Parents' Use of Benzocaine for Oral Pain in Young Children

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Abstract

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Background: The U.S. FDA recommends against using benzocaine for oral pain in children younger than two years because of the risk of methemoglobinemia. The purpose of this study is to characterize parents' use of benzocaine in young children. **Methods:** A survey of 400 parents of children six to 72 months old was conducted at two pediatric clinics. It asked about oral pain experience, benzocaine use, receipt of benzocaine advice, and family demographics. **Results:** Overall, 44.2% of parents reported using benzocaine for teething pain, including 36.1% of parents of children six to 23 months old. The odds of using benzocaine in this age group was 14.4 times higher among those parents who received advice to use it than among those who did not receive this advice (95% CI = 1.7-117.8). **Conclusions:** Parents may lack awareness of the U.S. FDA's recommendation against benzocaine use in children younger than two years.

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DEDICATION

This thesis is dedicated to:

My sister, Carly Anne Klooster,

My mother, Mary-Anne Stieber, and

My father, James Matthew Stieber,

For their unconditional support of my unconventional dreams.

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Introduction

In 2011 and 2012, the United States Food and Drug Administration (FDA) issued safety announcements advising against parents' use of benzocaine products in children younger than two years of age due to the risk of methemoglobinemia.[1,2] Benzocaine is the active ingredient in over-the-counter (OTC) gels marketed to relieve oral pain. Methemoglobinemia is an uncommon but potentially lethal disorder of the blood in which an abnormal amount of methemoglobin is produced and oxygen distribution to the body is thereby impaired.[3] Since 2006, the FDA has received 15 reports of benzocaine gel-related cases of methemoglobinemia in children younger than two years of age.[2] Several case reports of methemoglobinemia associated with oral use of benzocaine in young children are described in the literature.[4–13]

No published studies characterizing OTC benzocaine use for oral pain in young children have been conducted in the United States following the FDA's safety announcements. Studies published prior to the safety announcements indicated that benzocaine use was not uncommon. For example, a 2009 study of 300 parent-child dyads seeking care at an emergency walk-in dental clinic in Columbus, Ohio reported that 15% of parents had managed their child's dental pain, occurring within 7 days of the emergency visit, by administering benzocaine.[14] Interviews in 2005 of 107 parents of children younger than two years who were patients at a hospital pediatric clinic in Detroit, Michigan found that 57% of these parents used benzocaine for their child's teething pain.[15] Outside of the United States, a 2010 national survey of 1,500 Jordanian parents accompanying their children to Maternal and Child Health Centers found that over 65% of parents administered a benzocaine-containing topical analgesic to their child for relief of teething symptoms.[16]

There are reasons to believe benzocaine gel is in widespread use now despite the FDA safety announcements. Benzocaine gel is readily available as an OTC drug marketed for relief of

teething and general oral pain in young children and the packaging does not warn about the risk of methemoglobinemia. Both the American Academy of Pediatric Dentistry and the American Academy of Pediatrics recommend against the use of benzocaine for teething pain.[17,18] To date, however, relatively little research attention has been given to its use by parents of young children. The purpose of this study is to characterize parents' use of OTC topical benzocaine to manage oral pain in their children since the 2011 and 2012 U.S. FDA safety announcements advising against its use in children younger than two years of age.

Methods

We conducted this cross-sectional study at an urban, university-affiliated pediatric medical clinic and an urban, university-affiliated pediatric dental clinic between April 4, 2013 and October 16, 2013. We collected data by a self-administered written survey (Appendices 1-4) completed by English-speaking parents of children between six and 72 months of age who presented to either clinic for any type of appointment. Data collection occurred at these two sites to achieve a large sample size within the time constraints of this study. As no other published studies have evaluated benzocaine use in this age group of children, we were unable to perform a power calculation for our study. Instead, we selected a sample size of 400 parents (200 at the medical clinic and 200 at the dental clinic) based on its comparability to the sample size used in a previous study of caregiver-reported oral pain in young children, assessed by a self-administered survey, that was conducted prior to the benzocaine safety announcements.[14,19]

For the present study, we identified children meeting the age inclusion criteria in the clinics' computerized scheduling systems on a daily basis and approached caregivers of age-eligible children before, during, or after the clinical appointment to confirm eligibility criteria, obtain written consent, and complete the self-administered survey. We excluded parents if they required the assistance of an interpreter for the English language or if they indicated recent adoption of their child. Parents completed only one survey, even if they accompanied multiple eligible children and/or if they presented to both the medical clinic and the dental clinic during the study period. If a parent accompanied multiple eligible children, we asked them to complete the survey for the youngest child between six and 72 months of age. Following completion of the survey, parents received an informational handout developed by the FDA entitled, "Benzocaine and Babies: Not a Good Mix".[2]

The survey included 19 multi-part questions developed by the study team. We determined the readability of the survey to be Flesch-Kincaid Grade Level 4.2. We divided the survey into three sections: Five questions on management of teething-related oral pain; five questions on management of non-teething-related oral pain; and nine questions that asked for demographic information. We defined non-teething pain in a similar manner as was used by the 2007 National Survey of Children's Health.[20] The oral pain questions asked parents if their child had a history of oral pain, what they used in the past to manage their child's pain, how effective it seemed (on a 3-point scale that range from a low score of "none" to a high score of "a lot"), and what advice they had received and from whom or where. The demographic questions asked the age of the parent, their relationship to the child, the child's birth month and year, the child's sex, the parent's racial background, the parent's highest level of education, the child's dental insurance type, the number of people age 18 years or older currently living in the parent's home, and the age distribution of children younger than 18 years old currently living in the parent's home. Parents' report of race and ethnicity was by self-report using the categories used by the United States Census Bureau: White; Black; American Indian or Alaska Native; Asian; Native Hawaiian or other Pacific Islander; Hispanic or Latino. Parents could indicate more than one category. We collected data on race and ethnicity as a way to determine if there were systematic differences in parents' reported use of benzocaine associated with race and/or ethnicity. The Institutional Review Board at the University of Washington in Seattle, Washington reviewed and approved this survey and the study procedures.

