Health Literacy Associated with Parental Management of Dental Pain in the Child

THESIS

Presented in Partial Fulfillment of the Requirements for the Degree Master of Science in the Graduate School of The Ohio State University

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2010

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Abstract

Purpose

The objective of this study was to determine 1) which analgesic medication parents would choose and why that medication was selected and, 2) whether health literacy of parents is related to medicating behaviors.

Methods

This IRB-approved cross-sectional design study consisted of a cohort of children 18-72 months examined at the Nationwide Children's Hospital Dental Surgery Center. Parents of qualifying patients completed a survey on pain medication dosage and utilization for their children. Parents were also given the short version of the Test of Functional Health Literacy (s-TOFHLA).

Results

Data from 108 caregivers were included in this analysis. The mean age of children was 48.0 months (±13.7). The average s-TOFHLA score was 34.5 ± 3.7; only one parent scored marginal health literacy and two scored inadequate health literacy. Parents with a high school education or less scored significantly lower on the s-TOFHLA than parents with more than a high school education (p=0.024). Parents with lower s-TOFHLA scores were significantly more likely to under dose their child (p=0.020). 90% of subjects who

daily overdosed their child chose Motrin, and 14.3% of parents relied solely on Orajel for management of tooth pain.

Conclusion

Children in pain had caregivers that were 3 times more likely to choose a dosing frequency of six times per day. Children with dental pain are at higher risk for daily overdosing due to frequency errors.

Dedication

This document is dedicated to my family.

Acknowledgments

I would like to thank Dr. Sarat Thikkurissy for all of his hard work and input on this research project which could not have been possible without his guidance. I would also like to thank Jessica Kull and Luke Simonis for their contributions.

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BL Spangelo, S Horrell, AL Goodwin, S Shroff, WD Jarvis. Somatostatin and Gamma-Aminobutyric Acid Inhibit Interleukin-1β-Stimulated Release of Interleukin-6 from Rat C6 Glioma Cells. Neuroimmunomodulation 2004;11(5):332-40.

Fields of Study

Major Field: Dentistry

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Introduction

The management of pain in children is a poorly understood aspect of pediatric health care. Clinical recommendations by bodies such as the American Academy of Pediatrics (AAP) and American Pain Society (APS) are somewhat inconclusive and vague due partially to the fact that research on pain management in children is limited and poorly represented in the literature. Modern understanding has challenged the theory, held well through the 1980's that children do not experience as much pain as adults due to "neurological immaturity."[1] However research has begun to demonstrate that infants and children experience pain on a similar scale to adults.[1]

Another recognized research barrier has been difficulty in properly assessing pediatric pain.[1,2,3] Children present the same challenge as other non-verbal patients, namely, communication of pain is poorly understood. Studies have consistently demonstrated that parents and health care practitioners judge a child to be in less pain than the child is experiencing.[1, 2] Age-appropriate pain scales have now been developed in order to better assess pain in children.[4]

In a 2002 study of 63 children aged 4-7 years with acute pain in the emergency department, 90% were able to use a validated ordinal scale (Smiley Analog Scale) to record their pain. Independent assessment from parents and practitioners using a validated visual analog scale (VAS) showed a correlation of 0.47 for parents and 0.08 for practitioners, revealing that parents are poor predictors of the severity of pain their child

is experiencing, and practitioners are even worse predictors.[1] Emergency medical service (EMS) commonly do not document pain and almost never (0.2%) used a validated pain assessment tool for injured pediatric patients.[5] Once an injured child 3-7 years old arrives at the hospital for triage, it was found that observational pain assessment by staff using the Alder Hey Triage Pain Score (AHTPS) significantly ($p<0.0001$) underestimated the child's self-reported perception of pain using the Wong-Baker Faces Pain Rating Scale (WBS).[3] A 2003 study of 73 children aged 4-14 years confirmed the poor assessment of pediatric pain by demonstrating that health professionals consistently scored pain lower (3.1) than do children (6.1) or caregivers (6.0).[2] These studies underscore the question whether or not parents, EMS, or practitioners are properly managing a child's pain if they are not even able to properly assess pain.

Studies within the past two decades have evaluated pain relief in patients presenting to the emergency department (ED) due to a limb or other traumatic injury. A study in the U.K. in 1999 showed that only 26% of children <17 years received pre-hospital pain relief.[6] Similarly, more recent studies in 2007 of children <19 years showed 28-37% received pain medication before arriving to the ED, with younger children less likely to receive medication.[7,8] Approximately 79% of children (3-20 years old) ultimately received analgesia in the ED.[9] Reasons parents cited for not giving their child pain medication included: concerns of potential masking of clinical signs and symptoms before being seen by a physician, the thought that giving "painkillers" would be harmful, and the thought that pain control was the hospital's responsibility.[6,7] It was of particular

interest that 32% of parents reported they did not have any painkillers suitable for children at home.[6]

Aside from traumatic injury, children are often given pain medication at home for management of fever. To study dosing by parents, 200 children (<11 years) given a known dose of acetaminophen or ibuprofen 24 hours prior to their ED visit in 2000 were evaluated. Fifty-one percent of children received an inaccurate dose, including 62% given acetaminophen and 26% given ibuprofen. Infants less than one year old were more likely to receive an inaccurate dose, and parents who correctly stated that dosage was based on weight were less likely to inaccurately dose.[10]

In a 2004 study of 213 caregivers who gave their children (<18 years) acetaminophen in the 24 hours before coming to the emergency department (ED), 47% gave the proper dose, 12% overdosed, and 41% underdosed, with non-English-speaking parents more likely to give the wrong dose of acetaminophen.[11] A recent study in Brazil reported that 46% of children given acetaminophen from their parents received the proper dose with 8% overdosed and 46% underdosed; inappropriate home dosing was unrelated to mother's age, child's age, or form of medication (infant drops vs. elixir).[12]

Proper dosing of pain medication is important for several reasons. Sub-therapeutic dosing will not properly manage pain/fever, may lead to unnecessary ED visits, and adds stress to the parent and child, still in pain.[10] Acetaminophen overdose is the number one reason Poison Control Centers are contacted and the cause of 56,000 emergency room visits, 2,600 hospitalizations, and approximately 458 annual deaths due to acute liver failure.[13] Conversely, ibuprofen overdose requires emergent care but,

according to *rxmed.com* no fatalities have been reported, and ibuprofen-associated acute renal insufficiency has been reversible in children.[14]

Children are incorrectly dosed by their caregiver for a variety of reasons. A study in 1992 evaluated 34 cases of reports to poison centers involving liquid medication errors. Seventy-nine percent of errors involved a two-threefold dosing error with 94% of errors involving a single dose of medication. Acetaminophen elixirs made up 18% of the cases with major causes of doing errors found to be teaspoon/tablespoon confusion and assumption that the full dispensing cup was the actual dose.[15] A later study presented a mock scenario requiring 100 caregivers to determine and measure a correct dose of acetaminophen for their child (9-16.5mg/kg was accurate). Only 40% correctly stated the dose and 67% accurately measured the dose they intended. Overall, 43% measured the correct dose for their child with almost 1/3 occurring by accident, leaving only 30% who stated and measured a correct dose. Also of note in this study, 66% reported Tylenol use, while only 8% reported the use of acetaminophen.[16]

More recent studies have found an important link between incorrect dosing and low caregiver health literacy. For example, of 292 caregivers, 23% used nonstandardized liquid dosing instruments and 68% were unaware of weight-based dosing; either misconception was associated with overall inadequate health literacy and lower reading comprehension, via the Test of Functional Health Literacy in Adults (TOFHLA).[17] Low health literacy is highly correlated with low overall literacy, leading these patients to commonly misunderstand prescription information, including often-used over-the-counter (OTC) formulations.

Patients with low literacy have been shown to often misinterpret prescription drug labels. A recent study of patients with low literacy skills (via the Rapid Estimate of Adult Literacy in Medicine – REALM) revealed rates of correct interpretation of 8 warning labels in the range of 0-78%. Besides the most basic label of "take with food," less than 50% of patients could provide adequate interpretations and 29% were reading at or below the 6th-grade level.[18] Another study of 395 English-speaking patients asked to interpret instructions on 5 container labels found that patients with low literacy were less able to understand all 5 labels. For example, given instructions of "take two tablets by mouth twice daily," only 35% could demonstrate the number of pills to be taken daily.[19] These studies highlight the importance of improving readability of medication labels via increasing font size, use of boldface, and policy implementation requiring medication labels to be written at or below the 6th-grade level.[20]

Dental pain is unlike the pain from trauma or a fever. "Toothaches" are often the acute exacerbation of a chronic condition where the child experiences anywhere from sporadic intense pain to constant low-level pain. However, many parents do not seek immediate treatment as they would for trauma/fever. Families may not have private dental insurance, may be unable to miss work, and bringing their child to a hospital's ED often provides only a transient solution.[21] The combination of these factors may drive many parents to attempt to control their child's toothache with OTC pain formulations instead of seeking definitive dental care.

