

ABSTRACT

Title of Document: FACTORS RELATED TO LISTERIOSIS
PREVENTION IN PREGNANT WOMEN: A
MIXED METHODS EXPLORATORY STUDY

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This research examined factors related to listeriosis prevention in pregnant women, with the aim of improving messages designed for pregnant women. Pregnant women are twenty times more likely than other adults to become infected by *Listeria monocytogenes*. Listeriosis can lead to miscarriage, stillbirth, or illness in the newborn. Current FDA guidelines for pregnant women advise avoiding foods that pose high risk of *L. monocytogenes* contamination: hot dogs or luncheon meats without reheating, soft cheeses made with unpasteurized milk, refrigerated pâtés, refrigerated smoked seafood, and unpasteurized milk. These were updated in 2003 as our understanding of *L. monocytogenes* contamination in foods has changed. Previous research found that pregnant women were unaware of the guidelines, defensive when made aware, and consuming high-risk foods. The impact of changing guidelines has not been examined. A sequential explanatory mixed methods study was conducted. First, data collected in the second Infant Feeding Practices Study was analyzed to determine whether demographic and health-related factors were related to awareness of *L. monocytogenes*

and the consumption of high-risk foods. Next, six focus groups with pregnant women were used to triangulate secondary data analysis findings, examine underlying beliefs related to listeriosis, and explore the impact of changing listeriosis prevention messages. The Extended Parallel Process Model was used as a theoretical framework to guide the groups. The results showed that awareness has increased, with 37% of IFPS II participants aware of *L. monocytogenes*. However, almost 75% reported eating unheated cold cuts. Subgroup differences were identified and fell along income and educational lines. Those with less education and lower incomes were less aware and more likely to consume high-risk foods. Focus group findings suggest that risk and efficacy beliefs affected adoption of the guidelines, consistent with the EPPM. Participants felt that too much emphasis on the potential of advice to change weakens response efficacy. The findings suggest that listeriosis prevention messages should heighten risk perceptions, enhance efficacy perceptions, and suggest, but not belabor, the notion of changing messages.

FACTORS RELATED TO LISTERIOSIS PREVENTION IN PREGNANT
WOMEN: A MIXED METHODS EXPLORATORY STUDY

By

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DEDICATION

For Mom

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CHAPTER 1: INTRODUCTION

Introduction

Pregnant women have increased susceptibility to listeriosis, a serious foodborne illness that can lead to miscarriage and stillbirth (Bondarianzadeh, 2007; Gandhi & Chikindas, 2007; Ogunmodede et al., 2005; Reddy, Fry, Pass, & Ghidini, 2004). Government agencies have developed guidelines that advise pregnant women to avoid eating foods that have a high likelihood of contamination from *Listeria monocytogenes* (Food and Drug Administration [FDA], United States Department of Agriculture [USDA], & Centers for Disease Control and Prevention [CDC], 2003). Previous research found that pregnant women were not only unaware of and resistant to following these guidelines, but also reported eating high-risk foods (Athearn et al., 2004; Bondarianzadeh, Yeatman, & Condon-Paoloni, 2007; Cates et al., 2006; Ogunmodede et al., 2005; Rungan & Badkar, 2005; Trepka, Newman, Dixon, & Huffman, 2007). An additional complexity is that the guidelines were updated in 2003 based on new research findings, but the impact of this change has not been studied. To address these issues, the present research was conducted to (1) examine awareness, beliefs, and behaviors related to listeriosis prevention in pregnant women, (2) determine the effect of changing recommendations related to listeriosis prevention on pregnant women's adoption of listeriosis prevention behaviors, and (3) use these findings to suggest strategies to improve listeriosis communication messages for pregnant women.

Foodborne illnesses occur when people ingest harmful microorganisms or chemicals that have contaminated foods or drinking water (Center for Food Safety and Applied Nutrition [CFSAN], 2005a). The specific causes of foodborne illnesses have changed over time. These changes have occurred because strategies have been developed to control some pathogens, while other pathogens have adapted to new environments, recently emerged, or been newly identified (CDC, 2005; Tauxe, 2002). *L. monocytogenes* had been recognized as a pathogen for many decades, but its means of transmission was unknown (Schlundt, 2002; Tauxe, 2002). The occurrence of several serious outbreaks in the early 1980's led to its recognition as a foodborne pathogen (FDA et al., 2003; Schlundt, 2002).

Listeriosis, the infection that can result from exposure to *L. monocytogenes*, causes only 0.02 percent of all foodborne infections (International Life Sciences Institute Research Foundation & Risk Science Institute [ILSI RF/RSI], 2005; MacDonald et al., 2005). However, it has the highest case-fatality ratio of all the foodborne pathogens and causes 27.6 percent of deaths due to foodborne illness (ILSI RF/RSI, 2005; MacDonald et al., 2005). Further, *L. monocytogenes* has been found to seriously affect specific subgroups: the elderly, the immunocompromised, pregnant women and their fetuses, and newborns (FDA et al., 2003; Gandhi & Chikindas, 2007; ILSI RF/RSI, 2005; Ogunmodede et al., 2005; Tauxe, 2002). This research focused on one high-risk subgroup, pregnant women.

Pregnancy is generally considered a joyous time; however, it is also accompanied by its own unique physical, psychological, and social challenges (Affonso, Liu-Chiang, & Mayberry, 1999; DiPietro, Ghera, Costigan, & Hawkins, 2004; Melender, 2002). Good

maternal nutrition can positively influence the health of the baby (American Dietetic Association [ADA], 2008; Fowles & Fowles, 2008). Recommendations for good maternal nutrition include eating a balanced diet containing adequate calories for appropriate weight gain and recommended amounts of specific vitamins and minerals, such as folate and iron; avoiding alcohol, tobacco and other drugs; and ensuring food safety through safe food handling and avoiding high-risk foods (ADA, 2008). Pregnant women receive a great deal of information related to having a healthy pregnancy, but information related to foodborne illness and food safety during pregnancy has been more limited (Athearn, et al., 2004).

Problem Statement

Pregnant women are twenty times more likely than other healthy adults to become infected by *L. monocytogenes* (Ogunmodede et al., 2005). This increased susceptibility is caused by two factors: a normal change in immune system functioning that prevents the mother's immune system from rejecting the fetus (Bondarianzadeh, 2007; Delgado, 2008; Ogunmodede et al., 2005) and the ability of *L. monocytogenes* to rapidly multiply in the placenta where it can then spread to infect other organs (Bakardjiev, Theriot, & Portnoy, 2006; Delgado, 2008). Pregnant women accounted for between 16 to 90 percent of patients in recent listeriosis outbreaks (Reddy et al., 2004). Ultimately, listeriosis in pregnant women can cause miscarriage or fetal death (Gandhi & Chikindas, 2007; Reddy et al., 2004). Newborns of mothers infected with *L. monocytogenes* can suffer from other illnesses with high morbidity and mortality, such as sepsis or meningitis (Ogunmodede et al., 2005; Reddy et al., 2004). Thus, a critical need exists to identify strategies to reduce the incidence of listeriosis in pregnant women.

Current FDA guidelines for pregnant women advise avoiding foods that pose high risk of contamination with *L. monocytogenes* (CFSAN, 2005b). The high risk foods include: hot dogs or luncheon meats eaten without reheating, soft cheeses made with unpasteurized milk, refrigerated pâtés or meat spreads, refrigerated smoked seafood, and raw or unpasteurized milk or foods that contain unpasteurized milk (CFSAN, 2005b). These recommendations were based on a quantitative risk assessment conducted by the FDA and the USDA Food Safety and Inspection Service (FSIS), with consultation from the CDC (FDA, USDA, & CDC, 2003). A draft of the risk assessment was released in 2001 (FDA, USDA, & CDC, 2003). Revisions were made to the draft based on invited comments, new data related to *L. monocytogenes* contamination and growth in different foods and at different storage times, and improved modeling techniques (FDA, USDA, & CDC, 2003). The final risk assessment was released in 2003.

One change in the final risk assessment was related to the recommendation about listeriosis risk from soft cheeses. The draft risk assessment advised pregnant women and other high-risk subpopulations to avoid soft cheeses completely. Newer data showed a low prevalence rate of listeriosis linked to soft cheeses, despite other research that showed a correlation between Hispanic-style fresh soft cheese and listeriosis (FDA, USDA, & CDC, 2003). However, the cheeses linked to listeriosis were found to be associated with non-commercially-produced cheeses and with cheeses made from unpasteurized milk. The final risk assessment concluded that avoiding the consumption of fresh soft cheese made from unpasteurized milk could reduce the risk associated with soft cheeses. Advice to consumers was updated with a new recommendation advising pregnant women to avoid soft cheeses unless they are made with pasteurized milk.

Pregnant women are considered active seekers of pregnancy-related information (Carolan, 2007). They use a variety of information sources including healthcare providers, friends and family, books and magazines, and the Internet (Carolan, 2007; Cates, Carter-Young, Conley, & O'Brien, 2004; Hsieh & Brennan, 2005; Szwajcer, Hiddink, Koelen, & van Woerkum, 2005). Despite this, previous research has shown that pregnant women have limited knowledge of *L. monocytogenes* (Cates et al., 2006; Ogunmodede et al., 2005) and decreased awareness that pregnancy increases susceptibility (Athearn et al., 2004; Cates et al., 2004; Trepka, Murunga, Cherry, Huffman, & Dixon, 2006). A focus group study (n=11 focus groups) found that pregnant women reacted negatively to some of the guidelines and wanted to know the reasons why specific recommendations were being made (Athearn et al., 2004). Further, pregnant women have also reported eating foods associated with a high risk of listeriosis, including deli meats, hot dogs, pâtés, and soft cheeses (Bondarianzadeh et al., 2007; Ogunmodede et al., 2005; Rungan & Badkar, 2005; Trepka et al., 2007).

Thus, several problems appear to be related to listeriosis prevention in pregnant women, including a lack of awareness of *L. monocytogenes* in general, negative reactions to the guidelines when they were made aware, and the consumption of high-risk foods. The data in most of these studies were collected at the time of the previous guidelines, which suggests a need for more current findings about awareness, beliefs, and behaviors related to listeriosis prevention. In addition, only two of the studies that examined consumption behaviors were conducted in the United States. One collected data at the time of the previous guidelines (Ogunmodede et al., 2005), while the other focused on a limited demographic group of women receiving services from the Special Supplemental

Nutrition Program for Women, Infants, and Children (WIC) in Miami, Florida (Trepka et al., 2007). Two other studies examining consumption behaviors (Bondarianzade et al., 2007; Rungan & Badkar, 2005) were conducted outside the United States, and these studies reflect the advice given in those countries. For example, in Australia and New Zealand, pregnant women are also advised to avoid soft-serve ice cream, pre-prepared salads, and cold cooked chicken purchased as ready-to-eat (Food Standards Australia New Zealand, 2005). Given that different countries have somewhat differing guidelines related to listeriosis prevention and different practices related to food choices, food storage, and food preparation, gaining an understanding about the behavior of American women can suggest areas for intervention.

The impact of changing guidelines should also be considered. Experts recommend that educational strategies related to prevention of foodborne illness need to be flexible in order to allow for updates as consumption and preparation practices change, pathogens adapt to their environment, new research information becomes available, regulatory requirements change, or new product design and formulations become available (ILSI RF/RSI, 2005; Kendall, Medeiros, Hillers, Chen, & DiMascola, 2003). As stated above, the guideline related to soft cheeses was updated in 2003. Further, the USDA changed their guidelines in 2006 when, along with the 2003 recommendations, they also advised at-risk groups to avoid salads made in the store such as ham salad, chicken salad, egg salad, tuna salad, or seafood salad (USDA, 2006). Neither the FDA nor the CDC has adopted this guideline, although the FDA is currently studying this issue (M. Davidson, personal communication, October 20, 2008). Given that food science

continues to evolve, the listeriosis prevention guidelines have the potential to be modified in the future.

No study has been conducted to examine the impact of changing advice regarding listeriosis prevention on consumer behavior. Studies in other health areas suggest that conflicting or contradictory information evoked a variety of emotions including confusion, anger, and skepticism (Aldoory, 2001; Borra, Kelly, Tuttle, & Neville, 2001; Fitzgibbon, et al., 2007; Vardeman & Aldoory, 2008). Further, exposure to conflicting or contradictory information has been linked to the adoption of less healthful behaviors (Bernal, Rose, & Kaufman, 2006; Patterson, Satia, Kristal, Neuhauser, & Drewnowski, 2001) or behaviors that were even more restrictive than the recommended behaviors (Vardeman & Aldoory, 2008). Understanding more about how pregnant women react to changing guidelines can lead to improved strategies for presenting updated health information so that women are neither eating nor avoiding the wrong types of foods.

The Extended Parallel Process Model [EPPM] can be used to examine the emotional and cognitive factors that underlie an individual's decision to accept a health message (Witte, 1994). According to the EPPM, individuals appraise a threat by first determining how serious the risk is and whether they personally are susceptible to the risk. If they do not perceive themselves to be at risk, no further processing is done. If they perceive personal risk, they next appraise the efficacy of the recommended response and whether they believe they have the ability to implement the recommended response. The EPPM predicts that if the perceived threat and perceived efficacy are high, individuals will accept the message and adopt behaviors that will help them confront the

risk (Witte, 1994). If perceived efficacy is low, the message will be rejected. Individuals will work to manage their fear, such as by discounting the message (Witte, 1994).

More effective communication can be developed by systematically examining the beliefs pregnant women hold regarding the threat of listeriosis, their susceptibility to listeriosis, the efficacy of the recommended prevention behaviors, and their self-efficacy for following the listeriosis prevention behaviors. Although the EPPM has not been applied to listeriosis prevention to date, it provides a systematic framework that can be used to examine factors underlying the adoption of listeriosis prevention behaviors.

Research Questions

The purpose of this research was to (1) examine awareness, beliefs, and behaviors related to listeriosis prevention in pregnant women, (2) determine the effect of changing recommendations related to listeriosis prevention on pregnant women's adoption of listeriosis prevention behaviors, and (3) use these findings to suggest strategies to improve listeriosis communication messages for pregnant women. This research used a mixed methods strategy. First, a secondary analysis of quantitative data from the Infant Feeding Practices Study II (IFPS II) (CDC, 2007) was conducted to understand the extent of awareness of *L. monocytogenes* and related high-risk behaviors in a national sample of pregnant women (n=4902). Next, a qualitative strategy was used to complement and expand the quantitative findings. Six focus groups with pregnant women (n=46) were used to more deeply examine awareness of listeriosis, high-risk consumption behaviors, and underlying beliefs related to listeriosis and related prevention behaviors. The focus groups were also used to gain an understanding of how women react to changing health information.

The following research questions were addressed:

1. What are the person characteristics (sociodemographics, health care access and usage, information sources) related to knowledge of *L. monocytogenes*?

Previous research found inconsistent results related to subgroup differences in awareness of *L. monocytogenes*; however, these studies used small samples. This question was explored in the present research through a secondary analysis of data collected in the IFPS II. The IFPS II did not ask about awareness related to all high-risk foods; therefore, the focus groups were used to expand the secondary data analysis.

2. What are the person characteristics (sociodemographics, health care access and usage, information sources, knowledge of *L. monocytogenes*) related to the consumption of high-risk foods?

Previous research conducted in the United States has been limited. In the present research, subgroup characteristics associated with consumption of high-risk foods were explored through a secondary analysis of data collected in the IFPS II. As above, the IFPS II did not ask about consumption of all the high-risk foods so the focus groups were used to more deeply examine consumption behaviors.

3. What are pregnant women's beliefs related to severity of and susceptibility to listeriosis?

The EPPM predicts that pregnant women who believe they are susceptible to listeriosis and believe that listeriosis has serious consequences will be more likely to appraise the efficacy of listeriosis prevention behaviors. Conversely, pregnant women who do not perceive the risk of listeriosis will have no further motivation

to process information related to this health threat. This research question was explored through the focus group research.

4. How do perceived response efficacy and self-efficacy relate to engagement in listeriosis prevention behaviors?

The EPPM predicts that pregnant women who perceive personal risk of listeriosis and have strong efficacy beliefs related to both the effectiveness of the recommended behavior and their ability to enact the behavior will be more likely to engage in listeriosis prevention behaviors. Focus group research was used to explore this question.

5. How do pregnant women respond to changes in health messages related to listeriosis prevention?

Pregnant women's response to changing health messages related to listeriosis prevention has not been studied to date. This question was explored through focus group research.

6. How can listeriosis prevention messages for pregnant women be improved?

This question was explored through focus group research and through an integration of the quantitative and qualitative findings.

Significance

Listeriosis has serious consequences in terms of severity of disease, high case-fatality ratio, and the related economic impact of associated medical costs, lost wages, and product recalls (Gandhi & Chikindas, 2007; Medeiros, Hillers, Kendall, & Mason, 2001). Because of this, Healthy People 2010, the United States government's blueprint for improved health, contains objectives related to reducing foodborne illness: Objective

10-1: Reduce infections caused by key foodborne pathogens and, specifically, Objective 10-1c: Reduce the number of *Listeria* infections to 0.25 per 100,000 cases by 2005 (U.S. Department of Health & Human Services [DHHS], 2000).

Recent surveillance data indicated that the incidence of listeriosis was 0.29 cases per 100,000 in 2008 (CDC, 2009a), indicating that the 2005 target was not met. While the relative rate of infection due to listeriosis infection has decreased 36% from 1996 when surveillance began, it has not changed significantly when compared to the past three years (CDC, 2009a). Thus, attention needs to remain on developing strategies to reduce listeriosis (Klontz et al., 2008). The draft Healthy People 2020 objectives continue to focus on reducing foodborne illness caused by *L. monocytogenes* and other foodborne pathogens (DHHS, 2009).

Consumer education is an important component of listeriosis prevention and should focus on those who are most at risk (ILSI RF/RSI, 2005; Kendall et al., 2003). Pregnant women face a disproportionate burden of listeriosis with severe consequences; however, they have limited knowledge of *L. monocytogenes* (Cates et al., 2006; Ogunmodede et al., 2005). Further, previous research found that pregnant women have reported consuming high-risk foods (Bondarianzadeh et al., 2007; Ogunmodede et al., 2005; Rungan & Badkar, 2005; Trepka et al., 2007).

The mixed-methods study used in this research was designed to fill gaps in our understanding of factors related to listeriosis prevention in pregnant women. The quantitative component analyzed data on awareness and behaviors reported by a large number of American women participating in the IFPS II. The IFPS II data were collected between 2005 and 2006, which allowed examination of the extent of knowledge about

listeriosis and engagement in high-risk behaviors since the guidelines were updated in 2003. It also provided a sense of whether current communication strategies regarding listeriosis prevention are reaching pregnant women.

The qualitative component was conducted to increase understanding of the underlying beliefs related to listeriosis prevention. This research used the EPPM as its theoretical framework and extended the use of the EPPM by applying it to the topic area of listeriosis prevention, with pregnant women as the target population. Very little research has examined the effect of changing health recommendations, and none has related to the listeriosis prevention guidelines. The qualitative component was also used to provide insight into how pregnant women respond to changing guidelines.

This research has implications for how to better communicate listeriosis prevention information to pregnant women, which could ultimately lead to a reduction in listeriosis incidence in pregnant women. This research may also have implications for other areas of health and risk communication. Ongoing research will continue to increase our understanding of health-related phenomena and will undoubtedly lead to changing advice in many health areas. Understanding how to best communicate changing advice is a factor that can facilitate message acceptance and adoption of the new advice.

Definition of Terms

Beliefs: cognitions related to the attributes of an object or action (Montano, Kasprzyk, & Taplin, 1997). For this research, beliefs were examined in relation to severity of and susceptibility to listeriosis, and response efficacy and self-efficacy related to listeriosis prevention.

Extended Parallel Process Model (EPPM): a theoretical model that explains how people process fear appeal messages. The EPPM predicts whether the fear appeal will be effective based on the individual's perceptions of the severity of and susceptibility to the threat, perceived response efficacy, and perceived self-efficacy to implement the recommended behavior (Witte, 1994).

Perceived susceptibility: beliefs about the personal likelihood of experiencing a specific threat (Witte, 1994). In this research, perceived susceptibility related to whether a pregnant woman believed she was more likely to contract listeriosis than other healthy adults.

Perceived severity: beliefs about the significance or the magnitude of a threat (Witte, 1994). In this research, perceived severity related to whether a pregnant woman believed that listeriosis posed a serious threat to her and to her fetus.

Perceived response efficacy: beliefs about the effectiveness of the recommended response in averting the threat (Witte, 1994). With respect to listeriosis prevention, perceived response efficacy related to whether a pregnant woman believed that she could reduce her risk of listeriosis by adopting the listeriosis prevention behaviors.

Perceived self-efficacy: beliefs about one's ability to perform the recommended response to avert the threat (Witte, 1994). Perceived self-efficacy for this research related to whether a pregnant woman believed that she could avoid the high-risk foods or eat them under the conditions specified in the guidelines, such as choosing soft cheeses made from pasteurized milk.

Perceived threat or perceived risk: beliefs about an actual threat. Perceived threat has two underlying dimensions: perceived severity and susceptibility.

Threat: an actual danger or harm that exists in the environment (Witte, 1994).

This research examined the threat of listeriosis to pregnant women.

Food safety: assurance that orally consumed products do not cause illness (Roberts, 2001)

Foodborne illness: illness that occurs when people ingest harmful microorganisms or chemical contaminants found in some foods or drinking water (CFSAN, 2005a)

Listeriosis: bacterial infection caused by *Listeria monocytogenes* (ILSI RF/RSI, 2005)

Listeriosis prevention behaviors: Actions that can be taken to reduce one's risk of listeriosis. Specifically, this would be following the listeriosis prevention guidelines.

Listeriosis prevention guidelines: Specific guidelines for pregnant women and other high risk groups that recommend avoiding the following foods: hot dogs and luncheon meats unless they are reheated until steaming hot; soft cheeses unless they are made from pasteurized milk; refrigerated pâtés or meat spreads; refrigerated smoked seafoods; raw or unpasteurized milk or foods made from raw or unpasteurized milk (CFSAN, 2005b).

Listeria monocytogenes: a foodborne bacterium (ILSI RF/RSI, 2005)

Panel study: a form of longitudinal research in which a panel of respondents is selected and then interviewed over time (Babbie, 2001)

Consumer panel: a sample whose purchases or media consumption is recorded over time (Glossary of Market Research Terms, 2008)

CHAPTER II: LITERATURE REVIEW

This chapter presents a literature review that provides the basis for the current research. It begins with an overview of listeriosis and its prevention. It continues by exploring information-seeking during pregnancy, what pregnant women know about listeriosis, and their engagement in listeriosis risk and prevention behaviors. Next, an overview of the Extended Parallel Process Model (EPPM) is presented, followed by an overview of risk and efficacy beliefs related to food safety and listeriosis. Then, literature relating to the impact of changing health advice is reviewed. The chapter concludes with a summary and implications.

Articles were identified for inclusion in this literature review through searches in the PubMed, PsycInfo, HealthSource: Nursing, and the Communication & Mass Media databases. Search terms included combinations of the following: *Listeria*, listeriosis, food safety, pregnant, pregnancy, risk communication, health communication, conflicting advice, confusing advice, and the EPPM.

Listeriosis

Listeriosis is a bacterial infection caused by *Listeria monocytogenes*, which is primarily a foodborne pathogen (Gandhi & Chikindas, 2007; ILSI RF/RSI, 2005). *L. monocytogenes* is the cause of only 0.02 percent of foodborne infections (ILSI RF/RSI, 2005; MacDonald et al., 2005). However, it has the highest case-fatality ratio of all the foodborne pathogens and causes 27.6 percent of deaths due to foodborne illness (ILSI RF/RSI, 2005; MacDonald et al., 2005). Life-threatening illness from *L. monocytogenes* affects about 2,500 people in the United States each year (Reddy et al., 2004).

Many opportunities exist for foods to be contaminated with *L. monocytogenes* because it is found throughout the environment, including agricultural settings, food processing plants, homes, and in healthy humans and animals (ILSI RF/RSI, 2005; Ramaswamy et al., 2007). Further, *L. monocytogenes* can survive and grow in a variety of environmental conditions, including at refrigeration temperatures and in acidic and salty foods (Gandhi & Chikindas, 2007). Because of these factors, *L. monocytogenes* is more resistant than other bacteria to the conditions and treatments typically used to control foodborne pathogens (FDA, USDA, & CDC, 2003). Despite its ubiquitous presence, most exposures to *L. monocytogenes* do not result in listeriosis (ILSI RF/RSI, 2005).

Two key factors have been associated with contracting listeriosis: (1) whether an individual is susceptible to listeriosis and (2) whether an individual consumes a contaminated food (ILSI RF/RSI, 2005). Certain population subgroups are more susceptible to listeriosis. These include the elderly, those who are immunocompromised, pregnant women and their fetuses, and newborns (FDA, USDA, & CDC, 2003; Gandhi & Chikindas, 2007; Ogunmodede et al., 2005; ILSI RF/RSI, 2005). Secondly, certain foods have been more strongly associated with contamination from *L. monocytogenes*. High-risk foods are those that have the potential for contamination with *L. monocytogenes*, support the growth of *L. monocytogenes*, are ready-to-eat, require refrigeration, and are stored for an extended period of time (ILSI RF/RSI, 2005). Examples of these foods include deli meats and unpasteurized dairy products (ILSI RF/RSI, 2005).

L. monocytogenes had been a known pathogen for many decades; however, its means of transmission of the infection was unknown (Schlundt, 2002; Tauxe, 2002). The

occurrence of several serious outbreaks in the early 1980's led to its recognition as an emerging foodborne pathogen (FDA, USDA, & CDC, 2003; Klontz et al., 2008; Schlundt, 2002). Changes in food production and processing, the globalization of the food industry, and a trend of increasing consumption of ready-to-eat refrigerated convenience foods are factors associated with the increased incidence of foodborne illness cause by *L. monocytogenes* (Gandhi & Chikindas, 2007; Posfay-Barbe & Wald, 2004). Further, advances in medicine have led to increased lifespan and survival for groups who are greater risk for listeriosis, including the elderly and those who have compromised immune functioning (Gandhi & Chikindas, 2007).

Two primary forms of listeriosis have been described: a non-invasive form and an invasive form (ILSI RF/RSI, 2005). In most healthy adults, listeriosis presents in the non-invasive form, which causes mild febrile gastrointestinal illness. However, listeriosis can cause severe infection in susceptible populations. The invasive form leads to infection in the liver, meninges, lungs, lymphatic system, and the placenta (Gandhi & Chikindas, 2007; Ogunmodede et al., 2005). Many people with the invasive form of listeriosis had a history of gastrointestinal illness, but researchers do not yet know whether these represent two independent syndromes or if the invasive form represents a progression from the non-invasive form (ILSI RF/RSI, 2005).

Pregnant women are twenty times more likely than other healthy adults to become infected (Ogunmodede et al., 2005). They accounted for between 16-90 percent of patients in recent listeriosis outbreaks (Reddy et al, 2004). Two factors lead to increased risk during pregnancy: a normal decrease in immune system functioning that prevents the maternal immune system from rejecting the fetus (Bondarianzadeh, 2007; Delgado,

2008; Ogunmodede et al., 2005) and the ability of *L. monocytogenes* to rapidly multiply in the placenta and then infect other organs (Bakardjiev, Theriot, & Portnoy, 2006; Delgado, 2008). Listeriosis can occur at any point in the pregnancy, but most cases occur in the third trimester when immune system function is the most depressed (Jacobsen & Serwint, 2008; Janakiraman, 2008; Cheung, & Sirkin, 2009). Typically, symptoms of listeriosis in pregnant women are mild and flu-like, thus making early diagnosis difficult (Janakiraman, 2008). Another factor affecting early diagnosis is that listeriosis has a long incubation period that can be up to 70 days (Swaminathan & Gerner-Smidt, 2007).

Ultimately, listeriosis in pregnant women can cause miscarriage, fetal death, or illness in the newborn (Gandhi & Chikindas, 2007; Reddy et al., 2004). Studies have shown severe and enduring psychological consequences of pregnancy loss for both the women and their partners (Bowles et al., 2000; Klier, Geller, & Ritsher, 2002). Newborns of mothers infected with *L. monocytogenes* can suffer serious illness with high morbidity and mortality, such as sepsis or meningitis (Ogunmodede et al., 2005; Reddy et al., 2004). A portion of infants with meningitis will develop chronic neurological complications that require ongoing medical attention as well as special educational services (Busby, Roberts, Lin, & MacDonald, 1996).

Cultural factors related to food preference may also play a role in susceptibility. Surveillance data collected in several states from 1996-2000 showed a higher incidence of listeriosis among Hispanics as compared with non-Hispanics, with the incidence of listeriosis among Hispanic women of childbearing age (15-39 years) 11 times higher than that in non-Hispanic women of the same age (Lay et al., 2004). Several outbreaks

showed that illness occurred almost exclusively among Hispanic women who ate Mexican-style cheese (Reddy et al., 2004).

Listeriosis has significant consequences in terms of severity of disease, high case-fatality ratio, and the economic impact of associated medical and rehabilitation costs, lost wages, special education services, and product recalls (Gandhi & Chikindas, 2007; Medeiros et al., 2001). A 1996 report estimated the annual costs of listeriosis to range between \$232 million to \$264 million (Busby et al., 1996).

Because of this severity, Healthy People 2010, the United States government's blueprint for improved health, contains Objective 10-1: Reduce infections caused by key foodborne pathogens and, specifically, Objective 10-1c: Reduce the number of *Listeria* infections to 0.25 per 100,000 cases by 2005 (DHHS, 2000). Recent data indicated that the incidence of listeriosis was 0.29 cases per 100,000 in 2008 (CDC, 2009a). While the relative rate of infection due to listeriosis infection has decreased 36% from 1996 when surveillance began, it has not changed significantly when compared to the past three years (CDC, 2009a). This indicates that focus needs to remain on strategies to reduce listeriosis (Klontz et al., 2008). The objectives currently being drafted for Health People 2020 continue to focus on reducing foodborne illness caused by *L. monocytogenes* and other foodborne pathogens (DHHS, 2009).

Prevention of Listeriosis

Strategies to reduce foodborne listeriosis include preventing contamination of foods with *L. monocytogenes*, preventing the growth of *L. monocytogenes* to high numbers, and educating consumers about foodborne illness and food safety strategies (ILSI RF/RSI, 2005). Thus, efforts to reduce listeriosis should be directed toward

manufacturers, retail establishments, and consumers (ILSI RF/RSI, 2005). Good manufacturing practices, sanitation procedures, and in-package pasteurization can minimize *L. monocytogenes* contamination and prevent cross-contamination (ILSI RF/RSI, 2005). Storage temperature is a critical factor in determining the rate of growth of *L. monocytogenes*; therefore, keeping foods refrigerated at or below forty degrees Fahrenheit to inhibit growth is also an important prevention strategy (ILSI RF/RSI, 2005). Consumer education is the third critical strategy needed to reduce foodborne illness incidence, with the recommendation that such education be targeted toward those who are at the greatest risk of listeriosis (ILSI RF/RSI, 2005; Kendall et al., 2003).

Government efforts to reduce the incidence of listeriosis have included the development of a surveillance system for listeriosis, targeted efforts to specific foods, the use of specific regulatory and enforcement programs to ensure the safety of foods from processing to consumption, and outreach and education efforts (FDA, USDA, & CDC, 2003; Klontz et al., 2008). Currently, the FDA maintains a policy of zero-tolerance for *L. monocytogenes* in ready-to-eat foods, i.e. a food is considered adulterated if *L. monocytogenes* is detected in either of two samples of that food (FDA, USDA, & CDC, 2003). Similarly, the USDA maintains a zero-tolerance policy toward *L. monocytogenes* in meat and poultry products (FDA, USDA, & CDC, 2003).

Another government initiative designed to help reduce the incidence of listeriosis was the development of a quantitative risk assessment (FDA, USDA, & CDC, 2003). The purpose of the risk assessment was to determine the relative risk of serious illness or death resulting from consumption of different ready-to-eat foods that could be contaminated with *L. monocytogenes*. This information would be used to identify foods

that should be the focus of regulatory attention (Klontz et al., 2008). In 2001, the FDA and the FSIS, with consultation from the CDC, released a draft risk assessment along with an action plan to reduce the risk of illness from *L. monocytogenes* (FDA, USDA, & CDC, 2003). The risk assessment evaluated ready-to-eat foods considered to be primary sources of *L. monocytogenes* by examining five factors that affect consumer exposure: amount and frequency of consumption of a food, frequency and levels of *L. monocytogenes* in ready-to-eat food, potential to support growth of *L. monocytogenes* in food during refrigerated storage, refrigerated storage temperature, and duration of refrigerated storage before consumption.

The draft version was revised based on invited comments, new data related to *L. monocytogenes* contamination and growth in different foods and at different storage times, and improved modeling techniques. The final version was released in 2003 (FDA, USDA, & CDC, 2003). The risk assessment identified five foods with the greatest risk of contamination per serving: deli meats, raw hot dogs, pâtés and meat spreads, unpasteurized milk, and smoked seafood. Each of these foods was then ranked based on the annual consumption of each food (see Table 1).

Deli meats and raw hot dogs were considered to be ‘Very High Risk’ based on the fact that they have relatively high rates of contamination, support rapid growth of *L. monocytogenes* under refrigerated storage, are stored for long periods, and have a high consumption rate. Pâtés and meat spreads, unpasteurized milk, and smoked seafoods were ranked ‘High Risk’ based on relatively lower contamination rates and/or fewer servings consumed per year. Heated hot dogs, fresh soft cheeses, fresh ripened cheeses, and deli-type salads were ranked ‘Moderate Risk,’ based again on relatively lower

contamination rates and/or fewer servings consumed. Findings from the risk assessment have been used to develop and update consumer guidelines.

Table 1: Estimates of the Total Number of Annual Servings of Foods Consumed by Pregnant Women in the United States (adapted from FDA, USDA, & CDC, 2003)

Food	Estimated Total Number of Annual Servings in Millions
Deli Meats	120
Frankfurters, reheated	38
Soft ripened cheese (e.g. Camembert, Brie, feta)	23
Frankfurters, not reheated	2.9
Unpasteurized milk	2.5
Smoked seafood	1.1
Pâtés and meat spreads	0.67
Fresh soft cheese (e.g. queso fresco, Panela)	0.48

For the general public, current food safety guidelines include frequent cleaning of hands and food preparation surfaces and tools; rinsing fresh fruits and vegetables; keeping raw meat, poultry, seafood and eggs separate from ready-to-eat foods; ensuring foods such as meat or poultry are cooked to high enough temperatures, such as cooking whole cuts of meat to 140 degrees Fahrenheit and poultry to 165 degrees, refrigerating foods promptly; and keeping foods cooled to refrigerator temperature at or below forty degrees Fahrenheit, and freezer temperatures to 0 degrees (Partnership for Food Safety Education, 2006). Additional guidelines include using ready-to-eat perishable foods as soon as possible, throwing out foods that are past the expiration and use-by dates, and regularly cleaning the refrigerator (CFSAN, 2005b).

