# Parents' Beliefs, Knowledge, and Action's Related to the Use of Over-The-Counter Cough and Cold Medications in Children Lori Thompson

Texas Woman's University

### Author Note

This Capstone Proposal was prepared by Lori Thompson, Doctor of Nursing Practice Student, Texas Woman's University Dallas, TX in partial fulfillment of the requirement for NURS 6163 Health Outcomes: Measurement, Management, and Analysis.

No grants of financial support are requested for this study. Dr Barbara Gray will assist with the critique of the study manuscript.

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Parents Perception of the Use of Over-The-Counter Cough and Cold Medicines in Children

There is increasing evidence that the use of cough and cold medications in children less than 2 years of age is dangerous and even deadly. (Yaghmai, Cordts, Schmidt, Issa, & Warren, 2010). Over the last 10 years, there have been numerous emergency room visits in children younger than 2 years old related to adverse reactions to cold medications. Emergency room (ER) reports from 2004 to 2005 document 54 deaths related to decongestants and 69 deaths related to antihistamines in this population (Yaghmai, et al., 2010). In response to the lack of evidence that cold medications are effective in pediatric populations, coupled with mounting evidence that these drugs may be harmful, in 2007 the Food and Drug Administration (FDA) issued a statement cautioning against the use of cold medications in children younger than 2 years old (Yaghmai, et al., 2010).

Since 1985, six randomized placebo-controlled studies have been conducted, related to the use of cough and cold medications in children 12 years and younger, none of which have indicated a significant difference between the active drug and the placebo (Sharfstein, North, & Serwint, 2007). The dosing guidelines for over-the-counter (OTC) cough and cold medications for children were developed in 1974 by a seven physician panel, which used the adult dosing, based on an average adult weight of 60 kg, and extrapolated the following guidelines: (a) physician consult is needed before administration of cold medications in children younger than 2 years, (b) give one fourth of the adult dose of cold medication to children aged 2 to 5 years, and (c) give one half of the adult dose of cold medication to children aged 6 to 11 years (Bell & Tunkel, 2010). Efficacy and safety studies were never conducted in children as the active ingredient efficacy was also extrapolated from adult studies. The purpose of this study is to explore parents' knowledge, attitudes, and actions related to the use of OTC cough and cold

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medications in young children. This study will also examine the relationship between acculturation and parent's knowledge, attitudes, and actions related to the use of OTC cough and cold medications in the same population. This study supports the focus of Ennis Children's Clinic in providing comprehensive patient focused care to the underserved children of Ellis County.

#### Context

- The paucity of research in children, along with pediatric dosing based on the adult dosing standards contributed to the occurrence of more than 1500 emergency room visits between 2004 and 2005 and 750,000 phone calls to poison control in the last 7 years due to effects of inappropriate use of cough and cold medication in children (Sharfstein, North, & Serwint, 2007).
- A total of 123 previously healthy children younger than 6 years of age have died related to adverse reactions or overdosing of OTC cough and cold medications (Rimsza & Newberry, 2008).
- Three infants, ages 1 to 6 months, died in 2005. Postmortem blood levels revealed that all three infants had pseudoephedrine levels ranging 9 to 14 times the recommended dosage for 2 to 12 year olds (Srinivasan, Budnitz, Shehab, & Cohen, 2007).
- Lokker et al.(2009) found that greater than 4 out of 5 caregivers were already using or would use OTC cough and cold medications for their children younger than two years, regardless of the FDA warning to consult a physician before use in this age group. Additionally, caregivers misunderstood the labeling instructions regarding the age group the medication was intended for as well as what dosage is appropriate to give their child.

# **Project Description**

#### Goals

- Determine parental knowledge, attitudes, and actions related to the use of OTC cold medications whose children are less than 2 years of age as compared to parental knowledge, attitudes, and actions related to the use of OTC cold medications whose children are 3 to 12 years of age.
- To inform parents on the use of OTC cold medications in children less than 2 years of age and in children 3 to 12 years of age.