In 2007, Fisher-Owens et al. noted that the dental care of children is often the result of interactions within a multi-factorial model.[26] Dental pain control can be thought

of in the same way in children, as it is affected by many different levels, including but not limited to; pain medications, child-specific factors, family situation, healthcare providers, and the community as a whole (figure 1). At the medication level, we can determine what, if any, pain medication has been given along with specific dosage and frequency, and the continuum of adverse effects. At the child level, factors influencing pain experience can usually be easily determined; for example, reported pain score (0-10), decayed-missing-filled tooth score (dmft) and extent of decay (pulpal involvement). When considering pain management behaviors from the family level, demographic information such as; marital status, education level, annual household income (AHI), and type of insurance are significant. The healthcare provider level explains where parents receive their health information; when this level does not exist for a family, the community becomes a source of information. Also at the family level and bridging into the community level is poverty and health literacy.

Health literacy can be measured by several different methods. The English version of the short TOFHLA (s-TOFHLA) is one way to evaluate health literacy in our population. Developed in 1995, the TOFHLA is a valid and reliable indicator of a patient's ability to read health-related materials.[22] This test consists of a timed, 12 minute reading comprehension section and a 10 minute numeracy section. In 1999, two abbreviated versions (s-TOFHLA) were developed.[23] The brief version is composed of a timed, 7 minute reading comprehension section and a timed, 5 minute numeracy section. While the reliability (as determined by correlation with the REALM) of the comprehension section (r=0.81) was good, the reliability of the numeracy section

(r=0.64) was questionable, hence this section was dropped for the short version. This short version of the TOFHLA with a 36 item reading comprehension section can be administered in 7 minutes with scores indicating inadequate health literacy (0-16), marginal health literacy (17-22), and adequate health literacy (23-36).

While the REALM was developed 8 years before the TOFHLA, it simply consists of patients reading words out loud, thus testing reading skills but not comprehension. Other advantages of the TOFHLA over other health literacy tools are its strong reliability and validity data in English, availability in Spanish, large-font versions, and passages with a wide range of reading levels. For these reasons, the TOFHLA is deemed the "gold standard" of health literacy testing.[24] The short version was preferred in this study due to the higher likelihood of participation if the overall study took no more than 15 minutes, and the limited amount of time the subject had available to participate before their child's case was completed.

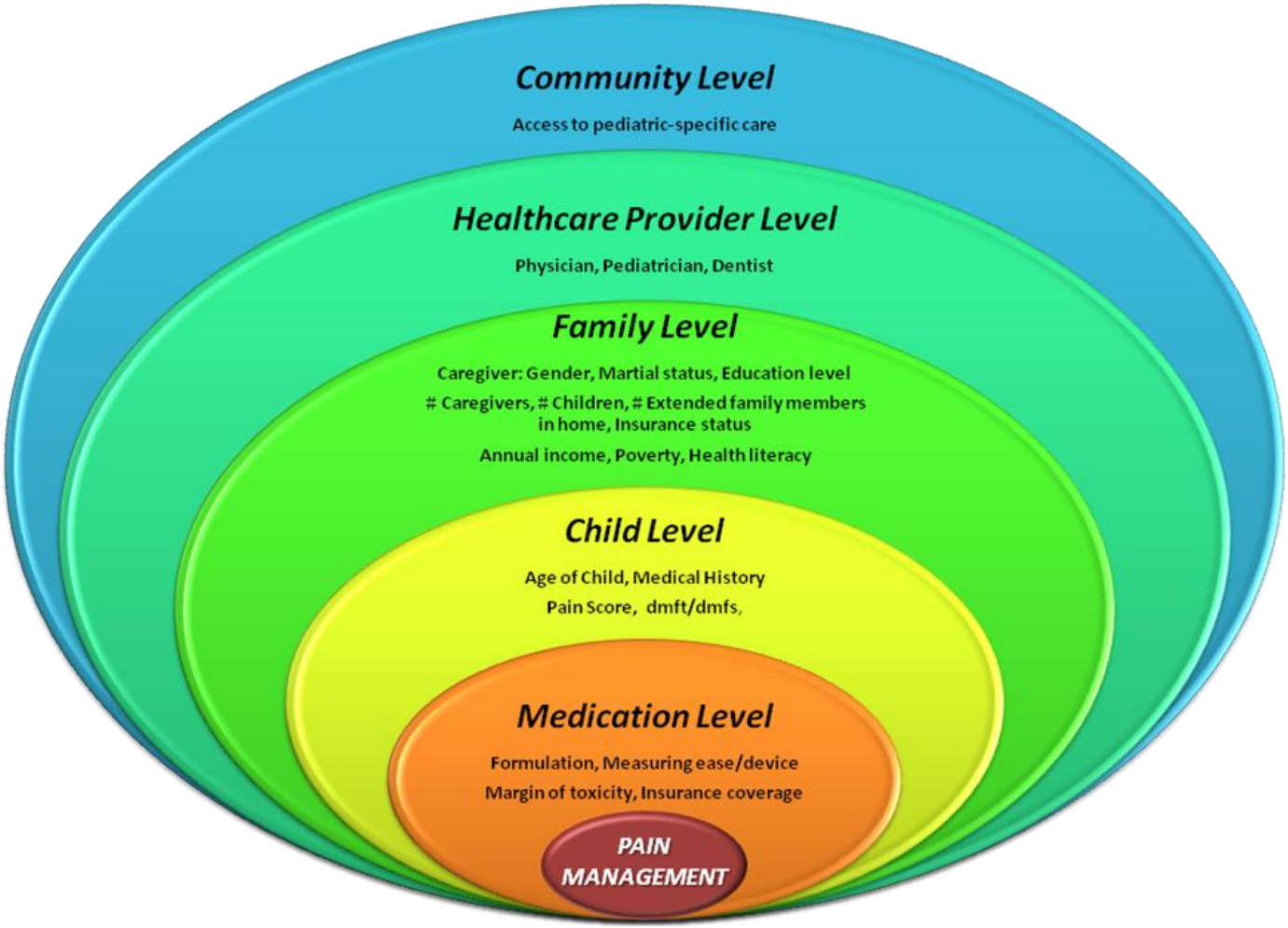

Figure 1: Pediatric analgesia decision ring

Objectives

The overall objective of this study was to examine the relationship between parental health literacy and use of over-the-counter medications. Our specific aims were to 1) determine which medication the parent would choose and why that medication was selected, and 2) evaluate how parents calculated the proper dosage and how the medication is delivered to the child.

Methods

This IRB approved observational study examined a population of primary caregivers of ASA class I or II children age 18-71 months undergoing full mouth rehabilitation under general anesthesia due to severe early childhood caries. Children taking routine pain medication for any chronic illness were excluded from the study. Due to the staff's limitations (only English-speaking), only English-speaking caregivers were included.

The sample (of convenience) was drawn from caregivers of patients scheduled for dental rehabilitation under general anesthesia in the Nationwide Children's Hospital Dental Surgery Center. The typical patient profile included patients that could not tolerate dental treatment in an ambulatory setting due to behavior and/or scope of treatment. Each patient required a diagnosis of severe early childhood caries (S-ECC) as defined by the AAPD. In children younger than 36 months, S-ECC is any sign of smooth-surface caries. From 36-71 months, S-ECC is the presence of ≥1 cavitated, missing, or filled smooth surfaces in primary maxillary anteriors, or a dmft score of >4 (age 3), >5 (age 4), or >6 (age 5).[25] Hereafter, 'subject' refers specifically to the caregiver who completed the survey and study protocol.

Caregivers were informed of the study and invited to participate by one of the two calibrated study staff. If the child's caregiver agreed to participate, verbal and written consent was obtained and the survey was conducted in a private room (appendix A).

First, the subject completed a demographic survey asking about age, sex, number of children, marital status, level of education of caregiver and spouse if applicable, presence and type of dental insurance, AHI, and whether or not they have ever given their child pain medication for a toothache (appendix B,C).

Next the staff showed the caregiver several types of popular children's pain medication: Children's Tylenol®, Infant Tylenol®, Children's Motrin®, Baby Aspirin®, Orajel® for adults, and Orajel® for teething. Using a standard script (appendix D), the subject was asked to choose which of the medications they would administer if their child had a toothache. Once a choice was made, the other medications were removed and the subject was asked how much medicine they would give their child. From this time onward, the subject was able to use information written on the medication bottle and/or package in order to answer study questions.

Unless Orajel® was chosen, measuring tools (syringe/cup that came with medication, measuring spoons for baking, and three sizes of kitchen spoons) were then placed in front of the subject and they were asked to measure out this amount of medication as though they were dosing their child. The amount of medication was then recorded. If the amount was measured using a kitchen spoon or was not at a pre-marked dosing line, medication was measured using a 10 mL graduated cylinder, rounding up to the nearest 1 mL. Study staff was calibrated regarding this protocol. The subject was also asked how much they thought their child weighed. If orajel was chosen, the subject was not asked to choose a measuring tool, but was asked how much they would give and

to demonstrate. The amount of orajel dispensed was estimated by drawing that amount on the survey sheet.

