing required. We have a standing agreement with Elsevier.

We would like to review your content for accuracy before publication. Our scale is for self-assessment, so hopefully, the pediatric patients were able to assess their own pain rather than a third party, such as parents or staff assessing for them.

Here are links to the digital formats of the scale, including all the necessary copyright and trademark information for publications: [JPEG-Blue](#), [JPEG-Black](#).

[Instructions for the use of the scale](#)

[Frequently Asked Questions](#)

The following example bibliography citation may be helpful to you:

Wong-Baker FACES Foundation (2020). Wong-Baker FACES® Pain Rating Scale. Retrieved [Date] with permission from <http://www.WongBakerFACES.org>.

Please let me know if you have any questions.

Kind regards,

Connie

Connie M Baker
Executive Director
Wong-Baker FACES Foundation
ConnieBaker@WongBakerFACES.org
(405) 608-8083 - Work | (405) 249-2006 - Mobile
wongbakerfaces.org/

Appendix B



Approval Notice Initial Review – Expedited Review

June 18, 2019
Amanda Frankel
Pediatric Dentistry

RE: **Protocol # 2019-0493**
"Management of Pediatric Urgent Dental Pain"

Dear Dr. Frankel:

Members of Institutional Review Board (IRB) #3 reviewed and approved your research protocol under expedited review procedures 45 CFR 46.110(b)(1) on June 10, 2019. You may now begin your research.

Your research meets the criteria for approval under the following categories: 4, 7

Please note the following information about your approved research protocol:

<u>Protocol Approval Date:</u>	June 10, 2019
<u>Approved Subject Enrollment #:</u>	200
<u>Performance Sites:</u>	UIC
<u>Sponsor:</u>	None
<u>Research Protocol(s):</u>	a) Management of Pediatric Urgent Dental Pain; Version 1.1, 05/31/2019

Documents that require an approval stamp or separate signature can be accessed via [OPRS Live](#). The documents will be located in the specific protocol workspace. You must access and use only the approved documents to recruit and enroll subjects into this research project.

Recruitment Material(s):
a) Recruitment Script; Version 1, 04/25/2019

Informed Consent(s):
a) Waiver of Documentation of Informed Consent granted [45 CFR 46.117(c)]
b) Information Sheet - Consent and Parental Permission; Version 1.1, 05/31/2019

Assent(s):
a) Assent - Ages 12-17 (Verbal), Version 1, 05/31/2019
b) Assent - Ages 7-11 (Verbal), Version 1, 05/31/2019

Appendix B continued



Please remember to:

- Use only the IRB-approved and stamped consent document(s) when enrolling new subjects.
- Use your research protocol number (2019-0493) on any documents or correspondence with the IRB concerning your research protocol.
- Review and comply with the policies of the UIC Human Subjects Protection Program (HSPP) and the guidance Investigator Responsibilities.

Please note that the UIC IRB has the right to ask further questions, seek additional information, or monitor the conduct of your research and the consent process.

Please be aware that if the scope of work in the grant/project changes, the protocol must be amended and approved by the UIC IRB before the initiation of the change.

We wish you the best as you conduct your research. If you have any questions or need further help, please contact the OPRS office at (312) 996-1711 or me at (312) 355-3949. Please send any correspondence about this protocol to OPRS via OPRS Live.

Sincerely,

Eddie Mendoza
IRB Coordinator, IRB # 3
Office for the Protection of Research Subjects

cc: Ian Marion, Faculty Sponsor, Pediatric Dentistry
~~Marcia Da~~ Fonseca, Pediatric Dentistry, M/C 850

Appendix C



**Approval Notice
[Amendment – Expedited Review
UIC Amendment # 1**

October 4, 2019

Amanda Frankel, DMD
Pediatric Dentistry

RE: **Protocol # 2019-0493**
"Management of Pediatric Urgent Dental Pain"

Dear Dr. Frankel:

Your application was reviewed and approved on October 4, 2019. The amendment to your research may now be implemented.

Please note the following information about your approved amendment:

Amendment Approval Date: October 4, 2019

Amendment:

Summary: UIC Amendment #1 dated September 30, 2019 and received October 1, 2019, is an investigator initiated amendment involving the submission of the English documents translated into the Spanish language: Assent (7-11) Spanish; V 1.2; 9/30/19; Assent (12-17) Spanish; V 1.2; 9/30/19; Management of Pain Consent Spanish; V 1.2; 9/30/19; Recruitment Script Spanish; V 1.2; 9/30/19; Screening Questions for Caregiver Spanish; V 1.2; 9/30/19; Survey Questions Spanish; V 1.2; 9/30/19.