Specific prevention guidelines for those at high risk of contracting listeriosis have been developed. The guidelines for pregnant women state, “Don’t eat

- Hot dogs and luncheon meats - unless they're reheated until steaming hot.
- Soft cheeses like Feta, Brie, and Camembert, ‘blue-veined cheeses,’ or ‘queso blanco,’ ‘queso fresco,’ or Panela - unless they're made with pasteurized milk. Make sure the label says, ‘Made with pasteurized milk.’

- Refrigerated pâtés or meat spreads.
- Refrigerated smoked seafood - unless it's in a cooked dish, such as a casserole. (Refrigerated smoked seafood, such as salmon, trout, whitefish, cod, tuna, or mackerel is most often labeled as 'nova-style,' 'lox,' 'kippered,' 'smoked,' or 'jerky.' These types of fish are found in the refrigerator section or sold at deli counters of grocery stores and delicatessens.)
- Raw (unpasteurized) milk or foods that contain unpasteurized milk.” (CFSAN, 2005b)

Effective educational strategies related to prevention of foodborne illness must be responsive to changes in behavior, food science, industry, and policy (ILSI RF/RSI, 2005; Kendall et al., 2003). This would allow for updates as consumption and preparation practices change, pathogens adapt to their environment, new research information becomes available, regulatory requirements change, or new product design and formulations become available (ILSI RF/RSI, 2005; Kendall et al., 2003).

Changing advice related to listeriosis prevention in susceptible populations is illustrated by examining the guideline related to soft cheeses. A specific recommendation based on the 2001 Draft Risk Assessment advised susceptible populations to avoid eating soft cheese such as Feta, Brie and Camembert cheeses, blue-veined cheeses, and Mexican-style cheeses such as “queso blanco” and “queso fresco.” The examination of newer data actually showed a low contamination rate for soft cheeses, despite conflicting data that showed a correlation between Hispanic-style fresh soft cheese and listeriosis (FDA, USDA, & CDC, 2003). However, the cheeses linked to listeriosis were found to be associated with non-commercially-produced cheese and with

some cheese made from unpasteurized milk. Thus, the risk assessment concluded that decreasing the consumption of fresh soft cheese made from unpasteurized milk could reduce the risk associated with soft cheeses. Advice to consumers was updated in the final version of the risk assessment, with the recommendation to avoid soft cheeses made from unpasteurized milk.

The USDA FSIS made another change to the guidelines in 2006. They added a guideline that stated, “Do not eat salads made in the store such as ham salad, chicken salad, egg salad, tuna salad, or seafood salad” (USDA, 2006). Neither the FDA nor the CDC has adopted this guideline, although the FDA is currently studying this issue (M. Davidson, personal communication, October 20, 2008).

The guidelines related to listeriosis prevention differ in other countries. For example, in Australia and New Zealand, pregnant women are also advised to avoid soft-serve ice cream, pre-prepared salads, and cold cooked chicken purchased as ready-to-eat (Food Standards Australia New Zealand, 2005). In the United Kingdom, vulnerable populations are advised to avoid all soft cheeses and all types of pâtés, including vegetable pâtés (Food Standards Agency, 2008). Research from other countries regarding contamination, outbreaks, and high-risk foods was considered in the 2003 Risk Assessment and could also impact listeriosis prevention guidelines in the future.

Changes in food consumption patterns may also point to the need for updating educational messages. An example may relate to the consumption of unpasteurized dairy products. In a 1995-6 survey of American adults, only about 1 percent reported drinking unpasteurized milk (Altekruse, Yang, Timbo, & Angulo, 1999). Recent anecdotal evidence suggests that the public demand for raw milk is increasing (Squires, 2007;

Weise, 2008). This suggests that the incidence of foodborne illness related to this food vehicle could increase.

Pregnancy and Health Information-seeking

Pregnancy is generally considered a joyous time; however, it is also accompanied by its own unique physical, psychological, and social challenges, such as changes in body and body image, physical discomforts, concerns and fears about delivery, worries about the baby's health, changing relationships, and financial uncertainties (Affonso et al., 1999; DiPietro et al., 2004; Melender, 2002). Good maternal nutrition is one factor that can positively influence the health of the baby, while complications such as low birth weight, congenital anomalies, and fetal death have been linked to poor nutrition during pregnancy (ADA, 2008; Fowles & Fowles, 2008). Recommendations for good maternal nutrition include eating a balanced diet containing adequate calories for appropriate weight gain and recommended amounts of specific vitamins and minerals, such as folate and iron; avoiding alcohol, tobacco and other drugs; and ensuring food safety through safe food handling and avoiding high-risk foods (ADA, 2008). Pregnant women have been inundated with information related to having a healthy pregnancy, but information related to foodborne illness and food safety during pregnancy has been more limited (Athearn, et al., 2004). Most of the pregnant women interviewed in a qualitative study thought that pregnancy-related nutrition information was important because making dietary modifications were one of the few things they could actually do to improve the health of their fetus (Szwajcer, Hiddink, Koelen, & van Woerkum, 2005).

Pregnant women actively seek pregnancy-related information. Several studies found that they use their healthcare providers, friends and family, books and magazines,

and the Internet as sources of pregnancy-related information (Bondarianzadeh et al., 2007; Carolan, 2007; Cates et al., 2004; Hsieh & Brennan, 2005; Szwajcer et al., 2005). Focus group participants reported that they often obtained more information from books, magazines, and the Internet than from their health care providers (Cates et al., 2004; Hsieh & Brennan, 2005).

No study to date has specifically asked pregnant women about their sources of food safety information or whether they actively seek food safety information. However, Ogunmodede et al. (2005) found that survey participants who had heard of listeriosis reported receiving that information from their healthcare provider or from pregnancy-related magazines and books. Athearn et al. (2004) found that when pregnant women were informed of current food safety guidelines for pregnant women, they felt that such information should come from their health care provider. Research from earlier in this decade suggested that food safety information was rarely given by healthcare providers (Cates et al., 2004; Morales, Kendall, Medeiros, Hillers, & Schroeder, 2004; Rungan & Badkar, 2005; Wong et al., 2004); however, a recent survey found that sixty percent of obstetricians and gynecologists reported providing their patients with information on listeriosis (Ross et al., 2009).

Listeriosis Awareness and Behaviors among Pregnant Women

Awareness of *L. monocytogenes* has been low in both the general population and among pregnant women. Analysis of data from the Food Safety Survey showed that awareness of *L. monocytogenes* among the general population was 9 percent in 1993, but had increased to 14 percent in 1998 (USDA, 2001). More recent survey data indicate awareness of *L. monocytogenes* in a sample of American adults to be 44 percent;

however, only about one-third of these could identify a food vehicle (Cates et al., 2006). This study also found no differences in awareness of *L. monocytogenes* between those whose households contained a member who was immuno-compromised or pregnant than those whose households did not.

Studies conducted with pregnant women showed limited knowledge of *L. monocytogenes*. Two surveys conducted in 2002-3 showed minimal awareness of listeriosis by pregnant women (15 percent in the Minnesota survey, n=286; 18 percent in the multi-state survey, n=403) and, overall, fewer than 30 percent knew that avoiding certain foods could decrease risk of listeriosis risk (Ogunmodede et al., 2005). This study found no significant subgroup differences in knowledge by race, age, level of education, trimester of pregnancy, and number of pregnancies (Ogunmodede et al., 2005). Trepka et al. (2007) found that pregnant women receiving services from the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) in Miami, Florida (n=62) with no other children had less knowledge of general food safety when compared to women who had other children. The researchers also noted that the first-time pregnant women were younger than those with other children. This suggests possible subgroup differences based on age and parity.

A 2006 survey of Australian women selected from three hospitals found that 66 percent were aware of listeriosis as a foodborne illness, but more than half of the respondents had incomplete knowledge of which foods were high risk (Bondarianzadeh et al., 2007). In this survey, women for whom English was a first language, women with a planned pregnancy, and women with a yearly household income of greater than \$50,000 were more likely to identify all of the high-risk foods. In addition, women who

had received some kind of advice from different sources were three times more likely to identify all of the high-risk foods.

Focus groups conducted with pregnant women or new mothers revealed that most were unfamiliar with *L. monocytogenes* (Athearn et al., 2004; Cates et al., 2004; Trepka et al., 2006). In another focus group study, most participants were unaware of the recommendations to avoid smoked seafood and deli salads and to reheat cold cuts (Athearn et al., 2004).

American women who are pregnant have reported eating foods associated with a high risk of listeriosis (Ogunmodede et al., 2005; Trepka et al., 2007). Ogunmodede et al. (2005) asked about the consumption of unpasteurized dairy products as well as deli-style and ready-to-eat foods. They found that more than eighty percent of surveyed pregnant women reported consuming these foods. Specifically, in their national sample, only eighteen percent reported avoiding deli-style and ready-to-eat foods, while 86 percent reported avoiding unpasteurized milk. No subgroup differences were identified. Trepka et al. (2007) found that 51.6 percent of pregnant women reported eating hot dogs or deli meats without reheating at least sometimes or more frequently, and 35.5 percent reported eating soft cheeses at least sometimes or more frequently. Although this was a more recent study, it asked about soft cheeses in general and did not distinguish between those made from pasteurized or unpasteurized milk.

Similarly, pregnant women outside the United States reported consumption of high-risk foods. Among the pregnant women surveyed by Bondarianzadeh et al. (2007), 43 percent reported regular consumption of cold deli meats, 18 percent regularly consumed pre-prepared salads, 12 percent consumed pâtés, 11 percent consumed soft

cheeses, and 3 percent consumed cold smoked salmon. They found that pregnant women who were more knowledgeable about high-risk foods were less likely to report eating high-risk foods. Rungan and Badkar (2005) found that 50 percent of pregnant women reported eating coleslaw, 35 percent reported eating cold cooked chicken and meats, 19 percent consumed soft cheeses, and 14 percent consumed cold cooked fish. No subgroup differences were reported.

The Extended Parallel Process Model

Health promotion and health education programs will have a greater chance of achieving their goals in a time-efficient and cost-efficient manner when they are guided by a theory of health behavior (Glanz, Lewis, & Rimer, 1997; Witte, 1997). The use of theory to guide the development of health programs can simplify and systematize the development process (Witte, 1995). The Extended Parallel Process Model (EPPM) (Witte, 1992) is a theoretical framework that can be used to more systematically understand the issues around the adoption of listeriosis prevention behaviors and to help design stronger communications around listeriosis prevention. This section provides an overview of the EPPM, which is then used to frame the discussion of food safety beliefs in the next section.

The EPPM explains the cognitive and emotional factors that people use when processing a fear appeal and predicts whether they will accept or reject the message (see Figure 1) (Witte, 1994). In this model, a fear appeal is defined as a persuasive message that arouses fear by depicting a personally relevant threat and then provides effective recommendations for deterring the threat (Witte, 1994).

According to the EPPM, a fear appeal elicits two cognitive appraisals (Witte, 1992, 1994). The first relates to perceived threat. Perceived threat contains two underlying dimensions: perceived severity and perceived susceptibility (Witte, 1992, 1994). Perceived severity relates to beliefs about the seriousness of the threat while perceived susceptibility relates to an individual's beliefs about their personal risk of experiencing the threat (Witte, 1992). When the threat is seen as small or irrelevant, the person will be unmotivated to process the message further and no response is made to the fear appeal.

When the threat is perceived as real, fear is elicited and the person will move to the second appraisal, an evaluation of the efficacy of the response (Witte, 1992, 1994). This appraisal also consists of two underlying dimensions: response efficacy and self-efficacy (Witte, 1992, 1994). Perceived response efficacy relates to the thoughts a person has about the effectiveness of the recommendations in deterring the threat. Perceived self-efficacy relates to the beliefs an individual has about their ability to perform the recommended behavior.

If the perceptions of efficacy are greater than those of threat, danger control processes will predominate (Witte, 1994). The danger control processes are primarily cognitive processes in which the individuals realize they are at risk from a severe threat, believe they can deter the threat, and are motivated to protect themselves. Ultimately, they accept the message and adopt the attitudes, intentions, and behaviors needed to control the danger. Fear appeals with high levels of threat and high levels of efficacy have been found to produce the greatest amounts of message acceptance (Witte, 1994).

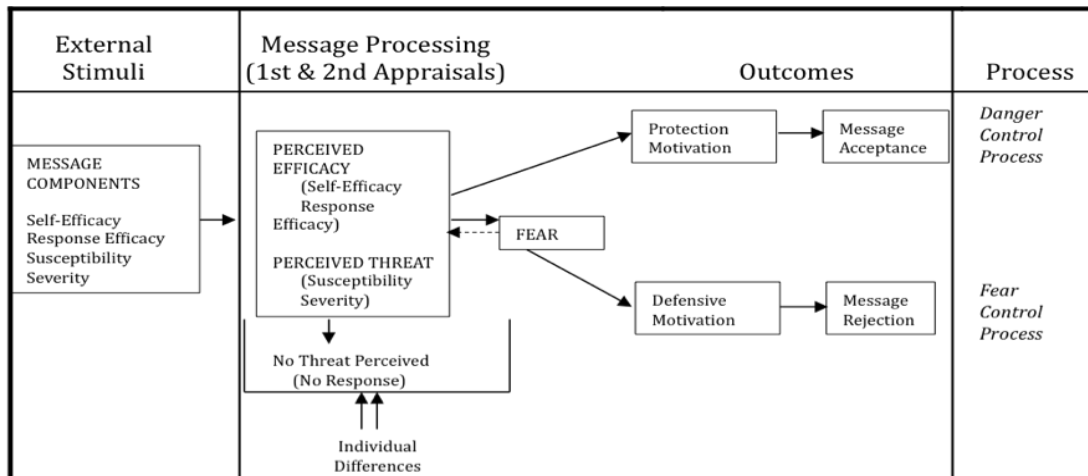


Figure 1: The Extended Parallel Process Model (Witte, 1994) [used with permission]

If a person believes that they cannot prevent the threat, either because they believe the response is ineffective or because they believe they cannot perform the recommended behavior, fear control processes predominate (Witte, 1994). These are emotional responses whereby people respond to and cope with their fear and not the danger. People try to control their fear through defensive avoidance or reactance (Witte, 1992; Witte & Allen, 2000). In defensive avoidance, the individual tries to avoid a message by being inattentive to it or by suppressing the thoughts of danger. Reactance occurs when the individuals feel angry about the message and believe that they are being manipulated. This also results in people minimizing the message (Witte, 1994). Fear appeals with high levels of threat and low levels of efficacy result in message rejection.

According to the EPPM, fear provides motivation to process the message through a feedback loop (Witte, 1992). Thinking about the threat may contribute to the experience of fear and experiencing fear may make the threat seem more severe. The perception of efficacy will determine what happens when fear is aroused (Witte, 1992). If efficacy is low, fear will be increased and lead directly to maladaptive fear control responses. Danger control processes interfere with fear control processes such that the more one is

making appropriate responses to a threat, the less likely they are to be defensively resisting the recommendations (Witte & Allen, 2000).

The EPPM has been tested empirically using messages related to many different health risks and behaviors including AIDS (Witte, 1994), meningitis (Gore & Bracken, 2005), cardiovascular disease (McKay, Berkowitz, Blumberg, & Goldberg, 2004) and smoking (Wong & Capella, 2010). Additional support for the EPPM comes from a meta-analysis of 98 studies (Witte & Allen, 2000). This meta-analysis confirmed that fear appeals that produce both high perceived threat and high perceived efficacy have the strongest effects on attitudes, intentions, and behavior. Low threat messages produced little persuasive effects. The model has also been examined with a more uncertain risk, the exposure to electromagnetic fields (McMahan, Witte, & Meyer, 1998). In this study, the fear appeals also acknowledged the scientific uncertainty regarding the risk of exposure to electromagnetic fields. Similar to research findings around known risks, this study found that the most effective messages for uncertain risks contained high levels of perceived threat and high levels of response and self-efficacy.

The EPPM provides a framework that explains how people process fear appeals. It also suggests strategies that can be used to develop messages, such as by including strong risk and strong efficacy components. A content analysis of nationally distributed general food safety messages found that messages were more likely to include content related to increasing risk perception, but rarely included information designed to impact self-efficacy (Gordon, 2003). This suggests that the development of food safety messages in general has not been consistently guided by health behavior theory. Using the EPPM to improve listeriosis prevention messages would require a thorough

examination of pregnant women's perceptions related to the severity of and susceptibility to listeriosis, response efficacy toward the listeriosis prevention behaviors, and self-efficacy for implementing the listeriosis prevention behaviors. The EPPM has not been applied in its entirety to food safety or listeriosis; however, its individual constructs have been applied in some research. The next section summarizes the research related to beliefs about food safety, using the EPPM as an organizing framework.

Risk and Efficacy Beliefs related to Food Safety and Listeriosis

Perceived severity of foodborne illness

Although foodborne illness has serious consequences, most people perceive the severity to be minimal (Gordon, 2003). Consumers underestimate the severity of foodborne illness, with most believing that foodborne illness is generally mild (Bruhn, 1997). Finn and Louviere (1992) found that food safety concerns were ranked very low when compared to ten other general risks, such as environmental protection, medical care, and taxation.

Consumer concerns and beliefs are likely to change over time in response to real-world events (Miles & Frewer, 2001). Some researchers contend that the public has been more concerned about food-related hazards over recent years because of well-publicized food scares and a decrease in trust over the regulation of the food supply and in scientific risk assessments (Kriflik & Yeatman, 2005; Miles & Frewer, 2001). The rising demand for organic foods has been linked to consumers' health concerns about eating contaminated foods (Kriflik & Yeatman, 2005). A study in Ireland (McCarthy, Brennan, Ritson, & de Boer, 2006) found that participants felt they were knowledgeable about *Salmonella* and attributed their knowledge to several high profile incidents in the United

Kingdom and Ireland. Bondarianzadeh et al. (2007) found that 55 percent of surveyed pregnant Australian women felt listeriosis was a great risk to their unborn baby, 38 percent were not sure, and 7 percent thought listeriosis was not a great risk.

Perceived susceptibility to foodborne illness

Several surveys found that people often underestimated their personal risk of food-related illness (Cody & Hogue, 2003; Redmond & Griffith, 2004a; Redmond & Griffith, 2004b). Respondents believed that they personally engaged in proper food safety behaviors, thus their risk of foodborne illness from self-prepared foods was minimal (Cody & Hogue, 2003; Redmond & Griffith, 2004a; Redmond & Griffith, 2004b). They also believed that other food preparers were more likely to be at risk of foodborne illness (Redmond & Griffith, 2004b). Participants in a focus group study, which was designed to get feedback related a brochure about the safe handling of fruits and vegetables, thought that people would not adopt all of the recommended behaviors unless they had had personally experienced foodborne illness related to produce (Li-Cohen, Klenk, Nicholson, Harwood, & Bruhn, 2002).

Focus groups conducted with pregnant women in the United States revealed that most were unaware that pregnant women are highly susceptible to foodborne illness (Athearn et al., 2004; Cates et al., 2004; Trepka et al., 2006). Similarly, only one participant in another series of focus groups had heard that pregnancy increased the risk of foodborne illness (Athearn et al., 2004). The survey of Australian women found that despite the fact that more than half identified listeriosis as a serious risk, 38 percent did not believe that they were personally at risk, with another 50 percent stating that they were not sure (Bondarianzadeh et al., 2007).

Response efficacy related to the listeriosis prevention guidelines

Only one study was identified that described pregnant women's reactions toward food safety and listeriosis prevention recommendations. This study found that pregnant women in focus groups were skeptical about specific food safety recommendations related to listeriosis prevention, particularly regarding reheating cold cuts and avoiding smoked seafood and deli salads (Athearn et al., 2004). The researchers noted that the discussion of these recommendations changed the tone of many of the focus groups to "defense and disbelief" (Athearn et al., 2004, p. 157). The participants expressed resistance to adopting these recommendations without understanding why the recommendations were being made.

Self efficacy to prevent foodborne illness

Because many consumers believe that their personal risk of foodborne illness is low and that they engage in proper food safety behaviors, Redmond & Griffith (2004b, p. 312) concluded that "judgments of 'optimistic bias' and 'illusion of control'" could prevent consumers from taking appropriate food safety measures. Similarly, a survey conducted in Ireland (McCarthy et al., 2006) found that most participants had confidence that they could control their risk from *Salmonella* at home due to their own food-handling techniques.

Bondarianzadeh et al. (2007) asked survey participants about their confidence in being able to follow recommendations by a doctor or government body to avoid foods that pose a risk to their unborn baby. Ninety percent felt they could avoid raw seafood, 76 percent could avoid soft cheeses, 58 percent could avoid pre-prepared vegetable salads, and 53 percent could avoid luncheon meats and cold deli salads. The focus groups

conducted by Athearn et al. (2004) found that pregnant women had many questions about the specific nature of each listeriosis prevention recommendation, such as which cheeses were considered soft cheeses and whether prepackaged luncheon meat was safer than meat sliced at the deli counter, which could affect self-efficacy for following the guidelines.

The Impact of Changing Health Messages

Public interest in health has increased as consumers take a more active role in their own health and self-care (ADA, 2006; Berry, 2004; Fineberg & Rowe, 1998; Patterson et al., 2001). At the same time, the amount of media coverage and the number of publications devoted to health-related topics has dramatically increased (Berry, 2004; Fineberg & Rowe, 1998). Consumers have not necessarily been enlightened by this wealth of information (Fineberg & Rowe, 1998). First, the health messages themselves have become increasingly complex (Patterson et al., 2001). Often, reports do not provide enough background information for consumers to correctly interpret the findings or apply the given advice (ADA, 2006; Covello & Peters, 2002; Kriflik & Yeatman, 2005). The messages may come from a variety of sources with differing agendas; thus, the content and accuracy of the messages can vary widely (Fitzgibbon et al., 2007; Patterson et al., 2001). Further, new and preliminary findings are often reported, and emerging evidence might appear to conflict with previous reports (Gandy, 2008). When the general public is not familiar with the evolutionary nature of science, these types of findings seem to be contradictory and confusing (Gandy, 2008; Fineberg & Rowe, 1998).

The general public has reported finding contradictions and feeling confused by messages related to a variety of health topics including nutrition (Borra et al., 2001;

Fitzgibbon, et al., 2007; Kriflik & Yeatman, 2005), women's health (Aldoory, 2001), breastfeeding (Hauck, Hall, & Jones, 2007), safe seafood consumption (Vardeman & Aldoory, 2008), and the prevention of Sudden Infant Death Syndrome (Colson et al., 2005; Mosely, Stokes, & Ulmer, 2007). In general, these studies found that when people were confronted with confusing or contradictory information, they felt a variety of emotions including helplessness, confusion, anger, frustration, distrust, stress, discouragement, skepticism, and a lack of confidence in being able to follow health recommendations. Some reported becoming hypervigilant about health information, while others chose to discount the information. Aldoory (2001) found that women exposed to contradictory messages reported less personal involvement in the message, which might limit further information processing or information seeking around the issue.

Exposure to changing or contradictory health messages can have a negative impact on behavior. Forty percent of participants in one survey reported being tired of hearing about which foods to eat and felt dietary recommendations should be taken with a degree of skepticism (Patterson et al., 2001). More importantly, those with more negative feelings about dietary recommendations were also found to eat diets higher in fat (Patterson et al., 2001). Bernal et al. (2006) found that when college students were exposed to a public service announcement against drinking and also exposed to an ad promoting alcoholic beverages, they were more likely to report increased intentions to consume alcoholic beverages as compared to students who saw the anti-drinking public service announcement along with a soft drink ad. In focus groups conducted around conflicting messages related to seafood consumption and methylmercury, pregnant women and new mothers reported that protective feelings toward their unborn/newborn

children would lead them to avoid fish altogether rather than to try to ascertain safe behavior from contradictory messages (Vardeman & Aldoory, 2008). Focus groups with new parents were conducted after medical advice was changed to recommend the supine sleep position to reduce SIDS risk (Mosley et al., 2007). Many of the parents discounted the health experts and believed that if they waited long enough, the message would change again. Therefore, they chose to follow the advice of those closer to them, specifically relatives who had successfully raised children. Only one study was found in which exposure to conflicting advice did not impact behavior (Hauck, Hall, & Jones, 2007). In this study, women initiated and continued breastfeeding, despite self-reported exposure to conflicting advice; however, the participants were older, educated, knowledgeable about breast-feeding, and had high self-efficacy for breastfeeding.

These studies show that when messages are confusing, either due to their own complexity or to contradictions within or between messages, they appear to have a strong and potentially negative impact on message effectiveness and ultimately on the adoption of healthful behaviors. No study has examined the effect of the changing listeriosis guidelines. Given that the listeriosis guidelines have been and will likely be updated again, understanding how pregnant women react to changing messages could help suggest strategies for how best to present updated information.

Conclusions

Pregnant women are at higher risk than other healthy adults for contracting listeriosis, a serious foodborne illness. This chapter reviewed what is known about awareness, beliefs, and behaviors related to listeriosis prevention among pregnant women. Several gaps in our understanding were identified. First, the data in the majority

of studies examining listeriosis knowledge and behaviors were collected prior to 2003 when the prevention guidelines were updated. An additional problem is that the researchers do not specifically ask about all of the high-risk foods, thus, we have only a partial understanding of the extent of listeriosis prevention knowledge and behaviors. To date, very little research has examined pregnant women's beliefs related to listeriosis prevention. Finally, literature related to changing health messages has not focused on changing advice related to the prevention of listeriosis.

Therefore, the literature review identified the need to assess current levels of awareness of listeriosis and engagement in high-risk behaviors, identify whether subgroup differences exist, examine underlying beliefs that affect the adoption of listeriosis prevention behaviors, and determine the impact of changing messages.

Examining awareness, behaviors, and subgroup differences on a broad scale suggests the need for quantitative methods. However, qualitative methods are considered an essential strategy for understanding actual food-related concerns that consumers have (Miles & Frewer, 2001). Therefore, qualitative methods are also needed to systematically examine the underlying beliefs related to listeriosis and the impact of changing messages. The research gaps identified in this literature review suggested that both quantitative and qualitative approaches would be needed to understand factors related to the adoption of listeriosis prevention behaviors and to ultimately improve listeriosis prevention messages for pregnant women. A mixed methods study encompassing these approaches is presented in Chapter 3.

CHAPTER 3: METHODOLOGY

The literature review presented in the previous chapter suggested the need for a mixed methods study to increase the breadth and depth of our understanding of factors related to listeriosis prevention in pregnant women. Mixed methods research has been defined as “research in which the investigator collects and analyzes data, integrates the findings, and draws inferences using both qualitative and quantitative approaches or methods in a single study or a program of inquiry” (Tashakkori & Creswell, 2007, p.4). This chapter describes the methods used in this study. It first presents an overview of the study, the methods used in the quantitative study, the methods used in the qualitative study, and concludes with how the results were integrated.

Study Overview and Research Questions

This study used a sequential explanatory mixed methods design (Creswell & Plano Clark, 2007). In the first phase of the research, a secondary analysis of quantitative data collected in the Infant Feeding Practices Study II (IFPS II) (CDC, 2007) was conducted. Then, qualitative data collected during focus groups with pregnant women were used to explain and build upon quantitative findings. The final phase of the research consisted of an integration of these qualitative and quantitative findings. A model of the study design is presented in Figure 2.

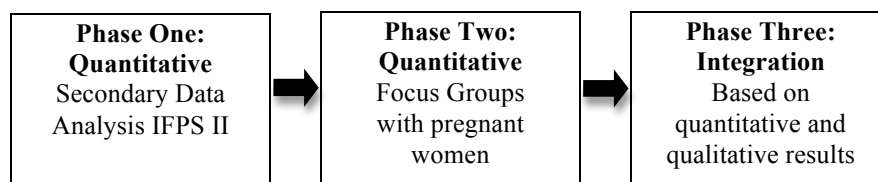


Figure 2: The Mixed Methods Study Design

The purpose of this research was to (1) examine awareness, beliefs, and behaviors related to listeriosis prevention in pregnant women, (2) determine the effect of changing recommendations related to listeriosis prevention on pregnant women's adoption of listeriosis prevention behaviors, and (3) use these findings to suggest strategies to improve listeriosis communication messages for pregnant women. The following research questions were addressed:

1. What are the person characteristics (sociodemographics, health care access and usage, information sources) related to knowledge of *Listeria monocytogenes*?
2. What are the person characteristics (sociodemographics, health care access and usage, information sources, knowledge of *L. monocytogenes*) related to consumption of high-risk foods?
3. What are pregnant women's perceptions of severity of and susceptibility to listeriosis?
4. How do perceived response efficacy and self-efficacy relate to engagement in listeriosis prevention behaviors?
5. How do pregnant women respond to the changes in health messages related to listeriosis prevention?
6. How can listeriosis prevention messages for pregnant women be improved?

This project was supported by a two-year research fellowship awarded by the Oak Ridge Institute for Science and Education (ORISE), which has provided a monthly stipend to this researcher. Additionally, the FDA provided financial support for all expenses related to the focus groups. These expenses included retention of the market

research firm to recruit participants, focus group incentives, facilities in which to hold the focus groups, a professional focus group moderator, and travel costs for this researcher.

Quantitative Study using Secondary Data Analysis

Population and sampling

The sample for the IFPS II was drawn from a nationally distributed consumer opinion panel consisting of more than 500,000 households (Fein et al., 2008). Information on pregnancy status within each member household was routinely collected in the consumer panel study. Women who were at least 18 years of age, pregnant, and expecting the birth of one child were invited to participate in the IFPS II. Women who were under the age of 18, not pregnant, or expecting the birth of multiples were excluded. Participants could be excluded later from the study based on additional exclusion criteria that were implemented after the birth of the child, such as if the infant developed a serious long-term health problem that affected feeding. In these cases, their data were included up to the questionnaire from which they were disqualified. The present research included data from a subset of IFPS II participants who completed three specific questionnaires within this panel study: the Demographic Questionnaire (DQ), the Prenatal Questionnaire (PQ), and the Prenatal Diet History Questionnaire (PDHQ).

Demographic information for the consumer panel was routinely collected for the designated panel member and spouse. Most demographic information for the participants was available through this routine collection of data. However, if the pregnant woman was a household member, rather than the designated panel member or spouse, she was asked to fill out a DQ for herself. Although some demographic information is available

for all participants, information related to three variables (education, employment status, and marital status) is missing for those who did not return the DQ.

The PQ was sent to 15,147 women. Of these, 529 were disqualified from the mailing list as undeliverable or duplicate mailings. A total of 4,902 questionnaires were returned from qualified respondents. The response rate for this questionnaire could not be calculated (Fein et al., 2008). This is because only qualifying households returned the survey. Those who did not return the survey may or may not have qualified for participation.

The PDHQ was sent to a subsample of women who returned the PQ early enough to allow them to complete the PDHQ before their infants were born (Fein et al., 2008). A response rate of 85.9% was calculated for the PDHQ (1757 mailed, 8 undeliverable, 1502 completed and returned) (Fein et al., 2008).

In sum, for the secondary data analysis, participants were selected if they were pregnant, age 18 or older, and if they had completed 3 specific questionnaires (DQ, PQ, and PDHQ) as part of the IFPS II. The sample size for the analysis was 1333.

Methods

Primary data collection

The IFPS II (CDC, 2007) was used as the source of data for the secondary analysis. This longitudinal panel study was administered to examine factors related to infant health and infant feeding (Fein et al., 2008). In a longitudinal panel study, data are collected from the same group of participants repeatedly over a period of time (Babbie, 2001). Use of a panel study was considered the most cost-effective way to identify a sample of pregnant women who would be likely to fill out repeated questionnaires (Fein

et al., 2008). The IFPS II collected data via mailed surveys, with the exception of one telephone interview conducted near the time of the infant's birth (Fein et al., 2008). Data were collected from May 2005 through June 2007, with prenatal data collected through early 2006.

Women completed the PQ in their seventh month of pregnancy, and then they completed additional surveys related to infant feeding and health throughout the infant's first year of life. The study also included two maternal dietary assessments. The PDHQ was administered after the PQ but before the birth of the child. The second DHQ was administered postnatally. Demographic information for the consumer panel was routinely collected for the designated panel member and spouse. As stated previously, if the pregnant woman was a household member, she was asked to fill out a DQ for herself.

Reliability and Validity of the IFPS II

Limited reliability and validity information was available for the IFPS I and II. For the IFPS I, test-retest reliability was shown by the consistency of responses to certain items that were administered month to month (DHHS, nd); however, no reliability coefficient was reported. Convergent and discriminant validity was shown by the expected similarity of certain study estimates with data from other studies and with expected differences of certain study estimates with other data (DHHS, nd). The IFPS I questions had undergone cognitive testing and pretesting.

Whenever possible, questions for the IFPS II were selected from the IFPS I. The FDA, the CDC, and members of a working group with specific expertise in a topic area developed new questionnaire items for the IFPS II (Fein et al., 2008). The assessment of mothers' dietary intake used a modified version of a previously validated instrument, the

Diet History Questionnaire (Fein, 2008). Modifications involved changing the timeline of questions from asking about ‘intake in the past year’ to asking about ‘intake in the past month’ to accurately measure intake while pregnant or postpartum. Additionally, specific foods of interest for pregnant women, such as specific kinds of fish, were added. New questions from all questionnaires were tested via cognitive interviewing with respondents chosen from the consumer opinion panel (Fein et al., 2008). Pilot tests of the questionnaires were also conducted (Fein et al., 2008).

Data preparation

SPSS Statistics GradPack 17.0 (2008) was used for all data analyses. Data cleaning was done prior to the public release of the data, particularly to adjust for inconsistent, conflicting, and implausible responses (Fein et al., 2008).

Two additional data checks were conducted for this research. First, consistency of responses for the question related to ‘Awareness of *Listeria*-related food vehicles’ (PQ45) was examined to determine if any participant checked any of the specific foods along with the ‘Don’t know’ response for this question. Three cases were found (Participants 01266301, 01741601, and 02282535). The “Don’t Know” response in each of these cases was reset to unchecked, keeping only the responses related to the specific foods.

The other data check examined satisficing. Satisficing is a response strategy that occurs when a survey respondent uses superficial strategies to answer survey questions, rather than adequately and accurately processing and responding to the questions (Krosnick, 2000). The data were examined to determine whether any participant simply checked all responses to the listeriosis items in question 46 on the PQ, which may

indicate the use of a satisficing strategy. No participant checked all responses; therefore, no evidence of satisficing was found according to this criterion.