We created an electronic database using Microsoft Excel 2010 (Microsoft Corp, Redmond, Washington, USA) for entry and storage of data and analyzed the data using Stata/IC 12.1 (StataCorp, College Station, Texas, USA). We calculated descriptive statistics (mean,

standard deviations, counts, and percentages) for all variables. We used Chi-square tests of association to compare demographic information between the medical and dental clinics and to compare benzocaine use for teething pain with child's age; Fisher's exact test to compare benzocaine use for non-teething pain with child's age (due to small cell sizes as few parents reported benzocaine use for non-teething pain in children six to 23 months old); and logistic regression to test the association between covariates and parents' use of benzocaine to manage oral pain in their child. We pre-set statistical significance at $\alpha = 0.05$.

Results

Four hundred surveys were collected: 200 at the medical clinic and 200 at the dental clinic. Twenty-two (5.5%) of the surveys did not contain the child's age and thus 378 surveys were used in analysis: 187 from the medical clinic sample and 191 from the dental clinic sample. Compared to parents surveyed at the dental clinic, a significantly greater proportion of parents surveyed at the medical clinic were white ($P = 0.03$) and had completed graduate or professional schooling ($P = 0.01$). Compared to children at the dental clinic, a significantly greater proportion of children at the medical clinic were six to 23 months old ($P < 0.001$) and had private dental insurance ($P < 0.001$). Despite these demographic differences, parents surveyed in the medical and dental clinics did not significantly differ in their use of benzocaine (32.9% and 38.3%, respectively) and thus we combined the two samples to achieve a larger sample size for data analysis. The majority of parents in the combined sample were younger than 35 years old, mothers, white, non-Hispanic, had at least a 4-year college degree as their highest level of education, and had at least one other adult living in their home. The majority of children in the combined sample were 24 to 72 months old, male, and had public dental insurance (Table 1).

More than three-quarters (80.6%) of the parents reported their child had experienced at least one episode of oral pain at any time in the past. One hundred twelve parents of children age six to 23 months answered the question about teething pain. Teething pain was reported for 81 of these 112 children (72.3%). Two hundred fifty-seven parents of children age 24 to 72 months answered the question about teething pain. Teething pain was reported for 167 of these 257 children (65.0%). Eighty parents of children age six to 23 months answered the question about non-teething pain. Oral pain not related to teething was reported for eight of these 80 children (10.0%). Two hundred sixteen parents of children age 24 to 72 months answered the question

about non-teething pain. Oral pain not related to teething was reported for 96 of these 216 children (44.4%) (Figure 1).

Benzocaine was more commonly used to treat teething pain than non-teething pain. Ninety-two parents (44.2%) who reported their child six to 72 months old had experienced teething pain indicated they used benzocaine at least once to manage that pain. Twenty-six parents (36.1%) who reported their child six to 23 months old had experienced teething pain indicated they used benzocaine at least once to manage that pain. Only 16 parents of children six to 72 months old who experienced pain not related to teething (18.2%) reported using benzocaine to manage it (Figure 1). Child's age was not associated with parents' use of benzocaine for teething or non-teething pain ($P = 0.09$ and $P = 1.00$, respectively).

Associations with benzocaine use to manage teething pain

We tested associations between parents' report of benzocaine to manage teething pain with all variables listed in Table 1. Among parents of children age six to 23 months, education was significantly associated with the use of benzocaine. Parents with graduate or professional schooling had lower odds of using benzocaine to manage teething pain compared to parents with a high school or equivalent education or less (OR = 0.08, 95% CI: 0.01, 0.60). Receiving advice to use benzocaine was also significantly associated with its use. The odds of using benzocaine to manage teething pain was 14.37 times higher among those who received advice to use it compared to those who did not receive advice to use it (95% CI = 1.75-117.80).

Among parents of children age 24 to 72 months, receiving advice to use benzocaine was significantly associated with its use. The odds of using benzocaine to manage teething pain was 7.47 times higher among those who received advice to use it compared to those who did not receive advice to use it (95% CI = 2.64-21.14). Advice to avoid benzocaine was not associated

with parents' use of benzocaine to manage teething pain for children in either age group (Table 2).

Association with benzocaine use to manage non-teething oral pain

Associations with benzocaine use to manage non-teething oral pain in children six to 23 months old could not be tested due to the small number of parents who reported using it in these circumstances. No variables listed in Table 1 were significantly associated with parents' use of benzocaine to manage non-teething oral pain in children 24 to 72 months old.

Sources of advice to use or avoid benzocaine

Parents received advice from multiple sources to use or avoid benzocaine to manage oral pain in their child. Sixty-eight (61.3%) parents of children six to 23 months of age received advice to use benzocaine and 31 (27.4%) were advised against its use. The most common sources of advice to use benzocaine to manage teething pain, reported by 45 (39.8%) parents of children age six to 23 months, were friends or relatives. Three (2.6%) parents of children age six to 23 months reported receiving advice from a dentist to use benzocaine for teething pain. The most common source of advice to avoid benzocaine to manage teething pain, reported by 13 (11.5%) parents of children age six to 23 months, was physicians. Seven (6.2%) parents of children age six to 23 months reported receiving advice from a dentist to avoid benzocaine for teething pain (Figure 2).