Documents that require an approval stamp or separate signature can be accessed via [OPRS Live](#). The documents will be located in the specific protocol workspace. You must access and use only the approved documents to recruit and enroll subjects into this research project.

Recruiting Material(s):

- a) Recruitment Script Spanish; Version 1.2; 09/30/2019

Informed Consent(s):

- a) Information Sheet - Consent and Parental Permission Spanish; Version 1.2; 09/30/2019

Assent(s):

- a) Assent (12-17) Spanish; Version 1.2; 09/30/2019
- b) Assent (7-11) Spanish; Version 1.2; 09/30/2019

Please be sure to:

Appendix C continued



- Use only the IRB-approved and stamped consent document(s) and/or HIPAA Authorization form(s) when enrolling subjects.
- Use your research protocol number (2019-0493) on any documents or correspondence with the IRB concerning your research protocol.
- Review and comply with the [policies](#) of the UIC Human Subjects Protection Program (HSPP) and the guidance [Investigator Responsibilities](#).

Please note that the IRB has the right to ask further questions, seek additional information, or monitor the conduct of your research and the consent process.

Please be aware that if the [scope of work](#) in the grant/project changes, the protocol must be amended and approved by the UIC IRB before the initiation of the change.

We wish you the best as you conduct your research. If you have any questions or need further help, please contact the OPRS at (312) 996-1711 or me at (312) 355-2939. Please send any correspondence about this protocol to OPRS via [OPRS Live](#).

Sincerely,

Jewell Hamilton, MSW
IRB Coordinator, IRB # 3
Office for the Protection of Research Subjects

cc: Ian Marion, Faculty Sponsor, Pediatric Dentistry
Marcio Da Fonseca, Pediatric Dentistry, M/C 850

Appendix D

Hello. May I talk to you about a survey we are doing with clinic patients and their parents?

[If parent is not interested in the survey]: Thank you for your time.

[If parent expresses interest in the survey]: We are conducting a voluntary survey on how parents/caregivers are managing their children's urgent dental pain at home prior to seeking care here today. It will take you about 10 minutes. In addition we will ask your child about their dental pain by having them point to a picture. Your name is not connected to the survey in any way. Again, the survey is completely voluntary. Your participation will have no effect on clinical care received. Do you have any questions? Would you like to hear more?

[If the parent is not interested, thank them for their time].

[If parent expresses interest in the survey]: Thanks so much for your interest. Can I answer any questions? Would you like to participate?

[If parent would like to participate, they will sign the informed consent and be given the screening questions and survey.

[If patient is not interested]. Thanks so much for your time. I appreciate it.



Appendix E



Hola. ¿Puedo hablar con usted acerca de una encuesta que estamos haciendo con pacientes y sus padres?[If parent is not interested in the survey]: Gracias por tu tiempo. [If parent expresses interest in the survey]:

Estamos realizando una encuesta voluntaria sobre cómo los padres / cuidadores manejan el dolor dental urgente de sus hijos en el hogar antes de buscar atención aquí hoy. Le llevará unos 10 minutos. Además, le preguntaremos a su hijo sobre su dolor dental al hacer que señalen una imagen. Su nombre no está conectado a la encuesta de ninguna manera. Nuevamente, la encuesta es completamente voluntaria. Su participación no tendrá ningún efecto en la atención clínica recibida. ¿Tiene usted alguna pregunta? Le gustaría escuchar mas?

[If the parent is not interested, thank them for their time].^[1][If parent expresses interest in the survey]:

Muchísimas gracias por su interés. ¿Puedo responder alguna pregunta? ¿Le gustaría participar? [If parent would like to participate, they will sign the informed consent and be given the screening questions and survey].^[1][If patient is not interested]. Muchas gracias por tu tiempo. Estoy agradecido.

Appendix F



**University of Illinois Hospital & Health Sciences System (UI Health)
Research Information and Consent [Parental Permission] for Participation in Biomedical
Research
Management of Pediatric Urgent Dental Pain**

Principal Investigator/Researcher Name and Title: Dr. Amanda Frankel, Pediatric Dental Resident

Department and Institution: University of Illinois at Chicago, Department of Pediatric Dentistry

Address and Contact Information: 801 S. Paulina Street Chicago, IL 60612

Sponsor: none

About this research study

You are being asked to participate in a research study. Research studies answer important questions that might help change or improve the way we do things in the future.