Sample size and missing data analysis

An *a priori* power analysis for multiple regression was calculated using Gpower 3.0 (Faul, Erdfelder, Lang, & Buchner, 2007). This analysis, using a .05 level of significance, a .80 level of power, a medium effect size, and 15 predictor variables, determined that the needed sample size was 139. Logistic regression requires a larger sample size than multiple regression (Wright, 1995). Recommendations for logistic regression range from 10 cases per predictor (Garson, 2008) to 50 cases per predictor (Wright, 1995). At the more conservative estimate of 50 cases per predictor, a sample size of 750 would be required for logistic regression.

An analysis of missing data was conducted for the subset of data used in this research using the SPSS Missing Values Analysis module. A preliminary examination of the dataset indicated very low percentages of missing data; however, the variable for employment was missing 6.2% of its data. Because this variable was included in some of the multivariate analyses, the resulting dataset was reduced to 1251 observations from 1333 observations. For other variables, missing data was 1.4% or less. When combined across variables, the amount of missing data can increase substantially (SPSS, nd). However, when cases with missing data were removed, the final sample size was still more than adequate based on the sample size analysis.

The data were also analyzed to determine whether differences existed between those participants who had returned the DQ and those who did not. As discussed above, participants were either panel members with demographic information collected prior to

participation in the IFPS II or nonpanel members. The nonpanel members were asked to complete the DQ, but not all returned the questionnaire.

Two different analyses were conducted. First, all participants with complete demographic data (panel members and non-panel members who returned the DQ) were compared to those who were non-panel members who did not return the DQ. The second analysis compared only those who were not panel members. In this analysis, those non-panel members who returned the DQ were compared with those who did not. For each of these analyses, crosstabulation analyses with chi-square tests of significance were conducted to see if differences existed based on race/ethnicity and income. If the crosstabulation analyses were significant, then one-way analyses of variance were run with post-hoc testing using Tukey's HSD test to determine where were the differences.

Measures included in the secondary data analysis

Research cited in the literature review suggested that pregnant women who were older, had other children, had higher incomes, and used more information sources had greater awareness of *L. monocytogenes* (Bondarianzadeh et al., 2007; Trepka et al., 2007). Variables related to these findings were included as predictors in the analysis: age, number of other children, income, and number of sources of dietary information while pregnant. These are hypothesized to act as in previous research. Other demographic variables were included to explore their usefulness in predicting awareness of *L. monocytogenes*: race/ethnicity, education, employment status, marital status, and geographic region of residence. Similarly, a final set of predictor variables was included to explore the relationship between healthcare access and use with *L. monocytogenes* awareness: type of prenatal care provider, time of first prenatal visit, whether the

participant was covered by health insurance or a health plan, and whether the participant received services from the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC). Data for each variable were grouped into categories when appropriate to ensure adequate cell size or to aid in interpretation.

Two measures of awareness were used as outcome variables for the analyses that were conducted to answer the first research question. The first was “Awareness of *Listeria*.” The second was “Awareness of *Listeria*-related food vehicles.” The latter variable was a summary score of responses to a multi-choice item that asked participants to indicate which foods were related to *L. monocytogenes* from a list of foods.

The same predictor variables were used in the analyses related to high-risk consumption behaviors. Previous research found that awareness of *Listeria*-related food vehicles was inversely related to consumption of high-risk foods (Bondarianzadeh et al., 2007). Therefore, the ‘Awareness of *Listeria*’ variable was also included as a predictor variable in the models examining high-risk food consumption.

The outcome measures for the high-risk behaviors included “Consumption of cold cuts without reheating,” “Consumption of hot dogs or frankfurters without reheating,” and “Consumption of refrigerated smoked seafood.” The PDHQ also asked about the consumption of raw milk. An examination of the data revealed that a low frequency of participants reported consuming raw milk; therefore only a descriptive summary of this behavior is provided in Chapter 4.

An overview of all variables used in the analyses, their questionnaire source, and any recoding or computation involved is provided in Appendix 1. Additionally, for

logistic regression analyses, SPSS requires that reference categories be specified for any categorical predictor variables. These are also specified in Appendix 1.

Methods

Descriptive analyses (frequency and percentage) were conducted to describe the study sample in terms of age, race/ethnicity, education, income, employment, geographic region, prenatal health care access and usage, WIC usage, number of other children, and information sources for dietary information. Descriptive analyses (frequency and percentage) were also used to summarize the awareness and consumption outcome variables.

Unadjusted regression analyses were conducted to explore the relationship between each predictor with each outcome variable. Because this study was exploratory, any predictor variable that was significant at the $p < 0.1$ level was included in the multivariate analysis. The multivariate analyses included multiple regression, binary logistic regression, and ordinal logistic regression. Each of these analyses can include two or more continuous or categorical predictor variables; however, they differ in terms of their outcome variable. Multiple regression requires a continuous outcome variable and binary logistic regression requires a dichotomous, categorical outcome variable. Ordinal logistic regression requires an outcome variable to have more than two categories that can be ranked.

A similar process was followed for each of the multivariate regression analyses (see Table 2). First, variables that were significant in the univariate models were entered into the multivariate model. For the multiple regression and binary logistic regression models, the predictor variables were entered using the block entry method (Field, 2000).

Table 2: Overview of Procedures and Assumptions for the Regression Analyses

Analysis Steps	Multiple Regression	Logistic Regression	Ordinal Logistic Regression
Tests of Model Fit	<p>Significance of the F test: This tells whether the overall model results in a good degree of prediction of the outcome variable. For this research, a significance level of $p < .05$ was used.</p> <p>R: multiple correlation coefficient between the predictors and the outcome</p> <p>R²: amount of variation in the outcome variable that is explained by the model</p> <p>Adjusted R²: adjusts R² based on sample size and number of predictors</p>	<p>Significance of the Omnibus Test: This compares the model with the predictor variables entered and a model that includes only the constant. For this research, if the chi-square test is significant at the $p < .05$ level, it was concluded that the model containing the variables is a significantly better predictor than the model containing only the constant</p>	<p>Significance of the Omnibus Test: This compares the model with the predictor variables entered and a model that includes only the constant. For this research, if the chi-square test is significant at the $p < .05$ level, it was concluded that the model containing the variables is a significantly better predictor than the model containing only the constant</p>
Assumptions	<p>(1) The relationship between the predictor variables and the outcome variable is linear</p> <p>(2) Errors are random, independent, normally distributed, with a mean of 0 and a constant variance</p> <p>(3) No multicollinearity between predictors</p>	<p>(1) The outcome variable must be dichotomous</p> <p>(2) The outcome categories must be exhaustive and mutually exclusive</p> <p>(3) No multicollinearity between predictors</p>	<p>(1) The outcome variable must have more than two ordered categories</p> <p>(2) Proportional odds ratios exist across all data partitions</p>
Significance of predictor variables	<p>Significance of the t-tests: The t-test associated with each unstandardized coefficient were used to determine if the predictor is making a significant contribution to the model. A significance level of $p < .05$ will be used.</p> <p>Standardized beta coefficients: These allow comparison of the relative contribution of each predictor. A positive coefficient indicates a positive relationship with the outcome variable, while a negative coefficient indicates a negative relationship.</p>	<p>Significance of the Wald statistic: This tests the significance of individual logistic regression coefficients for each predictor. If significant, then that predictor is assumed to be making a significant contribution to the outcome variable prediction. A significance level of .05 was used.</p> <p>Odds ratio: This indicates the change in odds of the dependent variable occurring that results from a unit change in the predictor. If the OR > 1, the odds of the outcome occurring increases as the predictor increases. If OR < 1, the odds of the outcome occurring decreases as the predictor increases.</p>	<p>Significance of the Wald statistic: See binary logistic regression</p> <p>Odds ratio: For the ordinal logistic regression models, an OR that is greater than one is interpreted to mean that a unit change in the predictor results in increased odds of being in a higher category of the ordinal outcome variable. Similarly, an OR of less than one indicates increased odds of being in a lower category of the outcome variable.</p>

This method allows the researcher to determine the order of entry of the variables and it can be used to determine whether and the extent to which additional blocks improve the model (Field, 2000). Typically, predictors identified in previous research are entered into the model first, followed by new predictors (Field, 2000). Additionally, some variables naturally relate to each other or pertain to a specific content area and lend themselves to being entered as a block (Meyers, Garnst, & Guarino, 2006).

For these analyses, the first block contained variables that were significant in the unadjusted regression analyses and that previous research identified as predictors of *Listeria* awareness or high-risk consumption behaviors. Other demographic predictors that were significant in the univariate regressions were entered in the second block as part of the exploratory analysis. The third block contained significant variables related to healthcare access and use. SPSS only allows the forced entry method for ordinal logistic regression. Therefore, three separate ordinal logistic regressions were conducted using the blocks as specified above. After each multivariate analysis was run, the overall model was examined for significance. This was followed by a determination of whether the assumptions were met. Finally, the individual predictors were examined for significance using a significance level of $p < .05$.

Multiple Regression

For multiple regression, several methods were used to determine the overall predictive adequacy of the model. The multiple correlation coefficient (R) was used to determine the correlation between the observed and predicted values of the outcome variable (Field, 2000). R^2 and the adjusted R^2 , which accounts for sample size and number of predictors, were used to determine what portion of the variance in the outcome

variable was explained by the predictors (Field, 2000). Additionally, the significance of the F-test for the ANOVA was used to determine whether the model is a better predictor of the outcome variable than the mean value (Field, 2000).

The assumptions of multiple regression are that (1) the relationship between the predictor variables and the outcome variable is linear, (2) errors are random, independent, normally distributed, with a mean of 0 and a constant variance, and (3) no multicollinearity exists (Lomax, 2001). Multicollinearity exists when two or more predictors in the model are strongly correlated, i.e. > 0.9 (Field, 2000). It increases the chances that a good predictor will be rejected from the model (Field, 2000).

SPSS procedures, including plotting residuals and collinearity diagnostics, were used to determine if the assumptions for multiple regression were met. Several criteria were used to assess multicollinearity. First, any bivariate correlation between predictor variables greater than 0.9, any variance inflation factors (VIFs) greater than 10, and any tolerance values below 0.2 were considered possible indicators. The final criterion used to determine multicollinearity was the examination of the condition indices. This is considered the best method of detecting multicollinearity because it examines all the predictor variables together (Schaub, 2005). A condition index greater than 30 is indicative of serious multicollinearity (Garson, 2009a; Schaub, 2004).

Finally, when the omnibus model statistics were significant and the assumptions were met, then the unstandardized coefficients were examined to determine the significance of each predictor. The standardized coefficients were used to determine the relative importance of each predictor.

Binary Logistic Regression

As in multiple regression, the first step in analyzing the binary logistic regression models was to examine the overall fit of the model. This was done using the omnibus test of model significance, which compares the model with the independent variables entered and a model that includes only the constant (Field, 2000). When the chi-square statistic is significant, it can be concluded that the model containing the variables is a significantly better predictor than the model containing only the constant (Field, 2000).

The assumptions of logistic regression include that the outcome variable must be dichotomous and the outcome categories must be exhaustive and mutually exclusive (Wright, 1995). Field (2000) also included the assumption of no multicollinearity between predictors.

Multicollinearity diagnostics were performed as described above. Examination of the multicollinearity diagnostics revealed that all bivariate correlations, VIFs, and tolerance values were within recommended limits for all analyses. However, multicollinearity was detected in several of the analyses with condition indices greater than 30 found. The bivariate correlation matrices between the independent variables showed that income had significant but low correlations with most of the predictors in the models. Given that receiving WIC services is dependent on income, these variables provided somewhat overlapping information. Therefore, the analyses were run again, first deleting 'receiving WIC' and then deleting 'income.' In all cases, removing 'receiving WIC' did not reduce the condition indices to acceptable values. Removing 'income' from the models resulted in satisfactory values for tolerance, VIF, and condition indices. When multicollinearity was found, it is noted in the Chapter 4 and the multivariate logistic regression models with the 'income' variable removed are presented.

When the overall logistic regression model was significant and the assumptions met, the Wald statistics were examined next in order to test the significance of individual logistic regression coefficients for each predictor variable (Garson, 2008). If the coefficient was statistically significant, then that predictor was assumed to be making a significant contribution to the prediction of the outcome variable. Because the actual relationship between the outcome variable and the predictor variables is non-linear, the unstandardized coefficients are not easily interpretable. In the final model, the odds ratio (OR), which is an indicator of the change in odds of the dependent variable occurring that results from a unit change in the predictor (Field, 2000), and 95% confidence intervals (CI) of the predictor variables were examined for further interpretation.

Ordinal Logistic Regression

This research used the proportional odds model of ordinal logistic regression, which is the most common model (Agresti, 1999). The omnibus test of model significance was used to examine the overall fit of the model. The proportional odds model sequentially partitions the data into dichotomous groups while accounting for the ordering of the data, with the assumption that there is an identical effect of the predictors for each cumulative probability (Agresti, 1999; O'Connell, 2006). According to the proportional odds assumption, if separate logistic regressions were conducted for each split in the data, a common odds ratio would be found for each predictor variable (O'Connell, 2006). The goal of this model is to simultaneously consider the effects of the predictor variables across these cumulative splits in the data (O'Connell, 2006).

The Score test was used to test the assumption of proportional odds in order to rule out lack of stability of predictors across the partitions (O'Connell, 2006). A non-

significant Score test would mean the assumption of proportional odds was met. As in the other regression models, when the overall ordinal regression model was found significant and the assumption of proportional odds was met, then the significance of the individual coefficients was examined.

Data analysis for Research Questions 1 and 2

Research Question 1: What are the person characteristics (sociodemographics, health care access and usage, information sources) related to knowledge of *L monocytogenes*?

The first analysis examined awareness of *L. monocytogenes*. The predictors were both categorical and continuous. The block entry method was used for this analysis using the three blocks described above. Variables were entered into the model if the preliminary univariate model found them significant at the $p < 0.1$ level. The outcome variable was ‘awareness of *L monocytogenes*.’ This variable was composed of two categories: ‘Aware of *L. monocytogenes*’ and ‘Unaware of *L. monocytogenes*.’ Because the predictor variables were both categorical and continuous and the outcome variable was dichotomous and categorical, binary logistic regression analysis was used to answer this question.

The second analysis examined awareness of *Listeria*-related food vehicles. It used the same categorical and continuous predictor variables as in the first model. These were entered in three blocks as above. This analysis used a continuous outcome variable, ‘Awareness of *Listeria*-related food vehicles.’ Therefore, this analysis used multiple regression.

Research Question 2: What are the person characteristics (sociodemographics, health care access and usage, information sources, knowledge of *L monocytogenes*) related to

consumption of high-risk foods (cold cuts without reheating, hot dogs without reheating, refrigerated smoked seafood)?

Three analyses were conducted to answer this research question, one for cold cuts, one for hot dogs, and one for refrigerated smoked seafoods. Predictor variables (those explored in Research Question 1 as well as ‘Awareness of *Listeria*’) were entered into the multivariate model in the three previously specified blocks if they were significant in the univariate regressions at the $p < 0.1$ level.

Ordinal logistic regression analysis using the proportional odds model was used to answer the research question related to the consumption of cold cuts eaten without reheating. This analysis was selected because the predictor variables were categorical and continuous, and the outcome variable was composed of 3 ranked categories: never ate cold cuts without reheating, sometimes ate cold cuts without reheating, and always ate cold cuts without reheating. This analysis compared those who **never** ate cold cuts without heating to those who **sometimes or always** ate cold cuts without heating, along with comparing those who **never or sometimes** ate cold cuts without reheating to those who **always** ate cold cuts without reheating. However, the analysis violated the assumption of proportional odds as determined by the Score test, which was found to be significant ($p < .01$). This meant that some of the predictors for which the odds of being at or beyond a specific category were not stable across the partitions (O’Connell, 2006). As recommended by O’Connell (2006), separate logistic regression analyses were conducted to examine the odds ratios at each data partition. The examination of the data confirmed that the assumption of equal slopes was not met, thus, the decision was made to work with separate logistic regressions. Only the model comparing those who **never** ate cold

cuts without reheating to those who **sometimes or always** ate cold cuts without reheating was significant. This model is presented in the Chapter 4.

Binary logistic regression analyses using the block entry method were used to answer the research questions related to the consumption of hot dogs without reheating and refrigerated smoked seafood. As in the previous analyses, all of the predictor variables were categorical and continuous. The outcome variables were binary and compared those who ate the high-risk foods to those who did not.

Qualitative Study using Focus Groups

Population and sampling

A purposive and convenience sampling strategy was used to recruit pregnant women for the focus groups. Inclusion criteria required that participants be at least 18 years of age and English-speaking. Participants must have eaten at least one of the high-risk foods in the past year (hot dogs; luncheon meat or cold cuts; soft cheeses like Feta, Brie, and Camembert, blue-veined cheeses, or queso blanco, queso fresco, or Panela; refrigerated pâtés or meat spreads; refrigerated smoked seafood or refrigerated fish labeled as "nova-style," "lox," "kippered," "smoked," or "jerky"; or raw or unpasteurized milk or foods that contain unpasteurized milk). This criterion ensured that women were identified who had included these foods as part of their diet. As a quality assurance strategy, the Research Involving Human Subjects Committee (RIHSC) at the FDA required that participants provide verification of pregnancy from their healthcare provider, so participants were only included if they agreed to provide verification of their pregnancy. For pregnancy verification, participants provided either a signed note from their healthcare provider or a dated sonogram picture

Participants were excluded if they were under 18, did not speak English, if they had not eaten any of the high-risk foods in the past year, or if they or someone in their immediate family worked for the FDA, USDA, National Institutes of Health, state/local health agencies, food manufacture or retail, marketing, advertising, or healthcare industries. They were also excluded if they had participated in a focus group in the past year. The FDA routinely implements this last criterion to reduce bias because repeated participation in market research may affect people's knowledge, attitudes, and behaviors.

A market research agency contracted by the FDA was used to recruit participants. The agency called potential participants from their market research pool and used a recruitment script prepared by this researcher to determine if a potential participant qualified for participation. Because the sample from the IFPS II was found to be more highly educated when compared to a nationally representative sample of new mothers (Fein et al., 2008), the groups were segmented by education. Half of the groups consisted of women with a high school education or lower and the other groups were composed of women who had attended some college or who had more education. Recruitment was conducted with the intention of including a diversity of age and race/ethnicity within each group. Twelve participants were recruited for each group, with the expectation that between eight and ten women would actually participate.

As part of the development process for the focus group guide, two women were recruited by this researcher to pretest the guide. Inclusion criteria for the pretest interviews were that the women were pregnant, age 18 or older, and English-speaking. They were recruited from locations of convenience and were screened for eligibility

according to a screening script. Participants were also asked to submit a note from their healthcare provider verifying their pregnancy and due date, as required by the FDA.

Instrumentation

Demographic Questionnaire for focus group participants

Prior to participation in the focus groups, participants were asked to complete a short demographic questionnaire (see Appendix 2). This questionnaire used demographic questions from the IFPS II. It contained items related to age, race/ethnicity, marital status, employment status, education level, income, number of weeks pregnant, number of other children, type of prenatal care provider, healthcare insurance coverage, and WIC status. This information was collected to allow comparison of the demographic characteristics of the focus group participants to the IFPS II participants.

Focus Group Moderator's Guide

Development of the Focus Group Moderator's Guide

Developing specific questions that will be used in a focus group is an important strategy to ensure that the focus group topics will be addressed as intended and to ensure consistency between focus groups (Krueger, 1998). Several steps were undertaken to develop the focus group moderator's guide. First, two pilot studies were conducted that provided the foundation for the content of the guide. Then, an initial set of questions was drafted. After the first draft was completed, four experts reviewed the guide and modifications were made to the questions based on their feedback. After the expert review, the guide was pretested with two members of the target audience. Final modifications were made to the guide.

Pilot Studies. The pilot studies were conducted in 2009, prior to the dissertation proposal. In the first pilot study, interviews were conducted with nine experts in the fields of public health, health and risk communication, and food safety. They provided feedback on one of the FDA's current listeriosis prevention websites, compared the current soft cheese guideline to the previous guideline, and discussed possible theoretical frameworks, constructs, and strategies that could be useful in improving messages for pregnant women. The second study was an observation and interview study with eight pregnant women that was conducted in order to determine whether they could find current listeriosis prevention guidelines online and whether they found consistent messages, their feelings about the information they found, and their response to three prototypes related to changing messages.

The pilot studies' results suggested content areas that would be further examined in the focus groups. For example, results from the observation study showed that all participants were aware of some of the high-risk *Listeria*-related foods as foods that pregnant women should avoid, although they did not know that listeriosis risk was the reason for avoiding these foods. The IFPS II asked only about awareness of *L. monocytogenes* and *Listeria*-related foods.

Findings from both pilot studies suggested that the Extended Parallel Process Model (EPPM) could provide a valuable framework through which to examine listeriosis prevention messages. In general, the experts felt that content designed to impact susceptibility, severity, response efficacy, and self-efficacy would strengthen the current FDA message and they offered suggestions for how to do this, such as by explaining why pregnant women are at greater risk and including first-person accounts from pregnant

women. The observation study provided support that EPPM constructs were associated with behavior. For example, one participant believed that risks to her unborn child decreased as her pregnancy progressed so she stopped reheating cold cuts in the latter part of her pregnancy. Another had heard to avoid cold cuts, but did not believe the risk was severe so she continued to eat them.

With respect to changing messages, the experts were generally unconcerned about the change to the soft cheese message because the newer guideline was less restrictive. However, a few suggested the need to present the guidelines in the context of ongoing scientific research and evolving knowledge. Observation study participants also reviewed three prototypes related to changing messages. A dichotomy was noted among participants in regard to preference for the prototypes. Some participants reported they just wanted to be told what to do. Others felt that additional information was important to their decision-making. Most liked being reminded that they should check for new information in future pregnancies, but disliked the idea that the message could change during their current pregnancy.

Findings from the pilot studies led to the development of the first draft of the Focus Group Moderator's Guide. The draft guide was designed to more deeply examine awareness by first asking about foods pregnant women have heard to avoid, why they were told to avoid them, then asking about *Listeria* awareness, and finally about foods related to *Listeria*. The draft guide contained questions designed to examine participant beliefs around severity of and susceptibility to listeriosis, and response efficacy and self-efficacy for listeriosis prevention behaviors. The draft also included questions designed to probe reactions to changing messages, using the soft cheese change as an example.

Several prototype messages were developed that would be used as tools to elicit discussion about possible ways to communicate listeriosis prevention messages. These included messages with enhanced risk content, enhanced efficacy content, and information about changing messages. The draft also contained a question to address behavioral intentions regarding listeriosis prevention based on the information they heard in the group.

Expert review. Four experts in the fields of public health, health and risk communication, and food safety reviewed the guide during a 45-minute interview. The reviewers were oriented to the focus group objectives and were asked to rate each question's relevance to the focus group objectives. They were also asked to provide feedback on the wording and clarity of each question, along with any other specific recommendations for each question. After reviewing the entire guide, they were asked open-ended questions related to the length and organization of the guide as well as the appropriateness of the questions for those with a high school education or less. They were also asked to provide any other comments or suggestions.

The reviewers felt that all questions were relevant to the research aims of the focus groups. They felt the questions would be understandable for those with lower education, although minor suggestions were made to improve the comprehensibility of some of the questions. Two reviewers made suggestions for substantial re-ordering of the questions. One felt that many of the questions were close-ended and would not generate discussion. This reviewer suggested reframing the entire guide to start with the messages and then probe to get at the desired information. For example, a prototype message could be used to provide the participants with information about listeriosis. Then the facilitator

could probe to see what information was new to participants, what they had previously known, what information they considered important, and whether the information would change what they would do. Another reviewer suggested that the messages related to the enhanced risk and efficacy content should be placed prior to the discussion on changing messages.

Some additional suggestions made by two or more reviewers included making the warm-up more general, providing a definition of foodborne illness, combining and reordering the questions related to perceived severity of and susceptibility to listeriosis, modifying the question related to response efficacy to ask if participants thought that following the guidelines would reduce their risk of getting listeriosis rather than asking if following the guidelines would keep you from getting listeriosis. One reviewer suggested using a food that is already on the list as an example in the prototype message that presented the scenario that a new food was added to the guidelines in order to decrease confusion. The expert feedback was incorporated into the next draft of the focus group guide. This new draft was used for the pretest interviews.

Pretest interviews. The revised draft was pretested with two members of the target audience. Informed consent procedures took place prior to the interviews (See Appendix 3 for Informed Consent form). The purpose of the pretest interviews was to ensure that the questions were understandable and could generate discussion. Additionally, the research participants were asked to suggest improvements to the order and wording of the questions. The interviews were conducted at quiet locations of convenience for the participants and lasted 45 minutes.

The interview followed a structured interview guide. Each focus group question was read to the participant. The research participant was asked to answer the question as if she was a member of the focus group. If she was not sure how to answer the question, she was asked to let the interviewer know and then asked to restate it in her own words, identify areas that were confusing, or make suggestions for improvement. Participants were also asked to make suggestions in terms of wording and overall question order. The pretest interviews were tape-recorded.

At the end of the interview, participants were debriefed. They had the opportunity to ask any questions they might have about the study and the food safety guidelines. They were given a pamphlet containing the current FDA recommendations for food safety for pregnant women (see Appendix 4 for the Debriefing pamphlet). Participants in the pretest interviews received a \$25 gift card for their participation.

The first participant was able to easily answer all of the questions except the probe question, “Is there anything that would make it easier for you to follow this advice?” In response, the interview was modified by first asking about what makes it hard to follow the advice and then asking what makes it easier. With this modification, she was able to answer the initial question. The second participant had no difficulty answering any of the questions. Based on the interviews, a minor modification was made to the question order in the focus group guide to ask about barriers before asking about facilitators.

The Focus Group Moderator’s Guide

The final Moderator’s Guide included questions related to the awareness of high-risk foods, *Listeria*, and *Listeria*-related food vehicles, consumption behaviors, perceived

severity of and perceived susceptibility to foodborne illness and listeriosis, response efficacy and self-efficacy related to current guidelines, and intentions to follow the guidelines (see Appendix 5). Questions were also included related to changing messages. Table 3 provides an overview of the topics that were covered in the focus groups as well as how the specific focus group questions map to the research questions.

Table 3: An Overview of the Focus Group Moderator's Guide

Topic	Focus Group Guide Question Number	Research Question Addressed
• Knowledge of high-risk foods, foodborne illness, <i>Listeria</i> , and <i>Listeria</i> -related food vehicles	1, 4	1
• Perceived severity of foodborne illness and listeriosis	2, 3	3
• Perceived susceptibility to foodborne illness and listeriosis	2, 3	3
• Behaviors related to listeriosis	4, 5	2
• Self-efficacy	5	4
• Response efficacy	6	4
• Changing messages	9, 10	5
• Message development	7-11	6
• Intention	12	4

Six prototype messages were included to facilitate discussion. These provided an overview of listeriosis (Message A), the listeriosis prevention guidelines (Message B), enhanced risk content (Message C), enhanced efficacy content (Message D), a message providing context for scientific change (Messages E) and a message that could be used if a new food were added to the guidelines (Message F). The prototype messages are presented and described in the next section.

Message A contained content that can be found on many listeriosis prevention websites; however, experts in the pilot test advised removing extraneous content and focusing on critical risk information. Bulleted lists and boldface type were used to make the content easier to scan and to highlight important information. The guidelines presented in Message B were modified slightly from the FDA's presentation of the

guidelines by the use of bulleted lists and boldface font. Experts in the pilot study suggested the content for the remaining messages. This content was adapted from currently available information when possible and modified by the experts who reviewed the Moderator's Guide. The vignettes were adapted from postings to pregnancy-related message boards.

Methods

A total of six focus groups were conducted, with 2 groups conducted in each of three locations: Greenbelt, Maryland; Philadelphia, Pennsylvania; and Boston, Massachusetts. The first location was chosen because of convenience. The latter locations were selected to add geographic diversity and because the sale of unpasteurized milk is legal in these states, thus these groups provided the opportunity to obtain more information about the consumption of raw milk.

Eligible participants were invited to participate in a 90-120 minute focus group. The focus groups were professionally moderated and were conducted in conference rooms arranged by the market research agency. These rooms allowed observers to view the groups from behind a one-way mirror. All groups were audio and video recorded. The market research firm transcribed the tapes from the proceedings.

Participants were given copies of the Informed Consent form prior to the group (see Appendix 3). The Informed Consent form was verbally reviewed with participants at the start of each group and participants were given the opportunity to ask questions. All participants signed the Informed Consent form. Participants were also asked to complete the Demographic Questionnaire prior to the group.

The moderator structured the groups using the Focus Group Moderator's Guide. The prototype messages used in the groups were printed separately on letter-size paper, using black font on colored backgrounds. The moderator handed them out during the group as indicated in the guide.

Following the introductions and warm-up, questions were asked to probe awareness of high-risk foods and whether participants knew why they were to avoid them. If they did not know why, the moderator asked if they had heard of *Listeria*. Participants were next asked how serious they thought foodborne illnesses were and whether all people were equally susceptible.

Participants then viewed and discussed Message A, which gave an overview of *Listeria* (see Figure 3). This message was used to probe participant's awareness of *Listeria* and of pregnancy-related risks.

Next they viewed and discussed Message B (see Figure 4), which contained the current FDA listeriosis prevention guidelines. This message was used to probe recognition of other foods they may have either heard about or were unaware of, consumption behaviors, self-efficacy, and response efficacy.

After discussing Message B, prototype messages containing enhanced risk content, enhanced efficacy content, and information about changing messages were sequentially presented and discussed. Message C contained enhanced risk information that explained why pregnant women were more susceptible to listeriosis and that listeriosis is common in the third trimester, along with two short vignettes by women who had suffered pregnancy loss due to listeriosis (See Figure 5).

Message D contained content designed to impact efficacy beliefs. In this message, participants were reminded that avoiding the high-risk foods could reduce their risk of miscarriage, stillbirth, or life-threatening illness in their newborn (see Figure 6). The message stated that if it is hard to follow the guidelines, remember that pregnancy does not last forever. This message also included quotes from women who had made the decision to follow the guidelines and strategies they used.

Messages E and F contained information about changing messages related to listeriosis. Message E provided background information related to the soft cheese change in listeriosis prevention guidelines and reminded women to make sure they had current information if they were pregnant again (see Figure 7). Message F was a sample message that could be used if the guidelines had changed. In order to decrease the potential for confusion, this message used a food already on the list (hot dogs) as an example (see Figure 8).

After reading each message, participants were asked to react to the message, identify any new information, and discuss whether the messages would impact their behavior. After viewing all of the messages, participants were asked to work in small groups to highlight the message content they felt should be included in listeriosis prevention communications for pregnant women. The moderator used this time to confer with this researcher to see if there were any topics that needed additional probing or discussion. To close the group, participants were asked whether they planned to make any behavioral changes as a result of anything they heard in the group.

At the end of the focus groups, this researcher conducted a debriefing. All participants were given a pamphlet containing the current FDA recommendations for

What is Listeria?

Listeria is a kind of **harmful bacteria** that can contaminate many kinds of foods.

- It is different from other bacteria because it can grow at refrigerator temperatures.

If you eat a food that has been contaminated with *Listeria*, you could get an infection called listeriosis.

- **Pregnant women are 20 times more likely to get listeriosis than other healthy adults.**

Pregnant women might not even feel sick from listeriosis, but they can pass the infection to their babies.

- This infection can cause **miscarriage or stillbirth.**
- In newborns, it can cause serious problems like blood infections or meningitis (an infection around the brain and spinal cord).

Figure 3: Text from Message A, an Overview of Listeriosis

Don't eat:

Hot dogs and luncheon meats *unless they're reheated until steaming hot*

Soft cheeses *unless they're made with pasteurized milk*

- Make sure the label says, "Made with pasteurized milk."
- **What are soft cheeses?** Feta, Brie, and Camembert, blue-veined cheeses, queso blanco, queso fresco, or Panela

Refrigerated pâtés or meat spreads

Refrigerated smoked seafood *unless it's in a cooked dish, such as a casserole.*

- Refrigerated smoked seafood, such as salmon, trout, whitefish, cod, tuna, or mackerel is most often labeled as "nova-style," "lox," "kippered," "smoked," or "jerky."
- These types of fish are found in the refrigerator section or sold at deli counters of grocery stores and delicatessens.

Raw (unpasteurized) milk or foods that contain unpasteurized milk.

Figure 4: Text from Message B, the Listeriosis Prevention Guidelines

Listeriosis is rare, but pregnancy increases your risk

- **Here's why:** Your immune system is weaker when you are pregnant. This is normal—It helps you and your baby get along with each other. This weakness makes it harder for your body to fight off harmful bacteria, like *Listeria*.
- You could get listeriosis at any time in your pregnancy, but it is most **common in the third trimester.**

"If I had known about the risks of consuming deli meat while I was pregnant, I might have been able to prevent my miscarriage." – *Silvia*

"For those of you who think it cannot happen, YOU'RE WRONG! My perfectly healthy baby was stillborn at 35 weeks from what my doctors believe to be a listeriosis infection." – *Michelle*

Figure 5: Text from Message C, the Enhanced Risk Message

If you think it's hard to follow these guidelines, remember that your pregnancy won't last forever.

Keep in mind that following these guidelines can help you prevent a miscarriage, stillbirth, or a life-threatening infection to your newborn.

Here's what other pregnant women have said about preventing listeriosis:

"Even a slim chance of miscarriage is still a chance. If there's a way to avoid listeriosis, why not do it?" —Shenice

"I am really not a worry-wart when it comes to being pregnant...But if heating my lunch meat eliminates a risk, I'll do it." —Jen

"I love queso blanco. So I just check the label when I buy it to make sure it's made from pasteurized milk." —Zaira

Figure 6: Text from Message D, the Enhanced Efficacy Message

In the 1980's, scientists learned that people could get listeriosis from eating contaminated foods. They keep studying *Listeria* so they can identify foods that are easily contaminated as well as new ways to control *Listeria*.

- *Here's an example of how research has affected the guidelines:*
 - Before 2003, pregnant women were told not to eat soft cheeses at all. Then, new studies showed that it is fine to eat soft cheeses when they are made from pasteurized milk.
- The guidelines could change as we learn more ways to keep you and your baby healthy.
 - If you get pregnant again, make sure you have the most up-to-date information. Remember, this advice could change as we learn more about *Listeria*.

Figure 7: Text from Message E, a General Change Message

New Findings about *Listeria*

Scientists have found that hot dogs are easily contaminated with *Listeria*. They are now telling pregnant women **NOT** to eat hot dogs unless they have been reheated until steaming hot.