A follow-up survey was then immediately given to the subject (appendix E). Parents were then asked why they selected the medication and to rank all the choices that applied (recommendation from my physician, child's pediatrician, friend, television commercial, it worked before, other). They were also asked how they decided what dose to give their child and to rank all the choices that applied (instructions on bottle, instructions from healthcare provider, child's age, child's weight, amount of pain). Lastly, the parent was asked how often they would give this dose of medication to their child (when my child complains of pain, twice a day, three/four/six/eight times a day).

After the survey on pain medication was completed, the s-TOFHLA (short) was then administered to the subject using standard instructions provided by the test maker. The s-TOFHLA was used in this study for several reasons. The idea of testing the functional aspect of health literacy goes hand in hand with the goals of this study. We are interested in how the subject's health literacy transfers to a functional setting where they are asked to actively participate in a component of health literacy – dosing out medication. One of the authors (ST) was licensed to use the s-TOFHLA instrument (license # 113/08) for research. After reading the instructions out loud, the subject was left alone in the room to complete the survey, unaware they were being timed. During this time other critical information was gathered, such as the child's true weight from their recent history and physical, pain score, and charting of caries. If after seven minutes the subject had not yet completed the survey, no more answers were recorded, as

instructed by the s-TOFHLA manual. The subject was not informed that scoring had stopped if they were unable to complete the s-TOFHLA in 7 minutes.

Once the s-TOFHLA was completed, the subjects were asked if they had any questions or concerns. If they did not properly measure or dose the pain medication, they were advised on how to correctly manage their child's pain, specifically including systemic pain management and dosage based on child's weight. Subjects that properly measured out the pain medication were praised and also informed that dosing is always based on the child's weight. All surveys were administered by either a dentist or a dental student. The dmft/dmfs scores and the number of pulpotomies/extractions were recorded once the child was under general anesthesia.

Analysis

Frequencies for demographics were first calculated and then collapsed if necessary for statistical evaluation. For example, the variable "number of children" had five categories on the survey. Analysis was done on the original data, and then on collapsed data so there were only two or three categories. Collapsed variables include "children in home," "marital status," "education level," "spouse education level," "dental insurance," "AHI," and "poverty."

The predicator variable "poverty" was created after all the surveys were collected. The "2009 Poverty Guidelines for the 48 Contiguous States and the District of Columbia" uses AHI and number of people in the home to determine if a family is living in poverty. To calculate how many people were in the home, we used marital status and number of children in the home. This was compared to the AHI and families were placed in the following categories: definitely in poverty, maybe in poverty, definitely not in poverty. Due to our survey's AHI range in $10,000 increments, some subjects may or may not have been in poverty, thus they were placed in the "maybe in poverty" category.

Predictor variables included; the subject's demographic information and data pertaining to the subject's child. All predictor variables were evaluated for any associations with the outcome variables using Fisher's exact test, the chi-square test, or logistic fit, as appropriate. Additionally, these tests were run between the predictor variables themselves.

Several outcome variables regarding dosing (overdose, correct dose, or underdose) were later calculated using information from the box of chosen medication and also calculated using the medically recommended mg/kg doses (5-10mg/kg for Children's Motrin and 10-15mg/kg for Children's/Infant Tylenol). Additionally, different forms of the same data were evaluated using 1) continuous or ordinal data of the specific amount of ml or kg difference (+/-), 2) ordinal data of an overdose, correct dose, or underdose (over/under), and 3) nominal data of a right versus wrong dose (right). When calculating the daily overdose, medically recommended daily mg/kg doses were used (40mg/kg/day for Children's Motrin and 75mg/kg/day for Children's/Infant Tylenol).

Results

All but five of the caregivers approached by investigators agreed to participate in the study, yielding a total of 108 subjects. No parents were excluded from the study due to incomplete data collection – the analysis was adjusted accordingly (table 1).

Child Level Predictor Variables

The 108 children whose caregivers participated were divided into 57 boys and 51 girls. The mean age of children was 48.0 ± 13.7 months old and the mean weight was 17.4 ± 3.8 kg. Subjects were asked what their child's pain score was that day. 79 subjects (75.2%) responded that their child did not have any tooth pain on the FACES scale, which rated pain from 1-10. Ten children (9.6%) had mild (1-3) pain and 15 (14.4%) had moderate to severe (>3) pain. Subjects were asked if they had ever given their child pain medication for a toothache, and 61.1% (N=66) responded "yes." The mean dmft score was 8.9 ± 3.7 and the mean dmfs score was 22.9 ± 15.1. On average each child had 4 pulpotomies and 3 extractions performed. 17.0% of children did not have any pulpotomies or extractions, and 38.7% of children had ≥ 1 extraction.

Family Level Predictor Variables

When viewing data from a family level, we found that the average subject was 30.3 ± 7.2 years old (range=20-57) with 88.0% being female. Subjects had an average of 2 children at home; 25.0% (N=27) had 1 child, 38.0% (N=41) had 2, 14.8% (N=16) had 3, 9.3% (N=10) had 4, and 13.0% (N=14) had 5 or more. 52 subjects (48.1%) were

married with 36.1% (N=39) being single, 11.1% (N=12) divorced, and 4.6% (N=5) separated.

Reported education level of subjects consisted of 7.5% (N=8) of subjects never completing high school, 47.7% (N=51) with a high school education, 27.1% (N=29) with some college, 14.0% (N=15) with a college degree, and 3.7% (N=4) educated beyond college. If the subject was married, their spouse had a similar education level with 7.0% (N=4) whom did not complete high school, 49.1% (N=28) completed high school, 22.8% (N=13) went to college, 15.8% (N=9) had a college degree, and 5.3% (N=3) were educated beyond college.

Subjects either reported having no insurance (6.5%, N=7)), public insurance (70.4%, N=76), or private insurance (23.1%, N=25). The AHI of most subjects (41.1%, N=44) was under $20,000 with 21.5% (N=23) making $20,000-$30,000, 14.1% (N=15) making $30,000-$40,000, 6.5% (N=7) making $40,000-$50,000, and 16.8% (N=18) making > $50,000. Evaluation of the federal poverty level found 37.0% (N=40) of subjects clearly in poverty, 11.1% (N=12) close to poverty, and 51.9% (N=56) not in poverty.

Predictor Variable Associations

Several factors on the child level were found to correlate with one another or with factors on the family level (table 2). Children in pain were 3.5 times as likely to have been given pain medication before. For children with >3/10 pain, they were 9 times as likely to have been given pain medication before. Likewise, the more pulpotomies/extractions a child needed, the more likely they were given pain medication

before (p=0.039), but also had caregivers who were more likely to measure out less medication than they said they would give (p=0.005), and were more likely to be underdosed according to the box (p=0.003). Male children were less likely to have been given pain medication by their caregivers (p=0.02) but were not significantly less likely to have pulpotomies/extractions (p=0.053). The more decayed teeth a child had (↑dmft), the lower the education of the caregiver (p=0.013), the less likely they had private insurance and the more likely to have no insurance (p=0.012). Subjects making <$20,000 have a child with more carious teeth. Similarly, dmfs also corresponds to education level and type of dental insurance. In addition, subjects with less educated spouses (p=0.007), those who had given their child pain medication before (p=0.044), and children in pain (p=0.020) had a higher dmfs.

Certain demographic variables were found to correlate with one another, as reported here. Subject age was related to the number of children in home, marital status, education level, and AHI. Older subjects were more likely to have more children living at home (p<0.0001) and to be married (p=0.0014). Less educated (p=0.021) subjects and those with a lower AHI (p=0.028) tended to be younger. Male subjects tended to have older children (p=0.033), but no other significant associations were found between gender. Subjects with more children at home were more likely to be married (p=0.042), and more likely to be in poverty (p<0.0008). Subjects with only one child were the most likely to have given their child pain medications before (p=0.035).

Marital status was related to age, number of children at home, education level, AHI and poverty. Single parents are younger (p=0.001), twice as likely to have no

education beyond high school ($p=0.008$), have lower AHIs ($p<0.0001$), and higher levels of poverty ($p=0.0004$). If a subject was married, their spouse's education level was also related to dental insurance type, AHI, and dmfs.

Education level of subjects was associated with age, marital status, spouse education level, type of dental insurance, AHI, poverty, whether pain medications had been given, and dmfs/dmft. Less educated subjects tend to have less educated spouses ($p=0.0008$), and public insurance ($p=0.005$). More educated subjects have higher incomes ($p=0.003$), are less likely to be in poverty ($p=0.0004$), and have a child with a lower dmft ($p=0.013$) and dmfs ($p=0.001$) scores.

A subject's type of dental insurance was correlated with their and their spouse's level of education, AHI, poverty, and dmft/dmfs. Subjects with more than a high school education are twice as likely to have private instead of public insurance ($p=0.005$). As income increases ($p<0.0001$) and poverty declines ($p=0.007$), subjects are more likely to have private or no insurance. Subjects with private insurance had children with lower dmfs ($p=0.003$) and dmft ($p=0.012$) scores.