Taking part in this study is voluntary

Your participation in this research study is voluntary. You may choose to not take part in this study or may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled and will not affect your relationship with the University of Illinois Hospital and Health Sciences System (UI Health) and/or University of Illinois at Chicago (UIC).

This consent form will give you information about the research study to help you decide whether you want to participate. Please read this form and ask any questions you have before agreeing to be in the study.

Note: This research includes subjects who are minors who are not able to consent for themselves. If you are a parent, guardian, or legal representative, the terms "you" or "your" refer to the research subject.

Important Information

This information gives you an overview of the research. More information about these topics may be found in the pages that follow.

**WHY IS THIS
STUDY BEING**

The aim of this study is to identify how urgent dental pain is being managed at home by parents/caregivers prior to seeking definitive

UIC IRB Health and Biological Sciences
Informed Consent Template: 11/10/2018
Do NOT Change This Field - IRB Use ONLY

Page 1 of 6

[Management of Pain]
[Version 1.1, Date 5/31/2019]

Appendix F continued

DONE?	care at a University based pediatric dental clinic.
WHAT WILL HAPPEN TO ME DURING THE STUDY?	<p>If you agree to be in the study, you will be asked to do the following procedures:</p> <ul style="list-style-type: none"> You will be asked to answer questions regarding demographic information such as age, gender, race/ethnicity, dental insurance, and education level. You will also be asked questions concerning your child's dental pain and management techniques utilized. In addition, a pediatric dental resident will administer the Wong-Baker FACES Scale® (Wong-Baker FACES foundation) pain scale to the patient before any treatment is initiated. Finally, the pediatric dental resident will obtain your child's weight using a scale.
HOW MUCH TIME WILL I SPEND ON THE STUDY?	It will take approximately 10 minutes to complete the research study.
ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?	Participants will not benefit directly from taking part in this study. However, anticipated benefit is for pediatric dentists gaining knowledge on how children's acute dental pain is currently managed.
WHAT ARE THE MAIN RISKS OF THE STUDY?	A risk of this research is a loss of privacy (revealing to others that you are taking part in this study) or confidentiality (revealing information about you to others to whom you have not given permission to see this information).
DO I HAVE OTHER OPTIONS BESIDES TAKING PART IN THE STUDY?	You have the option to not participate in this study. .
QUESTIONS ABOUT THE STUDY?	<p>For questions, concerns, or complaints about the study, please contact Dr. Amanda Frankel or Dr. Ian Marion at 312-413-9651 or email at afrank33@uic.edu or imarion@uic.edu</p> <p>If you have questions about your rights as a study subject; including questions, concerns, complaints, or if you feel you have not been treated according to the description in this form; or to offer input you may call the UIC Office for the Protection of Research Subjects (OPRS) at 312-996-1711 or 1-866-789-6215 (toll-free) or e-mail</p>

Appendix F continued

	OPRS at uicirb@uic.edu
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Please review the rest of this document for details about these topics and additional things you should know before making a decision about whether to participate in this research. Please also feel free to ask the study team questions at any time.

Who may participate in the study?

You are being asked to participate in the research study because you are presenting to the University of Illinois at Chicago Post Graduate Pediatric Urgent Care Clinic.

Approximately 200 subjects may be involved in this study at UIC.

What about privacy and confidentiality?

Efforts will be made to keep your personal information confidential; however, we cannot guarantee absolute confidentiality. In general, information about you, or provided by you, during the research study, will not be disclosed to others without your written permission. However, laws and university rules might require us to tell certain people about you. For example, study information which identifies you and the consent form signed by you may be looked at and/or copied for quality assurance and data analysis include:

- Representatives of the university committee and office that reviews and approves research studies, the Institutional Review Board (IRB) and Office for the Protection of Research Subjects.
- Other representatives of the State and University responsible for ethical, regulatory, or financial oversight of research.
- Government Regulatory Agencies, such as the Office for Human Research Protections (OHRP).

A possible risk of the study is that your participation in the study or information about you and your health might become known to individuals outside the study. Your personal information will be stored on a password-protected computer to prevent access by unauthorized personnel.

Your individual data will be stripped of all direct and indirect identifiers. De-identified electronic data will be kept indefinitely for use of future publication.

When the results of the study are published or discussed in conferences, no one will know that you were in the study.

What are the costs for participating in this research study?

There are no costs to you for participating in this research study.

Appendix F continued

Will I be reimbursed for any of my expenses or paid for my participation in this research study?

