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Topical Fluoride Hesitancy Among Caregivers: Development of a Content-Valid Topical Fluoride Hesitancy Identification Item Pool

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Abstract

Objectives.—To develop a content-valid set of items to characterize different types of topical fluoride hesitancy among caregivers. We will use this information to develop and test tailor-made

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Todd C Edwards: contributed to conception or design, contributed to acquisition, analysis, and interpretation, drafted the manuscript, critically revised the manuscript.

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All authors gave their final approval and agree to be accountable for all aspects of the work.

The underlying research materials, including the study interview guide, can be obtained from Dr. Edwards (toddce@uw.edu).

Conflicts of Interest

The authors have no conflicts of interest to declare.

interventions directed to caregivers with varied types and levels of topical fluoride hesitancy, to ultimately improve child oral health.

Methods.—Caregivers participated in three study activities, in the following order: 1) semi-structured concept elicitation interviews (n=56), 2) cognitive interviews (n=9), and 3) usability interviews (n=3). Interviews were conducted via telephone and audio-recorded and transcribed for qualitative analysis. Twelve pediatric dental providers and researchers participated in item review. An assessment of reading level of items was made with goal of 6th grade reading level or less.

Results.—Based on elicitation interviews, we initially developed 271 items, which the investigative team evaluated for conceptual clarity, specificity to topical fluoride hesitancy, and sensitivity to potential interventions. After four rounds of review and cognitive interviews, we retained 33 items across five previously identified domains. Changes after cognitive interviews included item revision to improve comprehension and item re-ordering to avoid order effects. Changes after usability testing including clarification regarding referent child for families with multiple children. The reading level of the item pool is grade 3.2.

Conclusions.—The resulting 33-item fluoride hesitancy item pool is content valid and will address an important need for identifying and addressing topical fluoride hesitancy in the context of dental research and clinical practice. Next steps include psychometric evaluation to assess scale and test-retest reliability and construct validity.

Keywords

dental caries; dental treatment; social factors; trust; caregivers; children

Introduction

Although preventable, dental caries remains the most prevalent chronic disease in children and adults [1]. Fluoridation of public water systems has long been utilized as a preventive measure in many communities in the United States. Additionally, topical fluorides, including fluoride varnishes, gels, toothpastes, and mouth rinses are widely used and accepted [2] and clinically recommended as effective caries preventive strategies [3].

Despite the demonstrated efficacy and safety of fluoride [4], hesitancy regarding fluoride treatment and refusal of this treatment among childrens' caregivers has become more common[5]. In a survey administered to 582 dentists, a majority (89.6%) believed fluoride hesitancy was a growing problem in their practice; and 37% reported feeling uncomfortable talking to fluoride hesitant caregivers [6]. While the research is limited, previous studies have suggested some caregivers are fluoride hesitant because they do not know what fluoride is [6] and because they have concerns about safety and side effects [7, 8]. Research has also demonstrated a significant association between caregiver refusal of childhood vaccinations and topical fluoride [9]. Yet, a deeper understanding of the drivers of fluoride hesitancy eludes the field. A major impediment to this understanding is the lack of a reliable and valid way to measure topical fluoride hesitancy.

An important aspect of measure development is ensuring that all items comprising the measure have content validity. Content validity is achieved when all essential aspects of

a measured construct are represented in an item pool. Common methods for obtaining evidence about content-related validity include the use of patient, parent, and clinician judgments regarding the clarity, comprehensiveness, and redundancy of items. Often, item content is best derived from the population being studied or having experience with the particular health issue[10].

The intended purpose of this study was to develop a content-valid set of items to identify topical fluoride hesitancy among caregivers in the context of dental care and dental treatment research. With this in mind, we asked a diverse sample of caregivers, dental care providers, and researchers about their perceptions of topical fluoride and fluoride hesitancy, including the varying degrees of hesitancy and correlates and causes of topical fluoride hesitancy among caregivers.

Methods

Study Design and Participants

We used a qualitative design to develop an item pool across five previously-identified topical fluoride hesitancy domains: 1) Topical fluoride is unnecessary; 2) Keep chemicals out of the child's body; 3) Fluoride is harmful; 4) Too much uncertainty; and 5) Feeling pressured to get topical fluoride. A sixth domain (feeling fluoride should be a choice) was not included in this study because it was a general concern caregivers expressed not amenable to an immediate clinical intervention. To achieve this, we included caregivers and pediatric dental providers and researchers in one or more study steps (Figure 1) [11].