Discussion

The most important finding in this study is that, one year following the FDA-issued safety announcement advising against it, over one third (36.1%) of parents reported using benzocaine to manage teething pain in children younger than two years of age. A second important finding is that nearly 40 percent of parents of children six to 23 months old received advice from friends or relatives to use benzocaine to manage their child's teething pain, and parents' use of benzocaine in this age group was significantly associated with receiving this advice. Physicians gave the majority of advice to avoid using benzocaine for teething pain in children six to 23 months old. However, only 11.5% of parents of children six to 23 months old reported receiving this advice to avoid, and such advice was not associated with parents' benzocaine use.

A major strength of the study is the sample size. Four hundred parents of young children, including 113 parents of children younger than two years of age, completed the self-administered survey. This large sample size made it possible to detect significant associations. A second strength is that the study was conducted at two different pediatric clinic types, thereby reducing the bias introduced by context in which the survey was taken. Another unquantifiable but important strength is the low non-response rate for the survey. It is estimated that fewer than 5% of parents with age-eligible children approached by the principal investigator opted not to participate in the study. The low non-response rate suggests that the results are representative of the inclusion criteria at the clinic site at which they were obtained.

Our study can be compared to studies on the following three topics: 1) Parents' use of benzocaine to manage oral pain in children; 2) Parents' use of and advice for other OTC medications in children; 3) Parents' response to other OTC medication safety warnings. Our

study's estimate that over one third (36.1%) of parents of children six to 23 months old use benzocaine to manage their teething pain is lower than the estimates from two other published studies on benzocaine use for teething pain in young children: The Detroit interviews in which 57% of parents administered a benzocaine gel to their child for relief of teething symptoms,[15]and the Jordanian national survey in which 65% of parents administered a benzocaine-containing topical analgesic to their child for relief of teething symptoms.[16] In the Detroit study, there was no significant relationship between benzocaine use and the level of education of the caregiver. This is in contrast to our study where we found that parents with graduate or professional schooling had lower odds of using benzocaine to manage teething pain in their child six to 23 months old compared to parents with a high school education or less. Nearly 20 percent of parents in the Detroit study learned of benzocaine as a remedy for teething pain from their own mothers.[15] In our study, 40 percent of parents of children six to 23 months old received advice from friends or relatives to use benzocaine to manage their child's teething pain. Benzocaine use may differ between our study and the Detroit study due to substantial differences in parent age, race, and education between the study populations.

Previous studies of parents' use of and advice for other OTC medications in children can also be compared to our study. Our study's finding that parents with graduate or professional schooling have significantly lower odds of using benzocaine to manage to manage their six-to-23-month-old child's teething pain compared to parents with high school education or less differs from previous studies that found a positive relationship between mother's education level and administration of OTC medications to her children.[21,22] However, these previous studies included OTC medications which did not have a FDA safety announcement. A more recent study of parental OTC medication use and advice-seeking behaviors in response to their children's

complaints of discomfort showed that 44% of parents sought advice from family or friends on management of teething pain.[23] This compares closely to our findings that 40% of parents of children six to 23 months old received advice from friends or relatives to use benzocaine to manage their child's teething pain.

Previous studies that describe parental response to OTC medication safety warnings also relate to the present study. In 2008, the FDA issued a public health advisory not to use cough and cold products for children. In a survey administered within two years of the advisory, 79% of the parents of children younger than two years old were aware of the advisory.[24] Thirty-two percent of these parents learned about the advisory from a physician or nurse, compared to 11.5% of parents of children six to 23 months old having received advice from a physician not to use benzocaine in our study. Despite their awareness of the advisory, 68% of the parents did not believe that OTC cough and cold medications are dangerous.[24] Our study did not ask directly about parents' beliefs regarding the safety of benzocaine. However, it is possible that the prevalence of benzocaine use in children younger than two years old reflects, in part, a parental disbelief that benzocaine is potentially dangerous. This possibility could be explored in future studies.

There are several limitations of this study. First, even though the survey was written at a fourth grade reading level, it is possible that parents who could read the survey did not understand the questions; other studies have found parents' reading ability may not reflect their understanding of oral health information.[25] Another limitation is that the parents may not have accurately reported their child's pain and analgesic experience either due recall bias, other caregivers being involved in the child's life, or due to adoption of a child once the majority of

teething had been completed. The medical clinic used in our study serves many adoptive families.

External validity is also a concern. Due to time and budget constraints, we selected a convenience sample for our study population. These two clinic samples may not represent parents of young children throughout the United States who are the intended recipients of the FDA safety announcement.

Conclusion

Our study established a baseline description of parental use of benzocaine to manage oral pain in young children following the 2011 and 2012 FDA safety announcements advising against this practice in children younger than two years. We found that many parents who perceived their young children to be in teething pain responded by using benzocaine to relieve this pain. We also found that family and friends may have a greater influence than healthcare professionals on parents' use of benzocaine gels to relieve teething pain. This information is useful for clinicians, risk communication teams, and other individuals who seek to improve the health and wellbeing of young children.

Table 1: Characteristics of parents and children by survey site.