You will not be offered payment for being in this study.

Can I withdraw or be removed from the study?

If you decide to participate, you have the right to withdraw your consent and stop the survey at any time. Since your responses will not be linked to any information that identifies you or your child, the researchers will be unable to withdraw your responses once you have completed the survey and left the clinic.

What if I am a UIC student?

You may choose not to participate or to stop your participation in this research at any time. This will not affect your class standing or grades at UIC. The investigator may also end your participation in the research. If this happens, your class standing or grades will not be affected. You will not be offered or receive any special consideration if you participate in this research.

What if I am a UIC or UI Health employee?

Your participation in this research is in no way a part of your university duties, and your refusal to participate will not in any way affect your employment with the university, or the benefits, privileges, or opportunities associated with your employment at UIC or UI Health. You will not be offered or receive any special consideration if you participate in this research.

Remember:

Your participation in this research study is voluntary. Your decision whether or not to participate will not affect your current or future relations with the University. If you decide to participate, you are free to withdraw at any time without affecting that relationship.

Appendix G



Universidad de Illinois en Chicago
Información y consentimiento para participar en investigación biomédica
Manejo del dolor dental urgente pediátrico

Nombre y cargo del investigador principal/ investigador: Dr. Amanda Frankel, DMD
Departamento e Institución: Universidad de Illinois en Chicago, Departamento de Odontología Pediátrica
Dirección e información de contacto: 801 S. Paulina Street Chicago, IL 60612
Patrocinador: Ninguno

Sobre este estudio de investigación

Se le pide que participe en un estudio de investigación. Los estudios de investigación responden preguntas importantes que podrían ayudar a cambiar o mejorar la forma en que hacemos las cosas en el futuro.

Participar en este estudio es voluntario

Su participación en este estudio de investigación es voluntaria. Puede optar por no participar en este estudio o puede optar por abandonar el estudio en cualquier momento. La decisión de no participar, o la decisión de abandonar el estudio más tarde, no dará lugar a ninguna sanción o pérdida de beneficios a los que tiene derecho y no afectará su relación con el Hospital de la Universidad de Illinois y el Sistema de Ciencias de la Salud (UI Health) y / o Universidad de Illinois en Chicago (UIC).

Este formulario de consentimiento le dará información sobre el estudio de investigación para ayudarlo a decidir si desea participar. Lea este formulario y haga cualquier pregunta que tenga antes de aceptar participar en el estudio.

Nota: Esta investigación incluye sujetos menores de edad que no pueden consentir por sí mismos. Si usted es el padre, tutor o representante legal, los términos "usted" o "su" se refieren al tema de investigación.

Appendix G continued

Información importante

Esta información le brinda una visión general de la investigación. Puede encontrar más información sobre estos temas en las páginas siguientes.

¿POR QUÉ SE ESTÁ HACIENDO ESTE ESTUDIO?	El objetivo de este estudio es identificar cómo los padres / cuidadores manejan el dolor dental urgente en el hogar antes de buscar atención definitiva en una clínica dental pediátrica con sede en la Universidad.
¿QUÉ ME PASARÁ DURANTE EL ESTUDIO?	Si acepta participar en el estudio, se le pedirá que realice los siguientes procedimientos: <ul style="list-style-type: none"> Se le pedirá que responda preguntas sobre información demográfica, como edad, sexo, raza / etnia, seguro dental y nivel educativo. También se le harán preguntas sobre el dolor dental de su hijo y las técnicas de manejo utilizadas. Además, un residente de odontopediatría administrará la escala de dolor Wong-Baker FACES Scale © (base Wong-Baker FACES) al paciente antes de iniciar cualquier tratamiento. Finalmente, un residente de odontopediatría obtendrá el peso de su hijo usando una báscula.
¿CUÁNTO TIEMPO PASARÉ EN EL ESTUDIO?	Tomará aproximadamente 10 minutos completar el estudio de investigación.
¿HAY ALGUNA VENTAJA DE PARTICIPAR EN EL ESTUDIO?	Los participantes no se beneficiarán directamente de participar en este estudio. Sin embargo, el beneficio anticipado es que los odontopediatras adquieran conocimientos sobre cómo se maneja actualmente el dolor dental agudo de los niños.
¿CUÁLES SON LOS PRINCIPALES RIESGOS DEL ESTUDIO?	Un riesgo de esta investigación es una pérdida de privacidad (revelar a otros que está participando en este estudio) o confidencialidad (revelar información sobre usted a otras personas a las que no ha dado permiso para ver esta información).
¿TENGO OTRAS OPCIONES ADEMÁS DE PARTICIPAR EN EL ESTUDIO?	Tiene la opción de no participar en este estudio.