- If you have eaten hot dogs and feel fine, don't worry. Remember, listeriosis is very rare.
- Now that you know about the risk from hot dogs, you can make sure to eat them only if they're steaming hot—it's another way to keep you and your baby healthy.

Figure 8: Text from Message F, a Specific Change Message

food safety for pregnant women (see Appendix 4). Any specific questions that arose during the focus groups were answered and participants had the opportunity to ask additional questions. They were reminded that they had contact information if questions arose after the focus group. Participants received \$90 for their participation.

Two changes in procedure should be noted. First, time constraints led to the omission of the review of Message F from three of the focus groups. One lower education group and two higher education groups viewed message F. Second, traffic in the Washington DC area caused both of the Greenbelt groups to start late. As a result, the first Greenbelt group conducted the small group activity individually, while the second Greenbelt group conducted this activity orally.

To sum, the role of this researcher in the focus groups was to (1) develop the Focus Group Guide, (2) communicate with the market research company to ensure that the recruitment followed the prepared script to make certain that the specified inclusion and exclusion criteria were met, (3) ensure that informed consent procedures and human subjects protections were implemented, (4) discuss the goals of the focus group and review the Focus Group Guide with the moderator prior to the focus groups, (5) observe and take notes during each focus groups, (6) confer with the moderator before the end of each focus group to determine if there are any areas that require clarification or additional probing, (7) conduct the debriefing of participants at the end of each focus group, and (8) debrief with the moderator after each focus group.

Data analysis for the Focus Groups

Findings from the focus groups were used to answer all of the research questions. The focus group results were used to triangulate and expand the secondary data analysis

findings for Research Questions 1 and 2. Findings from the focus groups were used to answer Research Questions 3 to 6:

Research Question 3: What are pregnant women's perceptions of severity and susceptibility related to listeriosis?

Research Question 4: How do perceived response efficacy and self-efficacy relate to engagement in listeriosis prevention behaviors?

Research Question 5: How do pregnant women respond to the changes in health messages related to listeriosis prevention?

Research Question 6: How can listeriosis prevention messages for pregnant women be improved?

The focus groups were analyzed using the framework approach. The framework approach is an analytic method for qualitative data that allows themes to develop from both the *a priori* research questions and the participant narratives (Rabiee, 2004). This approach was developed for applied qualitative research, the purpose of which is to answer specific research questions that have implications for policy or health-practice decisions (Green & Thorogood, 2004; Pope, Ziebland, & Mays, 2000).

Analysis was facilitated by the use of qualitative software called the TAMS Analyzer (Weinstein, 2008). This open-source software program for the Macintosh computer allows the researcher to develop a codebook, assign codes to text passages, and then extract, organize, and save coded information (Weinstein, 2008). While the software does not perform the analysis, it does allow the researcher to quickly retrieve data and helps to ensure that the analysis is more thorough and systematic (Green & Thorogood, 2004).

The data were analyzed according to the five interconnected stages of analysis in the framework approach (Green & Thorogood, 2004; Pope et al., 2000; Rabiee, 2004):

1. Familiarization: The raw data from the focus groups in the form of transcripts, notes, and tapes were reviewed. Key ideas and recurrent themes were listed.

2. Identifying a thematic framework: All key issues and themes identified were based on both the research questions and issues raised by the interviewees. The questions from the Focus Group Guide were mapped to the research questions (see Table 3) and served as a starting point for developing the thematic framework. Knowledge, behaviors, the EPPM constructs, and the impact of changing guidelines were considered key issues. Additionally, strategies for improving messages provided another critical component of the analysis. Other themes were allowed to emerge from the data.

A coding scheme and codebook were developed based on the identified themes. At this stage, inter-rater reliability was calculated using the procedures described by Neuendorf (2002) in order to determine how well different coders agree when using the coding scheme. First, the primary researcher developed the initial set of codes and a preliminary codebook. Next, a second rater was oriented to the project and one transcript was coded together. Then both raters independently coded a second transcript. The Kappa coefficient for the ratings on the independently coded transcript was calculated. This coefficient examines the percent agreement beyond chance between coders and is considered to be a conservative measure of inter-rater reliability (Neuendorf, 2002). The Kappa coefficient was 0.73. According to Garson (2009b), 0.70 is considered to be an acceptable level of agreement. Differences in coding were discussed and resolved. The coding schema and codebook were modified to include the agreed-upon changes.

3. Indexing: In this step, the data were coded using the coding scheme. Single passages of text were given multiple codes as needed.

4. Charting: The data were rearranged into charts according to the coded themes. For example, charts were developed that related to perceived susceptibility, severity, response efficacy, and self-efficacy. The charts allowed comparison of data both within and across focus groups. The qualitative software allowed each data item to be coded with the focus group identification number to facilitate return to the original focus group transcript as needed.

5. Mapping and interpretation: In this stage, associations and relationships between the themes were identified in order to provide an explanation of the findings. Factors that were considered during the interpretation phase include: the frequency and extensiveness of comments related to a specific view, the intensity of feelings related to a specific view, the internal consistency related to changes in opinion or position by individual participants, and finally, the identification of larger trends that emerged from the overall accumulation of evidence (Rabiee, 2004).

Study Rigor

Qualitative researchers have identified criteria for judging the soundness of qualitative research (Trochim, 2000). Recommendations suggest that strategies for ensuring rigor should be built into the research process rather than conducting post hoc analyses of the research process. Thus, several methods were incorporated into this study to increase the rigor of this research. To improve the study reliability, the research methodology and analysis have been described in order to present an “audit trail,” as recommended by Green and Thorogood (2004) and Mays and Pope (1995). The audit

trail includes a description of how the participants were selected, how the data were collected, the rationale for coding categories and themes, and supporting quotations from participants. Secondly, inter-rater reliability for coding the data has been established, as described previously.

Maximizing the validity of qualitative findings is done to justify why the analysis should be considered credible (Green & Thorogood, 2004; Mays & Pope, 1995). Validity of the findings has been improved through the use of expert review of the focus group guide, the examination of deviant cases, and triangulation. The examination of deviant cases was used to develop and modify the coding schema in the early stages of the analysis and was accounted for in the final interpretation of the data. Focus group findings were triangulated with the findings from the secondary data analysis for points of agreement or disagreement.

Integration of Quantitative and Qualitative Results

In mixed methods research, integration is the point in the research process at which the researchers mix, or integrate, the findings from the quantitative and qualitative studies (Creswell, Fetters, & Ivankova, 2004). For this research, separate analyses of the quantitative and qualitative studies were completed. This represented the first stage of mixed methods analysis, which is called data reduction (Onwuegbuzie & Teddlie, 2003). Data display is the stage of mixed methods analysis that follows data reduction. (Onwuegbuzie & Teddlie, 2003). In this phase, the data are presented in easily understood configurations, such as tables, graphs, or matrices. The qualitative and quantitative findings related to awareness and consumption were mapped into tables to allow triangulation of findings. These tables are presented in Chapter 4. The focus group

findings were also used to expand the quantitative findings. The implications of the triangulated and expanded results are presented in the Chapter 5.

Human Subjects Protections

The Institutional Review Board (IRB) at the University of Maryland, College Park (UMD) agreed to let the FDA's Research Involving Human Subjects Committee (RIHSC) serve as the IRB-of-record for this research. The RIHSC approved this research on December 1, 2008 and approved an amendment to extend the research period on February 13, 2009. On June 23, 2009, the RIHSC accepted the modifications to the finalized Moderator's Guide that was used in the focus groups. (See Appendix 6 for all RIHSC approvals.) Copies of RIHSC applications and approvals were submitted to the IRB at UMD. The Office of Management and Budget reviewed the focus group research for participant burden. This approval was received on August 20, 2009.

Summary

This chapter described the methodology that was used in the sequential mixed methods study. In this study, a quantitative analysis of IFPS II data was conducted to examine awareness of and behaviors related to listeriosis and its prevention. The IFPS II did not provide complete information about awareness and consumption of all high-risk foods. Further, it did not address underlying beliefs at all. A qualitative focus group study was designed to triangulate and expand the findings from the secondary data analysis. The results from the mixed methods study are presented in Chapter 4.

CHAPTER 4: RESULTS

This chapter presents the results of the mixed methods study. First, the samples used in each study are described. Next, the results are presented, which are organized around each of the six research questions. The first two research questions, which related to awareness of *Listeria monocytogenes* and associated consumption behaviors, were examined through quantitative analysis of data collected in the second Infant Feeding Practices Study (IFPS II), and supported by additional findings from the qualitative focus group research. The remaining research questions were used to expand the quantitative findings and were answered through the focus group research.

Study Sample

Quantitative Study using Secondary Data Analysis

The sample used in this study consisted of IFPS II participants who completed three questionnaires: the Demographic Questionnaire (DQ), the Prenatal Questionnaire (PQ), and the Prenatal Diet History Questionnaire (PDHQ). Potential participants were either panel members with demographic information collected prior to participation in the IFPS II (n=1243) or non-panel household members (n=194). The non-panel members were asked to complete the DQ, but only 90 did so. Those with missing demographic questionnaires were eliminated, resulting in a sample size of 1,333.

The data were analyzed to determine whether differences existed between those participants who had completed the DQ and those who did not. First, all participants with complete demographic data (both panel members and non-panel members who returned

the DQ) were compared to those who were non-panel members who did not return the DQ. Cross-tabulation analyses with chi square tests of significance showed significant differences based on race/ethnicity ($p < .001$) and income ($p = .02$) (see Tables 4 and 5).

Table 4: Cross-tabulation of race/ethnicity and DQ completions among all potential participants (n=1,437)

	White	African American	Hispanic	Asian Pacific Islander	Other
Completed DQ	1117 (94.3%)	59 (79.7%)	89 (91.8%)	34 (87.2%)	29 (93.5%)
Missing DQ	68 (5.7%)	15 (20.3%)	8 (8.2%)	5 (12.8%)	2 (6.5%)

Pearson Chi-Square=25.59, $p < .001$

Table 5: Cross-tabulation of income and DQ completion among all potential participants (n=1437)

	\$24,999 or less	\$25,000-49,999	\$50,000-74,999	\$75,000-99,999	\$100,000 and higher
Completed DQ	291 (88.7%)	465 (93.6%)	312 (94.3%)	163 (95.9%)	102 (91.9%)
Missing DQ	37 (11.3%)	32 (6.4%)	19 (5.7%)	7 (4.1%)	9 (8.1%)

Pearson Chi-Square=12.15, $p = .02$

A one-way ANOVA with post-hoc testing using Tukey's HSD test revealed that white and Hispanic participants were more likely than African American participants to have complete demographic data. A one-way ANOVA with post-hoc testing using Tukey's HSD examining income showed that those earning \$24,999 or less were less likely to have complete demographic information than those in two higher incomes categories (\$50,000-\$74,999, and \$75,000-\$99,999).

The second analysis compared non-panel members who returned the additional DQ to non-panel members who did not. Cross-tabulation analyses with chi-square tests of significance showed no significant differences between these groups based on race/ethnicity ($p = .30$) or income ($p = .92$) (see Tables 6 and 7).

Table 6: Cross-tabulations of race/ethnicity and DQ completion among non-panel members (n=194)

	White	African American	Hispanic	Asian Pacific Islander	Other
Completed DQ	72 (51.4%)	8 (34.8%)	8 (50%)	1 (16.7%)	1 (33.3%)
Missing DQ	68 (48.6%)	15 (65.2%)	8 (50%)	5 (83.3%)	2 (66.7%)

Pearson Chi-Square=4.91, $p = .30$

Table 7: Cross-tabulations of income and DQ completion among non-panel members (n=194)

	\$24,999 or less	\$25,000-49,999	\$50,000-74,999	\$75,000-99,999	\$100,000 and higher
Completed DQ	35(48.6%)	26 (44.8%)	13(40.6%)	6 (46.2%)	10 (52.6%)
Missing DQ	37 (51.4%)	32 (55.2 %)	19 (59.4%)	7 (53.8%)	9 (47.4%)

Pearson Chi-Square=12.15, p=.92

These analyses showed that the IFPS II sample overall may be limited because those with lower incomes and those who were African American were less likely to have complete demographic information. However, no differences existed between the non-panel members who did and did not return the DQ based on income or race/ethnicity.

All participants in the final study sample (n=1,333) were eighteen or older and pregnant at the time these questionnaires were administered. The mean age of participants was 29.1 years (standard deviation [SD]=5.4 years). Most participants were white (84.1%) and had at least some college education (39.9%). Three-fourths of the participants were married (78.4%). The mean number of other children (not including the current pregnancy) was 1.19 (SD=1.13). Slightly more than half of participants worked outside the home (54.3%), while another third identified themselves as full-time homemakers (35.3%). The median household income was between \$25,000 and \$49,000. Almost one-third of participants were from the South (32.4%), with almost another third from the Midwest (30.8%) (see Table 8).

Information related to access to and use of health-related resources was also collected in the IFPS II (see Table 9). Almost all participants were covered by some type of health insurance or health care plan (95.4%), and most received prenatal care from an obstetrician (83.7%). Ninety percent of participants received prenatal care during their first twelve weeks of pregnancy. This is higher than an examination of 2006 birth certificate data in 18 states, which found that just 69 percent of pregnant women received prenatal care in their first trimester (Martin et al., 2009). Just under a third of participants

(28.3%) received WIC services in the month prior to the questionnaire completion. The mean number of information sources used related to dietary information during pregnancy was 3.33 (SD=1.66).

Table 8: Demographic Characteristics [Frequency (Percentage*)] of Study Participants

Variable	IFPS II Participants (n=1,333)	All Focus Group Participants (n=46)	Low Ed Focus Group Participants (n=23)	High Ed Focus Group Participants (n=23)
Age				
18-24	296 (22.3)	8 (17.8)	7 (31.8)	1 (4.3)
35-34	805 (60.6)	25 (55.6)	12 (54.5)	13 (56.5)
35 and older	227 (17.1)	12 (26.1)	3 (13.6)	9 (39.1)
Missing	5	1	1	0
Race/Ethnicity				
White	1117 (84.1)	23 (50.0)	6 (26.1)	17 (73.9)
Black	59 (4.4)	17 (37.0)	12 (52.2)	5 (21.7)
Hispanic	89 (6.7)	4 (8.7)	4 (17.4)	0
Asian Pacific Islander	34 (2.6)	0	0	0
Other	29 (2.2)	2 (4.4)	1 (4.3)	1 (4.3)
Missing	5	0	0	0
Education				
High school or less	290 (21.9)	20 (43.5)	20 (87.0)	0
Some college	530 (39.9)	12 (26.0)	3 (13.0)	9 (39.1)
College graduate or higher	507 (38.2)	14 (30.4)	0	14 (60.8)
Missing	6	0	0	0
Income				
\$24,999 or less	291 (21.8)	7 (15.2)	6 (26.1)	1 (4.3)
\$25,000 - \$49,999	465 (34.9)	16 (34.8)	11 (47.8)	5 (21.7)
\$50,000 - \$74,999	312 (23.4)	8 (17.4)	3 (13.0)	5 (21.7)
\$75,000 or higher	265 (19.9)	15 (32.6)	3 (13.0)	12 (52.2)
Geographic Region				
South	432 (32.4)	15 (32.6)	6	9
Midwest	410 (30.8)	0	0	
Northeast	217 (16.3)	31 (67.4)	17	14
West	274 (20.6)	0	0	
Employment**				
Full-time, part-time, or self-employed	679 (54.3)	36 (70.6)	16 (64.0)	20 (77.0)
Full-time homemaker	441 (35.3)	10 (19.6)	4 (16.0)	6 (23.0)
Unemployed, student, retired, or disabled	131 (10.5)	5 (9.8)	5 (20.0)	0
Missing	82	0	0	0
Marital status				
Never married	229 (17.2)	19 (41.3)	14 (60.9)	5 (21.7)
Married	1043 (78.4)	24 (52.2)	9 (39.1)	15 (75.2)
Widowed, separated, or divorced	58 (4.4)	3 (6.5)	0	3 (13.0)
Missing	3	0	0	0
Parity				
No other children	369 (28.2)	21 (45.7)	11 (47.8)	10 (43.5)
1 other child	555 (42.5)	18 (39.1)	9 (39.1)	9 (39.1)
2 or more other children	383 (29.3)	7 (15.2)	3 (13.0)	4 (17.3)
Missing	26	0	0	0

*Percent shown is valid percent

**Focus group participants selected more than one response

Table 9: Access to and Use of Health-related Resources by IFPS II and Focus Group Participants [Frequency (Percentage*)]

Variable	IFPS II Participants (n=1,333)	All Focus Group Participants (n=46)	Low Ed Focus Group Participants (n=23)	High Ed Focus Group Participant (n=23)
Type of prenatal care provider**				
Obstetrician	1115 (83.7)	34 (72.3)	13 (54.2)	21 (91.3)
Family doctor or other physician	117 (8.8)	6 (12.7)	5 (20.1)	1 (4.3)
Midwife	160 (12)	7 (14.9)	6 (25.0)	1 (4.3)
Other health care provider	17 (1.3)	0	0	0
No prenatal care	5 (0.4)	0	0	0
Has health insurance/health care plan				
Yes	1269 (95.4)	43 (93.5)	20 (87.0)	23 (100.0)
No	61 (4.6)	3 (6.5)	3 (13.0)	0
Missing	3	0	0	0
Mother enrolled in WIC in the past month				
Yes	337 (28.3)	12 (26.1)	10 (56.5)	2 (8.7)
No	954 (71.7)	34 (73.9)	13 (43.5)	21 (91.3)
Missing	42			
Weeks pregnant at first prenatal visit		Not asked	Not asked	Not asked
4 weeks or less	158 (12.0)			
5 – 8 weeks	702 (53.2)			
9 – 12 weeks	330 (25.0)			
13 – 18 weeks	69 (5.2)			
19-24 weeks	22 (1.7)			
25 weeks or more	38 (2.9)			
Missing	14			
Number of information sources related to diet used during pregnancy		Not asked	Not asked	Not asked
0	62(4.7)			
1	146 (11.0)			
2-4	752 (56.7)			
5-7	367 (27.7)			
Missing	6			

*Valid percentage

**Participants could check more than one response

Qualitative Study using Focus Groups

Six focus groups were conducted in three locations. The number of participants in each group ranged from 6-9, with a total of 46 participants (see Table 10). The mean age of the focus group participants was 30.8 years (SD=6.0 years). Half were white, with almost 40 percent African American. Just over half were married (52.2%). About 45 percent were expecting their first child (mean parity=.9, SD=1.3). Almost three-quarters (72.9%) of the participants were employed, with fewer than 20 percent identifying themselves as full-time homemakers. (See Table 8 for demographic characteristics.)

Table 10: Location, Education Level, and Number of Participants in each Focus Group

Location	Education Level	Number of Participants
Greenbelt, MD	Lower Education	6
Greenbelt, MD	Higher Education	9
Boston, MA	Lower Education	9
Boston, MA	Higher Education	8
Philadelphia, PA	Lower Education	8
Philadelphia, PA	Higher Education	6
		Total=46

The groups were segmented by education; however, three participants in the lower education groups checked ‘some college’ on their demographic questionnaire, despite responding that high school was their highest level of education on the telephone screener. Other demographic differences were found between the lower and higher education groups using cross-tabulation analyses with chi-square tests of significance. Participants in the lower education groups were more likely to be younger ($p<0.05$), either African American or Hispanic ($p<0.01$), and have lower incomes ($p<0.01$) than participants in the higher education groups.

Most focus group participants had health insurance (93.5%), and almost three-quarters received prenatal care from an obstetrician (72.3%). Just over one-quarter (26.1%) of participants were enrolled in WIC in the past month. (See Table 9 for access to and use of health-related resources). Those in the lower education groups were more likely to receive WIC services than those in the higher education groups ($p<0.01$).

Results

Research Question 1: Person Characteristics related to Awareness of Listeria Monocytogenes

Awareness of Listeria among IFPS II Participants

The first IFPS II analysis examined factors related to awareness of *L. monocytogenes*. In this study, 486 (36.5%) participants reported that they had heard of problems related to *Listeria*. Unadjusted logistic regression analyses found that age, income, number of information sources used, employment, education, marital status, receiving prenatal care from an obstetrician, receiving care from a family doctor or other physician, and receiving WIC services were significant predictors of awareness ($p < .10$). Due to multicollinearity, income was not included in the multivariate model.

These variables were entered into a multivariate model in three blocks. The first consisted of predictors identified from previous research: age, income, and number of information sources. The second block contained the additional demographic variables: education, employment, and marital status. The final block contained health-related variables: receiving prenatal care from an obstetrician, receiving care from a family doctor or other physician, and receiving WIC services. All three blocks were significant, with the -2 log likelihood (-2LL) value lowest in the third block, which indicated that the third block was the best-fitting model (see Table 11).

The final model indicated that pregnant women who were aware of *L. monocytogenes* were more likely to be older (OR=1.07, 95% CI=1.12, 1.32), use more sources of information about diet during pregnancy (OR=1.21, 95% CI=1.12, 1.31), and have a college education or higher as compared to a high school education or less

(OR=1.95, 95% CI=1.29, 2.93). Those who received WIC services were less likely to be aware of *L. monocytogenes* (OR=.66, 95% CI=.48, .92).

Table 11: Logistic Regression Analysis: Predictors of Awareness of *Listeria monocytogenes* (n=1,333)

	Unadjusted Odds Ratio (95% CI)	p	Block 1: Adjusted Odds Ratio (95% CI)	p	Block 2: Adjusted Odds Ratio (95% CI)	p	Block 3: Adjusted Odds Ratio (95% CI)	p
-2 Log Likelihood			1526.81		1480.83		1469.08	
Omnibus Chi-square Significance			p<.001		p<.001		p<.01	
Income ¹		<.001						
\$24,999 or less		1.00						
\$25,000-49,999	1.84 (1.30, 2.61)							
\$50,000-74,999	3.16 (2.20, 4.55)							
\$75,000 or higher	4.38 (3.01, 6.37)							
Age	1.10 (1.08, 1.13)	<.001	1.11 (1.08, 1.14)	<.001	1.07 (1.04, 1.10)	<.001	1.07 (1.04, 1.10)	<.001
Number of information sources used	1.14 (1.06, 1.22)	<.001	1.23 (1.14, 1.33)	<.001	1.21 (1.12, 1.31)	<.001	1.21 (1.12, 1.31)	<.001
Education		<.001				<.001		<.001
High school or less		1.00				1.00		1.00
Some college	2.04 (1.44, 2.88)				1.44 (.99, 2.09)		1.41 (.97, 2.06)	
College graduate or higher	4.37 (3.10, 6.15)				2.42 (1.64, 3.57)		2.15 (1.44, 3.20)	
Employment		<.001				.05		.098
Unemployed, student, retired, or disabled		1.00				1.00		1.00
Full-time homemaker	2.55 (1.57, 4.13)				1.75 (1.04, 2.95)		1.68 (.99, 2.83)	
Employed full-time, part-time, or self-employed	3.15 (1.97, 5.04)				1.87 (1.13, 3.08)		1.74 (1.05, 2.88)	
Marital status		<.001				.20		.37
Married		1.00				1.00		1.00
Never married	.35 (.25, .50)				.70 (.47, 1.04)		.75 (.50, 1.12)	
Widowed, separated, or divorced					.84 (.44, 1.57)		.88 (.47, 1.66)	
	.70 (.40, 1.23)							
Prenatal care from obstetrician	1.61 (1.16, 2.22)	.003					1.08 (.73, 1.62)	.70
Prenatal care from family doctor	.42 (.27, .67)	<.001					.62 (.35, 1.09)	.10
Receiving WIC	.37 (.28, .49)	<.001					.66 (.48, .92)	.01

¹Income is not included in the adjusted models because of multicollinearity.

Awareness of Listeria-related Food Vehicles among IFPS II Participants

The second analysis examined awareness of *Listeria*-related food vehicles.

Fifteen percent of those who were aware of *L. monocytogenes* reported that they did not

know any associated foods. However, 64% of participants who were aware of *L. monocytogenes* identified some or all types of cold cuts as food vehicles for *L. monocytogenes*. Almost half identified some types of cheeses as *Listeria*-related food. Just over a quarter of participants identified some kinds of meat or poultry and only 6% identified some types of fish. (See Table 12.)

Table 12: Identification of *Listeria*-related Foods (n=480)

Food	Frequency	Percentage
Some or all types of cold cuts		
Identified	309	64.4
Did not identify	171	35.6
Some types of cheeses		
Identified	226	47.1
Did not identify	254	52.9
Some types of meat or poultry		
Identified	134	27.9
Did not identify	346	72.1
Some types of fish		
Identified	28	5.8
Did not identify	452	94.2
Did not know any related foods	72	15.0

When the number of correct responses was summed, scores could range from zero to seven. The distribution of correct answers was bimodal, with a small peak representing women who did not know any related foods and a larger peak around the score of 4 (see Table 13.) Most participants were able to correctly identify four or five of the seven foods. Only four participants correctly identified all *Listeria*-related foods and did not identify any of the foods not related to *L. monocytogenes*.

Table 13: Scores for Awareness of *Listeria*-related food vehicles (n=480)

Total number of foods correctly identified	Frequency	Percentage
0	72	15.0
1	3	.6
2	13	2.7
3	11	2.3
4	174	36.3
5	137	28.5
6	66	13.8
7	4	0.8

Simple linear regression analyses between each predictor with the ‘Awareness of *Listeria*-related food vehicles’ score found the following variables significant at the $p < .10$ level: number of information sources, education, region, and receiving WIC. These variables were entered into the multiple regression model in 3 blocks: number of information sources were entered in the first block, education and region in the second block, and receiving WIC in the third.

Next, the assumptions of multiple regression were examined. All multicollinearity values were within recommended limits, indicating no multicollinearity. Inspection of the plots of the residuals revealed no heteroscedasticity. The plot examining the residuals for normality indicated some deviation; however, multiple regression is robust to this violation with a large sample size (Garson, 2009a).

All 3 models were significant according to the ANOVA F test. The F test change was significant from Block 1 to Block 2, but not from Block 2 to Block 3. Similarly, the R square value of .04 in Block 2 was a significant improvement ($p = .02$) from the R square value of .01 in Block 1. No significant improvement in the R square value was noted from Block 2 to Block 3 ($p = .24$). Therefore, Block 2 was considered the best model. The adjusted R-squared for Block 2 indicated that the predictors in the model accounted for 4% of the variance in the model. Results from the multiple regression models are presented in Table 14.

The number of information sources, education, and region were significant in the best-fitting model. The standardized beta coefficients indicated that education was a stronger predictor than geographic region or number of information sources used. The expected knowledge score for someone with a college level education or higher would be

.63 points higher than someone with a high school education or less. The expected knowledge score of someone from the Northeast would be .59 points higher than someone from the South. For each information source used, the expected knowledge score would increase by .14 points.

Table 14: Multiple Regression of Predictors of Awareness of Listeria-related Food Vehicles

Block	Predictors	B Coefficient	Standard Error	Beta Coefficient	t	p value	95% CI
Block 1	Number of information sources used	.14	.06	.12	2.61	.009	.04, .25
Block 2	Number of information sources used	.14	.06	.12	2.61	.009	.04, .25
	Education (Some college vs. High school or less)	.35	.29	.09	1.18	.238	-.23, .92
	Education (College graduate or higher vs. High school or less)	.63	.28	.17	2.27	.024	.09, 1.18
	Geographic Region (Midwest vs. South)	-.02	.21	-.01	-.09	.928	-.44, .40
	Geographic Region (Northeast vs. South)	.59	.25	.12	2.32	.02	.09, 1.01
	Geographic Region (West vs. South)	.14	.24	.03	.60	.549	-.33, .62
Block 3	Number of information sources used	.15	.06	.12	2.70	.01	.04, .257
	Education (Some college vs. High school or less)	.33	.29	.08	1.12	.26	-.25, .90
	Education (College graduate or higher vs. High school or less)	.55	.29	.15	1.92	.06	-.01, 1.12
	Geographic Region (Midwest vs. South)	-.03	.21	-.01	-.12	.91	-.45, .39
	Geographic Region (Northeast vs. South)	.57	.25	.12	2.24	.03	.07, 1.07
	Geographic Region (West vs. South)	.13	.24	.03	.57	.57	-.34, .61
	Receiving WIC	-.29	.24	-.06	-1.17	.24	-.76, .19

Awareness of Foods to Avoid, Listeria, and Listeria-related High-risk Foods among Focus Group Participants

The focus group discussions were used to complement the secondary data analysis results by providing a deeper and broader understanding of what pregnant women knew about high-risk foods. Focus group participants were asked about awareness of foods that pregnant women should avoid (independent of *Listeria*), *Listeria*, and all *Listeria*-related high-risk foods.

All but one participant across groups reported they had heard that they should avoid certain foods during pregnancy. When asked to identify which foods they had been told to avoid, participants had no difficulty generating a list of foods (see Table 15).

Several participants in each of the groups spontaneously identified some of the *Listeria*-related high-risk foods. Participants in all groups brought up soft cheeses. They talked about whether this meant all soft cheeses or just unpasteurized soft cheeses, and most were aware that they could consume pasteurized soft cheeses. They also debated the availability of unpasteurized soft cheeses in the United States, with some participants reporting that you could not purchase unpasteurized cheese in this county, while others stated that you could.

Participants in five of the six groups recalled cold cuts and hot dogs. Participants in the Greenbelt Lower Education group only recognized that they had been told to avoid cold cuts and hot dogs after reading the list of *Listeria*-related foods to avoid in Message B later in the focus group session. Some participants in three of the groups knew that they could eat cold cuts if they were reheated.

Unpasteurized milk and refrigerated smoked seafood were rarely recalled spontaneously or recognized on the list. No participants in any groups identified pâtés or meat spreads through recall or recognition.

Non-*Listeria*-related foods were identified as well, with participants in all groups mentioning seafood, which they linked to mercury contamination. Other non-*Listeria*-related foods mentioned across groups included alcohol, caffeine, raw eggs, and raw or undercooked foods.

Geographical and educational differences in awareness of *Listeria* were noted.

Many participants in both Boston groups and the Philadelphia Higher Education group spontaneously and specifically mentioned *Listeria* as a reason for avoiding the *Listeria*-related high-risk foods. Participants in the other groups mentioned “bacteria” as a reason for avoiding the foods, but did not specify *Listeria*. When the moderator introduced the term, *Listeria*, many participants in the Philadelphia Lower Education and the Greenbelt Higher Education groups reported they had heard of *Listeria* as compared to only one in the Greenbelt Lower Education group.

Table 15: Foods to Avoid During Pregnancy, as Identified in 6 Focus Groups

	High risk <i>Listeria</i> Foods: Recall	High risk <i>Listeria</i> Foods: Recognition	Other foods
Greenbelt Lower Education	<ul style="list-style-type: none"> • Soft cheeses 	<ul style="list-style-type: none"> • Unpasteurized milk • Lunchmeat • Hot dogs 	<ul style="list-style-type: none"> • Fish/Seafood (shellfish, shark, tuna, sushi) • Alcohol • Caffeine • Chocolate • Raw foods • Undercooked foods • Orange juice
Greenbelt Higher Education	<ul style="list-style-type: none"> • Soft cheeses • Lunchmeat • Hot dogs • Smoked seafood 		<ul style="list-style-type: none"> • Fish/Seafood (sushi, tuna) • Alcohol
Boston Lower Education	<ul style="list-style-type: none"> • Soft cheeses • Lunchmeat • Unpasteurized milk 		<ul style="list-style-type: none"> • Fish/Seafood (tuna) • Unwashed produce • Undercooked meats • Canned or processed foods • Raspberries
Boston Higher Education	<ul style="list-style-type: none"> • Unpasteurized cheeses/foods • Lunchmeat 		<ul style="list-style-type: none"> • Fish/Seafood (tuna, shellfish, sushi) • Raw eggs • Undercooked foods
Philadelphia Lower Education	<ul style="list-style-type: none"> • Soft cheeses • Lunchmeat • Hot dogs 		<ul style="list-style-type: none"> • Fish/Seafood (shark, swordfish, albacore tuna, sushi) • Orange juice
Philadelphia Higher Education	<ul style="list-style-type: none"> • Soft cheeses • Lunchmeat • Hot dogs 	<ul style="list-style-type: none"> • Smoked seafood 	<ul style="list-style-type: none"> • Fish/Seafood (swordfish, tuna, sushi)

Participants in most of the groups offered other explanations for why they should avoid eating the *Listeria*-related high-risk foods. These reasons included that cold cuts contained nitrates or fillers, problems in the cheeses stemmed from molds in the cheeses,

and smoked fish was carcinogenic. Some participants reported that they did not know why they were not supposed to eat these foods.

“I’ve heard about the different foods...where they do say to stay away, but not really too much as far as hearing anything about Listeria in itself. Just more so foods to stay away from.” – Boston participant, higher education

Information Sources used by Focus Group Participants

Participants reported obtaining pregnancy-related information from a variety of sources. All groups mentioned getting information from their healthcare provider and from other interpersonal sources, such as their mothers, sisters, and friends. The Internet was mentioned by many participants in all of the higher education groups and in one of the lower education groups. Participants in half of the groups mentioned getting information from the WIC program. The use of pregnancy-related reference-type books was rarely mentioned, and this was only by a few participants in the higher-education groups. The use of television news as an information source was mentioned briefly in only two groups, both lower-education groups.

Many participants described interpersonal sources as their first encounter with learning about foods to avoid during pregnancy. These contacts occurred in informal, food-centered settings in which a participant was told not to eat a particular food, often while she was eating it. Some accepted the advice and others were motivated to seek additional information.

“I pretty much learned everything from just talking to people. They say, ‘Oh, you’re not supposed to eat that.’” – Greenbelt participant, lower education

“When someone said it to me, I was eating a sandwich, it was like ‘You’re not supposed to eat that.’” – Philadelphia participant, lower education

“I went to a family party. And all the women had trouble getting pregnant...They absolutely refused to let me taste it [Brie]. They wouldn’t let me try it. They were like, ‘No, you can’t eat the Brie. You can’t eat the Brie.’...I didn’t know why.” – Greenbelt participant, higher education

“I heard through the grapevine about the various things that you’re supposed to avoid, but I wanted to know why. So I looked into it myself.” – Philadelphia participant, lower education

Participants who used the Internet for pregnancy-related information mentioned specific sites that they found useful, including general health sites such as WebMD and the Mayo Clinic websites. Many frequented pregnancy-specific sites, such as whattoexpect.com, babycenter.com, and babyfit.com. They described a willingness to register on these sites and liked receiving weekly informational emails from them. Participants reported that these sites frequently mentioned *Listeria* and foods to avoid during pregnancy.