#### **Objectives**

- To assess and ameliorate the potential for harm due to parental treatment of cough and cold symptoms in children.
- To determine the reliability and validity of the English version of the revised Yaghmai Parent Survey Tool in a population of parents who bring their children to a clinic for underserved children in rural Texas.
- To compare knowledge and actions related to the use and dosage of over-the-counter cough and cold medications in parents who have children aged 2 years and under and parents who have children aged 3 to 12 years.

# **Research Questions**

• Does the revised Yaghami Parent Survey perform as a reliable, valid measure of parental knowledge and action related to the use and dosage of over-the-counter cough and cold medications and other treatments for cold symptoms in a population of parents who bring their children to a clinic for underserved children in rural Texas?

- Is there a significant difference in knowledge and action related to the use and dosage of over-the-counter cough and cold medications and other treatments for cold symptoms as measured by the revised Yaghami Parent Survey between parents of children aged 2 years and under and parents of children between the ages of 3 and 12 years?
- What are the interactions among self-identified Mexican American parents with children aged 2 years and younger, parents with children aged 3 to 12 years, and acculturation, as measured by the Acculturation Rating Scale for Mexican Americans-II (ARSMA II)?

# **Null Hypotheses**

- There is no significant difference in knowledge and action related to the use and dosage of over-the-counter cough and cold medications and other treatments for cold symptoms as measured by the revised Yaghami Parent Survey between parents of children aged 2 years and under and parents of children between the ages of 3 and 12 years?
- There are no interactions among Mexican American parents with children aged 2 years and under, parents with children aged 3 to 12 years, and acculturation, as measured by the Acculturation Rating Scale for Mexican Americans-II (ARSMA II)?

### **PICO Questions**

- In parents of children less than 2 years of age and parents of children 3 to 12 years of age, is there a significant difference in knowledge and action related to the use and dosage of overthe-counter cough and cold medications and other remedies to treat cold symptoms in their children as evidenced by the Yaghami Parent Survey?
- In parents of children 2 years of age and parents of children 3 to 12 years of age, who selfidentify as Mexican American, is there an association between level of acculturation to the

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United States and parental knowledge and actions regarding the use over-the-counter cough and cold medications or other remedies to treat cold symptoms in their children?

#### Methodology

This will be a prospective correlation study to investigate parental knowledge and action in relation to the use of over-the-counter cough and cold medications in children less than 2 years of age and 3 to 12 years of age. A convenience sample of 119 parents of children 2 years or younger and 60 parents of children 3 to 12 years old who attend a rural pediatric clinic in Texas will be enrolled. The inclusion criteria are: (a) parents with children two years old and younger, (b) parents with children 3 to 12 years old, and (c) English speaking. The exclusion criteria are: (a) children with congenital heart and/or lung defects, (b) chronic lung diseases such as asthma and cystic fibrosis; tracheostomy; ventilator dependant; and (c) parents who are non-English speaking. Eligible parents will be identified by the front office staff at check in and given a consent form, completed consent forms will be collected by the receptionist and placed in an 8 ½ x 11 manila envelope labeled consents.

The Yaghami Parent Survey and the Acculturation Rating Scale for Mexican Americans-II (ARSMA II) will be administered by the investigator when the patient is placed in an exam room. A copy of the current FDA guidelines on cough and cold medication use in children will be given to each participant for supportive information. The completed questionnaires will then be collected and placed in an 8  $\frac{1}{2}$  x 11 manila envelope. No identifying information will be collected to ensure the anonymity of the participants.

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The data will be entered in to a Lime Survey and exported into SPSS for statistical analysis. The statistical analysis will consist of reliability testing: item-item, item-scale, scale-scale correlations and Cronbach's alpha; validity testing: scale-scale correlations and factor analysis; correlations; Mann-Whitney U, and ANOVA. A statistician will be consulted.