We recruited caregivers to participate in one or more of three study activities: 1) semi-structured concept elicitation interviews, in which the concepts to be measured are identified [10]; 2) cognitive interviews to assess item comprehension [12]; and 3) usability interviews to assess clarity and ease of use of the web-based data collection survey [13]. The Institutional Review Board of the University of Washington approved all study procedures before information was collected from study participants. All consent was obtained verbally by telephone.

We identified and enrolled most caregivers through a retrospective review of billing and health records at two pediatric dental clinics in the Pacific Northwest. Absence of dental billing codes for topical fluoride was used to identify children and adolescents who did not receive topical fluoride at a dental examination between August 2016 and September 2018. To verify that the child did not receive topical fluoride, a member of the study team manually reviewed the child's dental health records. We also recruited caregivers from private dental and naturopathic medical practices, social media (e.g., Facebook, Twitter), personal networks of study team members, and through snowball sampling.

A trained research assistant contacted caregivers via telephone and screened them for eligibility. Caregivers were ineligible if they could not speak English, were under 18 years old themselves, or declined topical fluoride for solely financial reasons. To verify hesitancy, the research assistant asked caregivers "On a scale of 1 to 10, with 1 being not opposed at all and 10 being totally opposed, how opposed are you to topical fluoride for your child or

any of your children?" Caregivers were considered eligible if they responded ≥ 2 on this scale and were asked to participate in a telephone interview. Caregivers who participated in the concept elicitation interviews and who agreed to be contacted for future research were eligible to also participate in the cognitive and usability interviews. A research assistant contacted eligible participants via telephone. We recruited dental providers and researchers through professional networks.

Procedures

Item development.—We exported the coded caregiver concept elicitation interview data into a MS Excel spreadsheet with each row having cells containing: interview text excerpt (phrase, sentence, or paragraph), category and domain codes associated with the excerpt, the interviewee's demographic information (e.g., sex, age, race, ethnicity), and their self-reported fluoride hesitancy level. We then sorted the data by category within each of the five domains. Next, study team members drafted items for each text excerpt, representing the concepts being expressed by caregivers (unless a comparable item had already been written). Items were written using active voice, first person singular pronouns, and simple sentences[14]. Whenever possible, we used the participants' own language (e.g., words, phrases) in writing the items. The detailed procedures we used for the caregiver concept elicitation interviews can be found in Chi et al. [11].

Through iterative investigator review, discussion, and consensus, redundant items were removed or combined, and remaining items were revised to improve comprehensibility. We selected final candidate items based on the following criteria: salience to the target population, clinical relevance, interpretability (i.e., having a clear positive or negative valence), ability to discriminate among levels and types of topical fluoride hesitancy, and likelihood of a response to change with an intervention. Items that were not potentially applicable to both hesitant and non-hesitant caregivers were not retained. Lastly, we selected response options for the items that were likely to produce meaningful variation in item responses.

Dental provider/researcher review.—Dentists and researchers reviewed the draft items for missing concepts and provided feedback during an online meeting and/or via email. After we reviewed and discussed the provider feedback, we revised the items prior to cognitive interviewing.

Reading level assessment.—Reading level was assessed using the Flesch-Kincaid Readability Test prior to each round of cognitive interviews and after final revisions [15, 16]. The target reading level for each item was 6th grade or less. Each item was tested without the words "topical fluoride" as these are above a 6th grade reading level and instead were defined for the study participants in the directions prior to the list of items. Items found to be above a 6th grade reading level were revised and retested.

Cognitive interviews.—We conducted cognitive interviews with caregivers to assess clarity, relevance, and comprehensiveness of the candidate items [12]. Caregivers were sent a link to the online survey within 24 hours of their scheduled interview and were instructed

not to open the link until the interview. Trained interviewers conducted one-on-one cognitive interviews with caregivers via telephone. After obtaining verbal informed consent, the interviewer asked the caregiver to complete the items via REDCap online survey platform [17]. Caregivers were encouraged to take notes on their thoughts, reactions, and observations while completing the items. Next, the interviewer and caregiver reviewed each item and response one-by-one together. The cognitive interview questions for each item were:

1. In your own words, what would you say this question (item) is asking?
2. How easy or difficult was the question (item) for you to answer? Please explain.
3. What were you thinking of when you answered the question (item)?
4. Were you able to easily find a response option that fit best for you?

Interviewers took detailed notes throughout the interview. The interviews were not audio-recorded. Interviewees received a $30 gift card for participating. There were three rounds of cognitive interviews each with three caregivers. After each round of cognitive interviews, the study team met to review the feedback and revise the items.

Usability interviews.—We conducted usability interviews to determine if caregivers had any difficulties with the electronic survey interface or with survey formatting. Procedures for the usability interviews mirrored procedures of the cognitive interviews, but different questions were asked. Questions included:

1. What are your general impressions of the web survey?
2. How easy or difficult was it to complete? Please explain.
3. Did you experience any problems with completing it?
4. How could we make it easier to complete?

We conducted one round of usability interviews with three caregivers. The usability interviews were not audio-recorded but the interviewers took detailed notes of issues to be addressed. Interviewees received a $30 gift card for participating. After the usability interviews, the study team reviewed the feedback and revised and finalized the online survey.

Results

Participants

We conducted concept elicitation interviews with 56 caregivers. Most caregivers were women (91.1%), non-Hispanic (87.5%), white (57.1%), and had at least a four-year college degree (62.5%). Their mean age was 41.9, standard deviation (SD) 9.7 years and the mean age of children and adolescents was 8.0, SD 4.3 years. The mean number of children per caregiver was 1.8, SD 0.9. The mean topical fluoride hesitancy score of caregivers was 7.1, SD 2.3 (range: 2 to 10), with 1 equaling “not opposed” and 10 equaling “totally opposed”. See Table 1 for the background characteristics of the caregivers who participated in the concept elicitation, cognitive, and usability interviews.

Item Development

The investigative team generated an initial long list of 271 items across the five domains. Through a first round of discussion and consensus applying the item selection criteria, 95 items of the long list were retained for further review. This process continued iteratively until 32 unique items were retained for clinician review that met item selection criteria and represented each of the five domains in the conceptual model. We used four item stems and two response scales in the construction of the items. Item stems “I think…”, “I trust…”, and “If my child... they do not need topical fluoride” have the four-point response scale Strongly Agree, Agree, Disagree, and Strongly Disagree. Item stem “I am concerned” has the four-point response scale of Extremely Concerned, Somewhat Concerned, Slightly Concerned, and Not at all Concerned.

Dental Provider/Researcher Review

Twelve dental providers/researchers reviewed the 32 items and provided feedback: seven pediatric dentists, four general dentists who saw pediatric patients, and one pediatric dental researcher who did not see patients. Most of the dental providers were also engaged in pediatric dental research programs based in academic settings distributed across the United States. Based on their suggestions, we included an item in the study data collection battery asking where caregivers got their information about topical fluoride (not part of the topical fluoride hesitancy item pool). As recommended, we defined “topical fluoride” for caregivers in the item instructions. We also revised some of the items in a positive direction as providers felt too many of the items framed fluoride in a negative light (e.g., instead of “I don’t think my child needs fluoride” use “I think my child needs fluoride”). Because providers expressed concern that items referenced dentists specifically rather than health care providers more generally, we included this revision. We also revised some of the item wording so it was more in the language of caregivers (e.g., “not natural” rather than “man-made”). Finally, as recommended, we moved more sensitive items (e.g., “I am concerned topical fluoride may cause my child to get cancer”) further down the order in the item list and included more neutral items near the beginning (e.g., “I am concerned about topical fluoride because my child already gets too much”).

Cognitive Interviews

Three caregivers participated in each of three iterative rounds of cognitive interviews (n=9 total). The cognitive interviews took between 34–60 minutes to conduct. As a result of feedback received during cognitive interviewing, we added one item to the item pool: “I am concerned about topical fluoride because I am not given enough information about it.” This resulted in a total of 33 items. Other revisions made after cognitive interviews included revising items to improve comprehension and clarity. For example, caregivers reported confusion because some items started with “I think…” and others started with “I do not think…” In light of this, we changed all relevant item stems to “I think…” Finally, based on caregiver feedback, we re-ordered some items so that they were less likely to affect responses on later items (i.e., “order effects”). We re-ordered items so that items from the same domain asking about the same topic were not next to one another. As noted previously, we also moved more sensitive items down in the order based on caregiver feedback.

Usability Interviews

Three caregivers participated in usability interviews, lasting approximately 30 minutes each. As a result of feedback obtained in the usability interviews that caregivers with multiple children might respond differently to particular items, we revised the instructions so it was clear that the caregiver was supposed to report for only their youngest child.

Reading Level Assessment

Based on the Flesch-Kincaid Reading Level Test we found that the readability of the topical fluoride hesitancy item pool is at the 3.2 grade level.

Final Item Pool

The final pool of 33 items organized by domain can be found in Table 2. Each domain contains between four and eight items.

Discussion

We used state of the art methods [18–20] to develop a much needed item pool for identifying the causes and correlates of topical fluoride hesitancy among caregivers of children and adolescents. This understanding will be valuable for designing approaches and interventions for reducing topical fluoride hesitancy and improving child dental health outcomes. Our multi-faceted item pool captures a wide range of caregiver perceptions relating to topical fluoride hesitancy.

As is the case with vaccines, fluoride acceptance or refusal has been operationalized as a binary behavior [5]. Caregivers who perceive interactions with healthcare providers about immunizations as negative may lose trust in their providers, seek out new providers, or avoid seeking care altogether [21–23]. A dichotomous characterization of these interactions however, does not reflect the full complexity of these relations. Similarly, intervention strategies addressing only acceptance or refusal, may not adequately address the nuances of behavioral, interpersonal and social factors affecting adherence to preventive care measures [24, 25]. Theoretical constructs of behavior change models have been shown to be relevant in the context of assessing hesitancy/refusal behaviors for both vaccines and fluoride. However, there are key determinants unique to topical fluoride hesitancy, such as caregiver perceptions about caries prevention through other means like toothbrushing, reducing sugar intake and water fluoridation [26].

While our study addresses a significant knowledge gap regarding the causes and correlates of caregiver topical fluoride hesitancy, there is a potential limitation to acknowledge. We developed item content only with hesitant and refusing caregivers only, rather than also interviewing caregivers who were not hesitant or refusing. We consider this approach defensible however, given that the purpose of the study was to understand topical fluoride hesitancy from the perspective of caregivers who were hesitant or refusing. We also only included English speaking participants.

Our study has three notable strengths. First, we used state of the art methods [10] to establish content validity of the topical fluoride hesitancy items we developed based on a conceptual

model we developed previously. We accomplished this with in-depth qualitative research with caregivers who were hesitant about topical fluoride for their children and with input from dental providers who serve this population [11]. In using these methods, we ensured that all essential aspects of topical fluoride hesitancy are represented by our items. A second strength is that we included caregivers from a broad range of backgrounds in order to establish content validity. While a majority of caregiver participants were White women (57.1%), there was broad representation on the whole in terms of race/ethnicity, education level, and family economic status. A final strength of our study is development of items for assessing topical fluoride hesitancy where, to our knowledge, none have been developed before.

The next steps in our research include conducting a field test of the item we developed where we will collect data with the items from a larger sample of caregivers in order to establish scales and scoring, test-retest reliability, and construct and criterion validity. Once these measurement properties are established, we will use the tool to characterize the different types of topical fluoride hesitancy among caregivers. We will use this information to develop and test tailor-made interventions directed to caregivers with varied types and levels of topical fluoride hesitancy, to ultimately improve child oral health.

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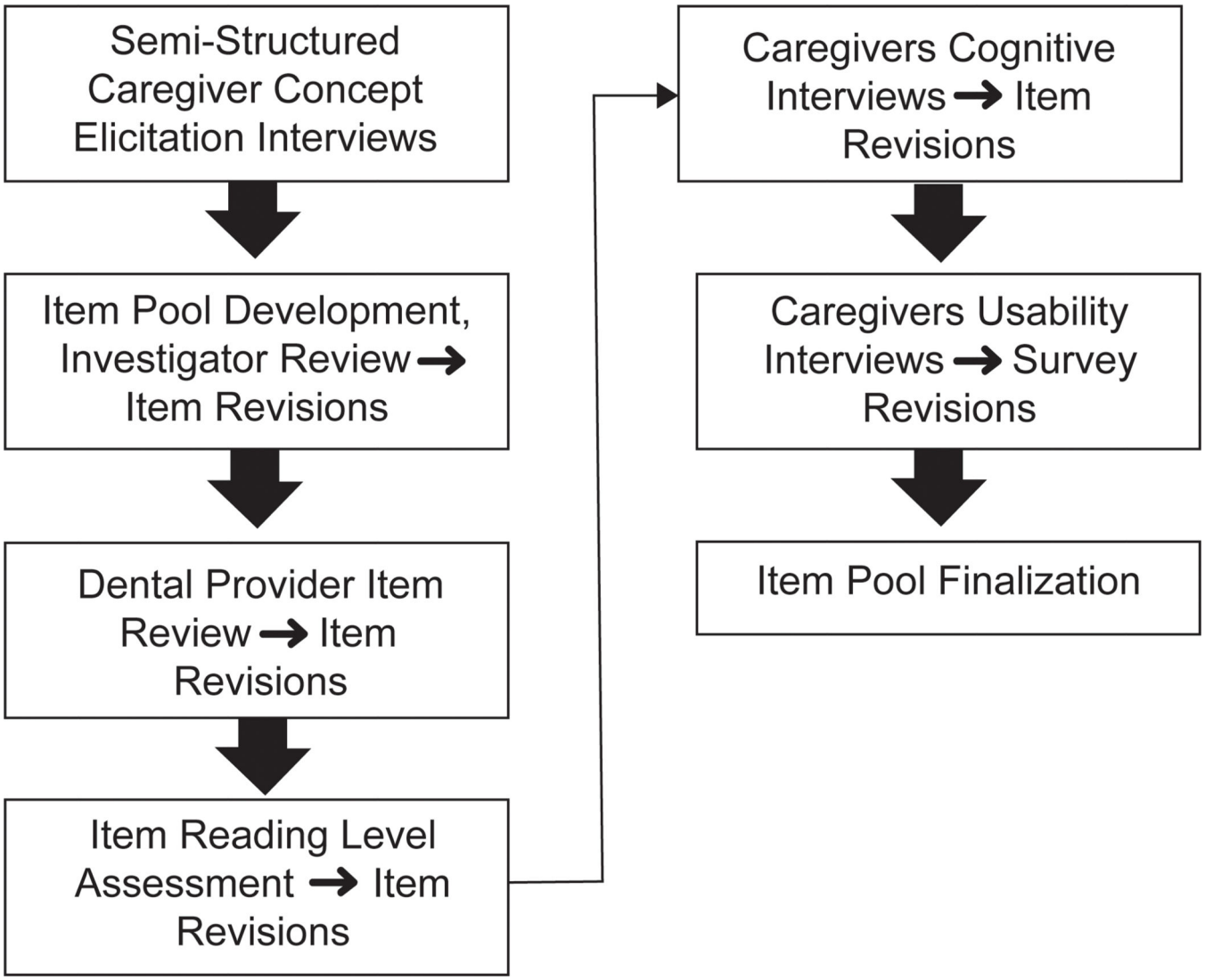

Figure 1.
Flow Diagram of Study Steps

Table 1.

Demographic characteristics of study participants (percentages in parentheses unless otherwise indicated)