	Survey Site[a]		
	Medical Clinic (N = 187)	**Dental Clinic (N = 191)**	**Total (N = 378)**
	N (%)	**N (%)**	**N (%)**
Parent age (years)[b]			
≤35	95 (61.3%)	85 (50.6%)	180 (55.7%)
>35	60 (38.7%)	83 (49.4%)	143 (44.3%)
Parent relationship to child			
Mother	145 (77.5%)	148 (77.5%)	293 (77.5%)
Father or other	42 (22.5%)	43 (22.5%)	85 (22.5%)
Parent race			
White	115 (61.8%)	98 (51.3%)	213 (56.5%)
Asian	29 (15.6%)	27 (14.1%)	56 (14.8%)
Black	14 (7.5%)	13 (6.8%)	27 (7.2%)
Other or multiple	28 (15.0%)	53 (27.7%)	81 (21.5%)
Parent Hispanic status			
Hispanic or Latino	15 (8.1%)	25 (13.1%)	40 (10.6%)
Not Hispanic or Latino	171 (91.9%)	166 (86.9%)	337 (89.4%)
Parent highest level of education			
High school/GED or less	15 (8.1%)	29 (15.2%)	44 (11.7%)
Some college or vocational training	54 (29.0%)	56 (29.6%)	110 (29.3%)
4-year college degree	44 (23.7%)	56 (29.6%)	100 (26.7%)
Graduate or professional schooling	73 (39.2%)	48 (25.4%)	121 (32.3%)
Number of adults living in home			
1	21 (11.4%)	25 (13.4%)	46 (12.4%)
≥2	163 (88.6%)	162 (86.6%)	325 (87.6%)
Child age			
6 – 23 months	95 (50.8%)	18 (9.4%)	113 (29.9%)
24 – 72 months	92 (49.2%)	173 (90.6%)	265 (70.1%)
Child sex			
Male	95 (51.6%)	102 (53.7%)	197 (52.7%)
Female	89 (48.4%)	88 (46.3%)	177 (47.3%)
Child dental insurance status			
Private	93 (50.8%)	59 (31.2%)	152 (40.9%)
Public	74 (40.4%)	115 (60.8%)	189 (50.8%)
Other or multiple	16 (8.7%)	15 (7.9%)	31 (8.3%)
Benzocaine use[c]			
Yes	50 (32.9%)	57 (38.3%)	107 (35.5%)
No	102 (67.1%)	92 (61.7%)	194 (64.4%)

[a] Variables may not sum to column totals due to missing values that were excluded.

[b] Parent age was missing for 12.0% of dental clinic surveys and 17.1% of medical clinic surveys.

[c] Benzocaine use was missing for 22.0% of dental clinic surveys and 18.7% of medical clinic surveys.

Table 2: Simple logistic regression testing associations between covariates and parents' use of benzocaine to manage teething pain in their child.

	Child's age (months)[a]					
	6-23[b]			**24-72[c]**		
	Benzocaine use N (%)		**Unadjusted OR (95% CI)**	**Benzocaine use N (%)**		**Unadjusted OR (95% CI)**
	Yes	**No**		**Yes**	**No**	
Parental Characteristics						
Age (years)						
<35	18 (72%)	26 (79%)	Reference	29 (51%)	24 (44%)	Reference
≥35	7 (28%)	7 (21%)	1.44 (0.43, 4.83)	28 (49%)	31 (56%)	0.75 (0.36, 1.57)
Relationship to child						
Mother	21 (81%)	32 (82%)	Reference	46 (75%)	50 (77%)	Reference
Father or other	5 (19%)	7 (18%)	1.09 (0.30, 3.89)	15 (25%)	15 (23%)	1.09 (0.48, 2.47)
Race						
White	20 (77%)	28 (72%)	Reference	40 (66%)	50 (77%)	Reference
Asian	1 (4%)	6 (15%)	0.23 (0.03, 2.09)	3 (5%)	5 (8%)	0.75 (0.17, 3.33)
Black	2 (8%)	1 (3%)	2.80 (0.24, 33.04)	3 (5%)	3 (5%)	1.25 (0.24, 6.53)
Other or multiple	3 (11%)	4 (10%)	1.05 (0.21, 5.22)	15 (25%)	7 (11%)	2.68 (1.00, 7.20)
Hispanic status						
Hispanic or Latino	1 (4%)	3 (8%)	0.48 (0.05, 4.88)	6 (10%)	4 (6%)	1.66 (0.45, 6.21)
Not Hispanic or Latino	25 (95%)	36 (92%)	Reference	55 (90%)	61 (94%)	Reference
Highest level of education						
High school/ GED or less	5 (19%)	2 (5%)	Reference	5 (8%)	6 (9%)	Reference
Some college or vocational training	8 (31%)	8 (20%)	0.40 (0.60, 2.70)	20 (33%)	18 (28%)	1.33 (0.35, 5.13)
4-year college degree	9 (35%)	10 (26%)	0.36 (0.06, 2.34)	21 (34%)	15 (23%)	1.68 (0.43, 6.54)