“You go on websites and they’ll...talk about the Listeria all the time.” – Boston participant, higher education

“I think I registered on ‘Baby Fit’ so I’m on that most of the time now...it talked about cold cuts and I believe hot dogs.” – Boston participant, lower education

“If you sign up for like the newsletters on e-mail, they’ll tell you things. Every week you get a newsletter, you know, what week pregnancy you’re in. And they’re actually really informative and quick to read. That will tell you right at the beginning what to stay away from or what to limit.” – Boston participant, higher education

Participants clearly and frequently expressed a desire to receive food safety information from the doctors. Their discussion confirmed that practitioners were not consistently providing food safety information. Some participants received no food safety information and expressed dismay about this after reviewing the listeriosis information presented in the focus groups.

“Because mostly my doctor kept saying, ‘No caffeine.’ He never said, ‘No lunchmeat.’ – Boston participant, lower education

“I know I’ve got a ton of information about breast feeding, but not one thing from my doctor that I read about Listeria.” – Greenbelt participant, higher education

Others reported receiving pamphlets and some received verbal instructions.

“It was a packet, you know, you get from the doctor, ‘Congratulations. You’re having a baby, all this stuff.’ And it was one of the doctor’s sheets.” – Greenbelt participant, higher education

“Well, when my doctor told me I was pregnant, she listed almost 100 items. And she...went through like a lot of items that you cannot eat while you’re pregnant. And it was so many that I didn’t even think of. Like wow, I can’t eat that?...But there was so many on that list.” – Greenbelt participant, lower education

“My doctor told me that blue cheeses and the soft cheeses, goat cheese, they’re not pasteurized, so you shouldn’t eat them.” – Greenbelt participant, higher education

In some cases, food safety information was provided only after the participant initiated the discussion with their provider, with mixed responses from their providers.

“When I asked her [her doctor] about lunchmeat and eating lunchmeat and if it was okay and how I had read online, she said, ‘Well, if you eat it, heat it up in the microwave for at least a minute.’ She was like ‘It might not taste so great or if you really want lunchmeat or some kind of meat like a deli sandwich...you can go and get it toasted where it goes through or they heat up the meat for you.’” – Greenbelt participant, higher education

“My husband forwarded something to me ‘cause he’s the one who’s all paranoid about everything and I asked my doctor about it because it said soft cheese, it did, just listed all kinds of stuff...I thought it was overkill and I asked my doctor and he really pooh-pooed the whole thing.” – Boston participant, higher education

Many considered physicians to be the most credible source of information. They would follow their physician’s advice over other information they had found. If their

doctors were not mentioning this issue, they concluded that maybe it is not really a big or serious problem.

“Maybe if my doctor gave it to me and said ‘I really want you to read it,’ then it would sink in more. But other than that, there’s so much information out there. And depending on where you actually get it, I think is where it would actually sink in too.” –Boston participant, higher education

“I think the big problem is...that although we can read all this stuff, but once you go ask your own doctor and they say things like, ‘Oh well, if you’re feeling fine, you’re fine,’ ‘Moderation,’ or whatever they tell you. I think a lot of people will take what a doctor says. My husband specifically...if I heard it in this group tonight and I went home and I told my husband something, he would dismiss it unless it comes from somebody with M.D. at the end of their name. So if an M.D. turns around and says it’s okay...I think a lot of people will dismiss really any written material like this, even if it’s written by the FDA or a big authority like that.” – Boston participant, higher education

“Because from what it sounds like, most of the doctors aren’t talking about it or don’t see that it’s a big problem.” – Greenbelt participant, higher education

In general, some participants with higher education seemed more likely to believe that physicians differed in their perceptions of the risk of listeriosis and recognized that physicians needed to weigh discussion of food safety issues with other information that they might need to communicate to a pregnant woman. These participants considered their doctor’s advice along with information they had gleaned from other sources.

“Sometimes I think our doctors because they know, they have a lot of information on these things. I think they have to discern how much to tell the patient so as not to make us so scared of everything. Not that it’s always a good thing. But sometimes too much information can be detrimental and sometimes not enough information can be very detrimental. So I think it’s a balance ... it’s a fine balance of how much do you say and when do you say it.” – Greenbelt participant, higher education

“Yeah. I think it depends on if you have, I don’t know, like if your doctor is more over-conscious about things as opposed to one that’s laid back. I don’t know. But I know that not everybody has this information.” –Boston participant, higher education

“So...that’s another thing with doctors. Every doctor says something different. So you have to kind of just do the best you can.” –Boston participant, higher education

“Always try to educate yourself, basically. You know, so you’ll stay informed...Sometimes doctors may not tell you the smaller things.” – Boston participant, lower education

Summary of Mixed Methods Results related to Listeria Awareness

Table 16 presents a summary of the quantitative and qualitative findings related to awareness of *Listeria*. Both analyses suggest that awareness of *Listeria* has increased. Subgroup differences were found related to education, income, and geographic region.

Table 16: Mixed Methods Findings Related to Listeria Awareness

Variable	Quantitative Analysis (n=1,333)	Qualitative Analysis (n=46)
Awareness of Listeria	<p>486 (36.5%) aware of <i>Listeria</i></p> <ul style="list-style-type: none"> • More likely to be aware if <ul style="list-style-type: none"> ○ older (OR=1.07, 95% CI=1.04, 1.10) ○ used more sources of information (OR=1.21, 95% CI=1.12, 1.31) or ○ had a college education or higher vs. a high school education or less (OR=2.15, 95% CI=1.44, 3.20) • Less likely if receiving WIC (OR=.66, 95% CI=.48, .92) 	<p>Many participants in two higher education groups spontaneously recalled <i>Listeria</i> as the reason for avoiding the high-risk foods. Participants in the third group recognized the term <i>Listeria</i> when the moderator introduced it. In contrast, only some participants in one of the lower education groups recalled <i>Listeria</i>, with some participants in another lower education group recognizing that they had heard of <i>Listeria</i>. Geographic distinctions were noted, with the highest awareness levels seen in the Boston groups and the lowest in the Greenbelt groups.</p>
Awareness of Listeria-related food vehicles	<p>15% of those who were aware of <i>Listeria</i> did not know any <i>Listeria</i>-related foods. Most participants scored 4 or 5 out of 7 when asked to identify <i>Listeria</i>-related food vehicles from a list of foods. Higher scores affected by</p> <ul style="list-style-type: none"> • Education level (Expected score for those with a college education or higher is .69 points higher than those with a high school education or less) 	<p>Most were aware that pregnant women should not eat soft cheeses, hot dogs, and cold cuts. Those in Boston and those in the higher education groups were more likely to attribute the reason to <i>Listeria</i>. Some participants did not know why they should not eat these foods. Others attributed reasons, such as the presence of nitrates or molds, as reasons to avoid these foods.</p>

Variable	Quantitative Analysis (n=1,333)	Qualitative Analysis (n=46)
	<ul style="list-style-type: none"> • Geographic region (Expected score for those from the northeast would be .59 points higher than those in southern states) • Number of information sources used (For each information source used, the expected score would increase by .14 points) 	
Awareness of cold cuts	64% of those who were aware of <i>Listeria</i> identified cold cuts as a <i>Listeria</i> -related food	Some participants in all groups either recalled or recognized that pregnant women should avoid cold cuts.
Awareness of soft cheeses	47% of those who were aware of <i>Listeria</i> identified soft cheeses as a <i>Listeria</i> -related food	Some participants in all groups identified soft cheeses as a food that pregnant women should avoid.
Awareness of hot dogs, refrigerated pâtés or meat spreads	27.9% of those who were aware of <i>Listeria</i> identified ‘some types of meat or poultry’ as a <i>Listeria</i> -related food.	Some participants in all groups either recalled or recognized that pregnant women should avoid hot dogs. None mentioned that hot dogs could be eaten if reheated. No participant recalled or recognized pâtés or meat spreads as foods to avoid.
Awareness of refrigerated smoked seafood	5.8% of those who were aware of <i>Listeria</i> identified ‘some types of fish’ as a <i>Listeria</i> -related food	Only one participant recalled refrigerated smoked seafood as a food to avoid, while another recognized that she had heard this after reading the “Do not eat” list.
Awareness of unpasteurized milk	Not addressed by the IFPS II	Unpasteurized milk/unpasteurized foods were identified in half of the groups.
Information sources	Pregnant women who used more sources of information had greater awareness of <i>Listeria</i> and <i>Listeria</i> -related foods.	Most participants heard about food safety issues from their mothers or girlfriends. Most believed their healthcare provider to be the most credible source of information. Internet users reported receiving food safety information from emailed newsletters from pregnancy-related sites.

Research Question 2: Person Characteristics related to High-risk Food Consumption
Consumption of Listeria-related High-risk Foods by IFPS II Participants

Pregnant women reported eating high-risk foods although consumption patterns varied by the specific foods. Eating cold cuts without reheating was the most frequently reported behavior, with consumption of raw milk the least frequent (See Table 17).

Table 17: Consumption of Listeria-related High-risk Foods by IFPS II Participants (n=1,333)

Food	Behavior	Frequency	Percentage
Turkey or chicken cold cuts	Never eats or never eats without reheating	589	44.3
	Sometimes eats without reheating	216	16.3
	Always eats without reheating	524	39.4
Deli-style ham	Never eats or never eats without reheating	700	52.7
	Sometimes eats without reheating	169	12.7
	Always eats without reheating	460	34.6
Other cold cuts	Never eats or never eats without reheating	889	66.9
	Sometimes eats without reheating	125	9.4
	Always eats without reheating	315	23.7
All cold cuts combined	Never eats or never eats without reheating	352	26.5
	Sometimes eats without reheating	860	64.7
	Always eats without reheating	118	8.9
Hot dogs	Never eats or never eats without reheating	1273	95.9
	Sometimes eats without reheating	46	3.5
	Always eats without reheating	8	.6
Refrigerated smoked seafood	Has not eaten in the past month	1276	96.2
	Has eaten in the past month	50	3.8
Unpasteurized milk	Has not consumed in the past month	1140	99.7
	Has consumed in the past month	3	.2

Consumption of cold cuts without reheating in the past month

This logistic regression analysis compared those who never ate cold cuts or never ate them without reheating to those who sometimes or always ate cold cuts without reheating. Unadjusted logistic regression analyses found the following variables significant ($p < .10$): income, parity, education, receiving WIC, and awareness of *L. monocytogenes*. Income was removed from the adjusted models due to multicollinearity.

The significant variables were entered into a multivariate model in three blocks: parity and awareness in the first block, education in the second, and receiving WIC in the third. The first and third blocks were significant, with the -2LL value decreasing from the first block to the third block; therefore, the third block is considered the best model. The results of the unadjusted and adjusted models are shown in Table 18.

The results of the adjusted logistic regression analysis indicated that pregnant women who had more children (OR=1.32, 95% CI=1.16, 1.50) and who received WIC services (OR=1.45, 95% CI=1.05, 2.01) were more likely to have reported eating cold

cuts without reheating in the past month. Pregnant women who were aware of *L. monocytogenes* were less likely to report eating cold cuts without reheating (OR=.71, 95% CI=.54, .92).

Table 18: Logistic Regression Analysis of Predictors of Consuming Cold Cuts without Reheating

	Unadjusted Odds Ratio (95% CI)	p	Block 1: Adjusted Odds Ratio (95% CI)	p	Block 2: Adjusted Odds Ratio (95% CI)	p	Block 3: Adjusted Odds Ratio (95% CI)	p
-2 Log Likelihood			1447.38		1442.475		1437.28	
Omnibus Chi-square Significance			<.001		.09		.023	
Income ¹		.009						
\$24,999 or less	1.00							
\$25,000-49,999	.90 (.63, 1.26)							
\$50,000-74,999	.91 (.63, 1.32)							
\$75,000 or higher	.56 (.39, .82)							
Parity	1.31 (1.15, 1.48)	<.001	1.33 (1.17, 1.51)	<.001	1.33 (1.17, 1.50)	<.001	1.32 (1.16,1.50)	<.001
Awareness of <i>L. monocytogenes</i>	.63 (.49, .81)	<.001	.64 (.49, .82)	.001	.68 (.53, .89)	.005	.71(.54, .92)	.01
Education		.014				.09		.32
High school or less	1.00				1.00		1.00	
Some college	.74 (.53, 1.05)				.72 (.50, 1.03)		.76 (.53, 1.10)	
College graduate or higher	.61 (.43, .85)				.67 (.46, .97)		.78 (.53, 1.14)	
Receiving WIC	1.68 (1.26, 2.25)	<.001					1.45 (1.05, 2.01)	<.001

¹Income is not included in the adjusted models because of multicollinearity.

Consumption of hot dogs without reheating in the past month

This logistic regression analysis examined factors relating to the consumption of hot dogs straight from the package without reheating. It compared those who reported that they had not eaten hot dogs at all or had not eaten them without reheating to those who reported sometimes or always eating hot dogs without reheating in the past month. Unadjusted logistic regression analyses found that income, age, awareness of *L. monocytogenes*, education, employment, marital status, and receiving WIC services were significant predictors at the p<.10 level.

Significant predictors were entered into a multivariate model in three blocks, with age and awareness of *L. monocytogenes* in the first block; education, employment, and

marital status in the second block; and receiving WIC services in the third. Income was removed from the adjusted models due to multicollinearity. All three blocks were significant, with the lowest -2LL found in the third block. The results of the unadjusted and adjusted models are shown in Table 19.

Table 19: Logistic Regression Analysis of Predictors of Consumption of Hot Dogs without Reheating

	Unadjusted		Block 1: Adjusted		Block 2: Adjusted Odds		Block 3: Adjusted Odds	
	Odds Ratio (95% CI)	p	Odds Ratio (95% CI)	p	Ratio (95% CI)	p	Ratio (95% CI)	p
-2 Log Likelihood			415.82		389.42		381.14	
Omnibus Chi-square Significance			.001		<.001		.004	
Income ¹		<.001						
\$24,999 or less	1.00							
\$25,000-49,999	.30 (.16, .57)							
\$50,000-74,999	.27 (.11, .53)							
\$75,000 or higher	.07 (.02, .30)							
Age	.95 (.90, 1.00)	.06	.96 (.90, 1.01)	.10	1.00(.95, 1.07)	.92	1.02 (.96, 1.08)	.56
Aware of L. monocytogenes	.33 (.16, .68)	.001	.37 (.17, .77)	.01	.47 (.22, 1.00)	.05	.49 (.23, 1.06)	.07
Education		<.001				.004		.01
High school or less	1.00				1.00		1.00	
Some college	.30 (.16, .57)				.37 (.19, .73)		.37 (.19, .73)	
College graduate or higher	.21 (.10, .44)				.32 (.14, .74)		.41 (.17, .98)	
Employment		.002				.118		.25
Unemployed, student, retired, or disabled	1.00				1.00		1.00	
Full-time homemaker	.45 (.22, .93)				.68 (.30, 1.52)		.71 (.31, 1.60)	
Employed full-time, part-time, or self-employed	.25 (.12, .52)				.43 (.19, .98)		.50 (.22, 1.15)	
Marital status		.004				.05		.08
Married	1.00				1.00		1.00	
Never married	2.00 (1.05, 3.81)				1.27 (.58, 2.77)		1.13 (.51, 2.48)	
Widowed, separated, or divorced	4.18 (1.77, 9.92)				3.18 (1.24, 8.12)		2.93 (1.14, 7.55)	
Receiving WIC	3.53 (2.02, 6.17)	<.001					2.57 (1.34, 4.92)	.004

¹Income is not included in the adjusted models because of multicollinearity.

Only two predictors remained significant in the final model: education and receiving WIC services. As compared to those with a high school education or lower, pregnant women with some college (OR=.37, 95% CI=.19, .73) and pregnant women who were college graduates (OR=.41, 95% CI=.17, .98) were less likely to eat hot dogs without reheating than those with a high school education or less. Conversely, pregnant women who received WIC services were more likely to report they ate hot dogs without reheating (OR=2.57, 95% CI= 1.34, 4.92).

Consumption of refrigerated smoked seafood in the past month

This analysis examined factors related to the consumption of refrigerated smoked seafood in the past month. The logistic regression analysis compared those who reported they have not eaten any seafood or refrigerated smoked seafood in the past month to those who reported eating refrigerated smoked seafood in the past month.

Unadjusted logistic regression analyses found that age, employment, and region significantly predicted consumption of refrigerated smoked seafood at the $p < .10$ level. Multicollinearity diagnostics indicated that tolerance, variance inflation factors, and condition indices were within recommended limits; therefore, the three significant unadjusted predictors were retained in the adjusted model. These were entered in two blocks, with age in the first block and employment and region in the second. Only the second block achieved significance at the $p < .05$ level. See Table 20 for results.

Pregnant women who reported eating smoked seafood in the past month were more likely to be older (OR=1.07, 95% CI=1.02, 1.14). Those who were full-time homemakers (OR=.32, 95% CI=.14, .76) or employed (OR=.26, 95% CI=.11, .61) were

less likely to report eating refrigerated smoked seafood than those who were unemployed, students, retired, or disabled. Geographic region was not significant in the final model.

Table 20: Logistic Regression Analysis of Predictors of Refrigerated Smoked Seafood Consumption

	Unadjusted Odds Ratio (95% CI)	p	Block 1: Adjusted OR (95% CI)	p	Block 2: Adjusted OR (95% CI)	p
-2 Log Likelihood			377.12		361.173	
Omnibus Chi-square Significance			.08		.007	
Age	1.05 (1.00, 1.11)	.08	1.05 (.99, 1.12)	.08	1.08 (1.02, 1.14)	.01
Employment		.05				.01
Unemployed, student, retired, or disabled	1.00				1.00	
Full-time homemaker	.46 (.20, 1.04)				.32 (.14, .76)	
Employed full-time, part-time, or self- employed	.35 (.16, .77)				.26 (.11, .61)	
Geographical Region		.06				.06
South	1.00				1.00	
Midwest	.55 (.24, 1.25)				.75 (.32, 1.76)	
Northeast	.82 (.34, 2.01)				.70 (.25, 1.98)	
West	1.62 (.81, 3.24)				1.99 (.94, 4.20)	

Consumption of Listeria-related High Risk Foods by Focus Group Participants

The focus group discussions added breadth and depth to the secondary data analysis results. Participants discussed all of the high-risk *Listeria*-related foods and provided more detail about the circumstances in which they consumed these high-risk foods.

Participants spontaneously talked about consumption of high-risk foods as they discussed awareness of foods to avoid, with some participants readily declaring that they consumed foods even when they knew they should not. Participants were also asked specifically about consumption behaviors after reviewing Message B, which listed the high-risk foods (see Chapter 3, Figure 4). Willingness to discuss personal consumption of the high-risk foods was more variable at this point in the group, with some participants more constrained and quieter than during other points in the discussion. One possible

explanation is that the general information about listeriosis that they had read in Message A (see Chapter 3, Figure 3) heightened their risk perceptions, making consumption behaviors a more sensitive issue. Personal consumption behaviors were now clarified with reasons, such as they did not know that pregnant women were advised to avoid a certain food or they knew they were supposed to avoid a food, but did not understand why. Many participants felt that other pregnant women were probably eating these foods for similar reasons. A few participants described their belief that they could eat any food in moderation.

“I always have an attitude... ‘everything is okay in moderation’ because I think from what I read...about fish and mercury and you can have one tuna fish sandwich kind of a thing. And so I would think the same thing about these kinds of food products... You can have a little bit of goat cheese on your salad as long as you don’t go overboard.” – Philadelphia participant, higher education

Many participants in all groups reported eating cold cuts during their pregnancy.

Most reported that they ate them without reheating.

“I usually just take it off the pack, put it on the bread, you know. Go for it.” – Greenbelt participant, lower education

Some participants expressed awareness that they could eat cold cuts if they were reheated. A few reported that they did not like their cold cuts heated so they either ate them out of the package or avoided them completely. Some said that if they purchased a cold cut sandwich out, they asked for it to be heated.

“They say to stay away from deli meats and stuff like that. But here and there...I was dying for an Italian sub, which is the worst thing for you. But when I called the place I told them to toast it in the oven for as long as they can...hopefully [that] kills the bacteria that’s like on the meat.” – Philadelphia participant, lower education

Many participants also reported eating hot dogs. While some reported they had eaten hot dogs straight from the package in the past, none reported doing so while they were pregnant.

“I used to eat them, back in the day, I ate them raw.” – Boston participant, lower education

Soft cheeses were avoided by many participants. Those who reported eating soft cheeses seemed to understand that they could eat soft cheeses if they were pasteurized and that most soft cheeses they would purchase in the United States would be pasteurized. A few said they asked about the cheeses they were served in restaurants.

“If you order something that has like...feta cheese...I’ll always ask, you always ask.” – Boston participant, higher education

Overall, consumption of refrigerated smoked seafood and pâtés was rarely reported by any of the participants. One participant reported eating lox at a family gathering. She said that while she had heard about cold cuts and soft cheeses, she had not heard about smoked seafood before participating in the focus group. Only two participants said they ate pâtés or meat spreads. One reported eating canned pâtés; the other reported that she made the pâté herself. No participants reported raw milk consumption. Most were unsure what raw milk was, whether or how it could be purchased, or why people would drink it.

Summary of Mixed Methods Results for Consumption of Listeria-related Foods

Table 21 presents a summary of the quantitative and qualitative findings related to the consumption of *Listeria*-related high-risk foods. The consumption patterns were similar in both studies, with unheated cold cuts being the most

widely consumed high-risk food. The quantitative analysis revealed subgroup differences in consumption, but these were not seen in the focus groups.

Table 21: Mixed Methods Findings related to Listeria-related High-risk Food Consumption

High-risk Food	Quantitative Analysis (n=1,333)	Qualitative Analysis (n=46)
Cold cuts without reheating	<ul style="list-style-type: none"> • 74% sometimes or always ate cold cuts without reheating • More likely if: <ul style="list-style-type: none"> ○ Receiving WIC (OR=1.45, 95% CI=1.05, 2.01) or ○ Had more children (OR=1.32, 95% CI=1.16, 1.50) • Less likely if they were aware of <i>Listeria</i> (OR=.71, 95% CI=.54, .92) 	Some participants in all focus groups reported eating cold cuts without, despite awareness that they should not. A few reported that they ordered “hot” sandwiches out, but most ate without reheating.
Hot dog consumption	<ul style="list-style-type: none"> • 4% sometimes or always ate hot dogs without reheating • More likely if receiving WIC (OR=2.57, 95% CI= 1.34, 4.92) • Less likely with some college (OR=.37, 95% CI=.19, .73) or college graduates (OR=.41, 95% CI=.17, .98) 	Some participants in all groups reported that they have eaten hot dogs, but none reported that they ate them without reheating. Generally, participants seemed unaware that they could eat hot dogs if they were heated.
Refrigerated smoked seafood consumption	<ul style="list-style-type: none"> 4% have eaten refrigerated smoked seafood • More likely if older (OR=1.07, 95% CI=1.02, 1.14) • Less likely if full-time homemakers (OR=.32, 95% CI=.14, .76) or employed (OR=.26, 95% CI=.11, .61) vs. unemployed, student, disabled, or retired 	Only one participant reported consumption of refrigerated smoked seafood.
Unpasteurized milk consumption	0.2% consumed unpasteurized milk in the past month	No participants reported consumption of unpasteurized milk
Soft cheese consumption	Not addressed by the IFPS II	Some participants in most groups reported eating soft cheeses, although their discussion indicated awareness of the need for soft cheeses to be made from pasteurized milk. None reported eating soft cheeses made from unpasteurized milk.
Refrigerated pâté or meat spread consumption	Not addressed by the IFPS II	Only two participants reported eating meat spreads, although neither reported eating refrigerated meat spreads.

Research Question 3: Pregnant Women’s Risk Perceptions related to Listeriosis

According to the Extended Parallel Process Model (Witte, 1992, 1994), a person performs two appraisals when exposed to a fear appeal. In the first, the person will

determine their personal risk by deciding whether they believe the threat is a serious threat and whether they are personally susceptible to it. Fear is elicited when risk perceptions are increased, which then further increases risk perceptions. Pregnant women's risk perceptions related to foodborne illness and listeriosis were explored in the focus groups.

Perceived Severity of Foodborne Illnesses and Listeriosis

Most participants believed that foodborne illnesses could vary in severity, but they described foodborne illnesses as “serious,” “very serious,” “extremely serious.” Participants mentioned specific bacteria, such as *Salmonella* and *E. coli*, and identified foods that were implicated in recent high-profile recalls, such as peanut butter (CDC, 2009b). They described the consequences of foodborne illnesses as ranging from gastrointestinal problems to death.

When asked how big a problem it would be for a pregnant woman to get a foodborne illness, many felt that it would be a serious problem. They believed that when you are pregnant, you are caring for another life; therefore, a foodborne illness would affect two people.

“Because it's two bodies, it's two bodies instead of one. That's the whole thing about pregnancy. They want you to know that you're ... not just taking care of your own body, but somebody else's body that you're bringing into the world.” – Greenbelt participant, lower education

One participant felt that foodborne illnesses could be problematic during pregnancy because pregnant women are limited in the kinds of medications they can take.

Participants in one group felt that foodborne illnesses would be more serious for the mother, because the mother protects the fetus.

“I don't even think the baby, you know, it affects the baby. Because as sick as we are, I think we take like 95 percent of it, especially from food poisoning.” – Greenbelt participant, lower education

“I think that we ... it's less likely for the baby to have any effects of it because we take the brunt of it all. We are the ones that get sick. And we protect the baby.” – Greenbelt participant, lower education

Only a few participants overall expressed awareness that foodborne illnesses could harm the fetus.

“And then by you being pregnant, your baby, unborn child, is weak at this time. It depends on you. So if you're sick, I think for a baby it could be fatal, you know, if you have some type of foodborne illness.” – Greenbelt participant, lower education

“You could jeopardize your pregnancy, the baby's life.” – Greenbelt participant, higher education

“My doctor did tell me that it is very serious. It can cause a miscarriage.” – Philadelphia participant, higher education

Perceived severity after message exposure

After reading Messages A and C (see Chapter 3, Figures 3 and 5), the majority of participants were surprised and shocked to learn the severe consequences of listeriosis.

“I've heard of Listeria. But I didn't know nothing about the pregnant section.” – Greenbelt participant, lower education

“When I read it online, it didn't go in-depth like this and talk about what could happen. It just said that it grows in refrigerated temperatures. And when I read that, that's all I read, it didn't say ... it didn't go in-depth like this does about what can happen.” – Greenbelt participant, higher education

“Yes. I'm really surprised that it says that it can cause meningitis and infection of the brain and the spinal cord. I read about it. I didn't know it can cause all that major problem in a newborn.” – Philadelphia participant, lower education

“I never knew it was as serious as to cause a stillborn or meningitis. I didn’t know that.” – Philadelphia participant, higher education

“Just the fact that it could cause a miscarriage or stillbirth was a surprise.” – Boston participant, lower education

“I didn't know about the, with the newborns, the blood infections or meningitis, I don't know about that part.” – Boston participant, higher education

Perceived Susceptibility to Foodborne Illness and Listeriosis

Across all groups, most participants were unaware that pregnancy increases susceptibility to listeriosis.

“Mine was really general information. And the only association I had with it was hot dogs, which I don't really eat. So I just didn't really pay attention to it too much. But it definitely didn't say that pregnant women were twenty times more likely to get that.” – Greenbelt participant, higher education

“I didn’t know pregnant women were more likely to get it than regular.” – Philadelphia participant, higher education

A few participants in the higher education groups were aware that pregnancy affects their immune function and also cited pregnant women’s increased susceptibility to swine flu as another example.

“I thought you were more immuno-compromised when you are pregnant. You're most susceptible to everything. Your body is like fighting off, like the baby's like a foreign object affecting your body.” – Boston participant, higher education

“That's why they want us to get the H1N1 vaccine.” – Greenbelt participant, higher education

Participants in the lower education groups tended to express beliefs indicating that people were generally at the same risk of getting a foodborne illness. One participant considered that maybe people who were “less fortunate” might be more at risk because of

unequal access to safe food, while another felt that foods prepared at home were probably safer than foods prepared outside the house.

Many participants across groups expressed the belief that individual differences were the greatest predictor of differences in susceptibility.

“I think people react to it differently. I know my brother can eat anything that's been sitting out, you know, for a week. He's like it's fine. And he never ever gets sick. It never ever bothers him. But me, the thought of it is just...” – Greenbelt participant, lower education

“I have to wonder too because we're all made differently. Some of us, our immune systems are not the same. Some of us have weaker stomachs. And I think the foods affect us differently.” – Greenbelt participant, higher education

“I would think it would be based on your immune system, you know, depending how it would affect each person. Say, I don't get sick too often but then she does, you know, so it might affect her a little different from me, but I still think it would be serious.” – Boston participant, lower education

“It affects us different, everybody takes in nutrients differently, so everybody's different to fight off different illnesses.” – Boston participant, lower education

“Another thing, you don't know, like, could it be something where the person...like something that they personally have going on, something medical that can actually counteract with eating certain foods that can bring Listeria about or anything.” – Boston participant, higher education

Perceived susceptibility after exposure to Message A

Most participants were also surprised to learn that the risk of listeriosis exists throughout pregnancy and that listeriosis is most commonly seen in the third trimester. This is contrary to a widely held belief that risks to pregnancy decrease after the first trimester.

“I was an older mother. So I went through all the testing and finally got the okay. And then the twenty-week sonogram said

everything's fine. And I finally felt like, 'Oh, I'm not going to worry anymore. Nothing's going to happen at this point.'" – Greenbelt participant, higher education

"I feel like the first three months is [when] you really watch like what you're eating because that's when things can go wrong. But then after that you kind of like feel more comfortable." – Philadelphia participant, lower education

"I think by the end you kind of feel like, 'Alright I'm almost there', maybe [get] a little more lax in what you do." – Philadelphia participant, higher education

"Yeah, it makes you, you know, you think passed all that scary stage and...all that's done. I mean, anything can still happen, but still when you're farther along, you're like 'Oh, I'm good.'" – Boston participant, lower education

"Especially because I think when you first get pregnant you're like anxious--it's just about... 'Will it be a good pregnancy?' and all that. Once you get farther along, you kind of get more lax in what you're doing and you're kind of like 'Okay, this is good, everything's going good.'" – Boston participant, higher education

Reactions to Message C, the enhanced risk message

Participants' responses to Message C indicated that the message did evoke fear.

After reading this message, participants in all groups become very quiet, and their

immediate responses to the message were "scary," "sad," "disturbing," and "horrible."

"I mean, I just, the worst fear is that you carry the baby and you tried to do the best you can and then you have a stillbirth or there's something wrong with your baby." – Boston participant, high education

"Yeah, that's a disturbing thing to read.... That [a miscarriage] could have been prevented just if you have the information. It's disturbing." – Boston participant, high education

Several responded empathetically to the women portrayed in the vignette and noted that one of the women in the vignette was in her third trimester, like some of the women in the group.

The immediate reaction in for some participants in each of the groups was that a message like this was “too much.” Participants felt that just knowing that listeriosis causes miscarriages and stillbirths would be enough to make pregnant women pay attention. They felt the vignettes were too alarming and unnecessary. Some of these participants engaged in fear control processes, with defensive reactions noted. One participant felt that the vignettes were probably “made up” and not from real people. A few participants became critical in their analysis of the message, noting that the vignettes were not conclusive.

“And, you know, the quotes, they're so poignant. But at the same time, we don't know who Michelle is. We don't know, is this her saying this? Is this her doctor's diagnosis of what happened? So I think kind of scientifically or factually it would be really important just to kind of have it straight and not have the alarmist. – Greenbelt participant, higher education

“You don't know for sure if it was the listeriosis. It says ‘may’ have been able to prevent my miscarriage and my doctor ‘believes’. So it's not that it was definite.” – Philadelphia participant, lower education

“And another thing, it says, ‘my doctors believe to be...’” – Boston participant, lower education

Despite these reactions, other participants across all groups felt that a message containing vignettes grabbed their attention. They felt the vignettes made the possibility of listeriosis more real to them, suggesting that the fear evoked by the vignettes served to further heighten risk perceptions as predicted by the EPPM.

“We don't like them. But I suppose if you're really trying to get people to pay attention now, then it worked.” – Greenbelt participant, higher education

“Because you have someone to identify with. Even though you still don't know who these people are...it can be you.” – Boston participant, higher education

“You need to know that it really does happen rather than, oh yeah, you can prevent it. These people really need to know, like all right, people have actually experienced that, it does happen.” – Boston participant, higher education

“The testimonial is almost like if you know a friend who it happened to. It kind of makes the reality that it does happen to some people. It's almost like when you hear about something that happened to a friend or a friend of a friend, it sticks in your head a little bit more.” – Boston participant, higher education

Across the groups, participants felt that the information stating that listeriosis is most common during the third trimester was important for pregnant women to know. As mentioned previously, most felt that pregnancy risks decreased after the first trimester. Many described becoming less vigilant about all the “do not’s” of pregnancy as their pregnancy progressed.

Participants felt the information about why pregnancy increases susceptibility would also be important for pregnant women to know. However, several disliked the wording of this section of the message and would prefer information that was more scientific.

“I think it's okay. It's not specific enough. ‘It helps you get along with each other’...I think people like more specific information than that.” – Greenbelt participant, higher education

Others reported that they would still need more factual information, especially about the actual incidence of listeriosis, in order to fully understand the risk of listeriosis.

Research Question 4: Relationship between Efficacy Beliefs and Listeriosis Prevention Intentions and Behaviors

The EPPM states that once a threat is perceived, people will perform a second appraisal, which is an evaluation of the efficacy of the response (Witte, 1992, 1994). According to the EPPM, people will be more likely to adopt the recommended behavior when they believe that they are susceptible to a serious risk, the recommended behavior will reduce their risk, and they can implement the behavior. When people have strong efficacy beliefs, they manage their fear by engaging in danger control processes and adopting the recommended behavior. When efficacy beliefs are weak, people use fear control processes to manage their fear.

Self-Efficacy for Listeriosis Prevention Guideline Implementation

When asked whether they thought they could follow the guidelines if they wanted to, most participants felt confident that they could.

“Yes. Definitely.” – Boston participant, higher education

“Absolute confidence.” – Greenbelt participant, higher education

“I don’t think it’s that hard.” – Boston participant, higher education

However, participants in the Greenbelt Lower Education group did not feel that they had enough information to allow them to readily follow the guidelines. Similarly, participants in the other groups immediately qualified their response by identifying factors that would make it difficult to follow the guidelines. These barriers are summarized in Table 22.