Characteristic	Concept elicitation interviews (n=56)	Cognitive interviews (n=9)	Usability interviews (n=3)
Caregiver age (years)			
≤ 35	16 (28.6)	5 (55.6)	0 (0.0)
36–50	31 (55.4)	2 (22.2)	3 (100.0)
≥ 51	9 (16.1)	2 (22.2)	0 (0.0)
Caregiver gender			
Man	5 (8.9)	0 (0.0)	0 (0.0)
Woman	51 (91.1)	9 (100.0)	3 (100.0)
Caregiver self-reported race			
American Indian or Alaska Native	2 (3.6)	1 (11.1)	0 (0.0)
Asian	6 (10.7)	0 (0.0)	1 (33.3)
Black or African American	5 (8.9)	1 (11.1)	0 (0.0)
White	32 (57.1)	2 (22.2)	2 (66.7)
More than one race	7 (12.5)	4 (44.4)	0 (0.0)
Unreported/other	4 (7.1)	1 (11.1)	0 (0.0)
Caregiver self-reported ethnicity			
Hispanic	6 (10.7)	2 (22.2)	0 (0.0)
Non-Hispanic	49 (87.5)	7 (77.8)	3 (100.0)
Number of children under 18 years old, mean (SD)	1.8 (0.9)	1.4 (0.7)	3.0 (1.5)
Child age (years), mean (SD)	8.0 (4.3)	10.0 (3.8)	8.1 (4.0)
Caregiver highest education level			
≤ High school	3 (5.4)	0 (0.0)	0 (0.0)
Some college or 2-year degree	18 (32.1)	6 (66.7)	0 (0.0)
4-year college degree	21 (37.5)	2 (22.2)	2 (66.7)
More than 4-year college degree	14 (25.0)	1 (11.1)	1 (33.3)
Annual household income			
< $25,000	7 (12.5)	2 (22.2)	0 (0.0)
$25,000 to $75,000	20 (35.7)	4 (44.4)	1 (33.3)
$75,000 or more	21 (37.5)	3 (33.3)	1 (33.3)
Unreported	8 (14.3)	0 (0.0)	1 (33.3)
Child eligible for reduced-cost meals at school[a]			
Yes	10 (17.9)	3 (33.3)	0 (0.0)
No	46 (82.1)	6 (66.7)	3 (100.0)
Health insurance type			
Private	28 (50.0)	1 (11.1)	0 (0.0)
Public	9 (16.0)	7 (77.8)	2 (66.7)
Unknown/not reported	19 (34.0)	1 (11.1)	1 (33.3)

[a]Among households with at least one school-aged child

Table 2.

Topical Fluoride Hesitancy Domains and Items

Domain	Item
Believing it is harmful to my child	1. I think getting topical fluoride too often is bad for my child 2. I think topical fluoride is unhealthy for my child 3. I think topical fluoride is harmless for my child 4. I am concerned topical fluoride may cause learning problems for my child 5. I am concerned topical fluoride may cause my child to have autism 6. I am concerned topical fluoride may cause my child to get cancer 7. I am concerned topical fluoride may make my child's teeth look bad 8. I am concerned topical fluoride may hurt my child's IQ
Feeling like there is too much uncertainty	9. I think there is enough proof that topical fluoride is safe for my child 10. I think topical fluoride has more benefits than risks for my child 11. I am concerned topical fluoride may cause my child unknown harm in the future 12. I am concerned about topical fluoride because I do not know how it works 13. I am concerned about topical fluoride because I am not given enough information about it 14. I am concerned about topical fluoride because some research says it is not safe 15. I am concerned about topical fluoride because some doctors do not approve of it 16. I am concerned about topical fluoride because I have friends or family who are opposed to it
Feeling pressured to get fluoride	17. I trust that my child's dentist will give me a choice to say no to topical fluoride 18. I trust what my child's dentist says about topical fluoride 19. I am concerned that topical fluoride is mostly a way for my child's dentist to make money 20. I am concerned that I am not being told the whole truth about topical fluoride 21. I am concerned that I will feel pressured at my child's dentist to say yes to topical fluoride
Keeping chemicals out of my child's body	22. I am concerned about topical fluoride because my child already gets too much 23. I am concerned about topical fluoride because my child might swallow it 24. I am concerned about topical fluoride because it is not natural 25. I am concerned topical fluoride may build up in my child's body
Thinking it is not necessary	26. I think topical fluoride prevents cavities for my child 27. If my child's teeth are brushed regularly, they do not need topical fluoride 28. If my child has a healthy diet, they do not need topical fluoride 29. If my child goes to the dentist regularly, they do not need topical fluoride 30. If my child gets fluoride from drinking water, they do not need topical fluoride 31. If my child gets fluoride from toothpaste, they do not need topical fluoride 32. I think my child's teeth can be healthy without topical fluoride 33. I think my child needs topical fluoride