Subjects that have given their child pain medication before are more likely to have less than a high school education ($p=0.031$), and have a child with dental pain ($p=0.004$) and an increased DMFS ($p=0.047$). Subjects with one child were twice as likely to have given pain medication before ($p=0.035$) while subjects definitely in poverty were less likely to have done so ($p=0.029$).

As previously stated AHI was associated with subject age, marital status, subject and spouse education level, type of dental insurance, and poverty. When evaluating the

community factor of poverty, the only findings that did not mirror AHI include number of children at home, spouse education level, and the child's age. Subjects definitely in poverty are significantly more likely to have more than one child ($p<0.0001$) and their child treated under GA is likely to be older ($p=0.0286$). There was no significant relationship between poverty and the spouse's level of education.

Outcome Variables

When asked to choose what pain medication they would give their child for a toothache, most subjects chose Children's Motrin (46.7%, N=49) or Children's Tylenol (37.1%, N=39; table 3). Hereafter, acetaminophen refers specifically to Children's Tylenol, not Infant Tylenol, and ibuprofen (IBU) refers to Children's Motrin. No subjects chose baby Aspirin or Orajel marketed for "toothache pain relief." Infant Tylenol was selected by 1.9% (N=2) of subjects (child ages 4 and 5 years old) and 14.3% (N=15) chose baby Orajel marketed for "teething pain relief." Four additional subjects chose Orajel (17.6% total) in conjunction with IBU or acetaminophen. Of the subjects who chose IBU or acetaminophen, 94.4% (N=85) used the measuring tool (cup or syringe) that came with the medication while 3.3% (N=3) used baking measuring spoons and 2.2% (N=2) used a medium-sized kitchen spoon.

The subjects were asked what dose they would give their child, and only 64.5% (N=60) measured out the same dose that they said they would give, with 25.8% (N=24) measuring out more, and 9.7% (N=9) measuring out less. Taken as a whole, on average the subjects measured out 0.07 ± 1.99 more ml of medicine than they said they would. Most subjects (73.6%, N=78) knew within a kg how much their child weighed; however,

18.9% (N=20) thought their child was lighter and 7.5% (N=8) thought their child was heavier. The average guess was 0.28±1.5 kg below the child's actual weight.

According to the chosen medication's directions and their child's actual weight, 34.5% (N=30) of subjects underdosed their child, 46.0% (N=40) gave their child the recommended dose, and 19.5% (N=17) overdosed their child. According to the physician-recommended mg/kg dose, 22.2% (N=20) of parents underdosed, 67.8% (N=61) dosed correctly, and 10% (N=9) overdosed.

Subjects (N=89) who chose a single top choice for why they selected a specific medication mostly did so due to their "child's pediatrician" (47.2%, N=42). Subjects also selected based on "recommendation from my physician" (22.5%, N=20), "it worked before" (20.2%, N=18), "friend" (2.2%, N=2), and TV commercial (2.2%, N=2). Only 5.6% (N=5) of subjects wrote their own answer as their top choice. When subjects who chose several top choices were included in the distribution (N=108), 51.9% (N=56) chose "child's pediatrician," 30.6% (N=33) chose "recommendation from my physician," 21.3% (N=23) chose "it worked before," 9.3% (N=10) chose their own answer, 3.7% (N=4) chose "friend," and "2.8% (N=3) chose "TV commercial."

Subjects (N=72) who chose a single top choice for how they decided on a specific dose mostly did so due to "instructions on bottle" (43.1%, N=31). Subjects also decided based on "instructions from healthcare provider" (26.4%, N=19)), "child's weight" (13.9%, N=10), "child's age" (11.1%, N=8), and "amount of pain" (5.6%, N=4). When subjects who chose several top choices were included in the distribution (N=108), they also mostly decided based on "instructions on bottle" (54.6%, N=59). Other reasons

included “child’s weight” (36.1%, N=39), “instructions from healthcare provider” (33.3%, N=36), “child’s age” (22.2%, N=24), and “amount of pain” (4.6%, N=5).

Most subjects (27.8%, N=30) reported they would give this dose four times a day; other subjects chose three times a day (24.1%, N=26), twice a day (17.6%, N=19), six times a day (15.7%, N=17) or when the child complains of pain (14.8%, N=16). No subject said they would give the dose eight times a day. Two subjects who chose a specific daily dose also said they would dose when the child complains of pain; this brings the total to 16.7% (N=18) of caregivers that would dose pain medication if the child complains of pain.

Using the physician-recommended daily maximum doses as a guide, 10 (11.1%) subjects would have overdosed their child. Three of these subjects gave a correct single dose, but due to the frequency of dosing, would have exceeded the daily recommended dose. The other 7 subjects who overdosed daily also overdosed their single measured dose.

TOFHLA Scores and Associations

The average TOFHLA score was 34.5 ± 3.66 with a total of 36 points possible. Only 8.4% (N=9) of subjects scored below a 34. This score was significantly associated with education level and spouse education level. Lower TOFHLA scores were associated with subjects with no more than a high school education (p=0.024). Subjects scoring lower on the TOFHLA were more likely to have spouses with no more than a high school education (p=0.018). Subjects scoring <34 on TOFHLA were almost 4 times as likely to underdose by mg/kg (p=0.010) and by the box’s instructions (p=0.012) while subjects

scoring higher on the TOFHLA were more likely to overdose (p=0.020). Those scoring <34 on TOFHLA were 11 times more likely to choose a medication based on a "TV commercial" (p=0.019).

Child Level Associations

Certain demographic or child factors were associated with specific outcomes (table 4). Analyzing the data at the child level revealed that the younger the child, the more likely the parent measured a different dose than they said they would (p=0.019). Older children are more likely to have caregivers who choose a medication based on the child's pediatrician (p=0.046) and dose based on the bottle's instructions (p=0.022). Younger children are more likely to have caregivers who dose based on instructions from a healthcare provider or based on the child's weight (p=0.022). Heavier children had caregivers more likely to both guess the wrong weight for their child (p=0.036) and to incorrectly dose based on the box's instructions (p=0.018).

Children in pain were more likely to have caregivers who correctly guessed their weight (p=0.039), chose medication based on a friend (p=0.046), and were 3 times as likely to chose a dosing frequency of 6 times per day (p=0.044). Children with higher dmft/dmfs scores were more likely to have caregivers who correctly guessed their weight (p=0.006/0.006), yet incorrectly underdosed using the box's instructions (p=0.024/0.013). High dmft scores were also associated with caregivers choosing a measuring tool other than what the medication came with (p=0.023). Children with low dmfs scores had caregivers who were more likely to choose a medication because it worked before

(p=0.045) and to dose based on the box's instructions (p=0.021). No associations with outcome variables were found with parents who had given pain medication before.

Family Level Associations

Evaluation at the family level revealed that younger subjects were more likely to give orajel alone or in combination, yet not significantly so. Every parent over 27 years old used the measuring tool the box came with, showing that younger subjects are more likely to choose a different tool (p=0.001). The older the subject, the more likely they know their child's weight (p=0.049) and measure out the same dose they said they would (p=0.040). Younger subjects are more likely to underdose per mg/kg recommendations (p=0.003) and using the box's instructions (p=0.004) while older parents are more likely to overdose via mg/kg (p=0.003) and the box's instructions (p=0.004). Older subjects are also more likely to give their child a daily overdose (p=0.009).

Evaluating gender, several differences were noted. While only 3.8% of females picked a different measuring tool, 20.0% of males did so (p=0.034). Male caregivers (90%) were also more likely to incorrectly dose according to the box's instructions compared to females (49.4%) (p=0.015). When mg/kg dosing was evaluated, males gave the wrong dose twice as much as females (p=0.046).

Only subjects with >1 child chose a medication as their number one reason because it worked before (p=0.032). Subjects with only one child were more likely to choose a medication based on the child's pediatrician (p=0.022) or based on a friend (p=0.048) than a subject with >1 child.

Divorced subjects (41.7%) were more likely to choose orajel only as a medication compared to all other subjects, especially married subjects (6.12%) (p=0.011). More married subjects than any other marital status chose a medication based on a recommendation from their physician (p=0.007) and were twice as likely to decide the dose based on weight (p=0.003).

Education level was found to be associated with several of the outcome variables when split into two groups. Subjects with more than a high school education were less likely to choose a different measuring tool (p=0.033F) yet more likely to overdose according to the box's instructions (p=0.035). Subjects with no more than a high school education were more likely to underdose according to the box's instructions (p=0.011). Of those who measured out less than they said they would, 88.9% had up to a high school education while only 11.1% had more than a high school education (p=0.042). Lower TOFHLA scores were associated with subjects with no more than a high school education (p=0.024). When education was broken into 5 levels, it was found that 2 of the 3 subjects with more than a high school education overdosed daily (p=0.044) and the only subjects who overdosed daily only due to an error in frequency of dosing had only a high school education (p=0.011).

The less educated a subject's spouse, the more likely the spouse was to choose orajel alone or in conjunction (p=0.013). The only subjects who chose orajel only had spouses with no more than a high school education (p=0.029). No subject with a spouse educated beyond high school decided on dosage based on amount of pain (p=0.028).