#### **Timeline and Duration**

1. Revise the Yaghami Parent Survey tool in August 2010.

2. Write the project concept proposal and obtain approval from my Capstone committee members by September 2010.

3. Submit the project concept proposal and consent form to Texas Woman's University (TWU) Institutional Review Board (IRB) for expedited approval in September 2010.

4. Enroll participants and collect data via the Yaghami Parent Survey and the Acculturation Rating Scale for Mexican Americans-II (ARSMA II) in late September through October 2010 and continuing until 119 participants with children 2 years of age or less, and 60 participants with children 3 to 12 years of age have been enrolled.

5. Enter data collected into a Lime Survey then export into the Statistical Package for the Social Sciences (SPSS) for analysis in November 2010.

6. Submit completed Capstone paper to the Texas Woman's University (TWU) committee by December 2010.

#### Site and Personnel Required for Project

The site of the study will be Ennis Children's Clinic in Ennis Texas. The personnel and support for the project will consist of the front office staff, the medical assistants, and the nurse practitioners currently employed by the clinic. The study questionnaires will be given to parents during standard office visits. A statistician will be consulted.

#### **Support Needed from Institution for Project**

The support needed from Texas Woman's University (TWU) consists of the Capstone committees review and approval of the project as well as the TWU Internal Review Board's (IRB) review and approval. The support needed from Ennis Children's Clinic will be the cooperation of the clinic owner, management, office staff, and medical assistants related to administering and collecting the survey tools.

#### **Deliverables to Institution**

A study of parents with children 2 years of age and less and parents with children 3 to 12 years of age to determine knowledge and action related to the use of OTC cough and cold medications and other treatments for cold symptoms as measured by the Yaghami Parent Survey and the Acculturation Rating Scale for Mexican Americans-II (ARSMA II). Based on the study findings, the clinic will be able to customize informational handouts based on the educational needs of its cliental, in addition to giving parents a current copy of the FDA guidelines related to the safe use of OTC cough and cold medications in children.

#### **Benefits/Anticipated Outcomes**

Assessing parental knowledge and action related to the use of cough and cold medications can allow for the identification of the need for education in this area. Once the areas of needed education have been identified, population specific educational materials can then be developed and distributed to this population thereby decreasing the injury to and possible death of young children.

#### References

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# Appendix A

# PICO Format Evidence Based Inquiry

# PICO Question 1

Patient	Parents of children less than 2 years of age and parents of children					
	3 to 12 year of age.					
Intervention	Yaghami Parent Survey					
Comparison	Knowledge and action of cough and cold medications or other					
	remedies to treat cold symptoms.					
Outcome	Determine the knowledge and action of parents related to the use					
	of cough and cold medications in their children.					
PICO Question 2						
Patient	English speaking, self identified Mexican American parents of					
	children less than 2 years of age and parents of children 3 to 12					
	year of age.					
Intervention	Acculturation Rating Scale for Mexican Americans-II					
Comparison	Knowledge and action of cough and cold medications or other					
	remedies to treat cold symptoms compared with their level of					
	acculturation.					
Outcome	Determine an association between the level of acculturation and					
	the knowledge and action of parents related to the use					
	of cough and cold medications in their children.					

# **Research Questions**

- Does the revised Yaghami Parent Survey perform as a reliable, valid measure of parental knowledge and action related to the use and dosage of over-the-counter cough and cold medications and other treatments for cold symptoms in a population of parents who bring their children to a clinic for underserved children in rural Texas?
- Is there a significant difference in knowledge and action related to the use and dosage of over-the-counter cough and cold medications and other treatments for cold symptoms as measured by the revised Yaghami Parent Survey between parents of children aged 2 years and under and parents of children between the ages of 3 and 12 years?
- What are the interactions among Hispanic parents with children aged 2 years and under, parents with children aged 3-12 years, and acculturation, as measured by the Acculturation Rating Scale for Mexican Americans-II (ARSMA II)?