Graduate or professional schooling	4 (15%)	19 (49%)	0.08 (0.01, 0.60)	15 (25%)	26 (40%)	0.69 (0.18, 2.66)
Number of adults living in home						
1	1 (4%)	1 (3%)	Reference	10 (16%)	8 (12%)	Reference
≥2	25 (96 %)	38 (97%)	0.66 (0.04, 11.01)	51 (84%)	57 (88%)	0.72 (0.26, 1.95)
Child Characteristics						
Sex						
Male	10 (38%)	22 (56%)	Reference	34 (57%)	30 (46%)	Reference
Female	16 (61%)	17 (44%)	2.07 (0.75, 5.70)	26 (43%)	35 (54%)	0.66 (0.32, 1.33)
Dental insurance status						
Private	11 (42%)	21 (54%)	Reference	18 (30%)	27 (43%)	Reference
Public	13 (50%)	14 (36%)	1.77 (0.62, 5.06)	37 (61%)	32 (51%)	1.73 (0.81, 3.71)
Other or multiple	2 (8%)	4 (10%)	0.95 (0.15, 6.06)	6 (10%)	4 (6%)	2.25 (0.56, 9.11)
Care Setting						
Clinic type						
Dental	6 (23%)	6 (15%)	Reference	37 (61%)	41 (63%)	Reference
Medical	20 (77%)	33 (85%)	0.61 (0.17, 2.14)	24 (39%)	24 (37%)	1.11 (0.54, 2.28)
Benzocaine Advice						
Advice to use benzocaine						
No	1 (4%)	15 (38%)	Reference	5 (8%)	26 (40%)	Reference
Yes	23 (96%)	24 (61%)	14.37 (1.75, 117.80)	56 (92%)	39 (60%)	7.47 (2.64, 21.14)
Advice to avoid benz.						
No	18 (82%)	21 (58%)	Reference	46 (78%)	51 (78%)	Reference
Yes	4 (18%)	15 (42%)	0.31 (0.09, 1.11)	13 (22%)	14 (22%)	1.03 (0.44, 2.42)

[a] Column percentages may not sum to 100 due to rounding.
[b] Missing data on benzocaine use ranged from 8% to 12% per covariate.
[c] Missing data on benzocaine use ranged from 15% to 18% per covariate.

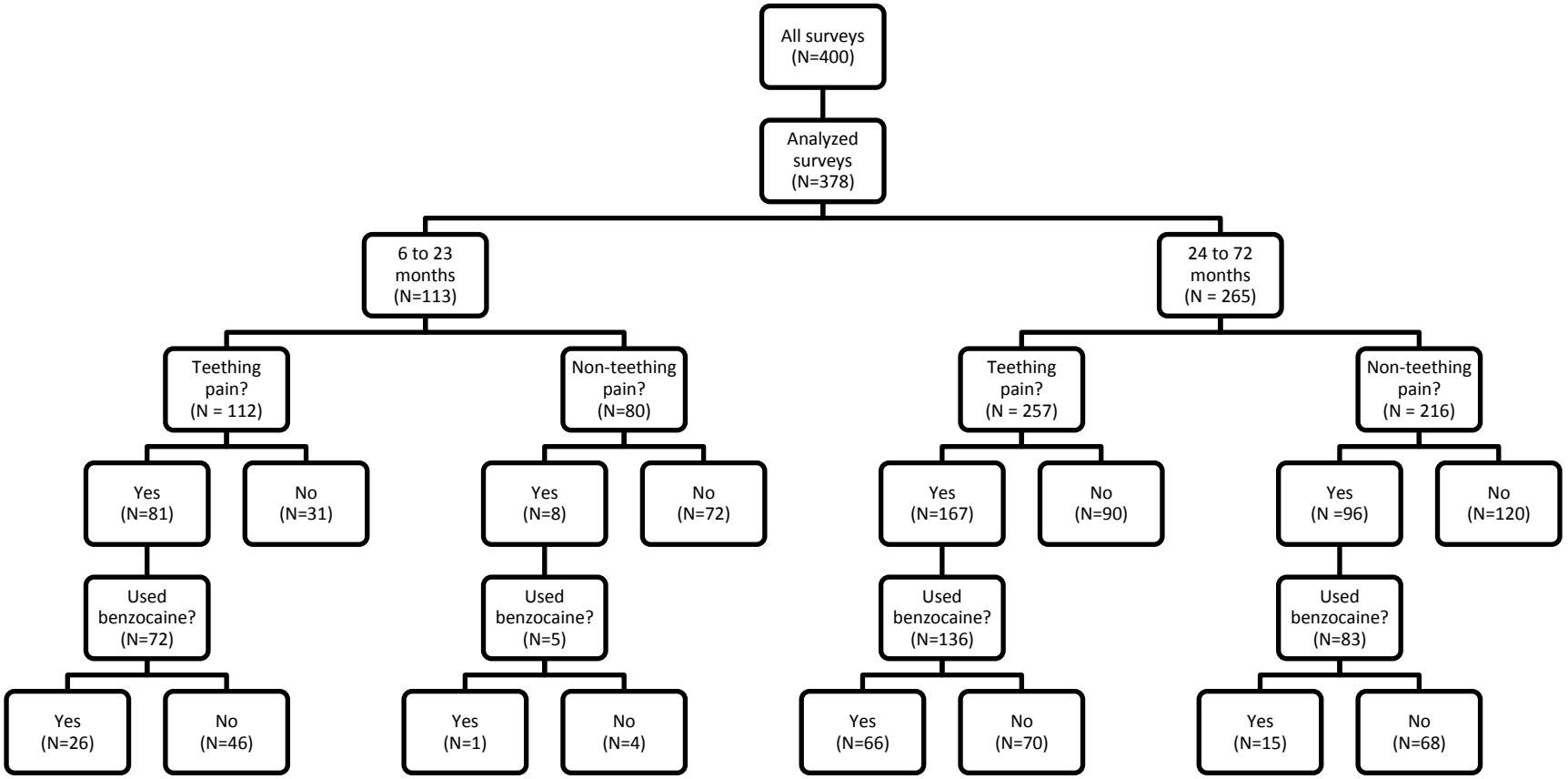

Figure 1: Parents' report of benzocaine use for teething and non-teething pain in their six-to-72-month-old child.

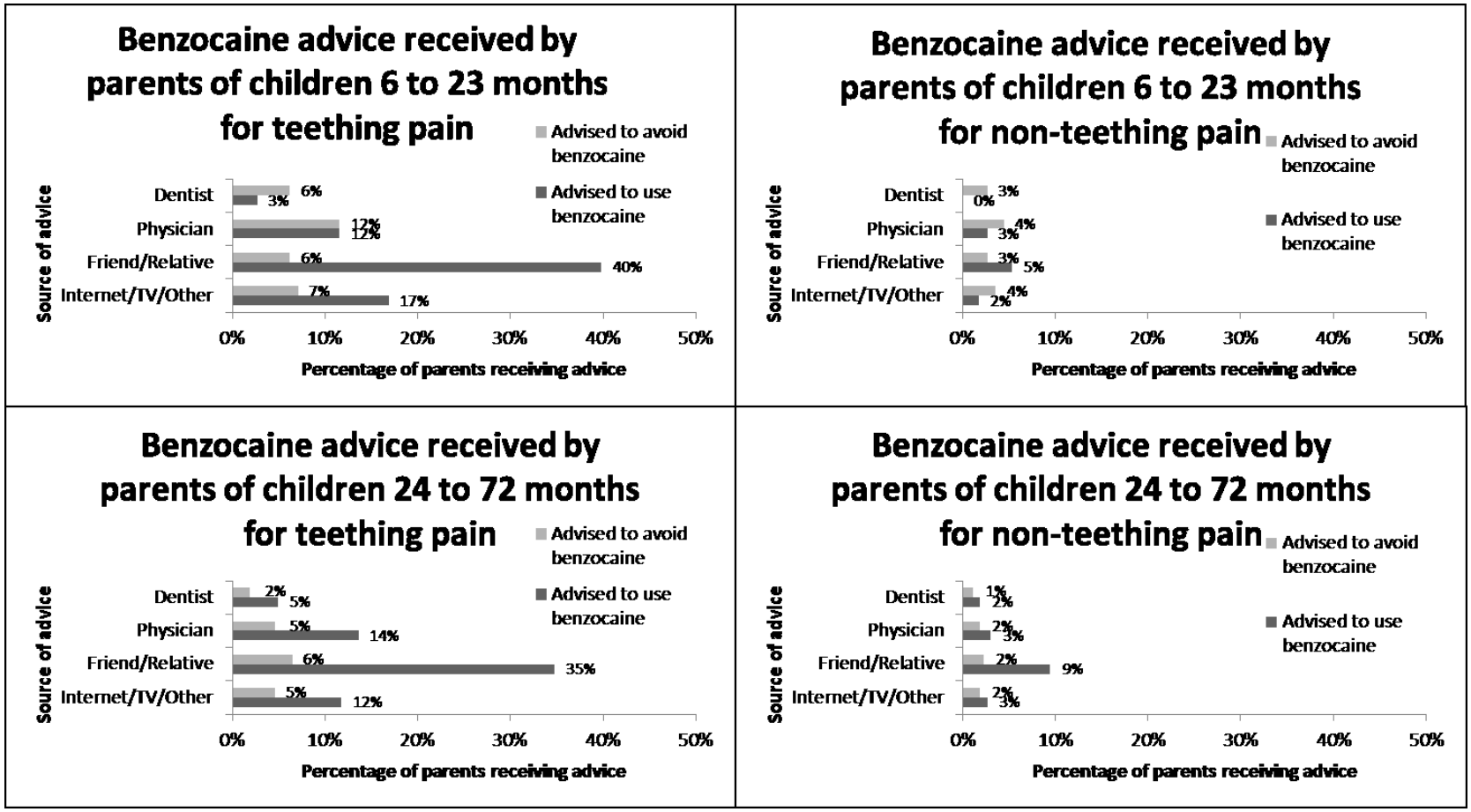

Figure 2: Sources of advice received by parents to use or avoid benzocaine for teething or non-teething pain in their six-to-72-month-old child.

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Appendix 1: Recruitment script

Recruitment script

"Hello, my name is _____. I am a member of the research team here. We're looking for parents of young children to help us with a quick and easy survey. May I tell you about our project?

- If they say yes → Continue with description below.
- If they say no → Thank them for their time.

"In this study, we are asking parents to answer questions about their child's experience with mouth or tooth pain. This will help us give better advice to families on how to help their children with this type of pain. Are you willing to participate in this study by filling out a short survey? Your child's care will not be affected in any way by your participation in this study."

- If they say yes → Obtain written consent and distribute survey.
- If they say no → Thank them for their time.

Appendix 2: Study eligibility checklist

Study eligibility

1. **Are you able to read and speak in English?**

   ☐ Yes → Continue to #2.
   ☐ No → STOP. You are not eligible to participate in this study. Thank you for your time.

2. **Have you participated in this study yet?**

   ☐ Yes → STOP. You are not eligible to participate in this study. Thank you for your time.
   ☐ No → Continue to #3.

3. **Is the child who has the appointment today between six months and six years old?**

   ☐ Yes → Continue to #4.
   ☐ No → STOP. You are not eligible to participate in this study. Thank you for your time.

4. **Does this child have special health care needs?**

   ☐ Yes → Continue to #5.*
   ☐ No → Continue to #5.

5. **Are you the child's primary caregiver and 18 years of age or older?**

   ☐ Yes → STOP. Congratulations! You are eligible to participate in our study.
   ☐ No → Continue to #6.

6. **Is the child's primary caregiver here today and available to participate in our study today?**

   ☐ Yes → Great! Please locate them and ask them to fill out this form.
   ☐ No → STOP. You are not eligible to participate in this study. Thank you for your time.

FOR RESEARCH PERSONNEL ONLY

Do the child and primary caregiver meet the inclusion criteria for the study?
(i.e., is "Yes" checked for #5?)

☐ **Yes** ☐ **No**

Date: _____

*Data for children with special health care needs may be excluded from analysis.

Appendix 3: Consent form

UNIVERSITY OF WASHINGTON
CONSENT FORM

CAREGIVER MANAGEMENT OF ORAL PAIN IN YOUNG CHILDREN

Researchers:

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JoAnna Scott, PhD, (206) 543-2973
Acting Assistant Professor of Pediatric Dentistry, University of Washington School of Dentistry

Researchers' statement

We are asking you to be in a research study. The purpose of this consent form is to give you the information you will need to help you decide whether to be in the study or not. Please read the form carefully. You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions, you can decide if you want to be in the study or not. This process is called "informed consent." We will give you a copy of this form for your records.

PURPOSE OF THE STUDY

Many children have tooth or mouth pain every now and then due to teething and other reasons such as cavities. However, we don't know how parents help their children with this pain. In this study, we are asking parents to answer questions about their child's experience with tooth or mouth pain. This will help us give better advice to families on how to help their children with this type of pain.

STUDY PROCEDURES

This study consists of a questionnaire. The first two pages ask you about your child's experience with teething and non-teething pain, how you managed the pain, whether or not you thought this management helped the pain, and whether or not you ever received advice to use or avoid certain methods of relieving your child's teething or non-teething pain. The third page asks you your age, your relationship to your child, the child's birthdate, the child's sex, your racial background,

your highest level of education, your child's type of dental insurance, the number of people 18 years of age and older currently living in your home, and the age distribution of children younger than 18 years of age currently living in your home.

We estimate that the survey will take approximately 10 minutes to complete. You may skip any questions that you do not feel comfortable answering. If you have any questions about the research study, you may contact any members of the research team at the phone numbers listed above.

RISKS, STRESS, OR DISCOMFORT

You may not know the answers to some of the questions we are asking. This may cause stress for you. We do not anticipate any physical risks or discomfort.

BENEFITS OF THE STUDY

Your contribution to our research will help researchers better how to help families manage children's mouth and tooth pain. There is no monetary compensation for participating in the study. You may not benefit directly from study participation. You will be provided with a printed handout of suggestions for managing teething pain.

CONFIDENTIALITY OF RESEARCH INFORMATION

All of the information you provide will be confidential. However, if we learn that you intend to harm yourself or others, we must report that to the authorities.

Government or university staff sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy. The study records will not be used to put you at legal risk of harm.

OTHER INFORMATION

You may refuse to participate and you are free to withdraw from this study at any time without penalty or loss of benefits to which you are otherwise entitled.

Printed name of study staff obtaining consent Signature Date

Subject's statement

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later about the research, I can ask one of the researchers listed above. If I have questions about my rights as a research subject, I can call the Human Subjects Division at (206) 543-0098. I will receive a copy of this consent form.

Printed name of subject Signature of subject Date

Copies to: Researcher
Subject

Appendix 4: Survey instrument

Part 1: Questions about teething pain

Many children have discomfort or pain while they are teething. Please answer the following questions to help us understand how parents help their children with teething pain.

1. Did your child ever have teething pain? ☐ Yes → Go to Question #2 ☐ No → Go to Question #4

2. Did you ever give your child any of these items to help with teething pain?

	Yes	No	If yes, how much did it help? (circle)		
Tylenol (acetaminophen)	☐	☐	none	a little	a lot
Aspirin	☐	☐	none	a little	a lot
Gel (e.g., Orajel or benzocaine)	☐	☐	none	a little	a lot
Advil (ibuprofen)	☐	☐	none	a little	a lot
A cold towel, washcloth, or drink	☐	☐	none	a little	a lot
A warm towel, washcloth, or drink	☐	☐	none	a little	a lot
Teething ring	☐	☐	none	a little	a lot
Did you try anything else? Please write below: _____	☐	☐	none	a little	a lot

3. If one of these items helped, how did you know it helped? Please describe in one sentence:

4. Did you ever hear any advice to TRY giving your child any of these items for teething pain?

	Yes	No	If yes, where did you hear the advice? (circle)					
Tylenol (acetaminophen)	☐	☐	dentist	friend/relative	Internet	physician	TV	other
Aspirin	☐	☐	dentist	friend/relative	Internet	physician	TV	other
Gel (e.g., Orajel or benzocaine)	☐	☐	dentist	friend/relative	Internet	physician	TV	other
Advil (ibuprofen)	☐	☐	dentist	friend/relative	Internet	physician	TV	other
A cold towel, washcloth, or drink	☐	☐	dentist	friend/relative	Internet	physician	TV	other
A warm towel, washcloth, or drink	☐	☐	dentist	friend/relative	Internet	physician	TV	other
Teething ring	☐	☐	dentist	friend/relative	Internet	physician	TV	other
Other advice? Please write below: _____	☐	☐	dentist	friend/relative	Internet	physician	TV	other

5. Did you ever hear any advice to AVOID giving your child any of these items for teething pain?

	Yes	No	If yes, where did you hear the advice? (circle)					
Tylenol (acetaminophen)	☐	☐	dentist	friend/relative	Internet	physician	TV	other
Aspirin	☐	☐	dentist	friend/relative	Internet	physician	TV	other
Gel (e.g., Orajel or benzocaine)	☐	☐	dentist	friend/relative	Internet	physician	TV	other
Advil (ibuprofen)	☐	☐	dentist	friend/relative	Internet	physician	TV	other
A cold towel, washcloth, or drink	☐	☐	dentist	friend/relative	Internet	physician	TV	other
A warm towel, washcloth, or drink	☐	☐	dentist	friend/relative	Internet	physician	TV	other
Teething ring	☐	☐	dentist	friend/relative	Internet	physician	TV	other
Other advice? Please write below: _____	☐	☐	dentist	friend/relative	Internet	physician	TV	other

Page 1 of 4

Part 2: Questions about non-teething tooth or mouth pain

Some children have tooth or mouth pain not related to teething. Please answer the following questions to help us understand how parents help their children with non-teething tooth or mouth pain.

6. Did your child ever have non-teething pain for any of the following reasons?

	Yes	No
Decayed teeth or cavities	☐	☐
Broken teeth	☐	☐
Bleeding gums	☐	☐
Other? Please write in below:	☐	☐

If all "No," Go to Question #9.

7. Did you ever give your child any of these items to help with non-teething pain?

	Yes	No	If yes, how much did it help? (circle)		
Tylenol (acetaminophen)	☐	☐	none	a little	a lot
Aspirin	☐	☐	none	a little	a lot
Gel (e.g., Orajel or benzocaine)	☐	☐	none	a little	a lot
Advil (ibuprofen)	☐	☐	none	a little	a lot
A cold towel, washcloth, or drink	☐	☐	none	a little	a lot
A warm towel, washcloth, or drink	☐	☐	none	a little	a lot
Did you try anything else? Please write below:	☐	☐	none	a little	a lot

8. If one of these items helped, how did you know it helped? Please describe in one sentence:

9. Did you ever hear any advice to TRY giving your child any of these for non-teething pain?

	Yes	No	If yes, where did you hear the advice? (circle)					
Tylenol (acetaminophen)	☐	☐	dentist	friend/relative	Internet	physician	TV	other
Aspirin	☐	☐	dentist	friend/relative	Internet	physician	TV	other
Gel (e.g., Orajel or benzocaine)	☐	☐	dentist	friend/relative	Internet	physician	TV	other
Advil (ibuprofen)	☐	☐	dentist	friend/relative	Internet	physician	TV	other
A cold towel, washcloth, or drink	☐	☐	dentist	friend/relative	Internet	physician	TV	other
A warm towel, washcloth, or drink	☐	☐	dentist	friend/relative	Internet	physician	TV	other
Other advice? Please write below:	☐	☐	dentist	friend/relative	Internet	physician	TV	other

10. Did you ever hear any advice to AVOID giving your child any of these items for non-teething pain?

	Yes	No	If yes, where did you hear the advice? (circle)					
Tylenol (acetaminophen)	☐	☐	dentist	friend/relative	Internet	physician	TV	other
Aspirin	☐	☐	dentist	friend/relative	Internet	physician	TV	other
Gel (e.g., Orajel or benzocaine)	☐	☐	dentist	friend/relative	Internet	physician	TV	other
Advil (ibuprofen)	☐	☐	dentist	friend/relative	Internet	physician	TV	other
A cold towel, washcloth, or drink	☐	☐	dentist	friend/relative	Internet	physician	TV	other
A warm towel, washcloth, or drink	☐	☐	dentist	friend/relative	Internet	physician	TV	other
Other advice? Please write below:	☐	☐	dentist	friend/relative	Internet	physician	TV	other

Part 3: Questions about you and your child

1. **What is your age in years?** _____

2. **What is your relationship to this child?** ☐ Mother ☐ Father ☐ Other: _____

3. **What is the month and year of your child's birth?** (example: May 1980) _____

4. **What is your child's sex?** ☐ Male ☐ Female

5. **Which of the following best describes your racial background? Check all that apply.**
   - ☐ White
   - ☐ Black
   - ☐ American Indian or Alaska Native
   - ☐ Asian
   - ☐ Native Hawaiian or Other Pacific Islander
   - ☐ Hispanic or Latino
   - ☐ Other: _____

6. **What is the highest level of schooling you have completed?**
   - ☐ Less than high school
   - ☐ High school/GED
   - ☐ Some college or vocational training
   - ☐ 4-year college degree
   - ☐ Graduate or professional schooling

7. **What type of dental insurance does your child have? Check all that apply.**
   - ☐ DSHS/Coupons/Medicaid
   - ☐ Private insurance
   - ☐ No insurance (self-pay)
   - ☐ Other: _____

8. **How many people age 18 and older (including you) live in your home now?**
   ☐ 1 ☐ 2 ☐ 3 ☐ 4 or more

9. **How old are the children (younger than 18 years old) who live in your home now?**
   For example, a 16-month-old child would be in the 1-2 category of "Age in years."

Age in years	Number of children
0-1	
1-2	
2-3	
3-4	
4-5	
5-6	
Older than 6	

Thank you for participating in our study.

Your answers will help us give better advice to families on how to help their children with tooth or mouth pain.

You will now receive an informational handout for you to keep. It is called, "Benzocaine and Babies: Not a Good Mix." Please let the research team know if you have any questions.