Table 22: Barriers to Guideline Implementation (n=6 focus groups)

Barriers	Frequency of identification
Lack of specific information about the guidelines <ul style="list-style-type: none">• To what temperature do I heat my cold cuts?• Do I have to heat them twice?• Do I have to eat them steaming hot?• Does [a specific food] count as a “do not eat” food?• Will freezing affect <i>Listeria</i>?• Are there any other foods that could be contaminated?	6
Personal experiences <ul style="list-style-type: none">• I ate these foods when I was pregnant before and did not get sick• Friends and relatives ate these foods when pregnant and did not get sick• My mother acts with disbelief about the foods I say I cannot eat	6
The “do not eat” foods are a regular and enjoyable part of my diet <ul style="list-style-type: none">• I eat these foods often and they are convenient• I don’t like my cold cuts heated• Moderation is my strategy	5
Pregnancy-related cravings or nausea <ul style="list-style-type: none">• Sometimes you just really crave one of these foods• If it is the only food that you can keep down, you eat it	5
Specific situations where these foods are served <ul style="list-style-type: none">• Parties, barbecues, eating lunch out when at work• Cultural ties to specific foods e.g. lox served during Jewish holidays	3
Have too much information or mixed messages about foods to avoid <ul style="list-style-type: none">• One source says one thing, one says another• There are too many foods to avoid and I can’t remember the list	3

The barrier most frequently mentioned related to specific questions participants had about the guidelines. Some participants wondered if these were the only foods that could be contaminated or whether there were other foods they should know about.

“So let me ask you a question, these things, that they named, are these the most common things that get the bacteria?” – Boston participant, lower education

Many questions were raised related to reheating cold cuts and hot dogs. Participants wanted to know the temperature to which the cold cuts should be reheated. Several groups wondered if they should eat the foods only while they were steaming hot. A few participants thought that the reheating instruction meant that you should heat the food twice before you eat it, with one explaining that her WIC counselor told her to take a hot dog off the grill at a barbecue and then run inside to microwave it.

“If they're talking about having it hot or steaming hot, what temperature?” – Greenbelt participant, lower education

“Like say you cook the hot dog. And you may put it in the refrigerator. Should you heat it up after that?” – Greenbelt participant, lower education

“Maybe just expound a little bit on like how long and at what temperature to cook things, because there is usually a threshold for what kills bacteria and what doesn't...but maybe just the specifics on how to prepare some of these foods that you can eat but you have to do this if you want to eat it, or you should do this.” – Boston participant, lower education

“Can it still grow on there after I heat it?” – Philadelphia participant, lower education

“I wonder if, you know how they say if you freeze certain things, it kills things? So I'm just wondering if you freeze the lunchmeat and then thaw it, would it make it better?” – Philadelphia participant, lower education

“Well, wait a minute. With the hot dogs and luncheon meats unless they're re-heated until they're steaming hot it doesn't--you know a hot dog can be heated until it's steaming hot and then it cools down...Does it need to be hot when you are eating it?” – Philadelphia participant, higher education

“But how hot would you have to get it to get the Listeria off?” – Philadelphia participant, higher education

Participants had questions about whether particular foods were on the list, such as specific kinds of cheese or fish. Questions were also raised about unpasteurized milk that indicated decreased awareness overall about unpasteurized milk.

“I guess the other hard part would be cheeses. I love cheese. I'm not a huge fan of some of the soft and moldy cheeses. But the queso blanco, queso fresco, you know, I love queso dip. So I'm just not sure what kind of cheese is in [queso dip] when you go out to eat.” – Greenbelt participant, higher education

“I could probably do that [follow the guidelines] if I really wanted to, yes. But beef jerky too or just jerky?” – Greenbelt participant, higher education

*“How about a shrimp cocktail? Or just shrimp, cold shrimp? Is that considered refrigerated even though it’s not listed on there?”
– Boston participant, lower education*

“Is goat cheese pasteurized? – Boston participant, lower education

“And my one question is, I read that mozzarella is safe including raw mozzarella. Does anyone know?” - Boston participant, higher education

“Well, what other food besides cheese that would contain it [unpasteurized milk]?” – Boston participant, higher education

“What is that in? Unpasteurized milk, what’s it in?” – Philadelphia participant, lower education

Their own personal experience and the experiences of others were frequently identified as barriers across the groups. Several women reported that they had eaten these foods in previous pregnancies and had healthy pregnancies and healthy children, so this made them more skeptical about the need to follow the guidelines.

*“I think as a mother already of two kids, when I see stuff like this I think about it. But I kind of... I don't feel like I'm untouchable. But yet, I've eaten these things before being pregnant and nothing's happened. So I take it and I think about it. But I also think about, well, I've done it before, you know. And, you know, it's like 50/50.”
– Greenbelt participant, lower education*

“I would say only because I've had children over a very long span of time, and I know for a fact that I've eaten lunchmeat and hot dogs and some refrigerated meat. And I'm fine.” – Philadelphia participant, higher education

Some told of other pregnant women who had eaten these foods or engaged in other unsafe behaviors during pregnancies with no harmful outcomes. Often, this was reflected as comments from a mother or grandmother who did not take current advice seriously because she herself did not have restrictions on what she could eat during pregnancy.

“And they say you can’t smoke, and I know people that smoked all through their pregnancy and drank coffee and came out and had healthy babies.” – Philadelphia participant, lower education

“I feel like there are so many things that they tell you not to do, like don’t have this, don’t do that, but then like we were saying earlier a long time ago like our parents, our grandparents they were probably drinking and smoking cigarettes, you know what I mean? There wasn’t anything like this. So...this is all kind of new to a lot of people.” – Boston participant, lower education

“Our parents ate hot dogs. They ate lunchmeat. They ate everything. And I’m fine. I’m normal. And I have friends who have done the same thing, who have eaten lunchmeat, who have eaten hot dogs and nothing happened to their kids. And these are recent children that have been born. So to see this and to read about it in here, you know, I’m twenty times more likely to catch it. But they didn’t.” – Greenbelt participant, higher education

“Well, I’m just thinking like talking to my mother and my aunt, when I tell them all the restrictions, they can’t believe it, because back then they ate everything. And my mother’s famous quote, ‘You guys turned out fine.’” – Boston participant, higher education

The foods on the “Do not eat” list were foods that were part of many participants’ regular diet. For these participants, eliminating these foods posed a barrier. Some participants described using moderation as a strategy. If they knew a food was unsafe, they just ate less of it than they normally would.

“Really hard, ‘cause you don’t want to give up things that you’re used to eating either.” – Philadelphia participant, higher education

“I have lunchmeat. I’ve had hot dogs on occasion. You can’t resist that stuff sometimes.” – Philadelphia participant, higher education

“I’m still gonna eat...I like hot dogs. I like lunchmeat. And I’m going to eat it.” – Greenbelt participant, lower education

“I always like try to like you know moderate it and kind of watch what I do, but there are things that you really want sometimes so you do have them.” – Philadelphia participant, lower education

Many described the convenience of cold cuts for lunch or as a snack. Although some had heard to reheat their cold cuts, several stated that they would avoid them rather than reheat them. Several felt that reheated cold cuts did not taste good.

“I think that's the hardest thing cause you want something for lunch, you just want a hoagie and it's quick and fast.” – Philadelphia participant, higher education

“I read about the lunchmeat, like heating it up. It doesn't taste so good.” – Greenbelt participant, higher education

“Like I said in the beginning, I won't eat the lunchmeat because I don't want to heat it up.” – Greenbelt participant, higher education

Along with a taste preference for the particular foods, participants described pregnancy-related factors that further interfere with following the guidelines. Many described having cravings for specific foods. One participant believed that her cravings were a signal that her body needed a particular nutrient; therefore, she would eat whatever her body craved.

The thing that would be hard is usually if you crave something, it's something that your body is missing...So if you want something and it's on this list and you're depriving yourself of it, it's counterintuitive. Because you're trying to do what your body is telling you to do which is natural for a woman in general. ” – Greenbelt participant, higher education

Several described having nausea and vomiting throughout their pregnancy. Even if they knew a food was one they should not eat, they ate it if it would “stay down.”

“That's hard, especially when you crave stuff or when there's only some things that you can keep down, so it's hard.” – Philadelphia participant, lower education

“And especially when I'm in the beginning like a lot of things make you sick and some things just help you, like this big fat hoagie and sometimes it's really good. And it's all you can hold down.” – Philadelphia participant, higher education

Participants identified certain situations in which it was harder to follow the guidelines. These included barbecues, parties in which cold cut platters were served, and eating out. While some participants asked the restaurant staff about the foods they were ordering when eating out, some felt that you could not always trust the responses received. One participant identified a cultural association for her with lox, which was an integral part of a family meal during the Jewish holidays.

A final barrier related to information quantity and quality. Some mentioned that participants received mixed messages about foods to avoid, with some recommending that foods should be avoided, others telling them that the same foods were safe.

“I feel like talking with my other friends who are pregnant or have been, they all have, like their doctors tell them something different about these things. Like some people say luncheon meat is fine, others say stay away. So I think there's a lot of different ideas and opinions about it.” – Boston participant, higher education

Others felt there were too many foods that they should be avoiding, which made them hard to keep track of. A few participants reported that they carried information related to which kinds of fish were safe to consume with them. Participants felt that just being told not to eat a food made them want to eat it. Those who did not really understand the associated risks of these foods reported that they would eat them occasionally.

“I have to remember. That's the hard part, remembering, thinking. I could probably remember hot dogs. I don't really eat those anyway. But the rest of this stuff, you know, what kind of cheeses and all that stuff. – Greenbelt participant, lower education

“I mean they throw so much information at you, ‘Don’t eat that,’ ‘Don’t eat that,’ and sometimes you just want it. If you're eating, you're like, oh, maybe I shouldn't, but you know.” – Philadelphia participant, higher education

“You know, ‘you want what you can't have’ kind of thing.” – Greenbelt participant, higher education

During the discussion, factors that would enable participants to better follow the guidelines were identified as well (see Table 23). Overall, many fewer facilitators were identified than barriers.

Table 23: Facilitators of Guideline Implementation (n=6 focus groups)

Facilitators	Frequency of identification (n=6 groups)
Increased prevalence of the message <ul style="list-style-type: none"> • If the message was out there more, I'd take it more seriously • There should be a warning label on the foods • If my doctor told me, I would listen 	6
Use of alternate strategies <ul style="list-style-type: none"> • There's always something else you can eat • You can eat these foods if you follow the instructions, e.g. eat pasteurized, reheat. 	3
Foods not regular part of diet <ul style="list-style-type: none"> • I don't eat these much, so they're easy to avoid 	4
Prepare foods yourself <ul style="list-style-type: none"> • You have more control if you prepare food yourself 	1

The most important facilitator identified by participants in all groups would be having the listeriosis message more prominently displayed, more consistently delivered, and available through multiple channels. Because they did not hear the message consistently across channels, participants have taken the guidelines less seriously. Again, participants mentioned that if the message came strongly from their physicians, they would take it very seriously. Many participants recommended the use of televised public service announcements, brochures, posters in their physicians' offices, and websites. Participants in all groups suggested the need for warning labels on the products or to have point-of-contact reminders, like posted signs at deli counters.

“‘Precaution’ or anything else, it wouldn't hurt to add a couple of more words to, you know, a label just to, say, pregnant women. You see a rollercoaster or anything, ‘A pregnant women cannot, should not’ ...It's telling you if you still want to buy this product, but it's telling you pregnant women should stay away from it.” – Greenbelt participant, lower education

“You know, I like beer. But I don't get beer when I'm pregnant. So I go back to the label thing. If it's a label and it says it on there and it's a well known thing, then yeah, I would stay away from it.”
– Greenbelt participant, lower education

“What about on things, like when you buy cigarettes, it says ‘the Surgeon General’ or whatever. So why not on certain things? Have it so the FDA says that consuming this could...(trails off)” – Boston participant, lower education

“The ‘keep in mind’ part, I feel like if you put it on here then you can put it on queso blanco, like you can put it on the product. I mean, that would eliminate the risk, like a pregnant person saw it and she would think twice.” – Philadelphia participant, lower education

“I always wish...you know how when some medications, stuff like that, it's says like, ‘Don't eat that’ or ‘Don't use this if you're pregnant.’ It should say, ‘Don't eat this if you're pregnant.’” – Philadelphia participant, higher education

Other facilitators identified included the existence of acceptable, alternative behaviors and that some participants did not regularly eat these foods. Participants in three groups mentioned the use of alternate strategies. Others who did not include these foods as part of their regular diet felt that avoiding these foods would be easy.

“But there's always something...rarely hot dogs without hamburgers to eat also. I mean it's not like--it's real specific things so I think there's always an alternate.” – Philadelphia participant, higher education

“Make a grilled ham and cheese.” – Greenbelt participant, lower education

“I'm a vegetarian so it's easy for me to avoid most of it.” – Boston participant, higher education

“I thought there's a risk with anything you eat, but none of this was a concern to me because I didn't eat it before I was pregnant and I probably never would.” – Philadelphia participant, lower education

Response efficacy

Participants were asked whether they believed that avoiding the foods on the “Do not eat” list or eating them according to the instructions would reduce their risk of listeriosis. Mixed responses were observed and appeared to be based on familiarity with listeriosis and the prevention guidelines prior to the focus group discussion. Those who were more familiar with the issue tended to agree that avoiding these foods would reduce their risk.

“I think that if you know that these things could be harmful and you're not eating them, then you're preventing the chances.” – Philadelphia participant, higher education

“Yeah, if it raises your risk, I would think it would reduce it.” – Greenbelt participant, higher education

“It would help, yes.” – Boston participant, lower education

Two groups were less convinced. One group consisted of women who had eaten these foods during previous pregnancies without problems and the other were those who were less knowledgeable prior to the group.

“For me, who hasn't heard about it from their doctor, whereas everybody else has, this is the first time I've actually heard about this. Other people may make that connection because they have the background on it from some medical professional or the Internet. But I don't make the connection right away.” – Greenbelt participant, higher education

Participants on both sides of the response efficacy discussion felt that their risk would be reduced, but not eliminated, because of the potential for other foods to become contaminated.

“Yeah, I'm thinking it could be a whole other group of things...say, [the] FDA is not aware that it's there, it's affecting, we're eating it, but we're only told about this. So now we're trying

to protect ourselves from this, but it's like all these other things. So there's still a possibility we could still be affected with this.” – Philadelphia participant, lower education

“Well, I say that because, like, suppose it's in your refrigerator. That's not to say that it isn't contaminating something else.” – Greenbelt participant, lower education

“I think this list will definitely reduce it, not eliminate it, because the other food in your refrigerator can still get contaminated with listeriosis.” – Philadelphia participant, lower education

Reactions to enhanced efficacy messages

Most participants felt that Message D (see Chapter 3, Figure 6) was less scary than the enhanced risk message (Message C) that they had viewed previously. They commented that the message was “less aggressive,” “softer-sounding,” and “didn't make my heart pound.”

Participants reacted to specific portions of this message. Many responded positively to the statement about pregnancy not lasting forever. They found that the concrete recognition of the finite period of pregnancy was encouraging. Others liked the message's emphasis on prevention. Several liked the quote that said, “Even a slim chance of miscarriage is still a chance. If there's a way to avoid listeriosis, why not do it?” Additionally, they felt they were being offered behavioral options that made the guidelines more do-able. They liked the specific hints contained in the quotes, such as checking the labels for whether the cheese was made with pasteurized milk.

“Like it's only nine months of that life. It makes me think about, you know, the things I shouldn't have been eating. Like it was only nine months. I could have did it.” – Greenbelt participant, lower education

“This is more preventative and it's more proactive and it's, kind of, you know, women talking very selflessly about the fact that ‘I can do this.’ ‘Sure, this is not so bad.’ ‘I can do one more thing

just to ensure the safety of myself and my child.’ And it’s not using such a scary and fearful tactic in terms of getting a message across.” – Philadelphia participant, lower education

Others felt this message did not offer them anything new. These participants commented that the hints in the message were redundant with what is already stated in the guidelines. Participants did say that parts of the enhanced efficacy message resonated personally with them, but they felt that other pregnant women would need a stronger message containing the risk information they had previously read in order to pay attention to the guidelines. They felt the enhanced efficacy message alone would not “stick” with people. Although many had been negative about the enhanced risk message they viewed previously, they now spoke more positively about it, feeling that understanding listeriosis risk was a critical factor in following the advice.

“It’s just saying, like, give suggestions on like how to avoid it, like heat your lunchmeat and check the labels so that [you] make sure it’s pasteurized. But I don’t think that, like, it makes as big an impression, you know, as message C.” – Philadelphia participant, higher education

“[Message D] didn’t sink in. Again, same thing. But I understand what she’s saying completely, and sometimes the shock factor [in Message C] can be a little manipulative. I think in a situation like this I’d rather hear it hard.” – Boston participant, higher education

“I think the only reason why it resonated at all with me, the first quote, is because I’ve experienced miscarriage a number of times. And I think if you are a worry wart and if you experienced miscarriage, I think that this would hit home. But a lot of people aren’t worry warts and a lot of people haven’t experienced those types of things. So for a general message, I don’t think it’s going to hit home with the masses.” – Boston participant, higher education

One participant thought that the statement about pregnancy not lasting forever would convey the opposite of its intent to women. She thought that after reading that statement, some women would decide that a little of these foods will not hurt them.

Another seemed to feel that this message was insulting. She felt that pregnant women who understood the risk would not purposefully put their babies at risk.

“You know, like we’re not going to, if we know the facts on what and what not to eat, we’re not going to intentionally hurt our babies, you know what I mean?” – Philadelphia participant, lower education

Intentions

Participants discussed their intentions to follow the guidelines spontaneously throughout the groups and in response to specific questions. Many were deeply affected by the enhanced risk message and felt that a message like this would impact their behavior, both in terms of seeking additional information and making changes in their eating behaviors and their general food safety practices.

“It gives you the awareness that you need to find out more about this.” – Greenbelt participant, lower education

“If I saw that, I wouldn’t think I’d be eating anything.” – Greenbelt participant, lower education

“This makes me never want to touch this, anything on here. That’s how I feel.” – Greenbelt participant, higher education

“I don’t think I went overboard on anything on that list, but I think I probably would have totally avoided things that I haven’t.” Boston participant, higher education

“I’m going home and cleaning my refrigerator to get everything out.” – Philadelphia participant, lower education

“That’s what I’m saying, especially lunchmeat, I’m taking it more seriously.” – Philadelphia participant, lower education

“I think it would definitely change peoples’ eating habits. I know for myself especially after reading...most common third trimester. That’s the most scary thing. You think you’re safe and you’re okay. I definitely don’t want to have any more lunchmeat until afterwards.” – Philadelphia participant, higher education

After the response efficacy message, one participant commented:

“This is actually what I was thinking on the last one that I read. It kind of does make sense...you are responsible for this life inside you, it is only nine months, so I understand it’s slim, but why even take that slim chance? And like I said, I know now I am going to try to be really cautious for the next five months until I have the baby. I’m going to check and not eat stuff I shouldn’t because of that slim chance. Why risk it? It’s not worth it. I can eat deli meats and hot dogs and all that after I have the baby. So I’m not going to risk it.” – Philadelphia participant, lower education

By the end of the groups, only a few reported that they would continue to eat the foods they had been eating without change. Some were not entirely sure whether they would change their behavior, but felt that they would definitely think about it more than they had previously. Past experience of eating these foods without a problem was a major factor for those who were not sure they would adopt the guidelines. One participant still felt that if her body craved a certain food, she should eat it.

However, most reported that they planned to change their behaviors, indicating the use of danger control processes. Even those who had already been following the guidelines stated that they would be even more careful, particularly now that they understood the risks to women in their third trimester. Most talked about making changes related to lunchmeats, which they planned to reheat or avoid entirely.

“I’m going to put my lunchmeat in the microwave” – Philadelphia participant, lower education

“I definitely will stay away from all of those things.” – Philadelphia participant, higher education

“I would eat ham and cheese or hot dogs, me, being 36 weeks and I’m in my third trimester, I’m just going to avoid it until I have the baby, just to be safe than sorry.” – Boston participant, lower education

“I wouldn’t stop eating. But, I mean, as far as looking at ... because I like cheese too. So I just have to make sure that I look at the package and see if it says pasteurized. And as far as meats and hot dogs and stuff, well, I don’t eat raw hot dogs. So I think I’m all right. But lunchmeat, I think I’m going to have to heat it up or something.” – Greenbelt participant, lower education

Many participants changed their intentions as the groups went on, becoming more earnest in their desire to follow the guidelines as they read more of the messages. One participant (Greenbelt, lower education) made a particularly striking change in her stated intentions over the course of the group. In the beginning of the group, she was almost proud to report that although she knew pregnant women were supposed to avoid certain foods, she herself did not. During the discussion of the enhanced risk message, she said:

“Yeah, so I don’t think it, you know, once a month I go to Subway and get a sub, I’m going to think, ‘Ugh.’ But I’m still going to eat it, you know.”

Her tone changed dramatically after reading Message D, the enhanced efficacy message:

“I think about it and it’s true. It’s only temporary...And, you know, obviously we’ve talked about it quite a bit now. So lunchmeat will obviously be taboo for me.”

Research Question 5: Response to the Changes in Health Messages related to Listeriosis Prevention

Spontaneous discussion about changing messages

Discussion around changing health messages arose spontaneously in the groups. Most discussed changing advice with an accepting and matter-of-fact attitude. They likened the listeriosis prevention guidelines to other examples of changing recommendations related to pregnancy and infant care, such as medications that they could safely take during pregnancy, placing infants on their backs to sleep, and the use of

bisphenol A in plastic baby bottles. They regarded changing health messages as inevitable and they were used to adapting to new advice.

“Things come and go.” – Boston participant, higher education

“I think the science, I think it advances every day. And maybe it wasn't as common or these type of things didn't happen before. And now because it's becoming so common, they're bringing it to the forefront and trying to educate women about the infection or disease.” – Greenbelt participant, lower education

Response to prototype messages about changing listeriosis advice

Their response to Message E, the message that presented the idea that the guidelines could change based on future research (see Chapter 3, Figure 7), was mixed. In each group, some participants liked the message, while others strongly disliked it.

Those who liked the message felt it reinforced the idea that they were getting the most current, research-based guidelines. They liked knowing that scientists were still learning more about *Listeria* and working “behind the scenes” for them and their families. They also liked the reminder that if they get pregnant again, they should ensure that they have the most up-to-date information. However, even those who liked the message felt that it should be shorter and more concise.

Those who disliked the message felt that people understand that advice changes and this fact did not need to be stated. One participant stated that she just wanted to know what the current advice is.

“I just think it's kind of a bunch of... what's the word? I'm not really concerned with what they used to tell people, what they couldn't eat in the 80s...So it's kind of things that don't really matter.” – Boston participant, lower education

Their overall response to this message was skepticism. They felt this message reduced the strength and credibility of the listeriosis prevention guidance. Thus, this message resulted in lower response efficacy beliefs.

“It makes me think they really don’t know yet.” – Boston participant, higher education

“It seems like they don’t really know exactly what you should do. I don’t really think it’s a good message...Because then I could be like, ‘Oh well, yeah, maybe next year they’ll tell me I can eat deli.’” – Boston participant, higher education

“It kind of does say though, that this might all be for naught. Like, so maybe just for nothing because we’re still learning about it. So maybe they’ll find out that you could eat all these things and would be fine.” – Philadelphia participant, higher education

They felt other people would be more likely to reject the guidelines after reading this message, although they themselves would not.

“It’s good to know that they’re learning more about it, but I think it also kind of, for me anyway, it kind of dismisses it. Not totally dismisses it. Like I said, it’s always going to be in the back of my mind.” – Greenbelt participant, lower education

“I feel like there are people who are like looking for reasons to discount it, you know, so that they would. It doesn’t affect me. I still believe everything from the previous messages but some people [could] use this as like, ‘Well, see, you know they said this, now we could do this.’” – Philadelphia participant, higher education

Because of time constraints, only three groups (two higher education and one lower education) viewed the last message, Message F (see Chapter 3, Figure 8), which contained an announcement that a new food was added to the “Do not eat” list and used hot dogs as an example.

The lower education group viewed this message positively, stating that it was clear and to the point. They found it very convincing and said that they would modify their behavior as a result of this message.

“It makes me not want to eat hot dogs.” – Greenbelt participant, lower education

However, both of the higher education groups felt the message conflicted with previous messages that they had read in the group. They felt that listeriosis was serious and that the message should emphasize the serious risks. Since they now knew that pregnant women might not have any symptoms, they considered it almost negligent to tell women not to worry if they had eaten a high-risk food and were asymptomatic. They also recommended the removal of the statement, “Don’t worry. Remember listeriosis is very rare.” from the message.

This message sparked many questions about how listeriosis is diagnosed and treated. They felt that the only way to reduce a pregnant woman’s anxiety if she had consumed the high-risk food would be to provide specific medical information related to diagnosis and treatment.

“You want to be telling pregnant women to take as many precautions as possible and not saying like ‘It’s very rare, so don’t really worry about it.’” – Philadelphia participant, higher education

“I would think in this day and age if it’s an infection that maybe they could do something about it if you were worried. Like, oh, you know, I went on a binge where I was eating hotdogs all the time. You know, if you reported it maybe they, even an antibiotic I would think would help. I don’t know. I don’t like this one at all.” – Boston participant, higher education

“It bothers me because it feels contradictory to...the first part. ‘If you have eaten hotdogs and feel fine, don’t worry.’ Based on the messages we read about, you know, even if you feel fine you still can pass it on. It feels contradictory and a bit irresponsible.” – Boston participant, higher education

Research Question 6: Improving Listeriosis Prevention Messages

As stated previously, participants felt that listeriosis prevention messages should be communicated more broadly, more consistently, and through a variety of sources. Participants who received inconsistent messages reported that they took the prevention message less seriously. Those who were less familiar with listeriosis and the listeriosis prevention guidelines felt that if the risk was truly serious, they would have already heard about it.

All groups felt that pregnant women needed information related to the severity of listeriosis and their susceptibility to listeriosis. Although they knew that foodborne illnesses were serious, they were not aware that listeriosis could cause miscarriage or stillbirth. They felt that a good message should include statistics related to the prevalence of listeriosis. A good message would also emphasize that the risk of listeriosis exists throughout pregnancy to counter the commonly-held belief that pregnancy risks decrease after the first trimester. They also felt it was important to communicate why pregnancy increases susceptibility, but felt that the language of such a message should be more scientifically stated than what was contained in the sample message.

During the initial discussion of the vignettes contained in Message C, the enhanced risk message, some participants felt the message was effective; however, many participants felt they were unnecessary and too intense. At that point in the groups, these participants felt that just telling pregnant women that listeriosis could lead to miscarriage would be enough for women to change their behavior. However, during this last exercise, most ultimately felt that the vignettes made them take the information more seriously and felt they should be included in a message to pregnant women. Others commented that vignettes would be appropriate in only certain forms of communication,

such as in a brochure or a televised public service announcement, but would not be appropriate for a single page fact sheet.

Some participants felt that the enhanced efficacy messages were not necessary to a listeriosis prevention message; however, most recommended including the bullet point that reminded them that avoiding the high-risk foods could help prevent a miscarriage, stillbirth, or life-threatening infection to a newborn. The use of vignettes to provide a model for following the guidelines was less effective than using vignettes to enhance communication related to risk; however, several participants responded positively to the specific tips offered in these vignettes. Based on this and the large number of barriers identified, providing more specific information about how to successfully follow the guidelines would be helpful.

Although participants were told that Message C and Message D contained information that could be added to a listeriosis prevention message, they tended to discuss them in an either-or fashion and felt that the enhanced risk message contained the elements that would be needed to take the recommended guidelines more seriously. From observing the groups, Message C definitely raised the anxiety and fear levels in the room. After reading Message D, participants were calmer and seemed to speak more emphatically about following the guidelines. This suggests that while enhancing risk information is critical, enhancing efficacy components is important in facilitating engagement in danger control processes, rather than fear control processes.

Participants clearly accepted the notion that health advice changes, but they felt that too much information about changing health advice would lead others to discount the current advice. They felt the most important points to communicate to pregnant women

were that scientists were still studying *Listeria* and that if they got pregnant again, they should ensure that they have the most current advice. They also suggested that links or resources should be provided for those who want more information.

Only three groups viewed Message F, the sample message that could be used to communicate a change in the guidelines. While the participants in the lower education group liked the message, those in the higher education groups felt that the reminder that listeriosis is rare would not alleviate their anxiety if they had been eating the high-risk food. They felt that such a message should convey the seriousness of listeriosis and provide specific information about how it is diagnosed and treated.

Summary of Results

This mixed methods study explored pregnant women's awareness, behaviors, and underlying beliefs related to listeriosis prevention. While awareness has increased, many pregnant women were still unaware. Both the quantitative and qualitative study found that many pregnant women reported eating cold cuts without reheating, though less consumption of the other high-risk foods was reported. Pregnant women believed that foodborne illness was serious, but they were largely unaware that pregnancy itself increases their susceptibility, that they were susceptible throughout their pregnancy, and that listeriosis can result in miscarriage or stillbirth. They generally believed that the listeriosis prevention guidelines would reduce their risk of listeriosis and that they would be able to follow the guidelines if they wanted to; however, they identified areas of concern and barriers to successful implementation. Pregnant women accepted that health advice can change, but they felt that over-emphasizing this fact can reduce the perceived response efficacy of the recommended behavior. They were in agreement that listeriosis

messages to pregnant women should emphasize pregnancy's risk, remind them that adhering to the guidelines can reduce their risk of miscarriage or stillbirth, and should suggest that they seek current food safety information if they become pregnant again. These findings are discussed in Chapter 5.

CHAPTER 5: DISCUSSION

Listeria monocytogenes was recognized as a foodborne bacterium in the 1980's (FDA et al., 2003; Schlundt, 2002) and the body of knowledge related to consumer awareness and behaviors related to *L. monocytogenes* is slowly growing. The previous chapters described the methods and results of a mixed methods study designed to examine the awareness of *L. monocytogenes*, consumption of *Listeria*-related high risk foods, and underlying beliefs about risks and efficacy in one high-risk group – pregnant women. In this chapter, key findings are summarized and their implications discussed. Next, recommendations for public health practice and future research are presented, followed by a discussion of the study's strengths and limitations. The chapter closes with discussion of the study's strengths and limitations and a summary and conclusions.

Key Findings and Implications

The discussion of results is organized around six main themes. These include the following: (1) Awareness of *Listeria monocytogenes* has increased, but many women are still unaware of the increased risk associated with pregnancy, (2) Three-quarters of pregnant women reported eating cold cuts without reheating, with much less consumption of the other high-risk foods, (3) Subgroup differences affected awareness of *L. monocytogenes* and consumption behavior, (4) Risk and efficacy beliefs were related to adherence to listeriosis prevention guidelines, which supports the use of the Extended Parallel Process Model (EPPM), (5) Changing or conflicting messages related to listeriosis prevention guidelines decreased the perceived response efficacy of the

guidelines, and (6) Some findings were not explained by the EPPM and suggest that the EPPM could be broadened.

Several new and important findings emerged from the research. These are briefly highlighted here. The first related to awareness of *L. monocytogenes*. The focus group findings showed that awareness is multifaceted and suggest that traditional surveys may underestimate some aspects of food safety awareness, while overestimating other areas. A continuum of awareness is presented in this chapter, along with discussion of the need to improve measurement of awareness.

The EPPM was used as a theoretical framework to guide the examination of underlying beliefs related to listeriosis prevention and changing health messages in the focus groups. Along with the examination of underlying beliefs, this research elicited pregnant women's reactions to prototype messages. Synthesis of the findings from these two approaches led to the identification of specific strategies that can be used to improve listeriosis prevention messages. In general, messages need to more strongly emphasize risk and efficacy content. On the other hand, the results showed that too much discussion of changing messages affected the perceived credibility of the listeriosis prevention guidelines. Findings related to beliefs, reactions to prototype messages, and implications for message content are discussed more fully in this chapter.

Other important elements for a communication strategy emerged from this research. The finding that awareness of listeriosis and engagement in high-risk listeriosis-related behaviors differed by education and income levels suggests the need to target messages to these subpopulations. This research also identified the channels

pregnant women use to find health information and which they prefer. The implications of these findings for future communication efforts are presented in this chapter.

The discussion should be tempered by the recognition that neither the secondary data analysis nor the focus groups used a randomized sampling strategy. Therefore, the results of the study cannot be generalized and should be confirmed through additional research. The strengths and limitations of this study are also discussed more fully in this chapter.

*Awareness of *Listeria monocytogenes**

The secondary data analysis, which collected prenatal data from 2005 through 2006, found that just over a third of pregnant women in the United States were aware of *L. monocytogenes*. The focus groups in this study, conducted in 2009, found that participants in most of the groups had heard of *L. monocytogenes*. Both analyses suggest an increase in awareness compared to an American study completed in 2003 that found only 18% of pregnant women were aware of listeriosis (Ogunmodede et al., 2005).

As in previous research (Bondarianzadeh et al., 2007; Ogunmodede et al., 2005), the secondary data analysis found that awareness of *Listeria*-related food vehicles was lower than general awareness of the bacterium. However, the focus group participants knew they should avoid some of the *Listeria*-related high-risk foods, particularly cold cuts, hot dogs, and soft cheeses, even though they did not understand why. Despite a general awareness of *Listeria*, few focus group participants knew that pregnant women have increased susceptibility to listeriosis and that listeriosis can cause miscarriage, stillbirth, or serious illness in the newborn.

The findings suggest a continuum of listeriosis awareness (see Figure 9). At the lowest level, no awareness of pregnancy-related high-risk foods exists. Only one participant in all of the groups reported that she had not been told to avoid any food during her pregnancy. At the second level, women were aware of high-risk foods without understanding the reasons behind the risk. Many focus group participants appeared to have this level of understanding. This finding suggests that surveys such as the IFPS II may underestimate pregnant women's awareness of pregnancy-related food safety. Next, some participants had heard of *Listeria* but were unaware of the related foods. This could be considered the third level of awareness. At the fourth level were women who could link the bacteria to specific food vehicles, yet they did not understand the high level of risk specific to pregnant women.

Those who understood that listeriosis is a foodborne infection, knew which foods were related to listeriosis, and were aware that listeriosis posed a special risk to pregnant women would be considered at the highest level. As will be discussed below, this highest level of awareness may be what impacts consumption behavior. It is possible that some of the IFPS II participants who were aware of *Listeria* and *Listeria*-related foods were also aware of the pregnancy-related risks; however, this was another facet of awareness not measured by the IFPS II. Instruments designed to measure all levels of awareness would provide a clearer picture of food safety awareness among pregnant women and help clarify the relationship of awareness to behavior. Communication efforts could then target specific gaps in understanding.



Figure 9: Continuum of listeriosis awareness

Consumption of high-risk foods

Pregnant women responding to IFPS II questionnaires also reported consuming high-risk foods, with about three-quarters of the sample reporting that they sometimes or always consumed cold cuts without reheating. Fewer than 5% of the sample consumed hot dogs without reheating, refrigerated smoked seafood, or raw milk. Focus group findings confirmed and expanded these findings. Many focus group participants reported consuming cold cuts without reheating, despite their stated awareness that they should be reheated or avoided. Similarly, consumption of hot dogs without reheating, refrigerated smoked seafood, and raw milk was rare to non-existent among focus group participants.

The focus groups allowed examination of two high-risk foods not measured by the IFPS II: soft cheeses and refrigerated pâtés. While none of the participants reported consuming refrigerated pâtés, some did report consumption of soft cheeses. Their discussion suggested that they were aware that they could consume soft cheeses made from pasteurized milk, indicating some awareness of the current guideline. Past outbreaks related to soft cheeses primarily occurred in Hispanic communities and were related to the consumption of homemade cheeses (Reddy et al., 2004). Given that few Hispanic women participated in the focus groups, consumption of soft cheeses and awareness of the need for pasteurization should be explored further in that population subgroup.

Subgroup differences

The analysis of the IFPS II data identified differences between those who were and were not aware as well as between those who did and did not engage in high-risk practices. In general, differences fell along income (as measured by WIC participation) and education lines. For example, those who were receiving WIC services were less likely to be aware of *L. monocytogenes* and more likely to report consumption of both cold cuts and hot dogs without reheating. On the other hand, those with a college education were more likely to be aware of *L. monocytogenes* and related food vehicles, while also being less likely to consume hot dogs without reheating. The focus groups also found that differences in education were related to differences in awareness, as more participants in the higher education groups were aware of *Listeria* and *Listeria*-related foods, while fewer in the lower education groups had heard of *Listeria*. One of Healthy People 2010's overarching goals is to eliminate health disparities (U.S. Department of Health and Human Services, 2000); this research provides another example of the ongoing nature of such disparities due to income and education. Further, it suggests a particular need to target listeriosis prevention messages to these groups.

Both the IFPS II and the focus group findings identified regional differences in awareness of high-risk foods, with results suggesting that women in the Northeast were more likely to be aware of *Listeria*-related high-risk foods than those in the South. The reasons for these differences cannot be ascertained from the present research. The results suggest the need to further explore these differences and perhaps formulate communication strategies based on these regional differences, with intensified efforts in areas outside the northeastern United States.

One of the most important findings from the secondary data analysis was that pregnant women who were aware of *L. monocytogenes* were less likely to engage in one high-risk behavior: eating cold cuts without reheating. Similarly, the relationship between awareness of *L. monocytogenes* and the consumption of hot dogs without reheating was significant in the univariate model and approached significance in the multivariate model. While knowledge is considered a necessary, but not sufficient, component of behavior change (Rimer & Glanz, 2005), these findings show a direct link between awareness and behavior. As such, it provides a strong rationale for continuing and strengthening listeriosis prevention efforts with pregnant women.

No relationship was found between the consumption of refrigerated smoked seafood and awareness of *L. monocytogenes* in the IFPS II analysis, but this is possibly due to the decreased awareness of refrigerated smoked seafood as a *Listeria*-related food vehicle in general and the fact that few consumed refrigerated smoked seafood. The focus group findings confirmed that refrigerated smoked seafood was rarely recognized as a high-risk food, while cold cuts and hot dogs were more well-known.

The focus group findings suggested that awareness of the specific pregnancy-related risks remains quite low. Most participants reported that the facts that pregnant women were more susceptible and that listeriosis could cause miscarriage or stillbirth were new to them. This particular level of awareness seemed to be the critical component that would motivate a pregnant woman to avoid high-risk foods. When participants were not sure why they were being told to avoid a food, they were more likely to eat the food than those who more deeply understood the risks. As participants

gained an understanding of the risk, they reported stronger intentions to modify their behavior. Again, this could be confirmed with more precise survey questions.

The secondary data analysis research also confirmed Bondarianzadeh et al.'s (2007) finding that pregnant women who reported using more information sources were more likely to be aware of high-risk foods. One possible explanation for this findings is that listeriosis prevention messages were not widely available. Pregnant women who consulted more sources would have a better chance of exposure to listeriosis prevention information. Alternatively, listeriosis prevention information may have been present in many sources; however, pregnant women may need to receive listeriosis prevention information from multiple sources in order to process and accept the message.

The focus groups suggest that the latter explanation may be more plausible. Participants who had not heard of *L. monocytogenes* prior to the focus groups appeared to be less convinced about the need to follow the prevention guidelines and the efficacy of the prevention guidelines than those who were more aware beforehand. Further, a recurring theme in the focus groups was that if listeriosis prevention messages were more widely and consistently delivered via credible sources, pregnant women would take the messages more seriously.

Findings from the IFPS II showed that another influence on awareness and behavior was parity. Women with more children were less likely to be aware of soft cheese as a high-risk food and more likely to consume cold cuts without reheating. Anecdotal evidence collected during the pilot study found that women with another child reported receiving less prenatal education during their current pregnancy as compared to their first pregnancy. They attributed this to their healthcare practitioners' assumption

that they “knew everything already” since they had been pregnant before. A few focus group participants made comments related to prior prenatal experiences. Several reported that they received the “same packets of information” they had gotten during previous pregnancies, and these did not contain food safety information. Only two reported that they had received listeriosis prevention information with their current pregnancy that they had not received during previous pregnancies. While the influence of parity should be verified through additional research, the findings suggest the need for healthcare providers to offer prenatal food safety advice to all women, regardless of the number of previous pregnancies, especially since guidelines may change over time.

Risk and efficacy beliefs

While the secondary data analysis provided compelling evidence that awareness of *Listeria* is increasing, the fact remains that more than half of pregnant women are still unaware of the risk and almost three-quarters reported consuming one of the high-risk foods. These findings suggest that efforts to educate pregnant women must continue in order to reduce the incidence of this preventable infection. Health behavior theories stress the importance of beliefs, attitudes, motivations, and skills in facilitating or hindering behavior change (Rimer & Glanz, 2005). The purpose of the focus groups was to examine pregnant women’s underlying beliefs related to listeriosis prevention using the Extended Parallel Process Model (EPPM) as a guiding theoretical framework. A better understanding of beliefs can increase the effectiveness of future communication related to listeriosis prevention.

While the focus groups findings would need to be confirmed using experimental methodology, the participants’ comments supported the assumptions of the EPPM. In

some sense, as participants were exposed to the prototype messages designed to enhance first risk and then efficacy perceptions, the focus group discussions provided voice to the internal cognitive appraisals consistent with the EPPM. The findings suggest that the EPPM is a viable framework through which to structure listeriosis prevention messages for pregnant women.

As stated previously, participants were generally aware of some of the *Listeria*-related high-risk foods and had heard of *Listeria* as a foodborne bacterium. The focus groups showed that they lacked the knowledge that pregnancy increases their susceptibility to listeriosis and that listeriosis has severe consequences. Those who were unaware of these specific risks described eating the high-risk foods at least occasionally despite knowing they were not supposed to eat them.

When participants were presented with the enhanced risk message, fear and anxiety levels increased in the room. Some participants reacted in a manner that suggested they were using fear control processes described by the EPPM. They suggested that the vignettes were “made up” and that the miscarriage suffered by the woman in the case study could have a cause other than listeriosis.

Others participants reacted more protectively. They reported that the risk information would directly affect their behavior, and they planned to become more careful in their eating habits. At this point, participants had already discussed the listeriosis prevention guidelines prior to viewing the enhanced risk message; thus, their intentions may have been influenced by an internal appraisal of the efficacy of the response. However, the perception of high levels of risk may have had an independent

effect on intentions, an effect that was also found in Witte and Allen's meta-analysis of studies examining the effects of fear appeals (2000).

Participants felt that most pregnant women would take messages that lacked strong risk components less seriously. Ultimately, many advocated for the use of vignettes to illustrate the risks of listeriosis. Some of the specific sources they described using, such as pregnancy websites and pregnancy reference books, do contain information about listeriosis and miscarriage/stillbirth risks as verified by this researcher. Many participants suggested that the sources they consulted did not have information about the consequences of listeriosis during pregnancy, indicating that the risk information was not salient enough. The vignettes appeared to effectively focus their attention on the risks.

After reviewing the enhanced efficacy message, participants were generally less anxious. With respect to self-efficacy, the participants' immediate responses indicated that they did not think it would be hard to follow the guidelines; however, they almost always qualified this. They identified with specific questions they had about the guidelines, such as how to reheat their cold cuts or whether a specific food was on the list. They identified other barriers as well, including personal experiences in which they consumed the foods without problems and specific situations like parties or barbecues where it would be hard to follow the guidelines.

Most believed that avoiding the foods would decrease their risk of listeriosis, indicating generally high levels of response efficacy; however, some participants were not convinced. These tended to be women who were unfamiliar with *Listeria* prior to participation in the group and women who had eaten these foods without problems during

prior pregnancies. Again, most participants qualified their response efficacy beliefs by expressing their concerns that other foods could be contaminated. However, most participants planned to adhere more closely to the guidelines by the end of the group.

Given that research has shown that the most effective fear appeals contained content that led to high levels of both perceived risk and perceived efficacy (Witte and Allen, 2000), the participants' elucidation of concerns related to self-efficacy and response efficacy suggested specific ways in which prevention messages could be improved. For example, messages should address worries about the contamination of other foods by including general food safety tips, such as ensuring that foods are refrigerated at or below forty degrees Fahrenheit, eating foods by the use-by date, and cleaning out the refrigerator regularly. Similarly, the listeriosis prevention guidelines should provide precise information about how to implement them, especially around reheating cold cuts.

The impact of changing or conflicting advice

Focus group participants were quite clear that too much emphasis on changing advice would reduce the perceived efficacy of the recommended behavior and would make them less likely to adopt the listeriosis prevention guidelines. This is consistent with previous research in which participants reported negative reactions to changing or conflicting health advice (Bernal, Rose, & Kaufman, 2006; Patterson, Satia, Kristal, Neuhauser, & Drewnowski, 2001). This is also consistent with the EPPM, which posits that decreased efficacy beliefs would lead someone to engage in fear control processes, rather than adopt the healthy behavior. Thus, focus group participants suggested mentioning any changes only in a very brief way, such as reminding them to make sure they had current advice in future pregnancies.

Similarly, participants discussed receiving contradictory advice from different sources. When faced with contradictory advice, they concluded that the experts really did not know what constituted the best food safety advice and deduced that more than one correct approach might exist. They were then left to construct their own “best practice” based on the various pieces of advice, which they weighted by the information source and their own past experience. For many, this led to a moderation strategy in which they would still eat the high-risk foods but less often or in smaller quantities. Although moderation might lessen their potential exposure, this behavior differs from the “avoid or heat” message that government agencies advise.

As mentioned in Chapter 1, the U.S. Department of Agriculture advises pregnant women to avoid salads prepared in stores, but the FDA has not adopted this guideline. None of the participants were aware of this guideline. However, based on the focus group participants’ comments, awareness of such differences in recommendations by government agencies would likely lead pregnant women to question the advice provided by these government agencies. Although achieving scientific consensus can be challenging due to different interpretations of risk even by experts, the focus group findings suggest that developing consistent guidance is critical.

Broadening the EPPM

Although the focus group findings supported the EPPM postulates, several findings from the focus groups were not fully explained by the EPPM. These include the impact of changing or conflicting messages, source credibility, and subjective norms. The EPPM posits that individual differences related to experience, culture, and personality affect how people appraise a fear appeal (Witte, 1992), but it does not

postulate how these differences affect fear appeal processing. One individual difference that could affect fear appeal processing is an individual's readiness to change. This section discusses how the EPPM could be extended based on this study's results.

Changing and Conflicting Messages

The EPPM describes how a fear appeal is processed; however, in reality, people typically receive multiple health messages from a variety of sources. Many instances exist where health information changes or is inconsistently delivered. The EPPM does not address how people process multiple messages in general or what might happen when the messages contain changing or conflicting advice. The focus group findings suggest that changing or conflicting advice negatively impacts response efficacy. In turn, this would likely make adopt fear control processes to manage their fear. As a result, they may be more likely to reject the advice. Thus, individuals are likely making an additional appraisal related to message consistency.

Source Credibility

Focus group participants also discussed the role of source credibility when they received conflicting messages. They weighted the various information sources differently and saw their physician as the most credible source of information. Even if they were exposed to multiple listeriosis prevention messages through other channels, their physician's opinion would determine whether they ultimately followed the advice. They also reported other interpersonal influences, such as friends who first made them aware of food safety issues and their mothers and grandmothers who had no dietary restrictions during their pregnancies.

The EPPM does not address the influence of source credibility; however other theories and frameworks, such as models used for developing persuasive communications (McGuire, 2001), stress its usefulness. Some models, such as Petty and Cacciopo's Elaboration Likelihood Model (Wilson, 2007), suggest that source credibility is more important when a message recipient is less involved with the issue. However, the current research suggested that source credibility was important to these highly involved participants and would impact the adoption of the listeriosis prevention guidelines.

Subjective Norms

A related construct is the subjective norms construct from Fishbein and Ajzen's Theory of Planned Behavior (Montano, Kasprzyk, & Taplin, 1997). Subjective normative beliefs relate to whether the individual believes that others, who are important to the individual, approve of the behavior or not, weighted by the individual's motivation to comply with these individuals. The Theory of Planned Behavior posits that subjective normative beliefs directly influence behavioral intentions. The current research suggests pregnant women do consider the opinions of others (their physician, their mother, their friends, their husbands) when adopting food safety behaviors and that these opinions can directly influence their behavior.

Readiness to change

The Transtheoretical Model (Prochaska, Redding, & Evers, 1997) suggests that individuals differ in their readiness to change a particular behavior and that different strategies are effective at the different stages of readiness. For example, people in the precontemplation stage are not thinking about changing their behavior; therefore, strategies to heighten their awareness of the problems associated with the behavior could

facilitate their decision to change. People who are already trying to change their behavior would benefit from different strategies, such as restructuring their environment or rewarding their change attempts. Wong and Cappella (2009) studied smokers and found a three-way interaction between perceived threat, perceived efficacy, and readiness to quit on quitting intentions. Both threat and efficacy messages were found to influence intention to quit in smokers with low readiness to quit, while efficacy messages alone were most important for those with high readiness to quit.

Although the present research was not designed to examine readiness to change, its importance was suggested in focus group discussions. Participants described other pregnant women they knew who were not following the guidelines. These women would be in the precontemplation or contemplation stages. The participants felt that these women would need messages with strong risk components to motivate them to follow the guidelines. Further, the focus group participants identified many barriers to guideline implementation, suggesting that messages should contain stronger efficacy components.

Another example from the focus groups supports the influence of the readiness to change construct. Some focus group participants had been trying to follow the listeriosis prevention guidelines prior to being in the group and could therefore be considered to be in the action stage of change. These participants seemed to be the ones who were most positive about the efficacy messages containing strategies for how to implement the guidelines.

This research suggested the need for strong risk and efficacy components for those who have not begun to change their behavior and the need for strong efficacy

components for those who are actively trying to change. Both of these are consistent with Wong and Cappella's (2009) findings.

An Expanded Message Processing Model for Listeriosis Prevention

Overall, these findings suggest the importance of including other theoretical components and constructs – such as the appraisal of message consistency, message source, social norms, and readiness to change – in any planning process for improving listeriosis prevention communication. Figure 10 shows how these constructs could be integrated into the EPPM.

In the External Stimuli column, the use of a layered graphic implies that people are likely to receive multiple messages about a topic from different sources. Message Source has been included with Message Components to suggest the importance of who delivers the message. Under the Message Processing column, two appraisals have been added. One examines the consistency of messages. The second examines social norms. The EPPM posits that the threat appraisal occurs before the efficacy appraisal. At this point, exactly where the consistency and social norms appraisals would fit into the overall appraisal process would need to be determined. The readiness to change construct was included under Individual Differences, recognizing that different message components may be important as an individual moves along the readiness to change continuum.

One factor that could impact the effectiveness of a listeriosis prevention message is the degree of definitiveness in vignettes used to enhance risk communication. Those used in the enhanced risk message presented to the focus group participants were adapted from stories posted on Internet sites and were written from a patient perspective; however, they used terminology that was not definitive enough, such as when a woman stated that her stillbirth resulted from what her doctors “believe to be a listeriosis infection.” This allowed participants to critique the wording of the message and conclude that this women’s stillbirth might have been caused by something other than listeriosis. Using a vignette that strongly shows that listeriosis was the cause of a miscarriage would remove the uncertainty and improve risk communication.

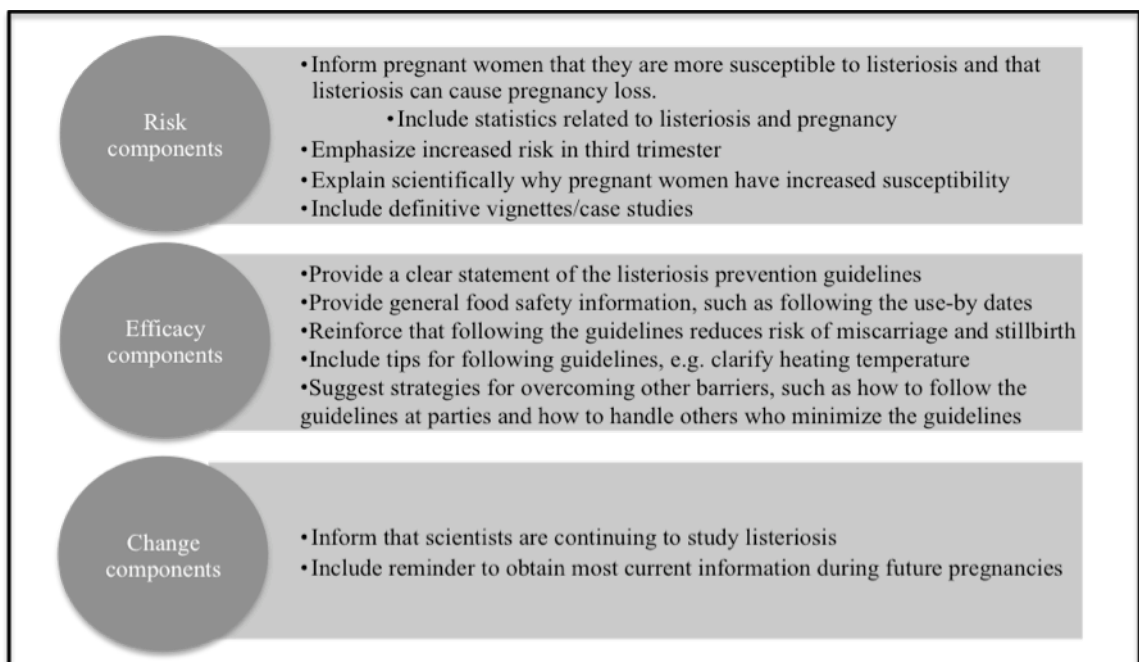


Figure 11: Recommended Content of Listeriosis Prevention Messages

Targeting Subgroups

Previous research did not identify subgroup differences in awareness and consumption, but this is likely because so few were aware of listeriosis at all. Now that

awareness is increasing, subgroup differences have been identified, and, not surprisingly, they fall along traditional disparity lines related to education and income. Therefore, additional listeriosis prevention efforts should be directed to pregnant women who have less education and lower incomes.

The messages used in the focus groups were developed with the intent that they would be understandable to women with less education. Some of the strategies utilized included defining complex terms, such as listeriosis and meningitis, as well as highlighting important information through the use of short sentences, bulleted lists, and bold-faced font. Participants were provided with a written copy of the message and the messages themselves were read aloud during the groups. Based on the comparable quality of the discussions in both the lower education and the higher education groups, it appeared that the participants in all groups understood the messages. The listeriosis prevention message was complex in unforeseen ways, such as when participants interpreted “reheating hot dogs” to mean that they should be cooked twice before eating. The importance of pretesting messages with the target audience cannot be underestimated. Careful attention to the design of messages for those with less education should be an integral part of future efforts to address the disparities identified in this research.

Dissemination Strategies

Participants in all groups reported obtaining food safety information from a variety of sources. Despite current trends emphasizing the need for personal health self-management, the findings from this research strongly suggest that healthcare providers still have the greatest influence on whether women will adopt the guidelines. The focus

group participants felt that pregnant women should receive food safety advice early in their pregnancy and again as they enter their third trimester, in recognition that immune system functioning is at its lowest level in the third trimester.

Most focus group participants were introduced to the concept of pregnancy-related food safety concerns by their mothers and girlfriends, suggesting that food safety education for pregnant women is not well institutionalized. Healthcare providers have reported that they personally lack food safety knowledge, with those who felt more comfortable with food safety information and who did not underestimate food safety risk more likely to provide this information to their patients (Bondarianzadeh, Yeatman, & Condon-Paolini, 2009; Morales, et al., 2004; Wong et al., 2004). This suggests a strong need to focus educational efforts on healthcare providers as well as on pregnant women. Developing materials that providers can use to facilitate food safety discussions with their patients would be an important component of this effort. Partnering with provider organizations, such as the American Congress of Obstetricians and Gynecologists (ACOG), in the creation of food safety messages for pregnant women would enhance the credibility of materials to both other providers and pregnant women. Using healthcare providers as spokespeople in the materials may also enhance their credibility. For example, a brochure could include a message from a well-known obstetrician stressing the need for pregnant women to know about and follow the listeriosis prevention guidelines.

Although women primarily wanted food safety information from their doctors, they also believed that if listeriosis prevention messages were more widespread and consistently delivered, credibility would increase. A few differences in information

sources used by participants in the lower education and higher education groups were noted. Those in the lower education groups reported obtaining food safety information from television news programs and they suggested the use of public service announcements to convey listeriosis prevention messages. WIC provides another potential source of food safety information for pregnant women with low incomes; however, the participants in this study who received WIC services were not consistently provided with information about listeriosis. WIC educators may be another important subgroup to target in listeriosis prevention efforts.

The Internet was mentioned as an information source by all of the higher education groups and one of the lower education groups. Participants described using general pregnancy sites that sent weekly emails to subscribers. Many mentioned that their knowledge of high-risk foods came from these emails. Partnering with popular pregnancy-focused sites would provide another method of ensuring that women receive current food safety information because it is relatively simple to update web-based information. As the number of people with lower education and income levels who use the Internet increases, online information may provide another means of reaching these subpopulations. A recent survey (Rainie, 2010) found that higher percentages of those with lower incomes and less education connect to the Internet using mobile devices rather than via home-based high-speed connections. Developers should take this into consideration when designing Internet-based communications for these groups.

Another communication channel suggested by participants in all groups involved the placement of warning labels either on the high-risk food products themselves or at the point-of-sale, such as deli counters. They cited other examples where warning messages

for pregnant women exist, including on medications, on cigarettes, and in establishments serving alcoholic beverages. They felt that warning labels would truly convey the seriousness of listeriosis and provide an immediate reminder that would help them keep the message in mind.

Some professionals concur with the need to provide food safety warnings to at-risk populations (Powell, 2009). A meta-analysis of research on warning labels (Argo & Main, 2004) found that warning labels had a moderate effect on attracting consumers' attention and on their behavior. Federal regulations allow manufacturers of ready-to-eat meat and poultry products to put labels on their products describing their use of regulated processes to minimize the presence of *L. monocytogenes* (USDA, 2003); however, manufacturers have expressed concerns that such labels may deter consumers from purchasing their products (Lenhart, Kendall, Doorn, Medeiros, & Sofos, 2008). Thus, the likelihood of voluntary labeling is low although Powell (2009) believes that highlighting food safety practices could be an effective marketing strategy.

Recommendations for Future Research

The present study suggests several areas for continued research. First, more precise measurement instruments are needed in order to gain a deeper understanding of how awareness affects behavior. The present research suggests that a continuum of awareness exists, but all facets of awareness were not measured in the IFPS II or in other studies examining awareness of *L. monocytogenes*. It would be important for such instruments to measure awareness of all of the high-risk foods independent of *L. monocytogenes* awareness, awareness of *Listeria* and *Listeria*-related foods, and awareness of specific pregnancy-related risk, i.e. perceived susceptibility and severity.

Similarly, measurement tools are needed to measure consumption of all high-risk foods. The IFPS II did not ask about consumption of soft cheeses because cognitive pretesting for the instrument showed great variation in the interpretation of ‘soft cheeses.’ Given that the issue in the current guidelines is really around pasteurization, perhaps awareness of the need for pasteurization of soft cheeses may be more important to examine.

The multiple regression model examining predictors of awareness of the *Listeria*-related high-risk foods explained only four percent of the variance. This suggests that other predictors of awareness of high-risk foods were not included. Additional research is needed to identify other important predictors. Possible factors to examine include attitudes related to health information seeking, such as health information-seeking/information-avoiding characteristics, barriers to information-seeking, and degree of reliance on physician as a source of health information; attitudes related to food safety including belief in the safety of the food supply and belief in one’s ability to control foodborne illness; subjective norms related to food safety; and responsibility for food shopping and preparation. Environmental factors could include the occurrence of recent foodborne outbreaks in the geographical region.

The issue of asking focus group participants about their consumption of high-risk foods should be discussed. When the focus group guide was being developed, two approaches to question format were considered: asking questions generally about other pregnant women or specifically directing questions to the participants themselves. The final decision was to direct the questions to the participants themselves as none of the topics appeared particularly sensitive. As the groups unfolded, the consumption of high-risk foods did turn out to be somewhat sensitive for participants. Some participants

appeared uncomfortable sharing their consumption behaviors related to the high-risk foods and were quieter during this discussion than at other points in the group. Although most did contribute to the discussion and the focus group consumption findings were similar to those of the secondary data analysis, the sensitivity of risk behaviors practiced by pregnant women should be considered in the planning of future focus groups.

Experimental research should be conducted to confirm study findings. Causality could not be determined from the present study. Experimental designs comparing the effects of messages with high and low levels of risk and efficacy content could confirm the suggested relationships between risk and efficacy beliefs and behavioral intentions. Studies such as these could definitively confirm the usefulness of the EPPM as an underlying framework for listeriosis prevention messages and for messages used to convey other health advice. Further, such studies could include measures related to readiness to change and social norms and manipulate message source and message consistency in order to examine their effect on beliefs and intentions. These investigations could help extend the EPPM by specifying relationships between EPPM constructs and those from other theoretical approaches.

Research related to food safety should continue to identify other high-risk foods, specify the current food safety advice, and identify effective means of combating *Listeria* in industrial and commercial establishments. Research related to consumer behavior could also be important. For example, several participants in the focus groups stated that when they ordered cold cut sandwiches in retail establishments, they asked for them to be “toasted,” believing that this would address the need for heating. Determining whether

this heating strategy actually kills the *L. monocytogenes* bacteria would establish whether this actually is a safe strategy.

Strengths and Limitations

A strength of this research is its mixed methods design. Mixed methods research can provide broader and more comprehensive evidence for the problem under study than either quantitative or qualitative approaches alone (Burke Johnson & Onwuegbuzie, 2004; Creswell & Plano Clark, 2007; Giddings & Grant, 2006). As such, it provides greater insight into complex phenomena and allows the weaknesses of one method to be compensated for by the strengths of the other method (Burke Johnson & Onwuegbuzie, 2004; Giddings & Grant, 2006; McKenzie & Smeltzer, 2001).

Another strength of this study lies in the use of pregnant women as study participants. Pregnant women are generally considered vulnerable participants in research studies due to additional health concerns during pregnancy and the need to avoid unnecessary risks to the fetus (Penslar & Porter, 1993). However, pregnant women are more susceptible to listeriosis than other healthy adults and having them participate allowed the examination of awareness, beliefs, and behaviors related to listeriosis prevention at a time when the guidelines are most relevant. Women of child-bearing age or women who have recently given birth could have provided an alternate subject pool, but study findings using these populations would be based on either behavioral predictions or recollections. While studying these populations would be interesting, such results could not be readily generalized to pregnant women whose beliefs and behavior are most critical to impact.

The strengths of the secondary data analysis included providing current information on awareness and behavior from a large national sample of pregnant women and identifying predictors of awareness and behaviors. The results showed that disparities existed along educational and income lines and suggest that women with lower incomes and less education should be targeted to receive listeriosis prevention communication.

Several factors limit the quantitative analysis. When compared to pregnant women from a nationally representative survey, the IFPS II respondents were more likely to have higher education levels; were older; more likely to be white, middle income, and employed; had fewer other children; and were less likely to be smokers (Fein et al., 2008). Another limitation is that the data were self-reported and can thus be subject to social desirability bias. A final limitation is within the survey itself. It was beyond the scope of the survey to examine all facets of knowledge and behaviors related to listeriosis prevention and it did not examine underlying beliefs at all. Many of these limitations were addressed in the qualitative portion of the research.

The focus groups complemented and expanded the quantitative survey findings in order to more deeply examine awareness, behaviors, and underlying beliefs related to listeriosis prevention. An additional strength of the focus groups was that they were guided by the use of a theoretical framework, the EPPM, which has been validated with many health behaviors among different populations. The focus groups also provided the opportunity to get direct feedback on current and prototype listeriosis prevention messages. Finally, by ensuring that at least half of the focus groups were made up of

pregnant women with lower education levels, the focus groups provided a voice to those who were not well represented in the IFPS II.

A limitation of focus groups was the small number of participants from only a few geographical locations. Budgetary constraints limited the geographic regions in which the groups could be conducted as well as the number of groups. A possible limitation on sample was caused by the pregnancy verification requirement imposed by the IRB, which therefore excluded pregnant women who were not receiving healthcare. As in the secondary analysis, focus group findings can also be biased by social desirability. To discourage this, focus group participants were encouraged to express their opinion and were told that all opinions were important. The participants did provide both positive and negative comments about the prototype messages and participants seemed willing to express disagreement, suggesting that this limitation may be small. Overall, the focus group sample limitations were compensated for, to some extent, by the large, more representative sample used in secondary data analysis.

Neither research component utilized a random sampling strategy; therefore, the results cannot be generalized to all pregnant American women. However, triangulating the results of the quantitative and qualitative studies provides stronger evidence than from either study alone.

Mixed methods research does have limitations. Generally, the design takes more time in terms of planning, analyzing the data, and integrating the findings (Burke Johnson & Onwuegbuzie, 2004; Giddings & Grant, 2006). It also requires a wider range of skills for the researcher/s in order to conduct both quantitative and qualitative research

(Giddings & Grant, 2006). While these limitations existed, it is believed that the strengths of such an approach for this research outweighed the limitations.

Summary and Conclusions

Awareness of *L. monocytogenes* is increasing, but the majority of pregnant women are still unaware and consuming *Listeria*-related high-risk foods. This research highlighted the potential effectiveness of using theory-based messages to impact beliefs related to listeriosis. Focus group participants who were aware of listeriosis, but unaware of pregnancy's specific risks, reported at least occasionally eating high-risk foods. As participants became aware of the listeriosis risks to pregnant women and the potential of the listeriosis prevention guidelines to decrease risk, they expressed greater intentions to follow the guidelines. Creating messages that result in both strong risk and efficacy beliefs have the potential to strongly affect behavior.

This research also showed the need for credible sources to consistently communicate listeriosis prevention information through a variety of channels readily available to pregnant women. Changing or conflicting messages were found to negatively affect beliefs related to response efficacy. Government agencies that provide health advice to consumers should strive to reach agreement in the messages they deliver. Additional educational efforts should specifically target healthcare providers, who were considered the most credible source of health information. Pregnant women with less income and education were less likely to be aware of listeriosis and more likely to eat some of the high-risk foods, suggesting the need to target these subgroups in order to reduce this disparity. Increasing listeriosis prevention knowledge among WIC educators would provide another means of reaching these women.

Most importantly, pregnant women who were aware of *L. monocytogenes* were less likely to consume some of the high-risk foods, which suggests that this population is amenable to education efforts. Current surveillance data still showed that the incidence of listeriosis is higher than national targets. This research shows that some progress has been made in reaching pregnant women. Additional efforts, guided by the findings from this research, will be needed to reach all pregnant women.

APPENDIX 1: ITEMS USED IN SECONDARY DATA ANALYSIS

Construct	Question Source	Item	Continuous/ Categorical *
Race/ Ethnicity	DQ	<p>This variable was created in the dataset with the following categories:</p> <ul style="list-style-type: none"> • White • Black • Hispanic • Asian/Pacific Islander • Other 	<p>Categorical</p> <p>No changes were made to these categories. White was the reference category.</p>
Income	DQ	<p>Please “X” the box which best describes the total yearly income of all members of your household before taxes. Please include any income from all sources – employment, pensions, social security, etc. [Respondents are offered 27 response choices ranging from “under \$5,000” to “300,000 and over]</p>	<p>Categorical</p> <p>The response choices were condensed into five categories:</p> <ul style="list-style-type: none"> • \$24,999 or less* • \$25,000-\$49,999 • \$50,000-\$74,999 • \$75,000-\$99,999 • \$100,000 and higher
Education	DQ	<p>Education Level</p> <ul style="list-style-type: none"> • Some Grade School • Grade School • Some High School • High School Graduate • Some College, No Degree (1-3 years) • Associate Degree in College (2 years) • Bachelor’s Degree (e.g. BA, AB, BS) • Master’s Degree (e.g. MA, MS, MBA) • Doctorate (PhD) • Professional Degree (e.g. MD, JD) 	<p>Categorical</p> <p>The response choices were condensed into the following categories:</p> <ul style="list-style-type: none"> • High school or less* • Some college or Associate’s degree • Bachelor’s Degree and higher
Employment status	DQ	<p>Employment Status</p> <ul style="list-style-type: none"> • Work for someone else full time • Temporarily unemployed • Self-employed • Works for someone else part-time • Retired, not employed • Student, disabled, etc., not employed • Full-time homemaker 	<p>Categorical</p> <p>The response choices were condensed as follows:</p> <ul style="list-style-type: none"> • Unemployed* (temporarily, retired, student, disabled) • Full-time homemaker • Employed (full time, self-employed, or part-time)

Construct	Question Source	Item	Continuous/ Categorical *
Marital status	DQ	What is your marital status? <ul style="list-style-type: none"> • Married • Widowed • Divorced • Separated • Single, Never Married 	Categorical The response choices were condensed as follows: <ul style="list-style-type: none"> • Married* • Widowed, divorced, or separated • Single, never married
Geographic Region	DQ	This variable was created in the dataset by using the state of residence for the participant. The states were grouped into the following regions: <ul style="list-style-type: none"> • Northeast • Midwest • South • West 	Categorical No changes were made to these categories. South was the reference category.
Age	PQ	Age	Continuous
Number of children	PQ	How many other babies have you had or adopted when younger than 12 months old? Do not include the baby you are expecting. <ul style="list-style-type: none"> • ____ Other babies had 	Continuous
Prenatal care provider	PQ	Who provides your prenatal care? An obstetrician?	Categorical Yes No*
Prenatal care provider	PQ	Who provides your prenatal care? A family doctor, general practitioner, internist, or other physician?	Categorical Yes No*
Prenatal care provider	PQ	Who provides your prenatal care? A midwife or nurse midwife?	Categorical Yes No*
Time of first prenatal visit	PQ	How many weeks were you when you went for your first prenatal visit? <ul style="list-style-type: none"> • 4 weeks or less • 5-8 weeks • 9-12 weeks • 13-18 weeks • 19-24 weeks • 25 weeks or more • 	Continuous
Health insurance	PQ	Are you covered by any kind of health insurance or any kind of health care plan, such as insurance obtained through an employer or a government program like Medicaid? Yes/No	Categorical Yes No*

Construct	Question Source	Item	Continuous/ Categorical *
WIC status	PQ	In the past month, were you enrolled in the WIC program or did you get WIC food or vouchers for yourself? <ul style="list-style-type: none"> • Yes, I was enrolled or got WIC food for myself • No 	Categorical Yes No*
Sources of dietary information while pregnant	PQ	Have you obtained information about your diet from any of the following sources for this pregnancy or a previous one? [Check all that apply] <ul style="list-style-type: none"> • Doctor, nurse, or other health professional • WIC food program • Relative or friend • Books or videos • Newspaper or magazine • Television or radio • The web site, www.4woman.gov • The web site, www.breastfeeding.com • Other government web site • Other non-government website 	This question was used to compute a continuous variable, 'Number of information sources used.' First, any checked response to the four website use categories was counted as a 'yes' for Internet use. If none of the website use categories were checked, then this was counted as a 'no' for Internet use. Internet use was then summed with the other information sources to create the final variable. Scores could range from 0 – 7.
Awareness of <i>L. monocytogenes</i>	PQ	Have you heard about any problems in food related to Listeria?	Categorical Yes No*
Awareness of <i>Listeria</i> -related food vehicles	PQ	Do you remember what kind of food was related to the problem? [Please "X" all that apply] <ul style="list-style-type: none"> • Some types of fish • All types of fish • Some types of shellfish • Some types of meat or chicken • All types of meat or chicken • Some types of cheeses • Some types of luncheon meats • All types of luncheon meats • Don't know 	Correct responses will be summed to create the variable that will be used in the analyses. Correct responses include some types of fish, some types of meat or chicken, some types of cheeses, and some or all types of luncheon meats. Responses for the non- <i>Listeria</i> foods that were left unchecked were counted as correct. Scores could range from 0-7.
High-risk behaviors: Cold cuts without reheating Hot dogs without reheating	DHQ	How often did you eat [turkey or chicken cold cuts][luncheon or deli-style ham][other cold cuts or luncheon meats (such as bologna, salami, corned beef, pastrami, or others, including low-fat)][hot dogs or frankfurters]? <ul style="list-style-type: none"> • Never • 1 time per month • 2-3 times per month • 1 time per week • 2 times per week 	Categorical For cold cuts, three intermediate variables were created: eating turkey or chicken, eating ham, and eating other lunchmeats. Participants who reported either never eating [turkey or chicken cold cuts][luncheon or deli-style ham][other cold cuts or luncheon meats (such as bologna, salami, corned beef, pastrami, or others,

Construct	Question Source	Item	Continuous/ Categorical *
		<ul style="list-style-type: none"> • 3-4 times per week • 5-6 times per week • 1 time per day • 2 or more times per day <p>How often were the [turkey or chicken cold cuts][luncheon or deli-style ham][other cold cuts or luncheon meats][hot dogs or frankfurters] you ate eaten straight from the package or wrapper, that is, without cooking or heating?</p> <ul style="list-style-type: none"> • Almost never or never • About ¼ of the time • About ½ of the time • About ¾ of the time • Almost always or always 	<p>including low-fat)] along with those who reported never eating without reheating were coded as '0.' Those who reported eating [turkey or chicken cold cuts][luncheon or deli-style ham][other cold cuts or luncheon meats] '¼ of the time' or more were coded as '1.' Responses across the three variables were summed. Any participant who received a '0' was coded as '0' and any whose total summed more than '0' received a '1.'</p> <p>For hot dogs, any participant who reported 'never' eating hot dogs or 'almost never or never' eating hot dogs without reheating was coded as a '0.' Any who reported eating hot dogs without reheating '¼ of the time' or more were coded as '1.'</p>
<p>High-risk behavior: Refrigerated smoked seafood</p>	<p>DHQ</p>	<p>How many servings of seafood, including fish and shellfish did you eat per week or per day?</p> <ul style="list-style-type: none"> • None • Less than 1 per week • 2 per week • 3-4 per week • 5-6 per week • 1 per day • 2 or more per day <p>Was any of the seafood you ate, including fish and shellfish, refrigerated smoked seafood, such as nova-style, lox, kippered, smoked or jerky?</p> <ul style="list-style-type: none"> • Yes • No 	<p>Categorical</p> <p>Participants who reported not eating seafood or not eating refrigerated smoked seafood were coded as '0.' Those who reported eating refrigerated smoked seafood were coded as '1.'</p>

APPENDIX 2: DEMOGRAPHIC QUESTIONNAIRE

Background Questionnaire

Please answer the following questions. Your answers will be combined with those of the other focus group participants to describe the focus groups. Do not put your name on this paper.

Age _____

Are you of Hispanic or Latino origin?

- Yes
 No

Race [You may choose one or more categories as they apply]

- White
 Black or African American
 Asian
 Native Hawaiian or other Pacific Islander
 American Indian or Alaska Native
 Some other race

What is your marital status?

- Married
 Widowed
 Divorced
 Separated
 Single, Never Married
 Domestic Partnership

What is your approximate total household income?

- \$24,999 or less
 \$25,000-49,999
 \$50,000-74,999
 \$75,000-99,999
 \$100,00 or more

Are you currently employed? [Please "X" all that apply]

- I work outside the home, full time
 I work outside the home, part-time
 I am self-employed
 I am a homemaker
 I am temporarily unemployed
 I am a student
 I am disabled, not employed

What is the highest grade or year of education that you have completed?

- Some high school
 High school graduate
 Some college, no degree (1-3 years)
 Associate degree (2 years)
 Bachelor's degree (e.g. BA, AB, BS)
 Master's degree (e.g. MA, MS, MBA)
 Doctorate (e.g. PhD)
 Professional degree (e.g. MD, JD)

How many weeks pregnant are you? _____

Do you have other children (not counting this pregnancy)?

- No
 Yes
If yes, how many? _____

Who provides your prenatal care? [Please "X" all that apply]

- An obstetrician
 A family doctor, general practitioner, internist, or other physician
 A midwife or nurse midwife
 Another type of health care provider
 I am not getting prenatal care from a health professional

Are you covered by any kind of health insurance or any kind of health care plan, such as insurance obtained through an employer or a government program like Medicaid?

- Yes
 No

In the past month, were you enrolled in the WIC program or did you get WIC food or vouchers for yourself or for any of your children?

- Yes, I was enrolled or got WIC food for myself
 No

APPENDIX 3: INFORMED CONSENT FORMS
Informed Consent Form for Pretest Interview Participants

Page 1 of 2
 Initials _____ Date _____

CONSENT FORM

Project Title	Interviews to examine a focus group guide on food safety for pregnant women
Why is this research being done?	This research project represents a collaboration with Dr. Marjorie L. Davidson and Dr. Elizabeth M. Calvey at the Center for Food Safety and Applied Nutrition at the FDA and Dr. Robert Gold at the School of Public Health at the University of Maryland, College Park. We are inviting pregnant women who are 18 or older to participate in this study. The purpose of this study is to get your opinion on how to improve a questionnaire that will be used in focus groups with pregnant women.
What will I be asked to do?	You will participate in an interview that will last about 45 minutes. You will be read each question from the focus group guide. You will be asked to answer the question or to restate it in your own words, identify areas that might be confusing, and make suggestions for improvement in terms of wording and overall question order. The interview will be tape-recorded.
What about confidentiality?	We will do our best to keep your personal information confidential. To help protect your confidentiality, (1) your name will not be included on the field notes or tapes of the focus group you participate in; (2) a code will be placed on this collected data; (3) through the use of an identification key, the researcher will be able to link your data to your identity; and (4) only the researcher will have access to the identification key. All collected data will be kept in a locked file cabinet. Any data transcribed to a computer file will use your identification number only and will be stored in a password-protected file. Data from this project will be reported in aggregate form, so individual identification will not be tied to data reporting. The field notes, tape recording, and associated data files will be retained for three years and then destroyed. <input type="checkbox"/> I agree to be taped during my participation in this study. <input type="checkbox"/> I do not agree to be taped during my participation in this study.
What are the risks of this research?	There are no known physical, social, legal, or financial risks to participating in this study. As you review the focus group guide, you may experience some anxiety as you learn about food safety issues that relate to pregnant women; however, we will answer any questions you have and provide you with current information at the end of the interview.
What are the benefits of this research?	This research is not designed to benefit you personally, but the results will help us learn more about effective communication strategies for pregnant women. It is possible that you will learn something useful about food safety and preventing foodborne illness through your participation. We hope that, in the future, other pregnant women will benefit from this study through availability of improved health communications related to prevention of foodborne illness.

Project Title	Interviews to examine a focus group guide on food safety for pregnant women	
Do I have to be in this research? May I stop participating at any time?	Your participation in this research is completely voluntary. You may choose not to take part at all. If you decide to participate in this research, you may stop participating at any time. If you decide not to participate in this study or if you stop participating at any time, you will not be penalized or lose any benefits to which you otherwise qualify.	
What if I have questions?	<p>This research is being conducted by Dr. Elizabeth M. Calvey & Dr. Marjorie L. Davidson at the Center for Food Safety and Applied Nutrition at the FDA and Dr. Robert Gold in the School of Public Health at the University of Maryland, College Park.</p> <p>If you have any questions about the research study itself, please contact:</p> <ul style="list-style-type: none"> • Dr. Robert Gold at: 3310 Health and Human Performance Building, University of Maryland, College Park, MD, 20742; (telephone) 301-405-2437, (email) rsgold@umd. • Dr. Marjorie Davidson at: 5100 Paint Branch Parkway, College Park, MD 20740; (telephone) 301-436-1588, (email) marjorie.davidson@fda.hhs.gov • Dr. Elizabeth M. Calvey: 5100 Paint Branch Parkway, College Park, MD 20740, (telephone) 301-436-1981, (email) elizabeth.calvey@fda.hhs.gov <p>If you have questions about your rights as a research subject or wish to report a research-related injury, please contact:</p> <ul style="list-style-type: none"> • Research Involving Human Subjects Committee, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, College Park, MD 20740, Caren Kieswetter, MD (liason), (email) caren.kieswetter@fda.hhs.gov (telephone) 301-436-2585 • Research Involving Human Subjects Committee, Executive Director, Parklawn Bldg., Room 17-35(HF-33), Rockville, MD 20857; (telephone) 301-827-4591 • Institutional Review Board Office, University of Maryland, College Park, Maryland, 20742; (e-mail) irb@deans.umd.edu; (telephone) 301-405-0678 <p>This research has been reviewed according to the FDA’s Research Involving Human Subjects Committee and the University of Maryland, College Park IRB procedures for research involving human subjects.</p>	
Statement of Age of Subject and Consent	Your signature indicates that you are at least 18 years of age; the research has been explained to you, your questions have been fully answered; and you freely and voluntarily choose to participate in this research project.	
Signature and Date	NAME OF SUBJECT	
	SIGNATURE OF SUBJECT	
	DATE	

Informed Consent Form for Focus Group Participants

Page 1 of 2

Initials _____ Date _____

CONSENT FORM

Project Title	Pregnant women’s attitudes toward food safety communications
Why is this research being done?	This research project represents a collaboration with Dr. Marjorie L. Davidson and Dr. Elizabeth M. Calvey at the Center for Food Safety and Applied Nutrition at the FDA and Dr. Robert Gold at the School of Public Health at the University of Maryland, College Park. We are inviting pregnant women who are 18 or older to participate in this study. The purpose of this study is to understand how pregnant women feel about food safety and to get their opinion about health messages related to food safety. This information will be used to improve food safety messages that are designed specifically for pregnant women.
What will I be asked to do?	You are being asked to participate in a focus group that will last no more than 90 minutes. First, you will complete a brief questionnaire that asks about your background. Next, you be asked to participate in a focus group discussion that will talk about food safety. Specifically, you will be asked to review and give your opinion about food safety guidelines for pregnant women and health communication materials related to food safety for pregnant women. The focus group will be videotaped to ensure accuracy and notes will be also taken.
What about confidentiality?	We will do our best to keep your personal information confidential. To help protect your confidentiality, (1) your name will not be included on the field notes or tapes of the focus group you participate in; (2) a code will be placed on this collected data; (3) through the use of an identification key, the researcher will be able to link your data to your identity; and (4) only the researcher will have access to the identification key. All collected data will be kept in a locked file cabinet. Any data transcribed to a computer file will use your identification number only and will be stored in a password-protected file. Data from this project will be reported in aggregate form, so individual identification will not be tied to data reporting. The field notes, tape recording, and associated data files will be retained for three years and then destroyed. <input type="checkbox"/> I agree to be taped during my participation in this study. <input type="checkbox"/> I do not agree to be taped during my participation in this study.
What are the risks of this research?	There are no physical, social, legal, or financial risks to participating in this study. You may experience some anxiety as you learn about food safety issues that relate to pregnant women; however, we will answer any questions you have and provide you with current information at the end of the study.
What are the benefits of this research?	This research is not designed to benefit you personally, but the results will help us learn more about effective communication strategies for pregnant women. It is possible that you will learn something useful about food safety and preventing foodborne illness through your participation. We hope that, in the future, other pregnant women will benefit from this study through availability of improved health communications related to prevention of foodborne illness.

Project Title	Pregnant women's attitudes toward food safety communications	
Do I have to be in this research? May I stop participating at any time?	Your participation in this research is completely voluntary. You may choose not to take part at all. If you decide to participate in this research, you may stop participating at any time. If you decide not to participate in this study or if you stop participating at any time, you will not be penalized or lose any benefits to which you otherwise qualify.	
What if I have questions?	<p>This research is being conducted by Dr. Elizabeth M. Calvey & Dr. Marjorie L. Davidson at the Center for Food Safety and Applied Nutrition at the FDA and Dr. Robert Gold in the School of Public Health at the University of Maryland, College Park.</p> <p>If you have any questions about the research study itself, please contact:</p> <ul style="list-style-type: none"> ○ Dr. Marjorie Davidson at: 5100 Paint Branch Parkway, College Park, MD 20740; (telephone) 301-436-1588, (email) marjorie.davidson@fda.hhs.gov ○ Dr. Robert Gold at: 3310 Health and Human Performance Building, University of Maryland, College Park, MD, 20742; (telephone) 301-405-2437, (email) rsgold@umd.edu. <p>If you have questions about your rights as a research subject or wish to report a research-related injury, please contact:</p> <ul style="list-style-type: none"> ○ Research Involving Human Subjects Committee, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, College Park, MD 20740, Caren Kieswetter, MD (liason), (email) caren.kieswetter@fda.hhs.gov (telephone) 301-436-2585 ○ Research Involving Human Subjects Committee, Executive Director, Parklawn Bldg., Room 17-35(HF-33), Rockville, MD 20857; (telephone) 301-827-4591 ○ Institutional Review Board Office, University of Maryland, College Park, Maryland, 20742; (e-mail) irb@deans.umd.edu; (telephone) 301-405-0678 <p>This research has been reviewed according to the FDA's Research Involving Human Subjects Committee and the University of Maryland, College Park IRB procedures for research involving human subjects.</p>	
Statement of Age of Subject and Consent	Your signature indicates that you are at least 18 years of age; the research has been explained to you, your questions have been fully answered; and you freely and voluntarily choose to participate in this research project.	
Signature and Date	NAME OF SUBJECT	
	SIGNATURE OF SUBJECT	
	DATE	
Witness	WITNESS SIGNATURE	

APPENDIX 4: DEBRIEFING PAMPHLET



Food Safety At-A-Glance

H A N D O U T

How to Protect Yourself and Your Baby

- What is foodborne illness?**
- It's a sickness that occurs when people eat or drink harmful microorganisms (bacteria, parasites, viruses) or chemical contaminants found in some foods or drinking water.
 - Symptoms vary, but in general can include: stomach cramps, vomiting, diarrhea, fever, headache, or body aches. Sometimes you may not feel sick, but whether you feel sick or not, you can still pass the illness to your unborn child without even knowing it.

- Why are pregnant women at high risk?**
- You *and* your growing fetus are at high risk from some foodborne illnesses because during pregnancy your immune system is weakened, which makes it harder for your body to fight off harmful foodborne microorganisms.
 - Your unborn baby's immune system is not developed enough to fight off harmful foodborne microorganisms.
 - For both mother and baby, foodborne illness can cause serious health problems — or even death.



Tips for a Lifetime

There are many bacteria that can cause foodborne illness, such as *E. coli* O157:H7 and *Salmonella*. Here are **4 Simple Steps** you should follow to keep yourself and your baby healthy during pregnancy and beyond!



1. CLEAN

- Wash hands thoroughly with warm water and soap.
- Wash hands *before* and *after* handling food, and *after* using the bathroom, changing diapers, or handling pets.
- Wash cutting boards, dishes, utensils, and countertops with hot water and soap.
- Rinse raw fruits and vegetables thoroughly under running water.



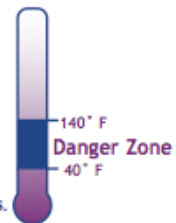
2. SEPARATE

- Separate raw meat, poultry, and seafood from ready-to-eat foods.
- If possible, use one cutting board for raw meat, poultry, and seafood and another one for fresh fruits and vegetables.
- Place cooked food on a clean plate. If cooked food is placed on an unwashed plate that held raw meat, poultry, or seafood, bacteria from the raw food could contaminate the cooked food.



3. COOK

- Cook foods thoroughly. Use a food thermometer to check the temperature. See the "Lifelong Food Safety" section of the Web site for the "Apply the Heat" chart of recommended cooking times for foods. Click on "Cook."
- Keep foods out of the **Danger Zone**: The range of temperatures at which bacteria can grow — usually between 40° F and 140° F (4° C and 60° C).
- **2-Hour Rule**: Discard foods left out at room temperature for more than two hours.



4. CHILL

- Your refrigerator should register at 40° F (4° C) or below and the freezer at 0° F (-18° C). Place an appliance thermometer in the refrigerator, and check the temperature periodically.
- Refrigerate or freeze perishables (foods that can spoil or become contaminated by bacteria if left unrefrigerated).
- Use ready-to-eat, perishable foods (dairy, meat, poultry, seafood) as soon as possible.

3 Foodborne Risks for Pregnant Women

As a mom-to-be, there are 3 specific foodborne risks you need to be aware of. These risks can cause serious illness or death to you or your unborn child. Follow these steps to help ensure a healthy pregnancy.

	What it is	Where it's found	How to prevent illness
1 Listeria	A harmful bacterium that can grow at refrigerator temperatures where most other foodborne bacteria do not. It causes an illness called listeriosis.	Refrigerated, ready-to-eat foods and unpasteurized milk and milk products.	<ul style="list-style-type: none"> Follow the 4 Simple Steps on previous page. Do not eat hot dogs and luncheon meats — unless they're reheated until steaming hot. Do not eat soft cheese, such as Feta, Brie, Camembert, "blue-veined cheeses," "queso blanco," "queso fresco," and Panela — unless they're labeled as made with pasteurized milk. Check the label. Do not eat refrigerated pâtés or meat spreads. Do not eat refrigerated smoked seafood — unless it's in a cooked dish, such as a casserole. (Refrigerated smoked seafood, such as salmon, trout, whitefish, cod, tuna, or mackerel, is most often labeled as "nova-style," "lox," "kippered," "smoked," or "jerky." These types of fish are found in the refrigerator section or sold at deli counters of grocery stores and delicatessens.) Do not drink raw (unpasteurized) milk or eat foods that contain unpasteurized milk.
2 Methylmercury	A metal that can be found in certain fish. At high levels, it can be harmful to an unborn baby's or young child's developing nervous system.	Large, long-lived fish, such as shark, tilefish, king mackerel, and swordfish.	<ul style="list-style-type: none"> Don't eat shark, tilefish, king mackerel, and swordfish. These fish can contain high levels of methylmercury. It's okay to eat other cooked fish/seafood, as long as a variety of other kinds are selected during pregnancy or while a woman is trying to become pregnant. She can eat up to 12 ounces (2 average meals) a week of a variety of fish and shellfish that are lower in mercury. <ul style="list-style-type: none"> Five of the most commonly eaten fish that are low in mercury are shrimp, canned light tuna, salmon, pollock, and catfish. Another commonly eaten fish, albacore ("white") tuna has more mercury than canned light tuna. So, when choosing your two meals of fish and shellfish, you may eat up to 6 ounces (one average meal) of albacore tuna per week.
3 Toxoplasma	A harmful parasite. It causes an illness called toxoplasmosis, which can be difficult to detect.	Raw and under-cooked meat; unwashed fruits and vegetables; soil; dirty cat-litter boxes; and outdoor places where cat feces can be found.	<ul style="list-style-type: none"> Follow the 4 Simple Steps on previous page. If possible, have someone else change the litter box. If you have to clean it, wash your hands with soap and warm water afterwards. Wear gloves when gardening or handling sand from a sandbox. Don't get a new cat while pregnant. Cook meat thoroughly, see the "Apply the Heat" chart for the proper temperatures.

for more information

- See your doctor or health-care provider if you have questions about foodborne illness.
- FDA Food Information line: 1-888-SAFE FOOD
- FDA Center for Food Safety and Applied Nutrition: www.cfsan.fda.gov
- Gateway to Government Food Safety Information: www.foodsafety.gov
- U.S. Partnership for Food Safety Education: www.fightbac.org

This fact sheet is a condensed guide to food safety. For more in-depth information, be sure to check out:

Food Safety for Moms-to-Be
www.cfsan.fda.gov/pregnancy.html



APPENDIX 5: FOCUS GROUP MODERATOR'S GUIDE

Focus Group Moderator's Guide

- Review and signing of Informed Consent Form
 - Completion of demographic questionnaire
 - **Objectives:** As you know, we are going to talk about food safety and pregnancy today. We're going to look at some current health information for pregnant women and some new messages. I'm going to ask what you think about the information that I will present. Your opinion is important and will help us as we develop new health messages for pregnant women.
 - **Ground rules:** Before we begin, I'd like to cover a few ground rules so that our group runs smoothly. First, it's really important to speak one at a time and not to have side conversations. I'll make sure that everyone has a chance to speak. Please treat everyone with respect. We do have a lot to cover today, so sometimes I may need to help move the group along. Also, there aren't any right or wrong answers to the questions that I will ask—we are just looking for your opinion and your experiences. Finally, you don't always have to agree. It's very important for us to get a lot of different opinions. Are there any questions before we begin?
 - **Warm up:** Let's go around and introduce ourselves before we start the group.
 - Tell us your first name, and maybe a little about your pregnancy, like what your due date is and whether you have any other children.
 - Now, let's talk about food: Has your pregnancy made you crave or stay away from any particular foods?
1. Have you ever heard that women should not eat certain foods while they're pregnant? Which foods? Has anyone else heard to avoid that?
 - a. Do you remember why you were told to avoid these foods?
 - b. I'm going to ask if any of you have ever been told not to eat certain foods because of foodborne illness, but first, I just want to tell you what I mean by foodborne illness. When I say 'foodborne illness', I mean any sickness that you get from eating foods that have been contaminated with things like bacteria, viruses, or chemicals. You might also call it food poisoning.
 - i. Since you've been pregnant, has anyone ever told you to stop eating some foods because they could cause a foodborne illness? Which foods?
 2. How serious do you think foodborne illnesses are?
 - a. Do you think that everyone has the same chance of getting a foodborne illness? Why or why not?

- i. *[If anyone mentions that some people have a greater risk]* Who is at greater risk? Why?
 - b. How big a problem would it be for a pregnant woman to get a foodborne illness?
3. We're going to focus on one specific foodborne illness today. I'd like you to look at some current information about it.

[Hand out Message A and read aloud to lower education groups]

- a. How familiar is this information?
 - i. What had you heard before?
 - ii. Where did you hear about *Listeria*?
 - iii. What was new to you?
 - b. Had you heard about this particular risk to pregnant women?
 - i. How serious does listeriosis seem to you after reading this message?
 - c. How do you feel after reading this message?
4. There are two things to keep in mind. First, listeriosis is pretty rare. The second is that there are ways that pregnant women can lower their chance, or risk, of getting listeriosis. One way to lower your risk is to follow general food safety guidelines that are helpful for everyone, pregnant or not. We'll give you a copy of these before you leave. There's also advice just for pregnant women and that's what we're going to look at now. I'd like you to read through these guidelines.

[Hand out Message B, read aloud to lower education groups]

- a. How familiar are these guidelines?
 - i. Which ones had you heard of before?
 - ii. Where had you heard about them?
 - iii. Were any of these guidelines new to you? Which ones?
 - b. Did you eat any of these foods before you were pregnant? *[Probe for each food if it is not mentioned: hot dogs, lunch meats, soft cheeses, refrigerated pates or meat spreads, refrigerated smoked seafood, raw milk]*
5. Thinking about all of the guidelines, how well have you personally followed them during your pregnancy? *[Probe for food if it is not mentioned: hot dogs, lunch meats, soft cheeses, refrigerated pates or meat spreads, refrigerated smoked seafood, raw milk]*
- a. For those who have not been following the guidelines: How confident are you that you could follow the guidelines if you decided you wanted to follow them?
 - b. Is there anything hard about following this advice?
 - i. Does this message provide you with enough information so that you could follow the advice? Why or why not?
 - c. Is there anything that could make it easier for you to follow this advice?

6. Again, thinking about all of these guidelines: Do you think following these would reduce your risk of getting listeriosis? Why or why not?
7. We are trying to find ways to improve the information that pregnant women can use to learn about Listeria. I'm going to show you some information that might be **added** to the messages you've looked at earlier and ask your opinion about this additional information. [*Message C*]
 - a. What is this message telling you?
 - b. What do you think of this information?
 - i. Does this information change your understanding of Listeria? How so?
 - ii. Would this information be useful to you personally? Why or why not?
8. Here is the next message that could be added to the information you looked at earlier. [*Message D*]
 - a. What is this message telling you?
 - b. What do you think of this information?
 - i. Does this information change your understanding of Listeria? How so?
 - ii. Would this information be useful to you? Why or why not?
 - iii. Would this message make you change anything you were doing? How so?
9. Here is some information about the guidelines that's a little different from what you've seen before. [*Message E*]
 - a. What is this message telling you?
 - b. How do you feel knowing that this advice could change?
 - c. Would a message like this affect your decision to follow the guidelines? Why or why not?
 - i. Would it affect your confidence in the guidelines? Why or why not?
 - d. Would this information be useful to you? Why or why not?
10. Imagine that sometime in the future, a new food is added to the list of 'Do Not Eat' foods.
 - a. How would you feel if a food you were currently enjoying during your pregnancy was added to the list? [*Facilitator could pull in examples from the warm-up question*]
 - b. Let's say that you've been eating this food and have not experienced any problems from it. What could a health expert tell you that would make you stop eating this food?
 - c. Let's take a look at our last message [*Message F*]. This is an example of a message you could see if a new food was added to the list. It's using hot dogs as an example.

- i. Before you mentioned that if a new food was added, you would feel [*fill in emotions described in 10a*]. How would a message like this affect your feelings if a new food were added to the list?
 - ii. How would a message like this affect what you would do if a new food were added to the list?
 11. I'd like you to work together to decide which of the messages about Listeria you think should definitely be included in any kind of information for pregnant women, like in a brochure or on a webpage. You can specify entire pages or just sections.
 - a. What pieces of information are most important? Why do you think so?
 12. We've covered a lot of information today. Will anything you heard have an impact on what you're currently doing? Why or why not?
 - a. How will your behavior change?
- **Debriefing:** Before we end, I would like to give you a handout that you can take home. It contains the general food safety information that I talked about earlier and information on food safety specifically for pregnant women.
 - I would like to give you the opportunity to ask any questions you might have about what we covered today. Also remember that if you have questions after the study, you have contact information on the informed consent form that you have a copy of. If there are no more questions, I would like to thank you for coming today.

APPENDIX 6: IRB APPROVALS

MEMORANDUM

Department of Health and Human Services
Food and Drug Administration
Research Involving Human Subjects Committee

DATE: December 1, 2008

FROM: Chair, Research Involving Human Subjects Committee

Subject: RIHSC Protocol #08-016F
Study Title: Pregnant Women's Online Search for Listeriosis Prevention Information
Principal Investigator: Sandra Saperstein, M.S.
FDA Sponsors: Elizabeth Calvey Ph.D., & Marjorie Davidson, Ph.D.,

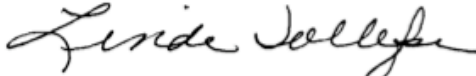
To: Elizabeth Calvey Ph.D., CFSAN
Marjorie Davidson Ph.D., CFSAN
Caren Kieswetter, MD, CFSAN Liaison to the RIHSC

You have submitted an amendment to your proposal entitled "Pregnant Women's Online Search for Listeriosis Prevention Information." You have requested that an additional phase be added to this study. The phase will have two components-a quantitative secondary analysis of data collected under RIHSC #04-021F on infant feeding practices, and a qualitative study using focus groups with pregnant women. Prior to conducting the focus groups, 2 individual interviews with pregnant women will be conducted to assure that focus group questions are understandable and can generate discussion.

Your amendment is approved.

Please note that this amendment does not alter the effective period of approval for your protocol. Your protocol is approved until April 29, 2009.

Should you have questions or require further information, please contact Dr. Fitzpatrick, Executive Director of the RIHSC, at (301) 827-4591, FAX (301) 827-3042 or by electronic mail.


Linda Tollefson, DVM, MPH
Chair, RIHSC

MEMORANDUM

Department of Health and Human Services
Food and Drug Administration
Research Involving Human Subjects Committee

DATE: February 13, 2009

FROM: Chair, Research Involving Human Subjects Committee

Subject: **RIHSC Protocol #08-016F**
Study Title: Pregnant Women's Online Search for Listeriosis Prevention Information
Principal Investigator: Sandra Saperstein, M.S.
FDA Sponsors: Elizabeth Calvey Ph.D., Marjorie Davidson, Ph.D., CFSAN

To: Elizabeth Calvey Ph.D., CFSAN
Marjorie Davidson Ph.D., CFSAN
Caren Kieswetter, MD, CFSAN Liaison to the RIHSC

You have requested that your protocol entitled "pregnant women's online search for listeriosis prevention information" be continued for an additional year. The purpose of your research is to (1) examine how pregnant women locate and interpret listeriosis prevention messages on the Internet and (2) obtain feedback from pregnant women about strategies to improve listeriosis prevention messages developed for pregnant women.

Because the study can be classified as "minimal risk", i.e. collection of data from voice video, digital, or image recordings made for research purposes, your continuing review request can be reviewed using the expedited procedure outlined in 45 CFR 46.110.

Your protocol is **APPROVED TO CONTINUE**.

EFFECTIVE PERIOD OF APPROVAL:

This protocol has been approved from April 30, 2009 - April 29, 2010.

IRB OF RECORD:

Research Involving Human Subjects Committee
Chair: Dr. Mathew T. Thomas
Office of the Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857
FWA #00006196

RESPONSIBILITIES:

The Principal Investigator is responsible for ensuring that the investigation is conducted according to the investigational plan and applicable regulations and for protecting the rights, safety, and welfare of subjects. The Principal Investigator is also responsible for complying with the following requirements:

1. Promptly reporting to the RIHSC all changes in the research activity including any modifications to the Study Protocol, or Informed Consent document. 45 CFR 46.103(b)(4)(iii) Changes in approved research may not be initiated without RIHSC review and approval except when necessary to eliminate apparent immediate hazards to the subjects. 45 CFR 46.103(b)(4)(iii)
2. Promptly reporting to the RIHSC all unanticipated problems involving risk to human subjects or others. 45 CFR 46.103(b)(5)(i)
3. Providing periodic reports to the RIHSC, as required. 45 CFR 46.109(e)

PROGRESS OR FINAL REPORT:

If you wish to continue your study beyond the approval date of April 29, 2010, you will need to submit a continuing review application and all supporting documentation to the RIHSC no later than March 29, 2010.

If your study is completed or terminated within the next year, please submit a **FINAL REPORT** to the RIHSC Executive Director. This report should contain the following information, if applicable:

1. RIHSC FILE Number/Study Title/Study Investigator(s)/Institution where study is being/was conducted.
2. Brief summary of the project status, including a description of all changes, amendments, or supplements to the previously approved protocol and consent form.
3. Number of subjects initially approved by the RIHSC for inclusion in the study and the number actually entered into the study.
4. Number of subjects whose participation was completed as planned.
5. Number of subjects that dropped out of the study.
6. Summary of Adverse Events that can reasonably be attributed to the study.
7. List of abstracts or publications, and/or a brief description of any available study results.

Should you have questions or require further information, please contact Dr. Fitzpatrick, Executive Director of the RIHSC, at (301) 827-4591, FAX (301) 827-3042 or by electronic mail at Suzanne.fitzpatrick@fda.hhs.gov.


2/13/09
Dr. Mathew T. Thomas
Chair, RIHSC

MEMORANDUM

Department of Health and Human Services
Food and Drug Administration
Research Involving Human Subjects Committee

DATE: June 23, 2009

FROM: Chair, Research Involving Human Subjects Committee

Subject: **RIHSC Protocol #08-016F**
Study Title: "Pregnant Women's Online Search for Listeriosis Prevention Information"
Principal Investigator: Sandra Saperstein, M.S.
FDA Sponsors: Elizabeth Calvey Ph.D., & Marjorie Davidson, Ph.D.,

To: Elizabeth Calvey Ph.D., CFSAN
Marjorie Davidson Ph.D., CFSAN
Caren Kieswetter, MD, CFSAN Liaison to the RIHSC

You have submitted an amendment to your study entitled "Pregnant Women's Online Search for Listeriosis Prevention Information." Your amendment involves several changes to the organization of the guide for focus groups, messages that the group will review, appearance and clarification of terms used to determine the severity and susceptibility to foodborne illness. Additionally some questions will be revised to probe participants for awareness of Listeriosis.

Your amendment is approved.

Please note that this amendment does not alter the effective period of approval for your protocol. Your protocol is approved until April 29, 2010.

Should you have questions or require further information, please contact Dr. Fitzpatrick, Executive Director of the RIHSC, at (301) 827-4591, FAX (301) 827-3042 or by electronic mail.



Dr. Mathew T. Thomas
Chair, RIHSC

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