### **PICO Questions**

- In parents of children less than 2 years of age and parents of children 3 to 12 years of age, is there a significant difference in knowledge and action related to the use and dosage of over-the-counter cough and cold medications and other remedies to treat cold symptoms in their children as evidenced by the Yaghami Parent Survey?
- In parents of children 2 years of age and parents of children 3 to 12 years of age, who self-identify as Mexican American, is there an association between level of acculturation to the United States and parental knowledge and actions regarding the use over-the-counter cough and cold medications or other remedies to treat cold symptoms in their children?

### **Null Hypotheses**

- There is no significant difference in knowledge and action related to the use and dosage of over-the-counter cough and cold medications and other treatments for cold symptoms as measured by the revised Yaghami Parent Survey between parents of children aged 2 years and under and parents of children between the ages of 3 and 12 years?
- There are no interactions among Mexican American parents with children aged 2 years and under, parents with children aged 3-12 years, and acculturation, as measured by the Acculturation Rating Scale for Mexican Americans-II (ARSMA II)?

# **Planned Instrumentation**

The Yaghami Parent Survey is a 15-question survey designed to assess parents' understanding related to the use of over-the-counter cough and cold medications. The tool gathers data on how parents dose medications, as well as what the parent's expectations of the medications are. In addition parents are asked to identify whether or not they use any alternative interventions for their child's cold symptoms. The Acculturation Rating Scale for Mexican Americans-II (ARSMA II) tool is a 30 question tool accessing the acculturation of Mexican Americans to the United States. Both of these tools are self-administered surveys.

#### **Proposed Statistical Analysis**

The data will then be entered in to a Lime Survey then exported to SPSS for statistical analysis. The statistical analysis will consist of reliability testing: item-item, item scale, scale-scale correlations and Cronbach's alpha; validity testing: scale-scale correlations and factor analysis, and correlations. A Mann-Whitney U, and ANOVA. A statistician will be consulted.

# **Instrument Permissions**

### Permissions to use the Yaghami Parent Survey

I apologize for not getting back to you sooner. I asked the other authors if they minded sharing

our survey. Please clarify which tool you are wanting to use. We used a few different

surveys/tools for this project and I want to make sure we send the correct one to you.

Thanks,

Brenda Issa, MD

Tue, July 6, 2010 8:41:51 AM

Here is the survey in English. I will see if the primary author has a copy of the Spanish.

Cari

Carolyn R. Schmidt, Ph.D. Research Assistant Professor Office of Research Department of Pediatrics KU School of Medicine - Wichita cschmidt3@kumc.edu (316) 293-1810

Mon, July 26, 2010 8:29:23 AM

#### Permission for Acculturation Rating Scale for Mexican Americans-II



#### Gratis

Permission is granted at no cost for sole use in a Master's Thesis and/or Doctoral Dissertation. Additional permission is also granted for the selection to be included in the printing of said scholarly work as part of UMI's "Books on Demand" program. For any further usage or publication, please contact the publisher.



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# Appendix B

# Yaghami Parent Survey

We are asking parents of children under age 6 what they think about "over the counter" cough and cold medications (medications that you can buy at the store without a doctor's prescription). This survey is voluntary and nobody will be able to identify you from the answers you give. It will not affect the service or care your child has in our clinic today.

If you have more than one child who is under 6 years old, we would like for you to answer the questions keeping only one child in mind. Think about the youngest child who is crawling or walking. If you don't have any children crawling or walking, that's okay. Think about the child CLOSEST to doing these activities.

When you are done with the survey and you go back to the exam rooms, tell the nurse which child you were thinking about. We want the nurse to record that child's exact weight today at the end of the survey page. Leave the survey with the nurse.

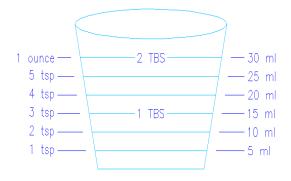
Thank you for your answers!