Appendix G continued

¿PREGUNTAS SOBRE EL ESTUDIO?	<p>Para preguntas, inquietudes o quejas sobre el estudio, comuníquese con la Dra. Amanda Frankel o el Dr. Ian Marion al 312-413-9651 o envíe un correo electrónico a afrank33@uic.edu o imarion@uic.edu</p> <p>Si tiene preguntas sobre sus derechos como sujeto de estudio; incluidas preguntas, inquietudes, quejas o si considera que no ha sido tratado de acuerdo con la descripción en este formulario; o para ofrecer su opinión, puede llamar a la Oficina de Protección de Sujetos de Investigación de UIC (OPRS) al 312-996-1711 o al 1-866-789-6215 (sin cargo) o enviar un correo electrónico a OPRS a uicirb@uic.edu.</p>
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Revise el resto de este documento para obtener detalles sobre estos temas y cosas adicionales que debe saber antes de tomar una decisión sobre la participación en esta investigación. No dude en hacer preguntas al equipo de estudio en cualquier momento.

¿Quién puede participar en el estudio?

Se le pide que participe en el estudio de investigación porque se presenta a la Clínica de Atención de Urgencia Pediátrica del Postgrado de la Universidad de Illinois en Chicago.

Aproximadamente 200 sujetos pueden participar en este estudio en la UIC.

¿Qué pasa con la privacidad y la confidencialidad?

Se harán esfuerzos para mantener su información personal confidencial; sin embargo, no podemos garantizar absoluta confidencialidad. En general, la información sobre usted, o proporcionada por usted, durante el estudio de investigación, no será revelada a otros sin su permiso por escrito. Sin embargo, las leyes y las reglas universitarias pueden requerir que le informemos a ciertas personas sobre usted. Por ejemplo, la información del estudio que lo identifica y el formulario de consentimiento firmado por usted puede ser revisado y / o copiado para garantizar la calidad y el análisis de datos incluyen:

- Representantes del comité universitario y la oficina que revisa y aprueba los estudios de investigación, la Junta de Revisión Institucional (IRB) y la Oficina para la Protección de los Sujetos de Investigación.
- Otros representantes del Estado y la Universidad responsables de la supervisión ética, regulatoria o financiera de la investigación.
- Agencias reguladoras del gobierno, como la Oficina de Protección de la Investigación Humana (OHRP).

Un posible riesgo del estudio es que su participación en el estudio o información sobre usted y su salud pueda ser conocida por personas ajenas al estudio. Su información personal se almacenará en una computadora protegida con contraseña para evitar el acceso de personal no autorizado.

Appendix G continued

Sus datos individuales serán despojados de todos los identificadores directos e indirectos. Los datos electrónicos no identificados se conservarán indefinidamente para su uso en futuras publicaciones.

Cuando los resultados del estudio se publiquen o discutan en conferencias, nadie sabrá que usted estuvo en el estudio.

¿Cuáles son los costos para participar en este estudio de investigación?

No hay costos para usted por participar en este estudio de investigación.

¿Se me reembolsará alguno de mis gastos o se me pagará por mi participación en este estudio de investigación?

No se le ofrecerá el pago por participar en este estudio.

¿Puedo retirarme o ser retirado del estudio?

Si decide participar, tiene derecho a retirar su consentimiento y detener la encuesta en cualquier momento. Dado que sus respuestas no estarán vinculadas a ninguna información que lo identifique a usted o a su hijo, los investigadores no podrán retirar sus respuestas una vez que haya completado la encuesta y haya abandonado la clínica.

¿Qué pasa si soy un estudiante de UIC?

Puede elegir no participar o detener su participación en esta investigación en cualquier momento. Esto no afectará su posición en la clase o sus calificaciones en la UIC. El investigador también puede finalizar su participación en la investigación. Si esto sucede, su posición en la clase o sus calificaciones no se verán afectadas. No se le ofrecerá ni recibirá ninguna consideración especial si participa en esta investigación.

¿Qué sucede si soy un empleado de UIC o UI Health?

Su participación en esta investigación no forma parte de sus deberes universitarios, y su negativa a participar no afectará de ninguna manera su empleo en la universidad, ni los beneficios, privilegios u oportunidades asociados con su empleo en UIC o UI Health. No se le ofrecerá ni recibirá ninguna consideración especial si participa en esta investigación.

Recuerda:

Su participación en este estudio de investigación es voluntaria. Su decisión de participar o no no afectará sus relaciones actuales o futuras con la Universidad. Si decide participar, puede retirarse en cualquier momento sin afectar esa relación.

Appendix H



University of Illinois at Chicago

ASSENT TO PARTICIPATE IN RESEARCH (Ages 7-11)

Management of Pediatric Urgent Dental Pain

1. We are asking you to take part in a research study because we are trying to learn more about how your parents help you with your tooth pain at home.
2. If you agree to be in this study, your parents will fill out a survey and we will ask you to show us how bad your teeth hurt by pointing at a picture.
3. A risk of this study is that you may have to spend a little more time showing us things on the scale, but it won't change anything else.
4. You will not directly benefit from this study.
5. You and your parents can both decide if you want to do this. Please talk with your parents before you decide. We will also ask your parents to give their permission for you to take part in this study. But even if your parents say "yes" you can still decide not to do this.
6. If you don't want to be in this study, you don't have to participate. Remember, being in this study is up to you and no one will be upset if you don't want to participate or even if you change your mind later and want to stop.
7. You can ask any questions that you have about the study.

Appendix H continued



University of Illinois at Chicago

ASSENT TO PARTICIPATE IN RESEARCH (Ages 12-17)

Management of Pediatric Urgent Dental Pain

1. We are asking you to take part in a research study because we are trying to learn more about how your parents help you with your dental pain at home.
2. If you agree to be in this study, your parents will fill out a survey and we will ask you to tell us about your dental pain by pointing to a number (1-10).
3. A risk of this study is that you may have to spend indicating your pain on a number scale, but it won't change anything else.
4. You will not directly benefit from this study.
5. You and your parents can both decide if you want to do this. Please talk with your parents before you decide. We will also ask your parents to give their permission for you to take part in this study. But even if your parents say "yes" you can still decide not to do this.
6. If you don't want to be in this study, you don't have to participate. Remember, being in this study is up to you and no one will be upset if you don't want to participate or even if you change your mind later and want to stop.
7. You can ask any questions that you have about the study.

Appendix I



University of Illinois at Chicago
ASSENT TO PARTICIPATE IN RESEARCH (Ages 7-11)

Management of Pediatric Urgent Dental Pain

1. Te estamos pidiendo que participes en un estudio de investigación porque estamos tratando de aprender más sobre cómo tus padres te ayudan con el dolor de dientes en casa.
2. Si acepta participar en este estudio, sus padres completarán una encuesta y le pediremos que nos muestre qué tanto le duelen los dientes al señalar una imagen.
3. Un riesgo de este estudio es que puede que tenga que pasar un poco más de tiempo mostrándonos cosas en la escala, pero no cambiará nada más.
4. No se beneficiará directamente de este estudio.
5. Tanto tú como tus padres pueden decidir si quieres hacer esto. Habla con tus padres antes de decidir. También le pediremos a sus padres que den su permiso para que participe en este estudio. Pero incluso si sus padres dicen "sí", aún puede decidir no hacerlo.
6. Si no desea participar en este estudio, no tiene que participar. Recuerde, participar en este estudio depende de ti y nadie se molestará si no deseas participar o incluso si cambias de opinión más adelante y deseas abandonarlo.
7. Puedes hacer cualquier pregunta que tengas sobre el estudio.

Appendix I continued



University of Illinois at Chicago

ASSENT TO PARTICIPATE IN RESEARCH (Ages 12-17)

Management of Pediatric Urgent Dental Pain

1. Te pedimos que participes en un estudio de investigación porque estamos tratando de aprender más sobre cómo tus padres te ayudan con su dolor dental en el hogar.
2. Si aceptas participar en este estudio, tus padres completarán una encuesta y te pediremos que nos informes sobre tu dolor dental señalando un número (1-10).
3. Un riesgo de este estudio es que es posible que debas gastar más tiempo para indicar tu dolor en una escala numérica, pero no cambiará nada más.
4. No te beneficiarás directamente de este estudio.
5. Tanto tú como tus padres pueden decidir si quieres hacer esto. Habla con tus padres antes de decidir. También le pediremos a tus padres que den su permiso para que participe en este estudio. Pero incluso si sus padres dicen "sí", aún puede decidir no hacerlo.
6. Si no deseas participar en este estudio, no tienes que participar. Recuerda, participar en este estudio depende de ti y nadie se molestará si no deseas participar o incluso si cambias de opinión más adelante y deseas abandonarlo.
7. Puede hacer cualquier pregunta que tenga sobre el estudio.

Appendix J

Screening Questions for Caregiver

1. Do you agree to be screened for this research study?
 - a. Yes
 - b. No (screening will be terminated)
2. Are you the legal guardian of the child with you today?
 - a. Yes
 - b. No (if selected, not eligible, survey will discontinue)
3. Which is your primary or preferred language?
 - a. English
 - b. Spanish
 - c. Other (if selected, not eligible, survey will discontinue)

Appendix K

Screening Questions for Caregiver (Spanish)

1. ¿Acepta ser examinado para este estudio de investigación?
 - a. Si
 - b. No
2. ¿Es usted el tutor legal del niño que está con usted hoy?
 - a. Si
 - b. No
3. ¿Cuál es su idioma principal o preferido?
 - a. Inglés
 - b. Español
 - c. Otro

Appendix L

Form completed by UIC Pediatric Resident

1. Does the child have a medical condition that will impact their ability to take medication?
 - a. Yes (patient is not a candidate for this research study)
 - b. No (patient will be screened)
2. Do you feel that the child has a medical condition, which may impact their ability to interpret pain?
 - a. Yes (patient is not a candidate for this research study)
 - b. No (patient will be screened)
3. What is the child's weight? (kg)
 - a. _____
4. In your best estimation, what is the diagnosis leading to the pain symptoms the patient is here for today?
 - a. Caries not affecting the pulp
 - b. Caries with reversible pulpitis
 - c. Caries with irreversible pulpitis
 - a. Necrotic pulp due to caries
 - b. Trauma
 - c. Other soft tissue pathology
 - d. Space maintenance or orthodontic problem
5. What was the child's pain based on their selection from the Wong Baker Faces Pain Scale? (1-10)
 - a. Drop down 0-10
 - b. Child was unable to answer

Appendix M

1. What is your child's age in years?
 - a. _____
2. What is your child's gender?
 - a. Male
 - b. Female
 - c. Other
3. Which of the following do you consider your child to be? (Circle all that apply)
 - a. Caucasian or White
 - b. Black or African American
 - c. Native American or American Indian
 - d. Asian/Pacific Islander
 - e. Other: (please specify) _____
4. Is your child Hispanic or Latino?
 - a. Yes
 - b. No
5. What is your age in years?
 - a. _____
6. What is your gender?
 - a. Male
 - b. Female
 - c. Other
7. Which of the following do you consider yourself to be? (Circle all that apply)
 - a. Caucasian or White
 - b. Black or African American
 - c. Native American or American Indian
 - d. Asian/Pacific Islander
 - e. Other: (please specify) _____
8. Are you Hispanic or Latino?
 - a. Yes
 - b. No
9. What is the highest degree or level of school you have completed? (If you are currently enrolled in school, please indicate the highest degree you have received)
 - a. Less than 9th grade
 - b. Some high school, no diploma
 - c. High school graduate, diploma or the equivalent (ex. GED)
 - d. Some college credit, no degree
 - e. Trade/technical/vocational training
 - f. Associate degree
 - g. Bachelor's degree
 - h. Master's degree or higher
 - i. Professional or Doctorate degree
10. What type of dental insurance do you have?
 - a. Public aid/Medicaid/Medical Card
 - b. Private insurance/PPO/HMO
 - c. No dental insurance or self pay
11. How many days has your child had the pain you are at the dentist for today?
 - a. _____

Appendix M continued

12. Have you given your child any medication for their dental pain you are at the dentist for today?
 - a. No (if selected survey will end)
 - b. Yes (if selected, survey will continue)
13. Was the medicine prescribed by anyone?
 - a. No, medication is over the counter
 - b. Yes, prescribed by a medical doctor
 - c. Yes, prescribed by another dentist
 - d. Yes, prescribed by other health professional
14. Do you remember the name of the medication?
 - a. No (if selected, survey will skip question 15)
 - b. Yes (if selected, parent will be asked to complete question 15)
15. If so, please write the name of the medication:
 - a. _____
16. Do you know what the dose of the medication is?
 - a. No (if selected, survey will skip question 17)
 - b. Yes (if selected, parent will be asked to complete question 17)
17. What is the dose of the medication?
 - a. _____
18. Do you know how many milligrams (mg) are in one dose?
 - a. No (if selected, survey will skip question 19)
 - b. Yes (if selected, parent will be asked to complete question 19)
19. How many milligrams (mg) are in one dose?
 - a. _____
20. How many times a day ~~do~~ you give the medication to them?
 - a. _____
21. How many days have you been giving them medication for?
 - a. _____
22. Are you using any other methods to help with your child's dental pain? (Such as herbal treatment, ~~Oral~~, mouth rinses?)
 - a. _____
23. For your child's dental pain, have you given your child a medication that was prescribed for another person and not your child?
 - a. Yes
 - b. No
24. Where did you receive information about how to manage your child's dental pain? (Please select all that apply)
 - a. Physician/Dentist
 - b. Pharmacist
 - c. Internet
 - d. Friend/Family member
 - e. Yourself
 - f. Other: (please specify) _____

Appendix N

1. ¿Cuál es la edad de su hijo en años?
a. _____
2. ¿Cuál es el género de su hijo?
a. Masculino
b. Femenino
c. Otro
3. ¿Cuál de los siguientes considera que es su hijo? (Encierra en un círculo todo lo que corresponda)
a. Caucásico
b. Afroamericano
c. Nativos americanos
d. Isleño de Asia / Pacífico
e. Otros (especificar) _____
4. ¿Es su hijo hispano o latino?
a. Si
b. No
5. ¿Cuál es su edad en años?
a. _____
6. ¿Cuál es su género?
a. Masculino
b. Femenino
c. Otro
7. ¿Cuál de los siguientes te consideras? (Encierra en un círculo todo lo que corresponda)
a. Caucásico
b. Afroamericano
c. Nativos americanos
d. Isleño de Asia / Pacífico
e. Otros (especificar) _____
8. ¿Eres hispano o latino?
a. Si
b. No
9. ¿Cuál es el grado o nivel de escuela más alto que ha completado? (Si actualmente está matriculado en la escuela, indique el título más alto que haya recibido)
a. Menos del octavo grado
b. ~~Algun~~ estudio de escuela secundaria, sin diploma
c. Graduado de secundaria, diploma o equivalente (ej. GED)
d. Algunos créditos universitarios, sin título
e. Comercio / formación técnica / profesional
f. Grado asociado
g. ~~Licenciatura~~
h. Maestría o superior
i. Grado profesional o doctoral
10. ¿Qué tipo de seguro dental tiene?
a. Ayuda pública / ~~Medicaid~~ / Tarjeta médica
b. Seguro privado / PPO / HMO
c. Sin seguro dental o al contado pago
11. ¿Cuántos días ha tenido su hijo el dolor que tiene hoy en el dentista?
a. _____
12. ¿Le ha dado a su hijo algún medicamento para el dolor dental que tiene hoy en el dentista?
a. No (if selected survey will end)
b. Si (if selected, survey will continue)
13. ¿La medicina fue recetada por alguien?
a. No, los medicamentos son de venta libre.
b. Si, recetado por un médico.
c. Si, recetado por otro dentista.
d. Si, recetado por otro profesional de la salud.

Appendix N continued

14. ¿Recuerdas el nombre del medicamento?
- a. No (if selected, survey will skip question 15)
 - b. Sí (if selected, parent will be asked to complete question 15)
15. Si es así, escriba el nombre del medicamento:
- a. _____
16. ¿Sabe cuál es la dosis del medicamento?
- a. No (if selected, survey will skip question 17)
 - b. Sí (if selected, parent will be asked to complete question 17)
17. ¿Cuál es la dosis del medicamento?
- a. _____
18. ¿Sabes cuántos miligramos (mg) hay en una dosis?
- a. No (if selected, survey will skip question 19)
 - b. Sí (if selected, parent will be asked to complete question 19)
19. ¿Cuántos miligramos (mg) hay en una dosis?
- a. _____
20. ¿Cuántas veces al día le da el medicamento?
- a. _____
21. ¿Por cuántos días le ha estado dado medicamentos?
- a. _____
22. ¿Está utilizando otros métodos para ayudar con el dolor dental de su hijo? (¿Como el tratamiento a base de hierbas, ~~Orajel~~, enjuagues bucales?)
- a. _____
23. Para el dolor dental de su hijo, ¿le ha dado un medicamento recetado a otra persona y no a su hijo?
- a. Sí
 - b. No
24. ¿Dónde recibió información sobre cómo manejar el dolor dental de su hijo? (Por favor seleccione todas las respuestas válidas)
- a. Médico / dentista
 - b. Farmacéutico
 - c. Internet
 - d. Amigo / miembro de la familia
 - e. Usted mismo
 - f. Otros (especificar) _____

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