Subjects scoring lower on the TOFHLA were more likely to have spouses with no more than a high school education (p=0.018).

Insurance type was associated with only two outcome variables. Subjects with private insurance were more likely to overdose their child according to mg/kg recommendations (p=0.037). More subjects with no insurance (28.6%) decided dosage based on amount of pain than subjects with public insurance (3.9%) or private insurance (0%) (p=0.006).

Depending on how AHI was split into groups, several outcome variables were found to be significantly different. Subjects making <$30,000 were more than three times as likely to choose orajel alone or in combination (p=0.024). Subjects making <$20,000 were more likely to choose a medication based on a T.V. commercial (p=0.020/0.067). As income increases, subjects were more likely to decide dosage based on weight (p=0.048).

While poverty is closely associated with AHI, different associations with outcome variables were found. Only subjects definitely in poverty incorrectly chose Infant Tylenol and were more than twice as likely to choose Orajel (p=0.034). Only subjects definitely in poverty said their number one reason for selecting a medication was due to a TV commercial and they never selected based on a friend (p=0.021). Only subjects definitely not in poverty chose a medication based on a friend (p=0.020) and never selected based on a TV commercial (0.034/0.108). The only subjects who primarily decided dosage based on the amount of pain were definitely in poverty (p=0.026).

Medication Level Associations

Several outcomes were found to correlate with which medication was chosen (table 5). Subjects who underdosed according to mg/kg were 2.5 times more likely to chose acetaminophen over IBU subjects who overdosed according to mg/kg were 4 times more likely to chose IBU over acetaminophen (p=0.005). Several significant associations were found involving the reason medication was chosen (p=0.008). Of subjects who chose acetaminophen, IBU or Orajel, the most common reason was "child's pediatrician." While the 2nd most common answer for subjects who chose acetaminophen or IBU was "recommendation from my physician," subjects who chose Orajel answered "because it worked before." Subjects who chose orajel were the only subjects to chose "friend" as their reason, and the only subjects who chose based on a "TV commercial" incorrectly chose Infant Tylenol or Orajel. 24% of subjects choosing Orajel wrote their own top choice, stating "because it's for a child," "my own judgment," "and "just a guess." 75% of subjects who decided dose based on "amount of pain" incorrectly chose Infant Tylenol or Orajel (p=0.014).

Subjects who chose Orajel alone or in conjunction were twice as likely to choose dosing frequency based on pain or twice a day; these subjects never chose a dosing frequency over four times a day (p=0.018). 90% (N=9) of subjects who daily overdosed their child chose IBU while the other 10% (N=1) chose acetaminophen (p=0.034). Subjects choosing a different measuring tool than what the medication came with were more than 8 times more likely to measure less than they said they would (p=0.012).

When a subject thought their child weighed at least 1kg less than the actual weight, they measured out more than they said they would; vice versa when a subject thought their child weighed at least 1kg more than the actual weight, they measured out less than they said they would (p=0.031). Subjects who are at least 1 kg off their child's actual weight were twice as likely to chose dosing frequency based on "amount of pain" (p=0.040F).

Different spoken and measured doses were correlated to measuring accuracy. 77.8% of subjects who measured less than the spoken dose underdosed according to the box and 50% of subjects who measure more than the spoken dose overdosed according to the box. Only 39.3% of subjects with the same spoken and measured dose incorrectly dosed according to the box (p<0.0001). Subjects who overdosed daily were 4 times more likely to have measured a different dose than spoken (0.026F).

Dosing according to the box was found to have several correlations beyond spoken dose differences. The only subjects who overdosed by mg/kg also overdosed by the box while 2.6% of subjects who correctly measured by the box actually underdosed by mg/kg (p<0.0001). Subjects who correctly measured by the box were over 6 times less likely to daily overdose their child (p=0.030F).

Dosing according to mg/kg was highly correlated with dosing according to the box's instructions (p<0.001). Of subjects who overdosed by mg/kg, 90% chose the medication due to their "child's pediatrician" (p=0.032F). Subjects who overdosed by mg/kg were 18 times more likely to daily overdose with 70% of subjects who daily overdosed their child also overdosing according to mg/kg (p<0.0001). When subjects

scored <34 on the TOFHLA they were almost 4 times more likely to underdose by mg/kg (p=0.010).

When evaluating why parents selected and dosed certain medication, associations varied whether assessing subjects with a single top choice or when including those with multiple top choices. Subjects who decided dose frequency based on "instructions on bottle" or "child's pediatrician" never selected a medication based on a "friend" or a "TV commercial" (p=0.003). Subjects who chose Orajel were almost 3 times less likely to select medication based on "child's pediatrician" (p=0.013F). Those who selected the medication based on a "friend" were 3.5 times more likely to chose dose based on "child's age" (p=0.034F).

Pain was related to medication selection and dosing. 40% of subjects who decided a dose based on "amount of pain" also chose Orajel (p=0.005P). Those who decided dosing schedule based on "amount of pain" most often chose a medication based on a "TV commercial" (p=0.006). When dosing frequency of "when child complains of pain" was selected, the subject was 13 times more likely to have chosen that dose based on the "amount of pain" (p=0.046). Vice versa, subjects who chose a dose based on the "amount of pain" were 7.5 times more likely to choose a dosing frequency of "when child complains of pain" (p=0.032F). Pain was also related to weight accuracy. Subjects who did not guess their child's weight within 1kg were twice as likely to choose a dosing frequency of "when child complains of pain."

Dosing frequency was related to medication selection and daily overdosing. As the dosing frequency increased, so did the likelihood the subject chose acetaminophen.

Subjects who chose IBU tended to dose less frequently, with subjects who chose Orajel dosing the least frequently ($p=0.045$). As expected, subjects who daily overdosed their child were twice as likely to choose a frequency of 4 or 6 times per day ($p=0.010$).

To summarize, risk factors for daily overdosing include choosing IBU ($p=0.034$), measuring out a different dose than spoken ($p=0.023$), measuring more than the box's instructions ($p<0.0001$), measuring more than the recommended mg/kg ($p<0.001$), and a dosing frequency of more than 3 times per day ($p=0.010$).

	Total (N=108)	
	mean ± SD	
Age (yrs)	30.3 ± 7.2	
Child's weight (kg)	17.4 ± 3.8	
Child's age (mo)	48.0 ± 13.7	
Child's DMFT	8.9 ± 3.7	
Child's DMFS	22.9 ± 15.1	
	No.	(%)
Gender		
Male	13	12.0
Female	95	88.0
No. of children in home		
1	27	25.0
2	41	38.0
3	16	14.8
4	10	9.3
≥5	14	13.0
Marital status		
Single	39	36.1
Married	52	48.1
Separated	5	4.6
Divorced	12	11.1
Education level		
< High school	8	7.5
High school	51	47.7
Some college	29	27.1
College degree	15	14.0
> college	4	3.7
Spouse education level		
< High school	4	7.0
High school	28	49.1
Some college	13	22.8
College degree	9	15.8
> college	3	5.3
Insurance type		
None	7	6.5
Public	76	70.4
Private	25	23.1
Annual income		
< $20,000	44	41.1
$20,000 - $30,000	23	21.5
$30,000 - $40,000	15	14.0
$40,000 - $50,000	7	6.5
> $50,000	18	16.8
Poverty		
Yes	40	37.0
Maybe	12	11.1
No	56	51.9
Pain meds given		
Yes	66	61.1
No	42	38.9
Child's pain score		
None (0/10)	79	75.2
Mild (1-3/10)	10	9.6
Moderate-severe (> 3/10)	15	14.4

Table 1: Demographic information

	Age	Gen	CIH	CIH3	CIH2	MS	MS2	EL	EL2	SEL	SEL2	DI	DI2	AHI	AHI4	AHI2	AHI2b	Pov1	Pov2	Pov3	PMG	Wt	CAM	Pain2	Pain3	DMFT	DMFS
Age	--		***	***	**	**	*	*	*					*	*		*										
Gen		--																					*		*		
CIH	***		--	--	--													***		**							
CIH3	***		--	--	--	*	*											***		**	*						
CIH2	**		--	--	--													***		***	*						
MS	**			*		--	--		**					***	***	***	**	**	**	**							
MS2	*			*		--	--	**	**					***	***	***	***	**	***	**							
EL	*						**	--	--	**	**	**	**	**	**	**	**	**	**	**	*					*	**
EL2	*					**	**	--	--	*	**	**		**	**	**	**	**	**	**						*	*
SEL								**	*	--	--	*		**	**	*											*
SEL2								**	**	--	--	**	**	**	**	**	*			*							**
DI								**	**	*	**	--	--	***	***	**	***	**	**	*						*	**
DI2								**	**	*	**	--	--	***	***	*	***	*	**	*						*	**
AHI	*					***	***	**	**	**	**	***	***	--	--	--	--	***	***	***							
AHI4	*					***	***	**	**	**	**	***	***	--	--	--	--	***	***	***							
AHI2						***	***	**	**	*	**	**	**	--	--	--	--	***	***	***						*	
AHI2b	*					**	***	**	**		*	***	***	--	--	--	--	***	***	***							
Pov1			***	***	***	**	**	**	**			**	*	***	***	***	***	--	--	--	*						
Pov2			*			**	***	**	**			**	**	***	***	***	***	--	--	--							
Pov3			**	**	***	**	**	**	**		*	**	*	***	***	***	***	--	--	--			*				
PMG				*	*			*										*			--			**	**		*
Wt																						--					
CAM		*																		*			--				
Pain2																					**			--	--		*
Pain3		*																			**			--	--		*
DMFT								*	*			*	*			*										--	--
DMFS								**	*	*	**	**	**								*			*	*	--	--

Table 2: Interactions between predictor variables

	Total (N=108)	
	mean ± SD	
Wt +/- (guessed weight)	-0.28 ± 1.5	
Measured-spoken +/-	0.070 ± 1.99	
MD +/-	-0.02 ± 0.46	
Box +/-	-.041 ± 0.64	
TOFHLA score	34.5 ± 3.66	
	No.	(%)
Q1		
(a) Children's Tylenol	39	37.1
(b) Infant Tylenol	2	1.9
(c) Children's Motrin	49	46.7
(d) Aspirin	0	0.0
(e) teething Orajel	15	14.3
(f) toothache Orajel	0	0.0
Orajel, alone/conjunction	19	17.6
Measuring tool		
Came with medication	85	94.4
Different tool	5	5.6
Wt over/under		
Thought child was lighter	20	18.9
Correct	78	73.6
Thought child was heavier	8	7.5
Wt right		
Correct	78	73.6
Incorrect	28	26.4
Measured-spoken over/under		
Measured less than said	9	9.7
Measured = spoken	60	64.5
Measured more than said	24	25.8
Measured-spoken right		
Correct	60	64.5
Incorrect	33	35.5
MD over/under		
Underdosed mg/kg	20	22.2
Correct	61	67.8
Overdosed mg/kg	9	10.0
MD right		
Correct	61	67.8
Incorrect	29	32.2
Box over/under		
Underdosed using label	30	34.5
Correct	40	46.0
Overdosed using label	17	19.5
Box right		
Correct	40	46.0
Incorrect	47	54.0

	Total (N=108)	
	No.	%
Med selection (single top choice)		
(a) My physician	33	30.6
(b) Child's pediatrician	56	51.9
(c) friend	2	2.2
(d) TV commercial	2	2.2
(e) It worked before	18	20.2
Med selection (all top choices)		
(a) My physician	33	30.6
(b) Child's pediatrician	56	51.9
(c) friend	4	3.7
(d) TV commercial	3	2.8
(e) It worked before	23	21.3
Dosage decision (single top choice)		
(a) Instructions on bottle	31	43.1
(b) Healthcare provider	19	26.4
(c) child's age	8	11.1
(d) Child's weight	10	13.9
(e) Amount of pain	4	5.6
Dosage decision (all top choices)		
(a) Instructions on bottle	59	54.6
(b) Healthcare provider	36	33.3
(c) child's age	24	22.2
(d) Child's weight	39	36.1
(e) Amount of pain	5	4.6
Frequency of dosing		
(a) Child complains of pain	16	14.8
(b) Twice a day	19	17.6
(c) Three times a day	26	24.1
(d) Four times a day	30	27.8
(e) Six times a day	17	15.7
(f) Eight times a day	0	0.0
Dosing if pain (in conjunction)	18	16.7
Daily Overdosing (OD3)		
Did not overdose daily	80	88.9
Overdosed - freq error only	3	3.3
Overdosed - single dose error	7	7.8
Daily Overdosing (OD2)		
Did not overdose daily	80	88.9
Overdosed daily	10	11.1
TOFHLA score2		
Scored < 34	9	8.4
Scored ≥ 34	98	91.6

Table 3: Outcome variables

	Age	Gen	ClH	ClH3	ClH2	MS	MS2	EL	EL2	SEL	SEL2	DI	DI2	AHI	AHI4	AHI2	AHI2b	Pov1	Pov2	Pov3	PMG	Wt	CAM	Pain2	Pain3	DMFT	DMFS
Q1						*p	*				*							*		*							
Orajel	*									*	**				*		*										
Med tool	**	*							**																	*	
Wt +/-																											
Wt o/u																											
Wt right	*														*							*		*	*	**	**
Meas-sp +/-																											
Meas-sp o/u									*																		
Meas-sp right	*																						*				
Meas MD +/-		*						*	**			*	*														
Meas MD o/u	**																										
Meas MD right		*																									
Meas box +/-	**								*																		
Meas box o/u	**	*							*																	*	*
Meas box right		**																				*					
Med selection					*	*	*													*							
sA																											
sB					*													*		**			*				
sC					*											*			*					*	*		
sD																*			*								
sE			**	**	**					*																	*
Dose decision																				*			*				
dA																											*
dB																											
dC								*																			
dD						**	**							*			**										
dE											*	*								*							
dF																											
Freq		*																						*	*		
If pain																											
DailyOD3	*							*																			
DailyOD2	**							*																			
Score									*		*																
Score2											*																

Table 4: Associations between predictors and outcomes

	Q1	Orajel	Med tool	Wt +/-	Wt o/u	Wt right	Meas-sp +/-	Meas-sp o/u	Meas-sp right	MD +/-	MD o/u	MD right	Box +/-	Box o/u	Box right	Med selection	sA	sB	sC	sD	sE	Dose decision	dA	dB	dC	dD	dE	dF	Freq	If pain	DailyOD3	DailyOD2	Score	Score2
Q1		***									**					**				*		*										*		
Orajel	***															**		*	*							*	*		*					
Med tool								*	*																									
Wt +/-																																		
Wt o/u							*																											
Wt right																														*				
Meas-sp +/-					*																													
Meas-sp o/u			*											***	**																*			
Meas-sp right			*											**	**																*			
MD +/-													***	**	*																*	*		
MD o/u	**												***	***	***			*												***	***		*	
MD right														***	***															***	*		*	
Box +/-								***			***	***																		***	**		*	
Box o/u								***	**		***	***																		**	**	*		
Box right								**	**		***	***																		*	*			
Med selection	**	**																				**				**						*	*	
sA																		**			**				*								*	
sB		*									*						**				***			*							*		*	
sC		*																							*									
sD	*																					*				**								
sE																	**	***				*	*												
Dose Decision	*															**				*										*				
dA																					*			***										
dB																		*					***											
dC																			*							*								
dD		*															*								*									
dE	**p	*														**				**										*				
dF																																		
Freq	*	*																													*	**		
If pain						*																*				*								
DailyOD3											***	***	***	**	*			*											*					
DailyOD2	*							*	*		***	*	***	**	*														**					
Score														*		*		*																
Score2											*	*	*			*	*																	

Table 5: Associations between outcome variables

Discussion

Our results suggest multiple variables in the management of a child's dental pain. These variables can be arranged graphically on levels in a Pediatric Analgesia Decision Ring (figure 1). It is intuitive to think that for different children the variables contribute with different weights to their course of analgesia. Through analysis of the variables presented in this study, we have arranged the levels as: community level, healthcare provider (HCP) level, parent level, child level, and medication level.

It is evident that certain specifics in each level may contribute to morbidity from acute and chronic dental pain management in children. These morbidities may include: organ toxicity, sub-therapeutic analgesia, and in some cases, death.

Healthcare Provider Level

While not expressly measured in this study, the healthcare provider (HCP) level can serve as a critical link between other levels. The HCP level explains where parents receive their health information, whether it is a physician, dentist, or nurse, etc. When the HCP level does not exist for a family, the community (including the media) becomes a source of information which is often misleading or incorrect. The goal of the HCP level is to bridge the gap between the family and the community in order for families to have accurate health information in order to make educated decisions regarding their healthcare.

Medication Level

Factors such as specific type of analgesic, systemic vs. topical route, ease of measuring, margin of toxicity and insurance coverage can directly influence management of the child's tooth pain.

In this prospective, case cohort series, 14% of caregivers chose benzocaine (Orajel) alone to manage their child's dental pain. There is no literature to establish that Orajel ameliorates odontogenic-based pain. Systemic pain medication has been confirmed as more effective in this situation, yet many caregivers chose "Baby Orajel – For Teething" to manage their child's toothache, despite the fact that their child was not a baby or teething. This suggests that caregivers are influenced by the community level in some fashion and not receiving proper information from the HCP level. As HCPs, dentists and physicians alike need to stress to all caregivers that pain medication is best managed systemically. It is the HCP level that provides this "bridge" between the community and family levels.

Almost all daily overdoses were with ibuprofen (IBU). All systemic side effects of IBU overdose have been found to be reversible in children, unlike APAP. Therefore, most of these caregivers have theoretically not run the risk of irreversible systemic damage in their child. IBU's acceptable range according to standard published medical guidelines is 5-10mg/kg[27] while according to the box instructions, the range is 6.3-9.2mg/kg. Acetaminophen's acceptable range according to standard published medical guidelines is 10-15mg/kg[28] while according to the box instructions, the range is 10.1-14.7mg/kg. When a single dose was evaluated using the box, significantly more

caregivers measured the incorrect amount of medication versus when the dose was evaluated using mg/kg. This suggests that even when a parent incorrectly doses according to the box, the child does not necessarily receive the wrong dose of medication according to mg/kg due to a wider range.

Child Level

The child can directly feed upon and from factors at the family and medication level. The caregiver may not want to give a large dose to a very young child, and feel comfortable with an adult dose for an older child. Also, the caregiver has the choice of what type of medication to give the child, and this may be influenced by how much the child says his teeth hurt and if the parents can see obvious large cavities. In addition, if a child has a low dmfs/dmft score, he may only be in mild pain, thus his pain will easily be managed.

Within subjects, 26.4% of caregivers did not know how much their child weighed and 14% said that the number one reason for choosing their dose was based on the child's weight. This underscores the importance of anticipatory guidance for caregivers about weight-based dosing. While not all caregivers know how much their child weighs, 74% in our study were within 1kg of the correct weight. Armed with knowledge from the "HCP level" about weight-based dosing, more caregivers should be able to choose the correct dose of pain medication for their child.

Our study found that younger children were more likely to have caregivers who measured out less medication than they said they would ($p=0.019$). One possible explanation would be that caregivers are concerned about giving too much pain

medication to a young child so even though they know the correct dose to give; they still measure out less to be cautious. As previously mentioned, sub-therapeutic dosing does not properly manage pain. This may lead caregivers to give a lower dose of pain medication more frequently since their child will not stop complaining of pain. Ironically this could put the child at risk for a daily overdose of pain medication, despite the fact that each individual dose was under-measured.

Children in pain had caregivers that were three times more likely to choose a dosing frequency of six times per day; hence children with dental pain are at higher risk for daily overdosing due to frequency errors. Conversely, it was found that children with high dmfs scores had caregivers whom were more likely to underdose ($p=0.013$). This may be due to caregivers giving pain medication frequently enough that they do not want to give too much each time, thus they compensate by underdosing each individual dose.

Of note, children whose caregivers said they were in pain were not significantly more likely to have pulpotomies and extractions done under general anesthesia ($p=0.222$). These findings are in accordance with other hospital-based studies revealing that parents (and HCPs) are poor predictors of the level of pain a child is experiencing.[1,2,3] This intuitively casts doubt on how well parents are able to recognize dental pain in their children and whether children are capable of effectively communicating this information.

Family Level

The family level includes many caregiver attributes that strongly influence how a child's dental pain will be managed, such as; caregiver gender, marital status, and

education level along with the number of children in the home, insurance status, AHI, and health literacy. The caregiver often chooses how to manage their child's dental pain based on personal factors and interactions at the HCP / community level.

Influence of Caregiver Health Literacy

When evaluating the s-TOFHLA in this study, it was clear that either there is another better measure of health literacy, or health literacy cannot be equated with the ability to correctly choose and measure medication. Evaluating the former, it should be noted that the s-TOFHLA has no numeracy section. *Numeracy* in health literacy assessment is defined as proficiency in the ability to apply mathematical knowledge. Therefore, either the full version of the TOFHLA, or health literacy tests such as the Newest Vital Sign (NVS) that includes both a numeracy and interpretation (of a nutrition label) component may have been more appropriate in this study. A counterpoint to this suggestion is the fact that, measuring out medication is simply a small part of health literacy, and perhaps something that has little to do with the overall health literacy of a patient. Regardless, the results from this study emphasize that because a subject scores well on a health literacy survey does not mean that the subject has the knowledge to correctly choose and measure out pain medication for a child. This underscores the importance of properly educating all caregivers about managing their child's pain.

The findings from this study emphasize a critical point in management of a child's dental pain; a child's pain can be mismanaged regardless of SES. Caregivers with no more than a high school education were significantly more likely to measure less than they said they would give ($p=0.042$) and underdose according to the box and mg/kg

(p=0.035). Conversely, caregivers with more than a high school education were more likely to overdose according to the box and mg/kg. We also found that 2/3 of caregivers with more than a college degree overdosed daily. In our study less-educated caregivers are more likely to give a sub-therapeutic dose of pain medication while more-educated caregivers are more likely to give their child too much pain medication and put their child at risk for drug overdose. This highlights the fact that we need to improve caregiver education regarding systemic pain medication. If caregivers are not receiving their information from the "HCP level," then they are possibly receiving misinformation from the "community level," whether through the media or a friend.

Conclusions

1. Children in pain had caregivers that were 3 times more likely to choose a dosing frequency of six times per day
2. Children with dental pain are at higher risk for daily overdosing due to frequency errors.

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Appendix A: Consent form

CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY

STUDY TITLE: Health Literacy Associated with Parental Management of Dental Pain in the Child

STUDY SPONSOR: Nationwide Children's Hospital – Dental Clinic

STUDY DOCTOR: Dr. Sarat Thikkurissy

CONTACT TELEPHONE NUMBER: 614-690-0398 (pager)

SUBJECT'S NAME: _____ DATE OF BIRTH: _____

NOTE: The words "you" and "your" are used in this consent form. These words refer to the study volunteer whether a child or an adult.

1) INTRODUCTION

We invite you to be in this research study because it will help us learn how parents give pain medication when appropriate for children with dental pain. Please learn enough about this research study, its risks and benefits, to decide whether you should agree to participate. We must explain the study to you, and give you a chance to ask questions about anything you do not understand. This process is called "informed consent". It is up to you to choose if you want to be in this study. You may refuse to be in this study or quit this study at any time, and standard medical care will still be available here or at a doctor of your choice without a penalty or loss of benefits to you. It is important to understand that there may not be any benefit from being in this study, but we may learn something that could help others.

Before agreeing to participate, it is important to read and understand the study information in this consent form**.** By signing the consent form, you agree to be in this study.

2) WHY ARE WE DOING THIS RESEARCH STUDY?

This is a study to find out what types of pain medication parents are giving their children for toothaches and why. It will also tell us whether or not children are receiving the right amount of pain medication. While physicians have looked at how parents manage their child's fever or sudden injury, few have studied how parents manage their child's tooth pain. This study is necessary to know if parents are giving the correct amount of medication for a tooth ache and will allow us to educate you on how to decide how much pain medicine to give your child. This study will also bring awareness to the dental community regarding use of over-the-counter pain.

3) WHERE WILL THE STUDY BE DONE AND HOW MANY SUBJECTS WILL TAKE PART?

This study will be done at Nationwide Children's Hospital. About 100 subjects will take part in this study in the Dental Surgery Center.

4) WHAT WILL HAPPEN DURING THE STUDY AND HOW LONG WILL IT LAST?

This survey will take approximately 15 minutes total.
1 – the consent form will be reviewed
2 – we will ask some questions to decide if you are eligible for this survey (1 minute)
3 – survey part I – questions about you; for example: age, education, income (1 minute)
4 – survey part II – measuring medication (5 minutes)
5 – S-TOFHLA (short version of the Test of Functional Health Literacy in Adults) (7 minutes)

5) WHAT BAD THINGS CAN POSSIBLY HAPPEN DURING THIS STUDY?

It is important that you give the study staff correct information about your child's medical history so that the proper amount of pain medication can be determined for your child.

6) WHAT GOOD THINGS CAN POSSIBLY HAPPEN DURING THIS STUDY?

You will learn how to give your child the correct amount of over-the-counter pain medication. Possible benefits might include raising awareness among dentists to reinforce proper pain management.

7) HOW WILL MY STUDY INFORMATION BE KEPT PRIVATE?

Information collected for this study is confidential to the extent provided by law. Data collected and entered into the Case Report Forms are the property of the study sponsor, Dr. Sarat Thikkurissy. In the event of any publication regarding this study, your child's identity or your identity will not be revealed. Employees from the following organizations may receive copies of the study records and may review your child's medical records related to this study:

PI and their research employees
The Office for Human Research Protections (OHRP)
The Nationwide Children's Hospital Institutional Review Board (a committee that reviews all human subject research)

Information collected for this study will be kept confidential to the extent allowed by law. Information used and/or disclosed (shared with someone outside of Nationwide Children's Hospital) may include information that can identify you. This is called "protected health information" or PHI. By agreeing to be in this study, you are giving permission or authorizing Dr. Sarat Thikkurissy and his study staff to collect, use, and disclose your PHI for this research study. Information collected is the property of Dr. Thikkurissy In the event of any publication regarding this study, your identity will not be revealed.

PHI that may be used or disclosed: *Birth Date; Survey Date; Medical Record Number of child*
Reason(s) why the use or disclosure is being made: These disclosures are made to be able to locate medical charts, and to have access to the child's dental record and its contents. The Birth date will provide us with the age of child, which is a variable that we will be analyzing.

You may decide not to authorize the use and disclosure of your PHI. However, if it is necessary for this study, you will not be able to be in this study. If you agree to be in this study and later decide to withdraw your participation, you may also withdraw your authorization to use your PHI. This request must be made in writing to the Principal Investigator. If you withdraw your authorization, no new PHI may be collected and the PHI already collected may not be used unless it has already been used or is needed to complete the study analysis and reports.

Dr. Thikkurissy keeps a database of all subjects who participate in a research study. Only *Dr. Thikkurissy* and his staff have access to this database. The database will not be disclosed or sold to others outside Nationwide Children's Hospital.

8) WHOM SHOULD I CALL IF I HAVE QUESTIONS OR PROBLEMS?

If you have questions about anything while on this study, you have 24 hour access to talk to your study coordinator, Dr. Amy Goodwin, at: 614-690-0398 (pager).

If you have questions or are worried about your rights as a research volunteer, please call (614) 722-2708, Nationwide Children's Hospital Institutional Review Board, (IRB, a committee that reviews all research in humans at Nationwide Children's Hospital).

Subject's Name _____ **Date of Birth**_____

SUBJECT or SUBJECT'S LEGAL REPRESENTATIVE STATEMENT

I have read this consent form and have had a chance to ask questions about this research study. These questions have been answered to my satisfaction. If I have more questions about participation in this study or a research-related injury, I may contact the Study Doctor. By signing this consent form, I certify that all health information I have given is true and correct to the best of my knowledge.

I have been given a copy of the Nationwide Children's Hospital Notice of Privacy Practices. I understand that my right to my patient information that is created or collected by Nationwide Children's Hospital in the course of this research can be temporarily suspended for as long as the research is in progress. I also understand that my right to access will be reinstated upon completion of this research.

I agree to participate in this study. I will be given a copy of this consent form with all the signatures for my own records.

CONSENT SIGNATURES

_____ _____

SUBJECT or SUBJECT'S LEGAL REPRESENTATIVE **DATE SIGNED**

_____ _____

PERSON OBTAINING CONSENT **DATE SIGNED**

I certify that I have explained the research, its purposes, and the procedures to the subject or subject's legal representative before requesting their signature.

_____ _____

STUDY INVESTIGATOR *(Optional)* **DATE SIGNED**

If this study involves investigational drugs, send a copy to the Pharmacy along with the prescription or no drugs will be dispensed.

Appendix B: Protocol for “Survey of parental management of child’s dental pain”

Confirm **Inclusion Criteria:** 18-71m, ASA I/II, ECC (by AAPD def'n)
Record child's weight on survey part II
Calculate correct amount of Tylenol/Motrin & record on survey part II

Give parent **consent form**

Verbally ask parents questions below:

Q1 – "Are you the primary caregiver?"
a. Yes
b. No ---- disqualify parent

Q2 – "Is your child taking routine pain medication for any chronic illness?"
a. Yes ---- disqualify parent
b. No

Physically give parent survey **part I** – demographics

Verbally give parent survey **part II** – measure meds

Physically give parent survey **part III** – follow-up

Physically give parent **TOFHLA**

"Here are some other medical instructions that you or anybody might see around the hospital. These instructions are in sentences that have some of the words missing. Where a word is missing, a blank line is drawn, and 4 possible words that could go in the blank appear just below it. I want you to figure out which of those 4 words should go in the blank, which word makes the sentence make sense. When you think you know which one it is, circle the letter in front of that word, and go on to the next one. When you finish the page, turn the page and keep going until you finish all the pages."

Stop at the end of 7 minutes (WHILE WAITING, CHART CHILD'S WEIGHT AND CARIES)

Notes: When you encounter low literacy, soften the impact of unmasking by stating compassionately, "**I am not here to embarrass you, frustrate you, or make you feel uncomfortable. I am willing to stop if you want to, but the information you can give me is very special and valued highly by all of us here**. (pause) **May I continue**?"

Notes: This is a timed test and should be stopped at the end of 7 minutes. Do not inform the respondent in advance that the test is timed. When 7 minutes have elapsed, tell the respondent that "**That should give us what we are looking for. Thank you for your cooperation**." And remove the test materials.

Appendix C: Survey of parental management of child's dental pain – Part I

1 – What is your date of birth (D.O.B.)? _____

2 – Please circle: I am male / female

3 – How many children do you have?

a. One
b. Two
c. Three
d. Four
e. Five or more

4 – Please circle marital status

a. Single
b. Married
c. Separated
d. Divorced
e. Widowed

5 – What is your highest level of education completed?

a. Less than high school
b. High school
c. Some college
d. College degree
e. Education beyond college (i.e. masters, doctorate, PhD)

6 – If you are married, what is the highest level of education your spouse has completed?

a. Less than high school
b. High school
c. Some college
d. College degree
e. Education beyond college (i.e. masters, doctorate, PhD)

7 – What type of dental insurance do you have?

a. None
b. Public (i.e. Medicaid, Caresource, Molina, etc.)
c. Private
d. Other _____

8 – What is your annual household (family) income?

a. < $20,000
b. $20,000 - $30,000
c. $30,000 - $40,000
d. $40,000 - $50,000
e. > $50,000

9 – Have you ever given your child pain medication for a toothache?

a. Yes
b. No

Appendix D: Survey of parental management of child's dental pain – Part II

Q1 – "Which of the following medications would you give your child if they had a toothache?"

(show parent each of the following labeled bottles of pain medication)

Say the name of each medication as pointing. "Please take the bottle you chose."
(circle parent's choice and put other medication bottles away)

a. Children's Tylenol
b. Infant Tylenol Drops
c. Children's Motrin
d. Aspirin Child Oral
e. Orajel (adult, baby)

Q2 – "How much medicine would you give?" Response: _____

(parent should still be holding medication of choice to help decide)
(later convert response into mL of medication)

Q3 – "Please measure out this amount of medication using any of the available measuring tools."

(Show parent all of the measuring tools)

"This came with the medication you chose."
(Add the measuring tool from the chosen medication)

(Circle chosen tool)

a. Syringe/cup that came with medication
b. Measuring spoons (tsp, tbs)
c. Large spoon (table spoon)
d. Medium spoon (tea spoon)
e. Small spoon (baby spoon)

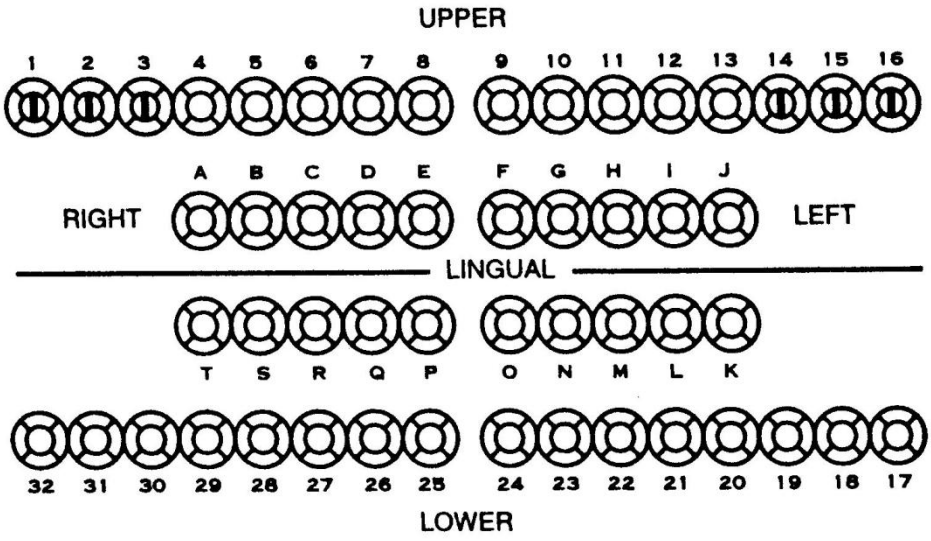
(Once parent measures, pour into graduated cylinder and record, rounding up to nearest 1 mL

Q4 – Study coordinator's measured dose = _____mL

Q5 – How much do you think your child weighs? _____

Child's Weight = _____ kg kg x 2.2 = _____ lbs	Correct = _____ mL Tylenol (10-15mg/kg Q6H. max=60/kg/d) _____ mL Motrin (5-10mg/kg Q6H. max=40/kg/d)

Please chart all decayed, missing, or filled teeth in red:



Pain Score:_____

Child's D.O.B._____

TOFHLA

___ Completed within 7 minutes

___ Ran out of time

___ Refused to complete

Appendix E: Survey of parental management of child's dental pain – Part III

1 – What made you select the medication you measured out?

Please rank all that apply from top/best reason (#1) on down

a. _____Recommendation from my physician
b. _____Child's pediatrician
c. _____Friend
d. _____Television commercial
e. _____It worked before
f. _____Other _____

2 – How did you decide what dose to give your child?

Please rank all that apply from top/best reason (#1) on down

a. _____ Instructions on bottle
b. _____ Instructions from healthcare provider
c. _____ Child's age
d. _____ Child's weight
e. _____Amount of pain

3 – How often would you give this dose of medication to your child?

a. When my child complains of pain
b. Twice a day (or every 12 hours)
c. Three times a day (or every 8 hours)
d. Four times a day (or every 6 hours)
e. Six times a day (or every 4 hours)
f. Eight times a day (or every 3 hours)