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1. What is your child's age?		Years
		Months
<ol> <li>How much does this child weigh? (Your best guess)</li> </ol>		Pounds
<ol> <li>When your child has been sick, have you given your child any "over the counter" medicines for cough and cold symptoms? (Circle one answer)</li> </ol>	Yes	Νο
<b>4.</b> Have you ever called a doctor about how much of these medicines you should give your child? (Circle one answer)	Yes	Νο
<b>5.</b> If you give a medicine like this, how fast do you expect it should work?	Min	Hours
If you felt you had to use a medicine for your child's cough or cold		
<b>6.</b> Would you use any of the medicines presented? (Circle one answer)	Yes	Νο
<b>7.</b> If <b>Yes</b> to number 5, tell us which medicine you would use by marking the box next to the name:		
Triaminic Night Time Cold & Cough		
Children's Tylenol Plus Multi-Symptom Cold		
Robitussin Pediatric Cough & Cold		
PediaCare Children's Multi-Symptom Cold		

**8.** Please indicate the amount you would give by marking the medicine cup with a line.



<b>9.</b> Do you know that stores have removed all combination cough and cold medicines for infants from their shelves?	Yes	Νο	
<b>10.</b> Did you ever have any of these medicines in your home?	Yes	No	Don't Know
<b>11.</b> Do you have these medicines in your home now?	Yes	No	Don't Know
<b>12.</b> If you do, will you use them, or throw them away?	Use	Throw Away	Don't Know

**13.** Sometimes people use other things to help when they have a cough or runny nose.

Have you used any of the following to help your child when they were sick?

(Circle any you've used)

Vitamin C	Garlic	Cool bath
Zinc Lozenges	Chicken soup	Vapor rub/Camphor
Echinacea	Onions	Rubbing alcohol
Elderberry	Massage	Prayer

Chamomile tea	Candeling (ears)	Healer or Curandero
Ginger root tea	Humidifier	Kava Kava
Any hot tea	Steamy room	Music
Cupping	Warm bath	Coining

14. How do you describe your race, or ethnicity? (Check one box or fill in the blank)

Caucasian or White	Asian
African American or Black	Other
Hispanic or Latino	

15. You are done! Thank you for your help. Please ask the nurse to record your child's exact weight here:and give this survey to the nurse.

\_\_\_\_\_KG or LB

If you have questions about cough and cold medicines, please ask your doctor here.

Thanks!

# Acculturation Rating Scale for Mexican Americans-II

[Circle a number between							[Marque con un círci	ula -						
I-5 next to each item that best applies.]		entre 1 y 5 a la respuesta que sea más adecuada para usted.]												
	1	2	3	4	5		,	1	2	3	4	5		
	Not at all	Very Little or sot vary often	Mo- der- sto- ly	Mu- ch or Very often	Ext- ro- mely of- ten or si- most Alw- nys			Nada	Un Po- quito o Ave- ces	Mo- der- alo	Mu- cho o Muy fas- cuo- nie	Mu- chi- si- m o Casi todo el tie- mpo		
1. I speak Spanish	1	2	3	4	5	1	. Yo hablo Español	1	2	3	4	5		
2. I speak English	1	2	3	4	5	2	. Yo hablo Inglés	1	2	3	4	5		
3. I enjoy speaking Spanish	1	2	3	4	5	3	. Me gustar habler en Español	1	2	3	4	5		
4. I associate with Anglos	1	2	3	4	5	4	Me asocio con Anglos	1	2	3	4	5		
5. I associate with Mexicans and/or Mexican Americans	1	2	3	4	5	5.	Yo me asocio con Mexicanos o con Norte Americanos	1	2	3	4	5		
6. I enjoy listening to Spanish language music	1	2	3	4	5	6.	Me gusta la musica Mexicana (musica en idioma Español)	1	2	3	4	5		
7. I enjoy listening to English language music	1	2	3	4	5	7.	Me gusta la musica de idioma Inglés	1	2	3	4	5		
8. I enjoy Spanish language TV	1	2	3	4	5	8.	Me gusta ver programas en la televisión que sean en Español	1	2	3	4	5		
9. I enjoy English language TV	1	2	3	4	5	9.	Me gusta ver programas en la televisión que sean en Inglés	1	2	3	4	5		
<ol> <li>I enjoy English language movies</li> </ol>	1	2	3	4	5	10.	Me gusta ver películas en Inglés	1	2	3	4	5		
1. I enjoy Spanish language movies	1	2	3	4	5	11.	Me gusta ver películas en Español	1	2	3	4	5		
2. I enjoy reading (e.g., books in Spanish)	1	2	3	4	5	12.	Me gusta leer (e.g., libros en Español)	1	2	3	4	5		
3. I enjoy reading (e.g., books in English)	1	2	3	4	5	13.	Me gusta leer (e.g., libros en Inglés)	1	2	3	4	5		
4. I write (e.g, letters in Spanish)	1	2	3	4	5	14.	Escribo (c.g., cartas en Español)	1	2	3	4	5		
5. I write (e.g., letters in English)	1	2	3	4	5	15.	Escribo (e.g., cartas en Inglés)	1	2	3	4	5		
6. My thinking is done in the English language	1	2	3	4	5		Mis piensamientos ocurren en el idioma Inglés	1	2	3	4	5		
7. My thinking is done in the Spanish language	1	2	3	4	5		Mis piensamientos ocurren en el idioma Español	1	2	3	4	5		
<ol> <li>My contact with Mexico has been</li> </ol>	1	2	3	4	5		Mi contacto con Mexico ha sido	1	2	3	4	5		

	1	2	3	4	5		l	2	3	4	5
	Not at all	Very Little or act very often	Mio- der- ato- ly	Mu- ch or Very often	Ext- re- mely Of- ten or Al- most Alw- ays		Nada	Un Po- quito o Ave- ces	Mo- der- ato	Mu- cho o Muy fie- cue- ate	Mu chí si- m o Ca tod el tis- mp
19. My contact with the USA has been	1	2	3	4	5	19. Mi contacto con los Estados Unidos Americanos ha sido	1	2	3	4	5
20. My father identifies or identified himself as 'Mexicano'	1	2	3	4	5	20. Mi padre se identifica (o se identificaba) como Mexicano	1	2	3	4	5
<ol> <li>My mother identifies or identified herself as 'Mexicana'</li> </ol>	1	2	3	4	5	<ol> <li>Mi madre se identifica         <ul> <li>(o se identificaba)</li> <li>como Mexicana</li> </ul> </li> </ol>	1	2	3	4	5
22. My friends, while I was growing up, were of Mexican origin	1	2	3	4	5	<ol> <li>Mis amigos(as) de mí niñez eran de origen Mexicano</li> </ol>	1	2	3	4	5
23. My friends, while I was growing up, were of Anglo origin	1	2	3	4	5	23. Mis amigos(as) de mí niñez eran de origen Anglo Americano	1	2	3	4	5
24. My family cooks Mexican foods	1	2	3	4	5	24. Mi familia cocina comidas mexicanas	1	2	3	4	5
25. My friends now are of Anglo origin	1	2	3	4	5	25. Mis amigos recientes son Anglo Americanos	1	2	3	4	5
26. My friends now are of Mexican origin	1	2	3	4	5	26. Mis amigos recientes son Mexicanos	1	2	3	4	5
<ol> <li>I like to identify myself as an Anglo American</li> </ol>	1	2	3	4	5	27. Me gusta identificarme como Anglo Americano	1	2	3	4	5
28. I like to identify myself as a Mexican American	1	2	3	4	5	28. Me gusta identificarme como Norte Americano* (México-Americano)	1	2	3	4	5
29. I like to identify myself as a Mexican	1	2	3	4	5	29. Me gusta identificarme como Mexicano	1	2	3	4	5
30. I like to identify myself as an American	1	2	3	4	5	<ol> <li>Me gusta identificarme como un(a) Americano(a)</li> </ol>	1	2	3	4	5

end of Scale 1 \*Estadounidenses de origen Mexicano

# **Demographic Instrument**

Please mark the answer that best represents you and your family with an X on the line.

- 1. My age is:
- 2. I see myself:
  - \_\_\_\_\_White
    - \_\_\_\_\_ Mexican/Hispanic
    - \_\_\_\_\_ African American
    - \_\_\_\_Other
- 3. I speak:

\_\_\_\_English

- \_\_\_\_\_Spanish
- 4. I have Insurance

- \_\_\_\_No
- 5. I am a single parent

- 6. My Insurance for my children is:
  - \_\_\_\_\_Medicaid (state insurance)
  - \_\_\_\_\_ Private Insurance (provided at your work place)
  - \_\_\_\_\_My children do not have Insurance at this time
- 7. I was :
  - \_\_\_\_\_born in the United States
  - \_\_\_\_I was born in another country
- 8. I have lived in the United States for \_\_\_\_\_ years
- 9. I am a:

\_\_\_\_Male

- \_\_\_\_Female
- 10. My age is \_\_\_\_\_

\_\_\_\_\_,

- 11. The last grade I finished was:
  - less than 12<sup>th</sup> grade
  - \_\_\_\_\_High School Graduate

\_\_\_\_\_, \_\_\_\_\_,

- \_\_\_\_Junior College
- \_\_\_\_Bachelors degree
- \_\_\_\_Graduate degree
- 12. Number of children \_\_\_\_\_
- 13. My children's ages are: (if less than 1 year old indicate months)

# **Informed Consent to Participate**

# TEXAS WOMEN'S UNIVERSITY CONSENT TO PARTICIPATE IN RESEARCH

Title: Parent Use of Over the Counter Cold Medication in Children

Investigator:	Lori Thompson	972-875-5220
Advisor:	Barbara Gray, PhD	214-689-6552

#### Explanation and Purpose of the Research

You are being asked to participate in a research study for Ms.Thompson's capstone project at Texas Women's University. The purpose of this research is to determine the acculturation, knowledge and action of parent's related use to over the counter cough and cold medication in their children in a solitary Spanish speaking population.

#### Research Procedures

For this study, the investigator will conduct an anonymous survey of parents as they visit their child's primary care pediatric office. You will be provided with staff to clarify questions. Your time commitment in the study is approximately 45 minutes

### Potential Risks

Potential risks related to you participation in the study include fatigue and physical or emotional discomfort during the completion of the questionnaire. To avoid fatigue you may take a break as needed. If you experience physical or emotional discomfort regarding the questions, you may stop answering the questions at anytime. The investigator will provide you with a referral list of

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names and phone numbers that you may use as you feel as though you need to discuss this physical or emotional discomfort with a professional

Another possible risk to you as a participant in this study is a release of confidential information. Confidentiality will be protected to the extent that is allowed by law. The survey will take place in a primary care pediatric office. No personal identifying information will be collected on the survey to protect you identity. Only the researcher will have access to these records. The surveys will be stored in a locked file cabinet in the researcher's office. The hard copies will be shredded within five years of the completion date of the study. It is anticipated that the results of this study will be published in the investigators capstone project as well as in other research publications. However, no names or other identifying information will be included in any publication.

The researchers will try to prevent any problem that could happen because of this research. You should let the researchers know at once if there is a problem and they will help you. However, TWU does not provide medical services or financial assistance for injuries that might happen because you are taking part in this research.

#### Participation and Benefits

Your involvement in this research study is completely voluntary, and you may discontinue your participation in the study at any time without penalty. The only direct benefit of this study to you is that at the completion of the study a summary of the results will be mailed to you upon request.\*

# Question Regarding the Study

If you have any questions about the research study you may ask the researchers; their phone number are at the top of this form. If you have questions about your rights as a participant in this research or the way this study has been conducted, you may contact the Texas Women's University Office of Registration and Sponsored Programs at 940-898-3378 or via e-mail at IRB@twu.edu. You will be given a copy of this signed and dated consent form to keep.

Signature of Participant

Date

\*If you would like to receive a summary of this study, please provide an address to which this summary should be sent: