

Nutrition Assistance Program Report Series
The Office of Analysis, Nutrition and Evaluation

Special Nutrition Programs

Report No. WIC-04-BFDSN

*Breastfeeding Intervention Design
Study*



United States
Department of
Agriculture

Food and
Nutrition
Service

August 2004

“The U.S. Department of Agriculture (USDA) prohibits discrimination in all its programs and activities on the basis of race, color, national origin, gender, religion, age, disability, political beliefs, sexual orientation, or marital or family status. (Not all prohibited bases apply to all programs) Persons with disabilities who require alternative means for communication of program information (Braille, large print, audiotape, etc.) should contact USDA’s TARGET Center at (202) 720-2600 (voice and TDD)”

To file a complaint of discrimination, write USDA, Director, Office of Civil Rights, Room 326-W, Whitten Building, 14th and Independence Avenue, SW, Washington, DC 20250-9410 or call (202) 720-5964 (voice and TDD). USDA is an equal opportunity provider and employer.



United States Food and
Department of Nutrition
Agriculture Service

August 2004
Special Nutrition Programs
Report No. WIC-04-BFDSN

Breastfeeding Intervention Design Study

Authors:

Joan E. McLaughlin
Nancy R. Burstein
Fumiyo Tao
Mary Kay Fox

Submitted by:

Abt Associates, Inc
Suite 600
4800 Montgomery Lane
Bethesda, MD 20814-5341

Submitted to:

Office of Analysis, Nutrition and Evaluation
USDA, Food and Nutrition Service
3101 Park Center Drive
10th Floor
Alexandria, VA 22302-1500

Project Director: Joan McLaughlin

Project Officer: Patricia McKinney

This study was conducted under Contract number 53-3198-2-3642 with the Food and Nutrition Service. This report is available on the Food and Nutrition Service web site: <http://www.fns.usda.gov/oane>.

Suggested Citation:

U.S. Department of Agriculture, Food and Nutrition Service, Office of Analysis, Nutrition and Evaluation, Breastfeeding Intervention Design Study-Final Evaluation Design and Analysis Plan. Joan E. McLaughlin Nancy R. Burstein, Fumiyo Tao, Mary Kay Fox. Project Officer, Patricia McKinney. Alexandria, VA: 2004.

Acknowledgements

This Evaluation Design and Analysis Plan for The Breastfeeding Intervention Design Study benefited from the input of many individuals. Three members of the study's expert panel worked with us throughout the course of the study and provided input at key project milestones: Rafael Perez-Escamilla of the University of Connecticut; Kathleen Rasmussen from Cornell University; and Holly Szcondronski of the Iowa Department of Public Health. Six other members of the expert panel provided their comments on our draft Plan and met to discuss the interventions and evaluation design. They include Kimarie Bibbs Bugg of Coan Middle School and Emory University School of Medicine in Atlanta, Mary Blankson of the Jefferson County-Alabama Department of Health, Jaqueline Grant of the University of Missouri at Columbia, Laurence Grummer-Strawn of the Centers for Disease Control and Prevention, Gail Harrison of the University of California at Los Angeles, and Linda Smith, of the Bright Future Lactation Resource Centre in Dayton, Ohio. With state-of-the-art knowledge and experience in breastfeeding support research, practice, and program administration, the panel helped us to develop breastfeeding intervention and evaluation designs that are operationally feasible and technically sound.

Patricia McKinney of the Food and Nutrition Service's Office of Analysis, Nutrition and Evaluation served as the federal project officer for this study. She facilitated the progress of this contract immensely with clear guidance and wise and practical suggestions throughout this effort. Ursuline Singleton of FNS' Supplemental Food Program Division also provided helpful input throughout the course of the study.

We also would like to thank the local and state WIC staff and peer counselors who took time to share with us their experiences with peer counseling programs. These include Mary Noppenberger, the director of the WIC Program in Harford and Cecil Counties in Maryland, and Laurie Miele who is a lactation consultant and serves as the breastfeeding supervisor there; Zulma Vargas, the peer counselor supervisor in the Arlington County, Virginia WIC Program; Katherine Wilson-Thompson who is a peer counselor in the Mt. Rogers health district in rural southwest Virginia; and Nancy Pribble and Amy Resnick who served or currently serve as the state breastfeeding coordinators in Virginia and Maryland, respectively.

We would also like to thank Abt Associates staff that contributed to this report. Larry Orr served as our technical reviewer and provided significant guidance to us in working out key components of the project, the experimental design in particular, and in reviewing multiple versions of the final report. Erik Becroft developed some of the basic components of the experimental design and worked extensively on the sampling issues for the draft report. Nancy Cole produced much of the background and contextual sections for first chapter. Denise Young was responsible for the final report production.

Contents

Executive Summary	v
-------------------------	---

Part I: Evaluation Design and Analysis Plan

Chapter One – Introduction	1
WIC Background and Legislative History	2
Participant Eligibility	2
Program Benefits	3
Federal, State and Local Roles in Program Administration	5
Breastfeeding Promotion and Support in WIC	6
Breastfeeding Trends	9
Peer Counseling Interventions	11
The Evaluation of Peer Counseling Interventions	12
Key Research Questions	12
Demonstration Design	13
Data Collection Plan	14
Organization of the Report	14
Chapter Two - Factors to Consider in Defining Peer Counseling Interventions for Evaluation	15
Selecting the Type of Intervention for Evaluation	15
Review of Peer Counseling Intervention Studies	16
Research Base for Peer Counseling Effectiveness	17
Peer Counseling Implementation in WIC	17
Design of Peer Counseling Intervention to be Evaluated	19
Factors to be Standardized Across All Study Groups	20
Factors Applicable to High-and Low-cost intervention Groups (but Not the Control Group)	23
Factors to Vary Between High- and Low-cost Treatment Groups	26
Peer Counselor Caseload	29
Intervention Start-up Period	32
Keeping a Stable Peer Counselor Caseload	32
Chapter Three - Alternative Random Assignment Research Designs	35
Why Random Assignment	35
Random Assignment of Sites versus Individuals within Sites	36
Two-way versus Three-way Individual-Level Random Assignment	38
Summary	39
Chapter Four - Site Selection, Sample Sizes, and Statistical Power	43
Site Selection	43
Criteria for Determining Numbers of Participants and Sites	44
How Many Participants, How Many Sites: RA3	46
How Many Participants, How Many Sites: RA2	47
How Many Participants, How Many Sites: SRA	48

Chapter Five - Implementation Study	51
Objectives of the Implementation Study.....	51
Research Questions.....	51
Implementation Study Analysis.....	55
Background Contextual Factors.....	55
Implementation Outcomes.....	56
Cost of the Intervention	56
Descriptive Analysis of Peer Counseling Demonstration.....	56
Analysis of Program Costs.....	57
Analysis of Implementation Process and Outcomes by Site Characteristics.....	60
Integrative Analysis of Quantitative and Qualitative Data	60
Chapter Six - Impact Study	61
Conceptual Model.....	61
Key Research Questions	63
Services Received and Proximal Outcomes.....	63
Distal Outcomes of Breastfeeding	65
Models to be Estimated.....	65
Variations in Impacts	68
Chapter Seven - Data Collection: Measures.....	71
Implementation Study.....	71
Sources of Data.....	71
Data Collection Methods	71
Impact Study.....	78
Sources of Data.....	83
Data Collection Methods	84
Chapter Eight - Data Collection: Procedures.....	87
Implementation Study.....	87
Baseline Site Survey	87
Baseline Site Visits	88
Interim Staff Interviews	90
Follow-up Site Visits	91
Evaluation Activity Records.....	91
Peer Counselor Records.....	91
Impact Study.....	91
Training of Site Coordinators	92
Enrolling Subjects.....	93
Completing Participant Surveys	93
Random Assignment.....	95
Record Abstractions.....	95
Minimizing Data Collection Challenges.....	95
References.....	99
Appendix A: Expert Panel Members	A-1

Appendix B: Current Federal Requirements for Breastfeeding Promotion in WIC B-1
Appendix C: Studies of WIC Peer Counseling Interventions Reviewed by Abt C-1

Part II: Review of Literature on Breastfeeding Promotion and Support Interventions

Chapter 1-Introduction..... 1
Chapter 2- Literature Review Methods 7
Chapter 3- Results of the Literature Review 11
Chapter 4- Summary and Conclusions..... 69
Bibliography 75
Appendix A: Summary of Information for Reviewed Interventions A-1
Appendix B: Profiles of Innovative and Successful Interventions B-1

Executive Summary

Background

WIC encourages breastfeeding as the best source of infant nutrition and currently earmarks funds for breastfeeding promotion and support activities. However, while a great deal of breastfeeding promotion and support is happening in WIC at both the state and local levels, there has been no systematic effort to evaluate what might work best in the WIC setting. Within this context, the Food and Nutrition Service contracted with Abt Associates Inc. for a breastfeeding intervention design study with the following goals:

- Identify interventions to increase the incidence, duration and intensity of breastfeeding among women participating in WIC; and
- Design an evaluation plan to examine the implementation and effectiveness of these interventions.

After a review of the literature, and in consultation with outside experts and FNS staff, peer counseling was recommended as a promising breastfeeding promotion intervention for implementation in WIC. An experimental design was chosen to provide clear evidence of the intervention's effectiveness. The design would involve randomly assigning pregnant WIC participants in selected sites to one of three groups: high-cost peer counseling, low-cost peer counseling, or a control group, which would receive postpartum support services currently offered by the WIC sites. Each phase of the design study is described below.

Literature Review

A thorough review of English-language breastfeeding promotion and support intervention efforts described in articles and reports written since 1990 was conducted. The interventions varied across a number of characteristics including the nature of the intervention, the target group, time period in which intervention was implemented (e.g., prenatal, postpartum), the delivery person or persons, and where the intervention took place. Although the review suggested interventions that have improved breastfeeding outcomes, there were gaps in research evidence, as well as methodological and implementation issues.

Most of the studies that focused on WIC participants were based on two types of interventions: peer counseling and various multifaceted interventions (i.e., interventions with three or more intervention strategies). Twelve peer counseling studies focused on WIC participants, although none of these studies used a methodologically strong design. Eleven of these 12 peer-counseling studies suggested a positive benefit on breastfeeding outcomes, including initiation and duration. Most of the multifaceted interventions with WIC participants were not designed to test the effects of the intervention on breastfeeding. The three multifaceted interventions that included evaluations used designs with methodological weaknesses, and only two of these reported positive intervention effects. Aside from these common intervention types, there were three prenatal education interventions of WIC participants. The two of these prenatal education interventions that had valid research

designs found no significant effects of the interventions on breastfeeding outcomes. One with a weak design found an effect on breastfeeding duration. Two postpartum support interventions involving WIC participants included evaluations with weak designs. One reported increases in breastfeeding initiation, while the other reported an increase in breastfeeding duration. No reports on hospital-based breastfeeding interventions with WIC populations were identified. Thus, there are only a small number of WIC-based studies that provide a basis for selecting the intervention(s) to be evaluated, and even fewer that used valid evaluation methods.

Peer Counseling Intervention Proposed for Testing in WIC

Based on findings from the literature review, four interventions were selected for consideration by FNS and expert consultants with expertise in breastfeeding promotion and support in WIC, extensive research in maternal and child health issues, and research on breastfeeding interventions with low-income and minority groups. The proposed interventions were those that had some evidence of success based on statistically significant increases in breastfeeding initiation and/or duration, appeared feasible for the WIC setting, had potential to be evaluated using an experimental design, and appeared sensitive to cultural differences or were shown effective with different racial or ethnic groups. Peer counseling was selected as the breastfeeding promotion and support intervention to be tested in WIC.

Evaluation Design for Peer Counseling Intervention

A draft evaluation design and analysis plan for peer counseling interventions was proposed and developed to assess 1) how well the interventions have been implemented and 2) their effectiveness in improving breastfeeding outcomes. The draft evaluation plan was provided to a panel of experts who strongly recommended an experimental design in which sites are selected from among those that volunteer and in which WIC study participants within each site are randomly assigned to one of three groups:

- high-cost peer counseling which might include, for example, one prenatal one-on-one counseling visit, one individual counseling in the hospital, four home visits and weekly phone calls;
- low-cost peer counseling which might include no one-on-one prenatal counseling, but one hospital visit, one home visit and a phone call every two weeks; or
- control group, which would receive existing postpartum support services currently offered by the WIC clinic.

Part 1:
Evaluation Design and Analysis Plan

Chapter One

Introduction

The Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) was designed to improve the health of nutritionally at-risk, low-income pregnant, breastfeeding, and postpartum women; infants; and children up to five years of age. WIC provides supplemental foods that are rich in nutrients known to be lacking in the target population, health and social service referrals, and nutrition education, which includes information about breastfeeding. About 7.5 million women, infants and children are served by WIC each month (Food and Nutrition Service, 2003a). Bartlett and her colleagues (2002) report that in 2000, WIC served just under 900,000 pregnant women and about 2 million infants, half of all infants born in the United States (Martin et al., 2002).

WIC encourages breastfeeding as the best source of infant nutrition and currently earmarks funds for breastfeeding promotion and support activities. However, there is relatively little information on the effectiveness of these activities (U.S. General Accounting Office, 2001). Thus, while a great deal of breastfeeding promotion and support is happening in WIC at both the state and local levels, there has been no systematic effort to evaluate what might work best in the WIC setting.

Within this context, the U.S. Department of Agriculture's Food and Nutrition Service (FNS) funded the Breastfeeding Design Intervention Study. FNS' goals for this study are to:

- Identify interventions to increase the incidence, duration, and intensity of breastfeeding among women participating in WIC; and
- To design an evaluation plan to examine the implementation and effectiveness of these interventions.

Included among the tasks of this study are a literature review of breastfeeding interventions to identify promising interventions that are effective and feasible for the WIC setting (McLaughlin et al., 2003), information-gathering on current WIC breastfeeding promotion and support activities, the development of an evaluation plan for each of the recommended intervention approaches, and discussions with expert consultants on the selection of candidate interventions for WIC and the evaluation plan. In this document, we describe the recommended intervention strategy (peer counseling) and the evaluation plan for peer counseling interventions.

A draft of this document was shared with FNS and a panel of expert consultants.¹ This revised Plan incorporates written comments by the expert panel and a discussion of key issues with the panel and FNS staff at a meeting held at FNS in September 2003.

This revised Plan also considers further work in breastfeeding promotion plans in the WIC Program Division at FNS. In particular, the WIC Program recently funded another initiative, *Using 'Loving Support' to Implement Best Practices in Peer Counseling*, aimed at developing a model for peer counseling in WIC in addition to this project. The goal of this initiative is to develop a model for peer

¹ The list of expert consultants is provided in Appendix A.

counseling and to provide training and technical assistance to help equip State and local WIC agencies to build and maintain peer counseling programs. The timing of this study was such that the Loving Support Peer Counseling initiative would not be completed prior to the submission of this Evaluation Design and Analysis Plan. FNS therefore requested Abt to make the evaluation design more generic, and not specific to the intervention models that Abt developed in the draft of this document. This would allow FNS to choose the specific peer counseling interventions once the Loving Support Peer Counseling Initiative has been completed.

The evaluation design recommended in this document has thus been made more generic, so it could be adapted to the interventions FNS will choose to be tested in WIC. The specific peer counseling interventions that Abt drafted in the earlier version have been kept in as examples of what could be chosen by FNS, and key factors that warrant consideration in choosing peer counseling interventions are highlighted.

The remaining sections of this chapter include a description of WIC and WIC breastfeeding promotion, a discussion of national breastfeeding trends, discussion of peer counseling as a promising intervention approach for WIC and of the recommended experimental evaluation design, and an overview of the remaining report chapters.

WIC Background and Legislative History

The Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) was established to provide “supplemental nutritious food as an adjunct to good health care during critical times of growth and development in order to prevent the occurrence of health problems and improve health status...” (Public Law 95-627). WIC began as a two-year pilot program in 1972 and was authorized as a permanent program in 1974. WIC has been one of the fastest growing of USDA’s programs. Between 1980 and 1993, federal funding nearly quadrupled from \$725 million to \$2.8 billion and program participation increased from 1.9 million to 5.1 million (Institute of Medicine, 1996). Favorable Congressional funding, largely driven by research that suggested that WIC participation during pregnancy had a positive impact on infant birthweight, fueled much of this growth. Funding and participation continued to grow through the 1990s with increased funding available at the local level as a result of cost-containment practices, including mandated competitive bidding for infant formula. In FY 2002, WIC served approximately 7.5 million participants each month at an annual cost of about \$4.4 billion (FNS, 2003a).

Participant Eligibility

WIC eligibility is based on four factors: state residence, categorical eligibility, income eligibility, and nutritional risk. Unless part of a migrant farm-worker family, WIC participants must be residents of the state or other jurisdiction (U.S. territory or Indian reservation) supplying the WIC benefits.

Participants must also belong to one of five categorically-eligible groups: women during pregnancy and up to six weeks after delivery, breastfeeding women (who can participate for up to a year after giving birth), postpartum women who are not breastfeeding (who can participate for up to six months after giving birth or other termination of pregnancy), infants (0-12 months), and children up to the age of five. Children and infants comprise the majority of WIC participants. Although this has always been true, the number of children participating in the program increased dramatically during the

1990s as increased funds allowed local programs to serve this lower-priority participant group. In April 2000, approximately half (49.6 percent) of all WIC participants were children and 26 percent were infants. The remaining participants were women: 11 percent pregnant women, seven percent postpartum non-breastfeeding women, and five percent breastfeeding women (Bartlett *et al.*, 2002). Of note is that, among all postpartum women receiving WIC, the proportion that initiated breastfeeding rose from 41.3 percent in 1998 to 45.7 percent in 2000.

WIC participants must also be income-eligible. Income eligibility is defined by each state agency; however, the cut-off may not exceed 185 percent or be less than 100 percent of the Office of Management and Budget's (OMB) poverty income guidelines. In April 1998, all state agencies except Guam defined income eligibility as less than 185 percent of poverty (Bartlett *et al.*, 2000). Participants in some states may have higher incomes because adjunct eligibility for WIC is achieved through participation in Medicaid, which may have a threshold of 225 percent.

Finally, each WIC participant must be determined, by a competent professional authority such as a physician, nutritionist, nurse, or other health professional, to be at nutritional risk. Until 1999, federal policy allowed state agencies to develop their own nutrition risk criteria within minimal defined standards: height (or length) and weight had to be measured and, with the exception of infants under six months, a hematological test (generally a hemoglobin) had to be administered. The list of nutritional risk criteria was standardized in April 1999. Thus, while states are still free to define the specific nutritional risk criteria used to determine program eligibility, these risks and their associated cutoffs must be selected from the approved list.

Program Benefits

WIC participants receive supplemental foods rich in the nutrients that are lacking in the diets of the low-income population served, nutrition education and counseling, and access to health and social services.

Supplemental Foods

The supplemental foods offered by WIC are good sources of protein, iron, calcium, and vitamins A and C. Since the early 1990s, the WIC program has also focused on providing foods rich in folate, vitamin B6, and zinc. Foods available in WIC food packages include milk, eggs, cheese, dried beans and peas, peanut butter, 100 percent fruit or vegetable juices, and breakfast cereals that are high in iron and low in sugar. Infant packages include iron-fortified infant formula and infant cereals as well as infant juices that are high in vitamin C. Seven separate food packages are offered in WIC, depending on the participant's status. Packages are designed for infants 0-3 months; infants 4-12 months; women and children with special dietary needs; children 1-5 years; pregnant and breastfeeding women (basic); non-breastfeeding postpartum women; and breastfeeding women (enhanced). In 1992, this last food package was added for women who were exclusively breastfeeding, and thus not receiving infant formula through WIC. It is a similar food package to those offered to pregnant and partially breastfeeding women, but it augments certain foods (i.e., juice, cheese, and dry beans/peas) and adds others (i.e., carrots and tuna). This enhanced package attempted to counterbalance other postpartum women's economic advantage of receiving infant formula (Baydar *et al.*, 1997).

Most WIC participants receive vouchers or checks to use in purchasing supplemental foods at local grocery stores. In a limited number of geographic areas, foods are delivered to participants' homes or

participants pick up foods at warehouses. In recent years, several states have conducted pilot tests on the use of electronic benefits transfer (EBT) systems in disbursing WIC benefits.

Nutrition Education

Nutrition education in WIC is directed toward improving participant knowledge, attitudes, and behavior about foods consumption. The goals of nutrition education, as stated in the WIC Program regulations are to:

- (1) Stress the relationship between proper nutrition and good health with special emphasis on the nutritional needs of pregnant, postpartum, and breastfeeding women, infants and children under five years of age; and
- (2) Assist the individual who is at nutritional risk in achieving a positive change in food habits, resulting in improved nutritional status and in the prevention of nutrition-related problems.

WIC agencies are required to address a variety of other issues as well, including the need to avoid cigarettes, alcohol, illicit drugs, and over-the-counter medications during pregnancy; the importance of childhood immunizations; and, most relevant to this study, breastfeeding promotion.

Regulations call for state agencies to dedicate at least one-sixth of annual administrative funds to nutrition education. Local WIC agencies must offer participants at least two nutrition education sessions during each certification period. Certification periods usually occur every six months, although prenatal participants are certified for the duration of their pregnancy and up to six weeks postpartum. For these participants, nutrition education must be offered on a quarterly basis.

WIC participants receive nutrition education in a number of ways, including counseling in one-on-one sessions, group classes, or through the viewing of videotapes. Regulations require local agencies to be sensitive to the geographic food preferences, ethnic and cultural preferences of the participants, as well as their educational levels in their nutrition education messages. Thus, there is a lot of variation among WIC agencies on the provision of nutrition education. More specific information on breastfeeding promotion in WIC is presented in a later section.

Note that although local WIC agencies are required to offer nutrition education, regulations state that participants may decline these services without losing other program benefits. Local WIC agencies try to maximize participation in nutrition education activities by scheduling them to coincide with WIC voucher pick-up.

Referrals to Health Care and Social Services

Each local WIC agency must provide WIC participants with access to health care, which is typically done through either on-site health services or referrals to other local health care facilities. Local agencies also refer clients, as needed, to a variety of social services, including public assistance programs, child support and child care services, and substance abuse counseling and smoking cessation programs. While there has historically been coordination between local WIC agencies and social service programs, it was given further emphasis in 1989 when Congress created adjunct eligibility for WIC benefits based on eligibility for other programs.

Federal, State and Local Roles in Program Administration

At the federal level, FNS and its seven regional offices provide cash grants to state WIC agencies² for program administration and operations, issuing regulations, and monitoring compliance with WIC regulations. State WIC agencies allocate funds to local WIC agencies and provide technical assistance to local agency staff. Although the majority of local agencies are state, county, or local health departments, other organizations such as hospitals, state or locally sponsored maternal and child health programs, and community action agencies also serve as WIC providers at the local level. Each local agency operates one or more service delivery sites, or clinics, where participants go to receive WIC services. Approximately 2,200 local agencies provide services to participants at one or more local service sites (Bartlett *et al.* 2002).

Funds received by local WIC agencies are used to provide supplemental foods to WIC participants and to pay administrative costs, including the costs of certifying applicants as eligible and providing nutrition education services.

WIC differs from most other food assistance and nutrition programs in that it is not an entitlement program. The program must operate within annual funding levels established by Congress. While some states augment federal allotments with state funds, in most states the number of participants annually served by the program depends on the level of federal funding. Within states, a maximum caseload is defined for each local agency based on the agency's funding level and predicted caseload turnover. When a local agency reaches this maximum, a system of priorities is used to allocate available caseload slots to eligible applicants. The priority system is designed to ensure that available services go to those most in need. Some agencies maintain waiting lists of eligible applicants and, as openings become available, fill them from their waiting lists. As vacancies occur, the priority levels below are generally used:

1. Pregnant women, breastfeeding women, and infants determined to be at nutritional risk because of serious medical problems;
2. Infants up to 6 months of age whose mothers participated in WIC or could have participated and had serious medical problems;
3. Children (up to age 5) at nutritional risk because of serious medical problems;
4. Pregnant or breastfeeding women and infants at nutritional risk because of dietary problems (like poor diet);
5. Children (up to age 5) at nutritional risk because of dietary problems;
6. Non-breastfeeding, postpartum women with any nutritional risk; and
7. Individuals at nutritional risk only because they are homeless or migrants, and current participants who without WIC foods could once again develop medical and/or dietary problems (FNS, 2003a).

² In addition to agencies in each of the 50 states, the District of Columbia, Puerto Rico, Guam, American Samoa, the American Virgin Islands, and 33 Indian Tribal Organizations serve as state WIC agencies.

Breastfeeding Promotion and Support in WIC

Breastfeeding promotion and support became an integral component of the WIC program in 1989, with passage of the Child Nutrition and WIC Reauthorization Act (Public Law 101-147). The act emphasized the importance of breastfeeding promotion in WIC by:

- Requiring USDA to define the term “breastfeeding” and to develop standards for state and local agencies to ensure adequate breastfeeding promotion and support;
- Authorizing the use of nutrition service and administrative funds to purchase breastfeeding aids (e.g., breast pumps) to support the initiation and continuation of breastfeeding; and
- Earmarking a minimum of \$8 million a year to be spent by state and local WIC agencies on breastfeeding promotion and support, which was to include providing materials in languages other than English, incorporating breastfeeding promotion and support in State Plans, and the designation of a breastfeeding coordinator to provide training and support to local agency staff responsible for breastfeeding promotion.

In subsequent years, Congress has continued to emphasize the importance of breastfeeding promotion. In 1992, Congress required USDA to establish a national breastfeeding promotion program and authorized USDA to enter into cooperative agreements with federal, state, local or other organizations to carry out breastfeeding promotion. USDA was also authorized to solicit and accept donations from outside sources for establishing a breastfeeding promotion program (Public Law 102-342).

In 1994, Congress revised the formula for expenditures for WIC breastfeeding promotion and support (Public Law 103-448), so that WIC state agencies are required to spend \$21 towards breastfeeding promotion and support for each pregnant and breastfeeding woman. State agencies are also required to collect data on incidence and duration of breastfeeding in WIC and to report to Congress every two years. In 1998, Congress authorized the expenditure of WIC food funds for the purchase and rental of breast pumps (Public Law 105-336).

The list of current federal requirements to encourage breastfeeding and provide support to breastfeeding WIC participants is provided in Appendix B. In general, they address the definition of breastfeeding in WIC, the designation of state agency staff as breastfeeding coordinator, the inclusion of breastfeeding promotion in State Plans, the priority of breastfeeding women and infants in certifying participants, the length of certification, the enhanced breastfeeding food package, and allowable expenditures for breastfeeding promotion and support. In terms of breastfeeding promotion as part of nutrition education activities, the federal regulations require state agencies to provide training for WIC staff, the development of educational materials for local agency use, and to establish standards for breastfeeding promotion and support. These standards are to include:

- A policy that creates a positive clinic environment which endorses breastfeeding as the preferred method of infant feeding;
- A requirement that each local agency designate a staff person to coordinate breastfeeding promotion and support activities;

- A requirement that each local agency incorporate task-appropriate breastfeeding promotion and support training into orientation programs for new staff involved in direct contact with WIC clients; and
- A plan to ensure that women have access to breastfeeding promotion and support activities during the prenatal and postpartum periods.

In addition, regulations require that “all pregnant participants shall be encouraged to breastfeed unless contraindicated for health reasons” (7 Code of Federal Regulations 246.11).

WIC agencies currently use a number of strategies to promote breastfeeding. The survey of local WIC agencies, conducted as part of the 1996 and 1998 WIC Participant and Program Characteristics Studies, found that a majority of local agencies provide nutrition education sessions focused solely on breastfeeding. In addition, as shown in Exhibit 1.1, local agencies promote and support breastfeeding through breastfeeding support groups, peer counselors, individual counseling, and home and hospital visits. In 1998, two-thirds of WIC participants were enrolled at agencies providing breast pumps to breastfeeding mothers.

Exhibit 1.1
WIC Breastfeeding Promotion and Support Services

Service	1996		1998	
	Percent of Sites	Percent of Participants	Percent of Sites	Percent of Participants
Nutrition education sessions devoted solely to breastfeeding	67.4	82.0	97.4	98.4
Provision of breast pumps	82.7	86.7	43.6	66.3
Peer counseling for breastfeeding	33.1	45.6	16.7	32.4
Breastfeeding support groups	17.7	31.4	80.7	88.1
Individual counseling on breastfeeding	*	*	31.4	44.1
Home/hospital visit	*	*	30.9	39.1
Other	13.3	13.4	5.4	5.4

* Category not reported.

Sources: *WIC Participant and Program Characteristics Studies, 1996 and 1998*

As evident in Exhibit 1.1, WIC breastfeeding support services vary across local WIC agencies and over time. Between 1996 and 1998, breastfeeding support groups and nutrition education sessions devoted to breastfeeding became more common. But there was a decline in the use of peer counseling and the provision of breast pumps. The local agency survey was discontinued after 1998, so more recent data are not available. However, in a recent update of peer counselor programs around the country, FNS found that as of November 2002, most state WIC agencies were reporting some peer counseling, with seven states reporting statewide efforts (FNS, 2002).

The California State WIC office recently released the results of a 2003 survey of WIC State breastfeeding coordinators (Eil, 2003). Forty-eight of the 50 state coordinators surveyed responded to the survey. Two activities that the survey focused on were peer counseling programs and the availability of telephone help lines for breastfeeding support. Thirty-six states reported peer counselor programs in at least some local agencies. Nine reported a statewide breastfeeding helpline

and 32 reported a help-line available to some local agencies through the sponsorship of the local-agency or region or outside organization (e.g., hospital or La Leche League). Twenty-nine respondents also reported providing funding over and above what was federally mandated to support breastfeeding-related activities. Funds went to such things as breast pumps, training, education, breastfeeding materials, funding for staff, peer counselor programs and media activities. About half of the respondents cited other activities in support of breastfeeding, including mother-to-mother support groups, outreach to medical professionals, incentive programs and participation in local health fairs.

One recent initiative that has been implemented in several states is the Food and Nutrition Service's *Loving Support Makes Breastfeeding Work*, also referred to as the WIC National Breastfeeding Promotion Project, a social marketing campaign designed to be implemented at the state agency level. FNS entered into a cooperative agreement with Best Start Social Marketing in 1995 to assist the WIC Program in developing and implementing the project. Ten pilot sites were included in this original project: Arkansas, California, Chickasaw Nation of Oklahoma, Iowa, Mississippi, Nevada, New Jersey, New York, Ohio, and West Virginia. The goals of the campaign were to encourage WIC participants to initiate and continue breastfeeding; increase referrals to WIC for breastfeeding support; increase general public acceptance and support of breastfeeding; and provide technical assistance to WIC state and local agencies in breastfeeding promotion and support. The key messages of this campaign focused on barriers discovered through consumer research: helping women feel comfortable with breastfeeding, providing tips on how breastfeeding can work around a busy schedule, and involving family and friends to make breastfeeding a success. The project included the development of state and local breastfeeding coalitions, conferences, training, dissemination of print materials, and state-wide media campaigns.

FNS estimates that more than 72 WIC state agencies and Indian Tribal Organizations are using campaign materials developed as part of the Loving Support campaign (FNS, 2003b). In 2002, FNS took the Loving Support initiative one step further and began an effort to provide training and technical support to a group of nine states to develop comprehensive community-based breastfeeding programs. The states are Alaska, Iowa, Kentucky, Maine, Michigan, Missouri, Pennsylvania, Vermont, and Wisconsin. The goal of this most recent effort, called *Using Loving Support to Build a Breastfeeding-Friendly Community*, is to use social marketing methods to raise public awareness, acceptance, and support for breastfeeding. Two-day trainings are held to identify and address state-specific barriers to breastfeeding. These trainings include WIC staff, community partners, and stakeholders.

As described earlier, FNS has recently begun implementing and expanding peer-counseling programs for breastfeeding mothers in WIC. The currently ongoing project, called *Using Loving Support to Implement Best Practices in Peer Counseling* will develop a peer counseling program and management model, and develop curricula for managers of peer counseling programs and for those who will train peer counselors in WIC. Training will be provided for WIC staff in each USDA region. The project began in the fall of 2003 and will continue through the summer of 2005.

In summary, there has been an increased emphasis on breastfeeding in the WIC program over the last decade, as reflected in legislation and federal regulations. WIC state and local agencies have responded to the requirements through the implementation of several initiatives aimed at promoting the initiation and duration of breastfeeding.

While some of these initiatives show promise (McLaughlin et al, 2003), definitive evidence is missing on most of them, especially as they are implemented in the WIC context. Data are needed on how well the various breastfeeding promotion interventions can be implemented in WIC, and most importantly, how effective these efforts are at increasing breastfeeding outcomes among WIC mothers. These data are critical at helping WIC program administrators and policy makers decide how best to spend scarce WIC resources earmarked for breastfeeding promotion and support.

Breastfeeding Trends

This section presents a summary of current breastfeeding recommendations and trends in the United States as a context for breastfeeding promotion efforts in WIC. Current recommendations of the American Academy of Pediatrics (1997), the American Dietetic Association (1997), the World Health Organization (2000), and the U.S. government Healthy People 2010 goals (U.S. Department of Health and Human Services, 2000) all call for increases in the proportion of mothers who breastfeed their babies. Healthy People 2010 specifically calls for a 75 percent breastfeeding initiation rate, a 50 percent continuation rate to six months, and a 25 percent rate at one year.

Breastfeeding is recommended as the preferred infant feeding method because of the nutritional value and health benefits of human milk. Benefits of human breast milk, relative to formula feeding, have been established through considerable research. "Breastfed infants experience fewer cases of infectious and noninfectious diseases as well as less severe cases of diarrhea, respiratory infections, and ear infections. Mothers who breastfeed experience less postpartum bleeding, earlier return to pre-pregnancy weight, and a reduced risk of ovarian cancer and premenopausal breast cancer" (U.S. Department of Health and Human Services, 2000). Exclusive breastfeeding is recommended for the first six months of life, with continued breastfeeding supplemented with appropriate solid foods at least until the infant's first birthday.

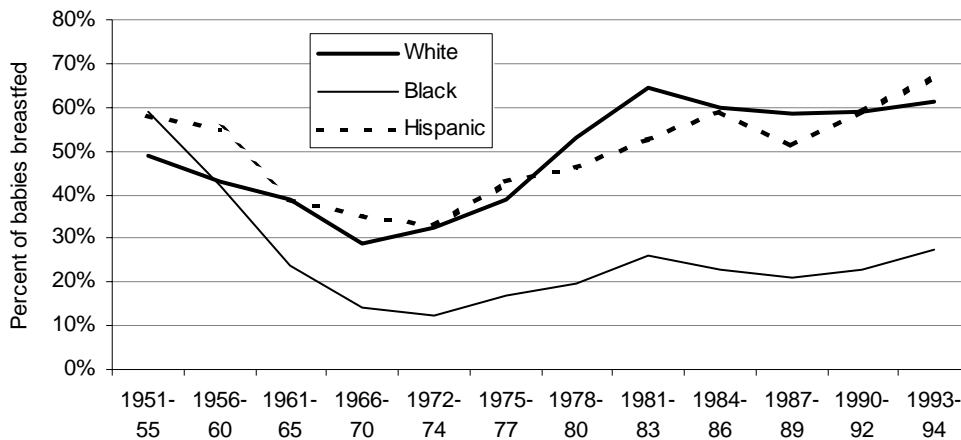
Despite the benefits, rates of breastfeeding in the United States declined dramatically during the mid-twentieth century, regaining most of the loss in the past 30 years. Data on breastfeeding rates are available from U.S. fertility surveys (beginning in the 1930s) and from market research by Abbott Laboratories' Ross Division (beginning in 1954).³ Rates of breastfeeding initiation were about 77 percent in 1936-40 (Institute of Medicine, 1991). Breastfeeding initiation gradually declined to a low of 25 percent in 1971 and then rose to a new peak of 62 percent in 1982. Through the 1980s, breastfeeding initiation declined again, to 52 percent in 1989; then increased through the 1990s and reached 70 percent in 2003 (Abbott Laboratories, 2003).

Significant differences in rates of breastfeeding have persisted among racial groups over time. Exhibit 1.2 presents rates of breastfeeding initiation by race, as measured by the National Survey of Family Growth, conducted by the National Center for Health Statistics. In the 1950s, black and Hispanic mothers were more likely to breastfeed their babies than white mothers. But during the decline in breastfeeding prevalence in the early 1970's, rates of breastfeeding dropped most dramatically for blacks and have not fully recovered. In contrast, breastfeeding rates among white

³ The Ross Mothers' Survey is a national mail survey designed to determine patterns of infant feeding through 6 months of age.

and Hispanic mothers rose sharply beginning in the 1970s, and reached or exceeded 1950s levels in the late 1980s.

Exhibit 1.2
Breastfeeding Initiation Rates by Race, 1951-55 through 1993-94



Sources: Data for 1951-55 through 1966-70: Hirschman and Hendershot. *Trends in Breast Feeding Among American Mothers*. Vital and Health Statistics, Series 23, No. 3. National Center for Health Statistics, 1979.
Data for 1972-74 through 1993-94: *Health, United States, 1998*. National Center for Health Statistics.

A report from the Ross Mother’s Survey (Abbott Laboratories, 2003) shows that the discrepancy still exists. In 2000, Ross data indicate that 51 percent of blacks initiated breastfeeding in the hospital, compared with 72 percent of whites and 71 percent of Hispanics. At 6 months only 21 percent of black respondents were breastfeeding compared with 34 percent of whites and 28 percent of Hispanics.

It should be noted that among Hispanic subgroups, there is a great deal of variation in rates of breastfeeding. In her recent review of the literature, Dennis (2002) cited research suggesting that this difference is associated with their level of acculturation in this country. In particular, breastfeeding initiation was highest among those who were least acculturated and lowest among those who were most acculturated. Perez-Escamilla and his colleagues (1998) report low rates among Puerto Rican women in the U.S., more comparable to the rates associated with black women than the overall Hispanic population.

Other socio-demographic factors have also been shown to be associated with breastfeeding initiation and duration. Breastfeeding rates increase with mother’s age, education, and income; and regional differences have persisted over time, with breastfeeding rates in the West far exceeding that of other regions.⁴ The relationship between socio-demographic factors and breastfeeding is an important consideration when examining rates of breastfeeding for WIC participants and non-participants because WIC participants are disproportionately disadvantaged. Data from the Ross Mothers’ Survey

⁴ In 1993-94, the percents of babies’ breastfed were: 79 percent in the West, 57 percent in the Northeast, and 50 percent in the South and Midwest (U.S. Department of Health and Human Services, 1999).

showed that, in 1990, 34 percent of WIC newborns were breastfed, compared to 63 percent of non-WIC newborns. This difference narrowed by 2003, when 59 percent of WIC newborns were breastfed, compared to 79 percent of non-WIC newborns (Abbott Laboratories, 2003).

The WIC Program began reporting the incidence and duration of breastfeeding among WIC participants in 1998.⁵ The measurements used to monitor breastfeeding are from administrative data on seven-to-eleven-month old infants: ever breastfed, currently breastfed, and length of time breastfed. These measurements will be used to measure progress against FNS' strategic goal for breastfeeding: to reach a breastfeeding initiation rate of 50 percent by 2003-04.

State WIC agencies have had difficulty complying with the request for breastfeeding data and, for the years 1996 and 1998, national estimates of breastfeeding from WIC administrative data have been based on incomplete data.⁶ Nonetheless, these data show that the percent of WIC infants ever breastfed rose between 1998 and 2000. Looking across the 52 state agencies that reported breastfeeding data for both years, breastfeeding initiation rose from 41.3 percent breastfeeding in 1998 to 45.7 percent in 2000.⁷ Breastfeeding rates show substantial variation among WIC states: in 2000, some states reported as many as 70 percent of infants ever breastfed, while other states reported less than 25 percent of infants ever breastfed (Bartlett *et al.*, 2002).

Peer Counseling Interventions

Based on the literature review and discussion with FNS and expert consultants, peer counseling appears to be a promising breastfeeding promotion intervention to be evaluated for use in the WIC program. The literature suggests that peer counseling has shown some success with increasing breastfeeding duration rates, a critical focus for WIC sites across the country. In addition, peer counseling has been shown to be associated with positive breastfeeding outcomes in minority groups that have proven hard for WIC to support in the initiation and continuation of breastfeeding.

FNS is interested in identifying two levels of peer counseling to test in the WIC Program. Both levels would be aimed at providing quality breastfeeding promotion and support by peer counselors to pregnant and postpartum women. However, given the limited resources that are available to sustain peer counselor programs over time, FNS is interested in identifying the lowest cost intervention model that can produce positive breastfeeding outcomes, with an increase in breastfeeding duration

⁵ This reporting requirement was mandated by Public Law 103-448 to be included in the biennial reports of *WIC Participant and Program Characteristics*. The breastfeeding statistics from WIC administrative data are expected to differ from estimates from the Ross Mother's Survey because the Ross estimates are based on a mail survey of mothers with a response rate that was as low as 31 percent in 2000 (Abbott Laboratories, 2003).

⁶ State WIC agencies were not required to record breastfeeding data in their management information systems prior to Public Law 103-448, and there was much variation in the availability of data across states. For some states, complying with Public Law 103-448 may have required significant modifications of WIC data systems.

⁷ Statistics are based on data from states reporting breastfeeding data for at least 75 percent of infants. The national estimates are based on 81 percent of all WIC infants age 7-11 months in 1998, and 78 percent of all WIC infants age 7-11 months in 2000. National estimates of breastfeeding duration among WIC participants have not been available due to significant amounts of missing data.

being of particular importance. Abt has developed two “levels” of peer counseling intervention as part of this study, referred to as “high” and “low” cost, as the two levels differ on the resources expended along a number of dimensions, such as the length of time peer counselors are available and the number of in-person contacts. However, as mentioned earlier, Best Start Social Marketing is also currently developing peer-counseling interventions. FNS plans to wait until Best Start has completed this work before identifying the interventions to be implemented. Thus, while we describe the framework for two peer counseling interventions in this document, they are for illustrative purposes only. The evaluation design and data collection plan have been made fairly general, so they could accommodate various interventions fitting within the high and low cost framework.

The peer counseling demonstration described in this document was designed to determine whether peer counseling as a breastfeeding promotion intervention can significantly improve breastfeeding outcomes for WIC mothers, and to determine the level of intensity of peer counseling services that is needed to generate positive impacts. Two “levels” of the peer counseling intervention are presented in this document, which we refer to as “high” and “low” cost for simplicity. These high- and low-cost interventions are provided as examples of possible interventions and are both designed to provide quality peer counseling to WIC women. The details of each of these interventions are presented in Chapter Two. In addition, Abt provides a description of key factors that FNS should consider when choosing the peer counseling interventions to implement.

The Evaluation of Peer Counseling Interventions

The goals of the evaluation of peer counselor interventions are to assess (1) how well the interventions have been implemented and (2) their effectiveness in improving breastfeeding outcomes. The Implementation Study recommended in this document describes the process of implementation in each study site, changes in staffing patterns, challenges faced and strategies used to overcome these challenges, evolution of the interventions over time, and intervention costs.

The Impact Study recommended here measures the effects of the interventions on the initiation, duration, and intensity (i.e., exclusivity) and on whether the mother breastfeeds on demand.⁸ The Impact Study also would collect and analyze information on participants’ reasons for not initiating or for terminating breastfeeding.

Key Research Questions

The key research questions to be addressed in the Implementation Study are listed below and discussed in detail in Chapter Five:

1. What are the characteristics of WIC agencies participating in the evaluation? How are they similar to or different from WIC agencies nationally?
2. What are the characteristics of WIC mothers participating in the study (treatment and control groups)? How do they compare with WIC mothers nationally?

⁸ FNS is interested in frequency of breastfeeding as an outcome. Given the variability in infants’ need to suck, the expert panel recommended that we focus on mother’s feeding the infant on demand rather than on the simple count of breastfeeds. This is discussed further in Chapter Seven.

3. What breastfeeding promotion services (other than the peer counseling intervention) are provided by participating agencies?
4. How are the peer counseling interventions implemented at participating WIC agencies (including changes made to the WIC program, peer counselor recruitment and training, and intervention activities and services)?
5. To what extent do WIC mothers in the treatment groups participate in the peer counseling interventions?
6. What are the responses of WIC mothers, WIC staff, and collaborating organization staff to the peer counseling interventions?
7. What are the costs of the peer counseling interventions?
8. What are the prospects for continuing peer counseling at the participating WIC agencies once the study is completed?

The key research questions to be addressed in the Impact Study are listed below and further discussed in Chapter Six:

1. Does each of the two peer counseling interventions (i.e., high and low cost) increase breastfeeding *duration*?
2. Do the interventions increase the *intensity* of breastfeeding?
3. Do the interventions increase breastfeeding *initiation* rates?
4. Do the interventions increase women breastfeeding *on demand*?
5. Does each of the two peer counseling interventions increase the receipt of peer counseling services?
6. Do the interventions affect the receipt of other types of breastfeeding services?
7. Do the interventions increase participants' perceptions of availability of social support for breastfeeding and breastfeeding role models?
8. Do the interventions increase participants' knowledge about breastfeeding?
9. Do the interventions improve breastfeeding techniques and problem solving, as seen in fewer reports of such barriers to breastfeeding as perceived insufficient milk and nipple soreness?

Demonstration Design

As reported above, while previous research has suggested positive breastfeeding outcomes associated with peer counseling, this research has been replete with methodological weaknesses, including studies of peer counseling in the WIC program (McLaughlin et al, 2003). In addition, a recent review by the U.S. Preventive Services Task Force for the Agency for Healthcare Research and Quality (2003) concluded that there was insufficient evidence to recommend for or against peer counseling initiated in a clinical setting. Within this context, Abt and a panel of experts convened for this study, strongly recommend an experimental design with random assignment of individuals for the evaluation of peer counseling interventions. The lack of methodologically sound evidence on peer counseling and the importance of answering unequivocally the research questions on the impact of peer counseling on breastfeeding outcomes for WIC mothers, argue strongly for the experimental design. As described more fully in Chapter Three, Abt recommends a design in which sites are selected from among those that volunteer and study participants within each site are randomly assigned to one of three groups (high-cost peer counseling, low-cost peer counseling, or control).

Data Collection Plan

Recommended data collection for the Impact Study will include a baseline survey of participants during the prenatal period, with follow up at roughly 2, 8, and 26 weeks postpartum to assess breastfeeding outcomes at key points in the postpartum period.

For the Implementation Study, basic program information will be obtained from study sites prior to implementation of the intervention. Additional data will be collected after a three-month start-up period, six months into the implementation of the intervention, and after 12 months of implementation. Site visits will be made at roughly three and 12 months after implementation, with phone interviews completed at the interim six-month time period. During site visits, interviews will be conducted with the key WIC staff (e.g., local WIC agency director, peer counselor coordinator, peer counselors) and relevant hospital staff (e.g., hospital lactation consultant). Focus groups will also be conducted with study participants (separate groups for each of the two Treatment and Control women). Interim phone interviews will be conducted with a more limited set of stakeholders (local WIC Director, peer counseling coordinator, and hospital staff). Cost information will be collected as part of the Implementation Study as well. The cost data will include one-time start-up as well as on-going costs of the interventions, which can be used by policy-makers in decisions about future implementation of peer counseling interventions.

Organization of the Report

The remaining sections of the report provide details on the recommended intervention approach as well as the evaluation design and analysis plan. Chapter Two describes the factors FNS should consider in defining peer counseling interventions for implementation in WIC. Chapter Three describes the recommended experimental design and its rationale. Chapter Four describes the sampling process, including site selection and sample sizes. Chapters Five and Six present the objectives, research questions and analysis plans for the implementation and impact components of the evaluation, respectively. Chapters Seven and Eight address the data collection measures and procedures, and include ways to minimize data collection challenges.

Chapter Two

Factors to Consider in Defining Peer Counseling Interventions for Evaluation

This chapter begins with a discussion of how peer counseling was chosen as the breastfeeding promotion strategy to be evaluated and a summary of findings from peer counseling intervention studies reviewed by Abt. The remainder of the chapter presents key issues for FNS to consider in selecting and defining the peer counseling interventions that would be implemented to assess their effectiveness in increasing breastfeeding outcomes among WIC participants. This discussion incorporates input received from the study's expert consultants and FNS staff.⁹ The discussion also refers to high-cost and low-cost peer counseling approaches developed by Abt as illustrative examples of how key intervention elements may be combined into feasible peer counseling models for evaluation.¹⁰

Selecting the Type of Intervention for Evaluation

A number of steps were used in choosing the peer counseling intervention as the appropriate intervention for testing in WIC sites. First, in Spring 2003, Abt Associates completed a thorough review of the literature on breastfeeding promotion and support research (McLaughlin *et al.*, 2003). Based on the literature review, project staff identified four intervention strategies that should be considered for implementation in WIC. They included interventions associated with prenatal education, postpartum education and support, peer counseling, and the Baby Friendly Hospital Initiative. In addition, based on information from the literature review, two intervention components also warranted discussion: offering incentives for breastfeeding activities and mass media campaigns.

Several factors were considered in choosing the four candidates for discussion. In general, interventions chosen were those that: had some evidence of success based on statistically significant increases in breastfeeding initiation and/or duration, included women similar to those in WIC, appeared feasible for the WIC setting, had potential to be evaluated using an experimental design, and appeared sensitive to cultural differences or were shown effective with different racial or ethnic groups. Of the two separate components or "add-ons," incentive programs were not well researched, but there were some indications of effectiveness among WIC participants. Mass media campaigns have been used by WIC in a number of states in the Loving Support campaign, but have not yet been adequately evaluated.

⁹ As described in Chapter One, a complete list of the study's expert panel members is in Appendix A.

¹⁰ The illustrative high- and low-cost intervention models were judged by the study's expert panel to be feasible for implementation in the WIC program setting. The expert consultants also agreed that there would be sufficient difference in the extent of services (and presumed effectiveness) between the high- and low-cost models to warrant testing them both in the WIC setting. Aspects of the two models have been modified from the original draft, based on comments from the expert consultants.

In May 2003, Abt project staff, FNS evaluation and WIC program staff, and three of the expert consultants met to discuss the candidate interventions. The consultants represented expertise in breastfeeding promotion and support in WIC, extensive research in maternal and child health issues and breastfeeding issues in particular, and research on breastfeeding promotion interventions with low-income and minority groups.¹¹ There was overwhelming support for the peer counseling intervention from all involved in the meeting. In the literature, peer counseling had shown some promise for increasing breastfeeding duration among women in the WIC program, as well as with important minority groups served by WIC (e.g., African-Americans). In addition, peer counseling is an intervention that has proven to be feasible to implement in the WIC setting and is conducive to study using an experimental design. While few studies of peer counseling have used an experimental design, and none of the studies in the WIC program, meeting attendees agreed that peer counseling may be a promising intervention for WIC that is worthy of a test by FNS.

Meeting attendees also agreed that two different peer counseling intervention strategies should be tested, varying in the level of services provided and resource requirements. One would involve providing sufficient peer counseling services that can be expected to bring about positive breastfeeding outcomes within WIC resource constraints (low-cost model). The other strategy would provide additional, enhanced services beyond the low-cost model to test the relative effectiveness of the high- and low-cost interventions.

Review of Peer Counseling Intervention Studies

Peer counselor interventions use community peers to provide breastfeeding education and support to mothers. Peer counselors are women with personal breastfeeding experience who are trained to provide breastfeeding information and supportive counseling, to model breastfeeding techniques, and to identify when medical referrals may be needed. Generally, peer counselors provide education and support starting in the immediate postpartum period, but may have some contact with mothers in the prenatal period, either individually or in group settings.

Among the 19 peer counseling intervention studies reviewed by Abt Associates,¹² ten studies involved a combination of in-person and telephone contacts between peer counselors and breastfeeding mothers, seven studies used only in-person contacts, and one used only telephone contacts. (One study did not report the type of peer counseling method used.) The number of peer counselor contacts mothers had and the duration of the interventions varied widely across interventions and across mothers in a given intervention. No research evidence points to a specific intervention protocol with regard to the type of peer counseling methods used, number of peer counselor contacts, or the duration of the intervention that is clearly associated with significant breastfeeding effects.

¹¹ The three expert consultants were: Holly Szcodronski, R.D., L.D., WIC Breastfeeding Promotion Coordinator for the Iowa WIC Program and Breastfeeding Coordinator for the National WIC Association, Dr. Kathleen Rasmussen, Professor in the Division of Nutritional Sciences at Cornell University, and Dr. Rafael Perez-Escamilla, Professor in the Department of Nutritional Sciences, University of Connecticut.

¹² The citations for these studies are listed in Appendix C. Research findings from these studies are discussed in Abt's breastfeeding promotion literature review (McLaughlin *et al.*, 2003).

The content of peer counseling depends largely on the timing of counseling. In prenatal contacts, peer counselors may explain to expectant mothers the benefits of breastfeeding and the general process and experience of breastfeeding. Postpartum visits focus on teaching specific breastfeeding techniques, providing individualized help with breastfeeding, and encouraging mothers to continue breastfeeding. Postpartum support is typically more individualized than prenatal counseling.

Research Base for Peer Counseling Effectiveness

The research evidence is mixed regarding the effectiveness of peer counseling as a method for promoting breastfeeding. Peer counseling interventions focus on increasing the initiation and duration of breastfeeding among mothers *who intend to breastfeed*. Women's intention to breastfeed, rather than bottle feed, is an important factor contributing to their breastfeeding outcomes, and 12 of the 19 peer counseling studies reviewed by Abt held this factor constant across comparison groups. Of these, nine studies reported significant positive effects on breastfeeding initiation and duration over various periods of time. Among four studies that used a random assignment design, three studies found significant increases in breastfeeding duration at 3 and 6 months; one found no difference in either initiation or duration. Eleven peer counseling studies involved WIC participants, although none of them was based on an experimental, random-assignment design. Of these, eight studies reported significant effects on breastfeeding outcomes.

The Oregon Health and Science University's Evidence-based Practice Center conducted a systematic meta-analysis of 22 breastfeeding intervention studies for the Agency for Healthcare Research and Quality and the U.S. Preventive Services Task Force (2003). All studies included in this meta-analysis: 1) used randomized controlled trials design; 2) were conducted in developed countries; and 3) involved breastfeeding promotion counseling or behavioral intervention which originated from a health care setting, conducted by various service providers including physicians, nurses, lactation consultants, and peer counselors.

The meta-analysis produced the following key findings (U.S. Preventive Services Task Force, 2003):

1. There is "fair evidence that programs combining breastfeeding education with behaviorally-oriented counseling are associated with increased rates of breastfeeding initiation and its continuation for up to 3 months";
2. There is "fair evidence that providing ongoing support for patients, through in-person visits or telephone contacts with providers or counselors, increased the proportion of women continuing breastfeeding for up to 6 months"; and
3. There is "insufficient evidence for or against... peer counseling used alone and initiated in the clinical setting ..."

The Task Force report underscores the need for additional research regarding the effectiveness of peer counseling as a breastfeeding promotion strategy.

Peer Counseling Implementation in WIC

The use of peer counselors appears to be fairly common in WIC programs, although the extent of use varies depending on the sources and time of information reported. According to information collected by FNS as of November 2002, some WIC agencies in most states were using peer

counseling as a breastfeeding promotion strategy, and seven states indicated that they supported a statewide WIC peer counseling program. More recently, in 2003 the WIC Supplemental Food Program in the California Department of Health Services conducted the Survey of WIC Program Breastfeeding Promotion Activities and collected data from 48 state WIC offices (Ell, 2003). In this survey, 36 states reported that at least some local agencies in their states use peer counselors for breastfeeding support, and one-half of the 48 responding states indicated that the state WIC program provides funding for peer counseling in local WIC agencies.

While the use of peer counselors to promote breastfeeding among WIC participants appears to be gaining support, the availability of research-based information regarding effective peer counseling intervention is limited. The studies reviewed by Abt highlighted the following factors that are thought to contribute to breastfeeding outcomes of peer counseling:

- Training peer counselors on both specific information related to breastfeeding and counseling skills. Peer counselor-training programs described in the studies reviewed ranged widely from 2.5 hours to 40+ hours, but typically lasted 20-25 hours.
- Assigning peer counselors to work with mothers one-on-one to facilitate building of a working relationship between the counselor and mother, rather than alternating between counselor-pairs or rotating counselors.
- Matching peer counselors and mothers as much as possible on socioeconomic and cultural backgrounds to facilitate the counseling process because attitudes towards breastfeeding vary across socio-cultural groups.
- Peer counselors providing support for mothers either in the hospital or as a follow-up to support services provided by professional staff in the early postpartum period, given the importance of the early postpartum period for promoting the use of breastfeeding.
- Peer counselors working with breastfeeding mother's key family members who are likely to provide support to the mother, particularly the maternal grandmother.
- Peer counselors using educational materials that are appropriately matched to the language, cultural backgrounds, and educational backgrounds of the breastfeeding mothers.
- Peer counselors providing guidance to mothers on how to continue breastfeeding when the mother returns to either school or work.
- Providing peer counselors access to a lactation expert to answer their questions as well as to supervise them throughout the intervention. In one of the studies reviewed, this strategy was reported to have contributed to the effectiveness of the peer counselor intervention.
- Paying peer counselors for their work to ensure their keeping regular contact with participating mothers. If peer counselors are matched demographically to the low-income, WIC mothers, the peer counselors are not likely to be able to volunteer their time.
- Training WIC staff on the rationale and process of the intervention to ensure their support for the intervention.

The following section discusses in greater detail these and additional issues that should be considered when FNS develops the peer counseling interventions to be implemented and evaluated in WIC.

Design of Peer Counseling Intervention to Be Evaluated

FNS specified three fundamental objectives that should guide the development of breastfeeding intervention models and evaluation designs to assess the effectiveness of these approaches:

- To identify and implement breastfeeding promotion intervention that can significantly increase the duration as well as initiation, intensity, and frequency of breastfeeding among WIC mothers;
- To design an evaluation that can provide conclusive, valid evidence for the effectiveness of the breastfeeding promotion method tested; and
- To determine the level of breastfeeding promotion services that can affect a measurable impact within a reasonable resource requirement.

To meet these objectives, Abt recommends that the evaluation: 1) employ a randomized treatment-control design that will allow attributing the study outcomes to the breastfeeding promotion intervention; and 2) examine at least two levels of the intervention to determine the minimal service and cost needed to effect a measurable outcome. The general evaluation design would involve comparisons among at least three study groups:

- A) A treatment group of WIC participants receiving high-cost peer counseling;
- B) A treatment group of WIC participants receiving low-cost peer counseling; and
- C) A control group of WIC participants receiving no peer counseling.

In the earlier draft of this document, Abt presented two peer counseling intervention models: a high-cost model that would involve starting peer counseling activities in the prenatal period and continuing them through six months postpartum, and a low-cost model that would provide only postpartum peer counseling through six weeks after delivery. In developing these models, we grouped various aspects of peer counseling interventions into factors that are:

1. Standardized across all study groups (treatment and control);
2. Standardized across the high- and low-cost treatment groups, but not applicable to the control group; and
3. Varied between the high- and low-cost peer counseling groups (but not applicable to the control group).¹³

¹³ The term “study groups” refers to groups of WIC participants who are randomly assigned to receive different peer counseling interventions (or no peer counseling), assuming that the evaluation is based on within-site random assignment of participants. However, the factors of intervention discussed in this chapter would also need to be considered under an alternative design that uses random assignment of sites to treatment and control groups.

In defining the contents of peer counseling interventions to be evaluated, it may be also useful for FNS to use this three-tier framework. In the next section, we discuss specific factors that may be considered in FNS intervention models, using the two models Abt developed earlier as illustrative examples. In Abt's illustrative models, the following factors would be standardized across all study groups:

- Definition of eligible study participants;
- Prenatal education provided to pregnant women; and
- Access to existing postpartum breastfeeding support services provided by participating WIC agencies (other than peer counseling).

The factors standardized across the high- and low-cost treatment groups would be:

- Peer counselor recruitment procedure, qualifications, training, and assignment to WIC participants;
- General content of peer counseling services and materials used by peer counselors in working with study participants; and
- Peer counselor pay.

The factors that would be varied between the high- and low-cost treatment groups would be:

- Whether peer counselors work with family members and spouse/partners of WIC participants;
- Timing of peer counseling initiation; frequency, duration, and delivery mode of peer counseling services;
- Provision of group counseling sessions to study participants; and
- Extent of peer counselor monitoring and supervision.

The specific details of Abt's illustrative intervention models are based on information gleaned from the literature review and discussions with several WIC directors, FNS staff, and the study's expert consultants. While the illustrative models may differ from the interventions FNS selects to evaluate, they are presented below to facilitate the discussion of factors that FNS will need to consider in finalizing the intervention design.

Factors to Be Standardized Across All Study Groups

Aside from the factors related to peer counseling that will be systematically varied and compared, all other factors or elements of the intervention should be held constant as much as possible across all study groups of participants. This is critical for minimizing unmeasured sources of error in the intervention impact assessment. Only then will an evaluation be able to address the effect of peer counseling alone (independent of other services or policies) on breastfeeding outcomes. In Abt's illustrative intervention models, the following three factors would be applied to all study participants in the treatment and control groups.

Definition of Eligible Study Participants

A decision needs to be made as to whether to include in the study all women who enroll in local WIC agencies or to screen women for breastfeeding intention and include only those who intend to breastfeed. Abt's illustrative intervention model would apply the following eligibility criteria:

- Intending to breastfeed or undecided regarding infant feeding method about six weeks before delivery; and
- Absence of contraindications for breastfeeding about six weeks before delivery.

The goal of WIC breastfeeding promotion is to increase the breastfeeding rates for all WIC participants. Thus, there should be minimal exclusion rules for study participants. For example, women would be included regardless of previous breastfeeding experience, and whether they are first-time mothers or have had children previously.

However, FNS may consider excluding mothers who are definitely planning to bottle feed their infants, if the peer counseling intervention will consist mainly of postpartum education and support for breastfeeding, and would not be assumed to be applicable to mothers who begin exclusive bottle-feeding immediately after child birth. Research shows that about 95 percent of women who say early in pregnancy that they definitely plan to bottle-feed usually do bottle feed (Dr. Kathleen Rasmussen, personal communication, 2003). Unless the primary focus of the intervention is to increase breastfeeding initiation, inclusion of women who definitely plan to bottle feed would greatly increase the study sample size and cost beyond what is necessary. (Issues related to study sample size are discussed in Chapter Four.)

Another evaluation issue is when, in the course of WIC participants' pregnancy, their infant-feeding intention should be assessed. Women enroll in WIC at varying times during their pregnancy. According to the WIC Participant and Program Characteristics Study (Bartlett *et al.*, 2002) nearly 50 percent enroll in WIC during their first trimester, close to 40 percent enroll during their second trimester, and slightly over 10 percent enroll during their third trimester. Nevertheless, all WIC participants must come in to the WIC agency at the time of their enrollment. Intention regarding breastfeeding could be initially assessed by WIC staff at this time.

A related issue, if a within-site random assignment design is used, is the timing of random assignment relative to WIC enrollment. If FNS chooses peer counseling interventions that begin when women enroll in WIC, then the women could be randomly assigned to study groups at enrollment. However, if the interventions start later in pregnancy, WIC staff may contact the women who intended to breastfeed or were undecided at enrollment and update their infant feeding intentions. Those who still do not definitely intend to bottle feed could be randomly assigned to the treatment or control group at this point. WIC staff or evaluation staff could also contact a sample of women who initially said they did *not* intend to breastfeed and include in the study those who have changed their mind and decided to breastfeed.

FNS staff and the study's expert consultants agree that only a few contraindications exist for breastfeeding. They include: HIV virus infection, substance dependency, untreated tuberculosis, and radiation and/or chemotherapy for cancer. Rather than systematically asking each potential study participants whether any of these conditions apply to her, it is recommended that potential participants be told about these contraindications for breastfeeding in their prenatal education. Then,

when they are asked about their infant-feeding intentions, women with these conditions are likely to indicate that they plan to bottle feed and/or simply decline to participate in the study.

Some of the women who pass the breastfeeding intention screen may experience high-risk birth or have an infant with problems that make it difficult for the mother to breastfeed (e.g., severe congenital anomalies). Although these cases may not be optimal for testing the breastfeeding intervention, they need not be dropped from the evaluation. The expectation would be that this type of cases will be randomly distributed among the treatment and control groups.

Content of Prenatal Breastfeeding Education and Support

This evaluation will focus on testing the effectiveness of peer counseling. In order to minimize confounding effects of other breastfeeding promotion services, FNS plans to develop a standard protocol for prenatal breastfeeding education and support services that all WIC agencies participating in the evaluation will be required to implement.

The protocol will define:

- The content and type of prenatal breastfeeding promotion services (e.g., individual counseling, group discussion sessions, distribution of printed materials);
- The point of time during pregnancy when the prenatal breastfeeding promotion service is provided to participants (e.g., at enrollment, during the last trimester); and
- The frequency and extent of these services.

Existing Postpartum Breastfeeding Support Services Offered by Participating WIC Agencies

Some of the WIC agencies participating in the evaluation may be offering various forms of breastfeeding education and support services to postpartum women, independent of the peer counseling intervention. If individuals are randomly assigned within sites, then participants in all study groups can receive these pre-existing services, and the study would test the *incremental* effect of the breastfeeding promotion intervention in sites with a particular basic level of services. Because the within-site randomization design is likely to involve a small number of sites, the potential problem of extreme variations in existing breastfeeding support services among the study sites should be addressed in site selection. If instead, the evaluation is based on site-level randomization with a large number of sites, the control group sites will represent the natural distribution of pre-existing services, and the treatment group sites will represent that same natural distribution with the intervention added on.

Regardless of the evaluation design, the existing breastfeeding support services offered in study sites should be carefully documented in the Implementation Study. This information will be important for the descriptive analyses of the Implementation Study and useful in understanding the impact estimates, including the possible absence of significant differences between the treatment and control groups.

Factors Applicable to High- and Low-cost Intervention Groups (but Not the Control Group)

A peer counseling intervention involves many issues and factors, each of which could be implemented in various ways. The evaluation will need to identify a set of critical factors related to peer counseling whose effects are to be tested systematically. If too many factors are varied across

participant groups, it will be difficult to identify which of the factors are responsible for the study outcomes.

The assumption is that there will be two levels of peer counseling intervention: high-cost and low-cost peer counseling. Many factors related to the peer counseling intervention would need to be held constant across the two levels of intervention. (They will not be applicable to the control group which will be precluded from receiving any peer counseling services.) The factors related to peer counseling that would be held constant in Abt's illustrative intervention models are described below.

Peer Counselor Recruitment Procedure

The peer counseling intervention studies that Abt reviewed indicated that various methods are used to recruit breastfeeding peer counselors, but the most common method is word of mouth. WIC agencies may use more than one method, including newspaper and other forms of advertisement. However, contacting former WIC participants and word of mouth are likely to be the prevalent recruitment methods.

Peer Counselor Qualifications

The studies reviewed reported the importance of matching the demographic and background experiences of peer counselors and the service recipients. The following peer counselor qualifications may be specified as minimum requirements for both high- and low-cost intervention models:

- Having current or at least six months of exclusive breastfeeding experience;
- Being a strong advocate of breastfeeding and the national breastfeeding goals (e.g., *Healthy People 2010*);
- Living in the same community or geographical area (in the case of rural areas) as the service recipients;
- Having current or previous WIC participation experience or living in a low-income household;
- Belonging to a racial/ethnic group represented among the service recipients; and
- Ability to read and write at the 10th grade skill level in order to perform peer counseling administrative tasks satisfactorily.

Peer Counselor Training

The review of peer counseling studies and breastfeeding promotion materials used in some local and state WIC agencies suggest that the quality and intensity of peer counseling training vary greatly, and this factor could have a significant effect on peer counseling outcomes. To conduct a valid test of peer counseling, we need to ensure that the peer counseling provided to WIC mothers is of sufficient quality. Thus, we recommend using the same training method/curriculum for the high- and low-cost interventions.

In addition to thorough teaching of knowledge and techniques related to breastfeeding peer counseling, the training should also include:

- Clear guidelines regarding boundaries of what peer counselors should and should not do;
- How to end the counseling relationship with WIC participants at the conclusion of peer counseling services; and

- Procedures used to protect study participants' privacy and confidentiality.

Comprehensive breastfeeding peer counselor training curricula are available (e.g., the La Leche League curriculum, Texas WIC Peer Counseling Program). Further, as described in Chapter One, FNS is currently supporting a project to develop a breastfeeding peer counselor training curriculum for WIC programs. Depending on the timing of this evaluation, this training curriculum may be a viable candidate as the standard peer counselor training method for use by all study sites. We recommend using a comprehensive curriculum that contains organized lesson plans and materials for a training lasting 20-25 hours. Once such a curriculum is chosen, the peer counselor training activities and materials would be consistent across high- and low-cost intervention groups.

To ensure consistent quality of peer counselor training, FNS may consider requiring participating WIC agencies to use an International Board Certified Lactation Consultant (IBCLC) to conduct the training. The well-structured, comprehensive peer counselor training curriculum needs to be taught by a professional with sufficient expertise relevant to the content and objectives of the curriculum. Abt's illustrative intervention models also provide for bi-weekly group sessions of peer counselors conducted by the local WIC director or the peer counselor supervisor to maintain the counselors' technical expertise and job commitment throughout the evaluation period.

It is possible for participating WIC agencies to experience peer counselor turnover, especially in the early months of the intervention. Some counselors may find their workload to be too burdensome, may experience personal or family problems that interfere with this work, or may decide to quit this position for any number of other reasons. In such cases, additional peer counselors would need to be recruited and trained, following the standard training procedure. FNS and the sites chosen for implementing the interventions should plan for this additional training.

Peer Counselor Assignment to Service Recipients

In one peer counseling intervention reviewed (McInnes, Love, & Stone, 2000), a pair of peer counselors was assigned to each service recipient so that the counselors could alternate between contacts.¹⁴ However, all other studies reviewed assigned one counselor to each mother to encourage the development of a trusting, supportive relationship. In Abt's illustrative intervention model, each WIC participant in both the high- and the low-cost interventions would be assigned one peer counselor. In addition, with the three-way randomization design, Abt recommends that serious consideration be given to randomly assigning individual peer counselors to either the high-cost or the low-cost intervention group to avoid local WIC agencies from assigning the "best" peer counselors to one group or the other.

Content of Peer Counseling Intervention Services

Peer counselors need to be trained to provide a wide range of information, assistance, and support. The content of their services could include:

1. Information about the benefits of breastfeeding, breastfeeding techniques, contraindications, common problems experienced by breastfeeding mothers, practical solutions for these problems, sources of additional information about breastfeeding, and sources of additional professional assistance;

¹⁴ This study found no significant impact of peer counseling on breastfeeding outcomes.

2. Modeling proper breastfeeding techniques and providing hands-on coaching in breastfeeding;
3. Making referrals to appropriate sources of additional professional assistance (e.g., medical services, social services); and
4. Providing encouragement and emotional support.

Once peer counselors are provided with appropriate materials (e.g., printed materials, video tapes, list of referral sources), education, and training in effective modeling and communication methods, they will be expected to apply these tools to accommodate varied needs of individual mothers. Each individual peer counseling session is likely to be unique in the content of activities. However, the standard peer counselor training should equip all peer counselors with the same basic set of materials and skills to apply to individual breastfeeding mothers as appropriate.

Materials Used in Peer Counseling

Designing a peer counseling intervention also requires specifying educational and counseling support materials. In Abt's illustrative intervention models, peer counselors in high- and low-cost intervention groups would be provided with the same set of materials including:

1. Printed materials and video tapes that promote breastfeeding (e.g., those developed by La Leche League, or FNS' *Loving Support* efforts);
2. Breastfeeding needs assessment instruments;
3. Practice dolls;
4. Breast pumps; and
5. Peer Counselor Activity Log form to keep a record of peer counseling contacts, dates, and status for each mother receiving peer counseling.

The selection of printed materials and videotapes should take into account cultural sensitivity and appropriateness for the participants receiving peer counseling.

Peer Counselor Pay

Information regarding peer counselor pay is scarce in published accounts of breastfeeding peer counseling, although discussions with WIC programs directors and the study's expert consultants strongly indicate that peer counselors should be paid. Based on some of the intervention studies reviewed and information obtained from several state and local WIC agencies, the current, common practice for WIC agencies is to hire peer counselors as part-time employees. The pay rate may vary from that of entry-level clerical staff to entry-level para-professional staff. The level of pay and availability of benefits could affect peer counselor job commitment and productivity. In Abt's illustrative intervention models, these factors would be standardized across the high- and low-cost treatment groups as indicated below to control for potential influence of peer counselor pay on their work effectiveness:

1. Paying peer counselors the hourly salary rate of entry-level clerical or paraprofessional staff in each local WIC agency participating in the study; and
2. Assigning 20 hours per week work time to each peer counselor.

FNS may consider a higher salary, more weekly work hours, or more flexible work hours. FNS may also consider varying the peer counselor compensation levels between the high- and low-cost

intervention models, if peer counselor pay is considered to be a key element that differentiates cost-effectiveness of the high- vs. low-cost interventions.

Factors To Vary Between High- and Low-cost Treatment Groups

FNS will need to identify critical factors or elements of peer counseling that will be varied systematically in the high- and low-cost interventions. The combined effects of these factors will then be assessed against participants' breastfeeding outcomes and provide information regarding cost-effectiveness of interventions in reference to available resources.

In Abt's illustrative intervention models, the following factors would be varied systematically to constitute the high- and low-cost peer counseling intervention strategies:

1. Recipient of peer counseling services;
2. Timing of peer counseling initiation (prenatal vs. in-hospital);
3. Location of peer counseling services;
4. Frequency of peer counseling services;
5. Accessibility of peer counselors by participants;
6. Duration of peer counseling services after hospital discharge;
7. Provision of participant support group sessions; and
8. Peer counselor monitoring/supervision.

The potential relevance of each of these factors to breastfeeding outcomes and the possible levels of these factors for the high- and low-cost treatment groups, based on information gleaned from the literature review and discussions with the expert consultants, are discussed below.

Recipient of Peer Counseling Services

Peer counseling intervention reports indicate the value of including breastfeeding mothers' spouses, partners, and other family members in breastfeeding promotion and support activities. Lack of support for breastfeeding from significant family members is one of the obstacles for successful breastfeeding. Providing information and support to family members is intended to enhance intervention effectiveness.

In Abt's intervention models, the WIC mother, her spouse or partner, and other significant family members (e.g., maternal grandmother) would be included in the **high-cost** peer counseling activities. In the **low-cost** intervention, only the WIC mother would receive peer counseling services.

Timing of Peer Counseling Initiation, Location, Frequency, and Accessibility of Peer Counseling Services

The assumption regarding this factor is that more frequent peer counseling contact, especially in the early weeks of infant feeding experience, will lead to greater breastfeeding outcomes, especially breastfeeding duration. In Abt's illustrative intervention models, peer counseling services for each study participant in the **high-cost** intervention would consist of:

- One individual prenatal counseling at the WIC clinic within one month of the expected due date;
- One post-delivery, individual counseling in the hospital before discharge;

- One home visit, individual counseling at the WIC clinic (with the infant), or a phone contact in the first 2-3 days after hospital discharge;
- Four home visits and/or individual counseling sessions at the WIC clinic, at 1 week, 2 weeks, 4 weeks, and 6 weeks post discharge;
- Monthly phone calls from 2nd through 6th month;
- Monthly postpartum participant group counseling sessions; and
- Each participant having access to her assigned peer counselor by phone, five days a week, during the regular WIC office hours (e.g., 9 a.m. to 5 p.m.), as well as access to a general breastfeeding help line, through six months post discharge. The help line could be staffed by rotating peer counselors, peer counselor supervisor, and/or WIC staff during the regular work hours and by tape recording messages during the non-office hours.

In Abt's **low-cost** intervention, peer counselors would provide each study participant:

- No prenatal counseling;
- One post-delivery, individual counseling in the hospital before discharge;
- One home visit, individual counseling at the WIC clinic (with the infant), or a phone contact in the first 2-3 days after hospital discharge;
- Phone calls at: 2 weeks, 4 weeks, and 6 weeks; and
- Access to a breastfeeding help line as described above.

The study's expert consultants identified additional issues for FNS to consider in choosing peer counseling interventions for evaluation. These include:

1. Feasibility of peer counselors making in-hospital visits before mothers are discharged. Initiating breastfeeding successfully in the first few days after delivery can be difficult for many women, and peer counselors who have already established rapport with the women can be an important source of support. However, implementing in-hospital visits may be challenging due to: a) typically short period of hospital stay for most women; b) reluctance of hospital staff to allow external service providers to work with their patients; and c) hospitals' concerns regarding the HIPAA requirements. The expert consultants recommend that WIC agencies participating in the study be advised to establish an official agreement with area hospitals as part of the study implementation task. The agreement would clearly indicate the purpose of the intervention and evaluation, the activities to be performed by peer counselors, and any approval/clearance to be required by the hospital. The peer counselor training should include discussions about the contents of this agreement and the importance of professional conduct in making the hospital visits.
2. Provision of access to peer counselors by study participants outside of regularly scheduled contact time. The general consensus of the expert consultants was that peer counselors cannot be "on-call" to provide emergency assistance at all times. The extent of "on-call" time needs to take into account their assigned workload and time requirements for other activities (e.g., their own child care, family management, other employment). However, there are additional ways to provide assistance to breastfeeding mothers such as providing a 24/7 help line where mothers can leave messages for their peer counselor and peer counselor supervisor, or assigning peer counselors to take turns

to be “on-call” during the off-business hours. Regardless of the methods used, if peer counselors are assigned the “on-call” duty that involves work hours beyond the regular hours, they should be paid for such “on-call” work they perform.

3. Telephone and transportation costs of peer counselors. The peer counseling intervention design needs to budget for the telephone costs (e.g., purchase of cell phones and usage costs) and transportation costs for making hospital and home visits.

Duration of Postpartum Peer Counseling Services

The duration of postpartum peer counseling in the studies reviewed ranged widely from six weeks to six months, a typical duration being three months. In Abt’s illustrative **high-cost** intervention, peer counseling would continue through the sixth month after delivery, driven primarily by FNS’ focus on breastfeeding duration. WIC mothers currently lag behind the Healthy People 2010 goal for 50 percent of mothers to be breastfeeding at six months. In Abt’s **low-cost** intervention, peer counseling would end at six weeks after the delivery.

Postpartum Participant Group Counseling Sessions

Group counseling sessions of breastfeeding mothers is another method of providing social support as well as opportunity to conduct additional breastfeeding education and coaching. In Abt’s **high-cost** intervention model, all participants would be encouraged to attend a group counseling session, held at the WIC clinic and led by a peer counselor(s) and peer counselor supervisor, on a monthly basis through six months after delivery. The group sessions would be scheduled to alternate biweekly with the monthly individual peer counseling. In Abt’s **low-cost** intervention, no group counseling sessions would be provided. The expert consultants warned that it may be difficult to convene a group of breastfeeding mothers to attend a group session at the same time and suggested that such sessions may be scheduled on the same day as WIC voucher pick-up.

Peer Counselor Monitoring and Supervision

Close monitoring and supervision of peer counselors, both in the high- and low-cost groups, will be essential in order to: 1) maintain the fidelity of the two intervention models, and 2) provide technical support and assistance for peer counselors to conduct their work. In Abt’s illustrative **high-cost** and **low-cost** interventions, peer counselors would complete and submit a weekly Peer Counselor Activity Log report (a check-off list and brief narrative text) to the peer counselor supervisor to describe the peer counseling activities conducted during the week.

In addition, the **high-cost** intervention would also assign a board-certified lactation consultant to provide clinical supervision and assistance to peer counselors. The lactation consultant would also assist breastfeeding mothers in areas that go beyond the peer counselors’ responsibilities or expertise (e.g., conducting baby oral assessment and mothers’ breast assessment, interfacing with physicians and other medical service providers if mothers develop illness or physical problems affecting breastfeeding).

While the provision of clinical supervision by International Board-Certified Lactation Consultant (IBCLC) has been recommended by some expert consultants, California’s Survey of WIC state offices suggests that access to IBCLC may be fairly limited for many local WIC agencies. The survey reported that, in 65 percent of states, less than 20 percent of WIC clinics have at least one

IBCLC on staff. FNS may therefore wish to broaden the required credentials of peer counselor supervisors to include other relevant professionals such as Certified Lactation Consultant, Certified Lactation Counselor, and/or Certified Breastfeeding Educator.

Peer Counselor Caseload

The peer counselor caseload is likely to vary between the high- and low-cost intervention models, due to the different amounts of services to be provided to each participant in the two treatment conditions. Because it is reasonable to assume that caseload size may affect a peer counselor’s work effectiveness, it would be ideal to specify the caseload for the high- and low-cost interventions. However, a “reasonable” caseload may depend upon a number of other factors such as: urban *versus* rural program setting (longer distances to cover for home visits in rural areas); the number of hours per week a peer counselor works; cultural and demographic characteristics of participants that may affect the amount of time peer counselors spend with each participant; and the mix of new vs. experienced breastfeeding mothers.

At a minimum, for the purpose of the evaluation, each peer counselor should be assigned no more participants than she can serve comfortably, given her agency setting, work hours, and specified number of contacts with each assigned participant.¹⁵ The success of the demonstration depends on ensuring that peer counselors in both intervention groups have sufficient time to provide the specified level of services to their assigned cases.

Exhibit 2.1 summarizes all factors that are incorporated into Abt’s illustrative intervention models and that FNS may consider in defining the interventions to be evaluated. The exhibit indicates the content or levels for each factor (based on our literature review and input from the expert consultants, FNS staff, and WIC directors), as well as the study groups to which each factor and specifications would apply in Abt’s illustrative intervention model.

Exhibit 2.1	
Standardized and Variable Factors for WIC Breastfeeding Promotion Interventions	
Standard Factors Applicable to:	
All Study Groups (Treatment and Control Groups)	
Factor	Example from Abt’s Illustrative Intervention Models

¹⁵ There is little information about peer counselor caseload in the published intervention studies. A few suggestions were provided by the expert consultants, based on professional experience and opinions, as follows: caseload of 8-10 women in high-cost intervention and 12-15 women in low-cost intervention; 10 women per peer counselor for routine education and support services, no more than 50 percent of them being postpartum mothers; and two women per peer counselor for intensive problem management. Making the judgment regarding the “reasonable” caseload for each study site may be assigned as a task for the peer counselor supervisor. The assigned caseload for each study site should be documented at every data collection point in the Implementation Study, so that its reasonableness can be systematically assessed.

Exhibit 2.1**Standardized and Variable Factors for WIC Breastfeeding Promotion Interventions**

Definition of eligible study participants	<ul style="list-style-type: none">▪ Include pregnant WIC recipients who intend to breastfeed (BF) or are undecided about BF, assessed about six weeks before expected date of delivery (EDD)▪ Include primiparous and multiparous women▪ Include mothers with or without previous breastfeeding experience▪ Exclude mothers with BF contraindications (e.g., AIDS, drug dependency, radiation/chemotherapy)
Prenatal education and support (other than peer counseling)	This will be the standard prenatal intervention protocol to be defined by FNS and will be consistent across all study groups in terms of: <ul style="list-style-type: none">▪ Content/type of service▪ Timing during the prenatal period▪ Frequency of exposure/contact
Postpartum breastfeeding support services other than peer counseling	Any breastfeeding education and support services offered by participating WIC agencies independent of the peer counseling intervention being tested will not be standardized across agencies but will be equally accessible to treatment and control group participants.

**Standard Factors Applicable to: High- and Low-cost Intervention Groups
(Not the Control Group)**

Factor	Example from Abt's Illustrative Intervention Models
Peer counselor recruitment procedure	Participating WIC agencies will be encouraged to use various methods of recruitment including: <ul style="list-style-type: none">▪ Contacting former WIC participants▪ Newspaper advertisement▪ Word of mouth
Peer counselor qualifications	<ul style="list-style-type: none">▪ Current or at least six months of exclusive BF experience▪ Local resident▪ Former WIC participant or women from low-income backgrounds▪ Race/ethnicity to match the WIC study participants▪ An advocate of breastfeeding▪ 10th grade level reading/writing skills
Peer counselor training content, curriculum	Based on a search and review of relevant peer counselor training materials, candidate curricula are: <ul style="list-style-type: none">▪ La Leche League curriculum▪ Texas WIC Peer Counseling Program (based on La Leche League curriculum)
Peer counselor training activities	A comprehensive peer counselor training curriculum selected for this intervention will specify training activities, including: <ul style="list-style-type: none">▪ Group discussions▪ Lectures▪ Role-playing▪ Supervised practice▪ Written tests
Peer counselor trainer	Participating WIC agency will designate an International Board Certified Lactation Consultant (IBCLC) to conduct the peer counselor training
Peer counselor assignment	One peer counselor assigned to each study participant

Exhibit 2.1**Standardized and Variable Factors for WIC Breastfeeding Promotion Interventions**

Content of peer counseling intervention services	Types of services for WIC programs to implement will include: <ul style="list-style-type: none">▪ Providing information on benefits of BF and BF techniques▪ Explaining potential problems in BF and solutions▪ Providing referrals to appropriate professional assistance, as needed▪ Providing encouragement and support▪ Modeling
Materials to be used by peer counselors	Materials that WIC programs may choose to use include: <ul style="list-style-type: none">▪ La Leche League materials▪ Other existing BF promotion materials▪ Needs assessment instruments▪ Culturally sensitive materials▪ Practice dolls▪ BF counseling videos
Peer counselor pay	<ul style="list-style-type: none">▪ Equivalent to pay scale for entry-level clerical or para-professional WIC agency staff

**Factors to Vary Between High- and Low-cost Intervention Groups
(Not Applicable to the Control Group)**

Factors to Vary	Abt's High-cost Intervention	Abt's Low-cost Intervention
Recipient of peer counseling services	<ul style="list-style-type: none">▪ WIC mother▪ Partner▪ Other family members	<ul style="list-style-type: none">▪ WIC mother
Timing and venue of peer counseling		
Prior to hospital admission	<ul style="list-style-type: none">▪ One individual meeting at WIC clinic within 6 weeks before the due date	<ul style="list-style-type: none">▪ None
In-hospital	<ul style="list-style-type: none">▪ One post-delivery visit	<ul style="list-style-type: none">▪ One post-delivery visit
Postpartum	<ul style="list-style-type: none">▪ One home visit or individual counseling at WIC clinic in the first 2-3 days after discharge▪ Home visit or individual meeting at WIC clinic at: 1, 2, 4, and 6 weeks post discharge▪ Monthly phone call from 2nd through 6th month▪ Counselors on-call by phone, Monday-Friday, 9 am-5 pm, and general breastfeeding help line through 6th month	<ul style="list-style-type: none">▪ One home visit or individual counseling at WIC clinic in the first 2-3 days after discharge▪ Phone call at: 2, 4, and 6 weeks post discharge▪ General breastfeeding help line, through 6th week
Duration of postpartum peer counseling	<ul style="list-style-type: none">▪ Through month six	<ul style="list-style-type: none">▪ Through six weeks
Participant group counseling sessions at WIC program site	<ul style="list-style-type: none">▪ Once a month after discharge from hospital, for 6 months (alternating biweekly with the monthly individual counseling)	<ul style="list-style-type: none">▪ None
Peer counselor monitoring/supervision	<ul style="list-style-type: none">▪ Weekly report (check-off list and brief narrative text)▪ Clinical supervision of peer counselors by a IBCLC	<ul style="list-style-type: none">▪ Weekly report (check-off list and brief narrative text)

Intervention Start-up Period

Both of the interventions discussed here would require each participating WIC agency to undertake substantial new tasks in order to begin offering the peer counseling services. The tasks include: recruitment, selection, and training of peer counselors; modifying job tasks for existing WIC staff and training them on the peer counseling interventions and evaluation procedures; and making new arrangements with hospitals and other collaborating agencies, if any, that will be involved in the peer counseling intervention. The start-up period will also need to be used for newly trained peer counselors to receive guided practice and job shadowing from a peer counselor trainer or supervisor.

Establishing an official agreement with local hospitals would be essential for allowing peer counselors to conduct in-hospital counseling visits. The agreement would need to clearly describe the intended activities of peer counselors in the hospital setting, protocol for coordinating with hospital staff, and procedures to comply with hospital policies. The agreement would also need to address any review and approval of the study by hospital officials and assurance of study's conformance with the HIPAA requirements.

Experienced WIC directors have indicated that the intervention start-up phase could be completed in three months, but some expert consultants feel that a longer period (e.g., up to six months) may be needed for preparation. A suggestion has been made that FNS consider establishing minimum criteria for peer counseling implementation readiness (Dr. Kathleen Rasmussen, personal communication, 2003). The criteria would include such things as: having hired a peer counselor supervisor, trained a sufficient number of peer counselors, established peer counselor management process, provided each peer counselor with practice experience for a set number of hours or participants shadowing the peer counselor supervisor, trained WIC staff, and established a relationship with the local hospitals. Rather than specifying a fixed start-up period, the minimum-readiness criteria approach would allow each sampled site to initiate the evaluation activities at a relatively consistent baseline. The enrollment and random assignment of study participants would begin after the intervention start-up tasks are completed.

Keeping a Stable Peer Counselor Caseload

After peer counselors complete the training and the initial practice, there could be a period of up to several months (the remaining project start-up period and the early months of assigning study participants to treatment or control groups) before their caseload of study participants reaches full capacity. It would be desirable during this period to provide peer counselors with additional work practice, a stable workload, and pay. Once the peer counselors have completed their initial practice, one strategy would be to assign them a full caseload of breastfeeding WIC mothers who have delivered their babies before the peer counseling interventions are fully implemented. Because these mothers would have enrolled in WIC before the study's random assignment began, they would not be eligible for the study. Under close guidance of their supervisors, peer counselors would conduct all counseling activities specified in the assigned intervention condition (e.g., making home visits, phone contacts, and conducting group counseling sessions) with the non-study WIC mothers. As their caseload of study participants increases, the non-study mothers' need for peer counseling would

decline due to their ceasing to breastfeed or becoming fairly well established in breastfeeding. If this approach is used, the peer counselor supervisor will need to ensure that each peer counselor has sufficient time to conduct all counseling tasks for the study treatment group participants as specified for the intervention.

Chapter Three

Alternative Random Assignment Research Designs

In this chapter we compare three potential research designs for a random assignment study of breastfeeding promotion interventions. The designs differ by whether the unit of random assignment is the *site* or the *individual*, and by whether within-site random assignment is carried out as a two-way or a three-way division. After discussing the advantages and disadvantages of each, we conclude that *three-way random assignment of individuals within sites* is the preferred option.

Why Random Assignment

The impact of an intervention is defined as the difference between what happens in the presence of the intervention and what would have happened in its absence, the “counterfactual.” As the counterfactual cannot actually be observed, it is determined in practice by examining a population that has not been subjected to the intervention. It should be emphasized that the counterfactual is not zero exposure to WIC breastfeeding promotion activities, but rather exposure to those activities that would occur normally, which we refer to as “standard site practice.” The live policy alternative is to replace this standard practice with one of the interventions. Hence the interest is not in whether the interventions do better than “nothing,” but in whether they do better than what is currently offered.

The internal validity of the analysis hinges on the assumption that the outcomes for that comparison group are indeed a good proxy for what would have been observed for the treatment group absent the intervention. This requires that the comparison group be similar to the treatment group before exposure, and that any differences in outcomes can be attributed solely to the intervention.

These conditions are well met in a carefully implemented random assignment study. The groups are alike, within the range of chance variation; and that range varies inversely with the sample size. That is, the variation (and the associated confidence interval around the statistical estimates) are great for small sample sizes and small for very large sample sizes. All designs that eschew random assignment are subject to threats to their internal validity—i.e., that observed differences in outcomes between treatment and comparison group members are due in whole or in part to pre-existing differences in the populations, or to differences in their environments. In particular,

- Comparing WIC participants who volunteer for the intervention with those who do not would pose severe issues of selection bias, as women who volunteered might be systematically different from those who did not in ways that affect the outcomes of interest; therefore, they could not be expected to have the same outcomes absent the intervention.
- A pre-post comparison within a site would risk confounding temporal shifts with effects of the intervention, because underlying rates of breastfeeding initiation and duration could vary over time with changes in the environment and the population served.
- Similarly, comparing treatment group members in one site with comparison group members in another would risk confounding site and population differences with effects of the intervention.

As we noted in our literature review (McLaughlin *et al.*, 2003), these threats to internal validity—selection bias, and confounding treatment effects with temporal, site, and population differences—are rife in the research on breastfeeding promotion in general, and in the research on peer counseling in particular. One impetus for doing this evaluation is to provide strong evidence on which to base future decisions on breastfeeding promotion activities. We feel strongly that if this study is to be done, it should be done using random assignment.

Random Assignment of Sites *versus* Individuals within Sites

Sometimes it is necessary to randomly assign entire sites, because the intervention is by its nature offered to a group. For example, a study of a universal free (non-means-tested) school breakfast program would have to take the school as the unit of random assignment. When a treatment comprises a highly personalized service, however, such as the interventions being considered here, there is no obvious *analytic* advantage to site-level randomization.

Nonetheless, a *political* advantage of site-level randomization may exist, because of program staff's potential discomfort with randomly assigning services to some clients and not to others. This could be an important consideration in recruiting sites to participate in the study.

Furthermore, randomization of sites has the *operational* advantage of lessening the potential for control group contamination through sharing of information.¹⁶ Within a site, control group members might perhaps be influenced or encouraged by their treatment group friends to continue breastfeeding, diluting the measured impact of the intervention.

An *analytic* advantage of randomization of (a large number of) sites is that it may be possible to relate success in implementation to site characteristics—in effect, to do subgroup analyses of sites. Impacts might be found to be related to such factors as client demographics, community support, and types of staff offering the services.

An additional potential consideration is *generalizability*. It is not realistic to aim for external validity *per se* (i.e., true national representativeness) in this study, for two reasons. First, the operational difficulties of selecting sites probabilistically are substantial, because sites must be persuaded to participate. It is far more practical to choose sites from among those that volunteer. Furthermore, purposive rather than probabilistic selection is arguably more appropriate, even if the former were feasible. The primary goal of this study is to establish the feasibility of increasing breastfeeding rates and durations, and perhaps in particular groups and environments. It would probably not be the best use of resources to test the intervention in sites that already had high rates of breastfeeding, that were already implementing peer counseling programs, or that were reluctant to implement the intervention.

Nonetheless, the number of sites participating in the study and their range of characteristics with regard to geographic location, types of women served, and so on, will affect how much can be learned

¹⁶ Many welfare waiver experiments subjected treatment and control group members in the same site to different requirements. A threat to validity was that treatment group members would learn of the requirements through conversations with friends and neighbors, and come to believe that they too would endanger their benefits by failing to get their children immunized, by failing to seek work, by failing to cooperate with child support enforcement, etc.

from the study. If sites rather than individuals are randomly assigned, the much greater number of participating sites would increase policymakers' confidence in the generalizability of the results to other locales.

The primary disadvantage of site-level random assignment is the *cost* associated with the large number of sites that would be required. Optimal number of sites for each design is discussed in Chapter Four, but an example will be useful here to show the magnitude of the problem. For simplicity, we compare two options: random assignment of individuals in a single site, and random assignment of sites using the *same total number of women*.

Suppose that the true rate of breastfeeding initiation among pregnant women who receive WIC in a particular site is 0.25. If we randomly assign 1,000 women in this site to the control group and 1,000 women to, say, the low-cost treatment group—clearly only possible in one of the larger WIC sites—then we can detect a treatment effect of *5 percentage points* with 80 percent power, using a one-tailed test with 5 percent significance level.

Suppose, on the other hand, that we randomly assign 10 sites to the control group and 10 sites to the low-cost treatment group. We will further suppose that the average breastfeeding initiation rate for the women in these 20 sites is also 0.25. Keeping the number of individual women in the study the same, we sample 100 women from each site. (The individual-level design sampled 1,000 + 1,000 women; this design samples 20×100 women.) As will be discussed in Chapter Four, even if we stratify by state before randomly assigning the sites, the design effect will be around 3.7, i.e. we will do no better than individual-level random assignment with 270 individuals in each group ($=1,000/3.7$). We could only detect a treatment effect of *15 percentage points* with 80 percent power, using a one-tailed test with 5 percent significance level.

If instead of randomly assigning a total of 20 sites to the treatment and control group, we assigned a total of 100 sites, we would get acceptable results. In particular, if we sampled 20 women per site (again for a total of 2,000 individuals), the design effect would be only 1.5, and we would do as well as individual-level random assignment with 667 women per group. The minimum detectable effect would be *6.3 percentage points*. The cost of running the evaluation in 100 sites, however, would be many times greater than running it in a single site.

We note that in two ongoing evaluations that Abt is conducting with site-level random assignment, the numbers of sites involved are respectively 143 (Evaluation of the School Breakfast Program Pilot Project) and 60 (the Reading First initiative). We believe the costs associated with such a large number of sites would be prohibitive for the current study.

An additional advantage of individual-level random assignment is the ability to control the *fidelity of the treatment*. With a handful of sites that would be involved with this design, one can be more confident that the proposed intervention is being offered as planned, and one can select sites in which the “standard site practice” conforms to a well-defined alternative. With a large number of sites, implementation may be variable, and the control group may comprise sites that offer a wide range of approaches.

Two-way *versus* Three-way Individual-Level Random Assignment

As there are two treatments and a control group to be compared, the design could entail three-way random assignment in each site (RA3). This would allow tests of both treatments in the same site. Alternatively, each site could be used to test a single peer counseling intervention, and two-way random assignment could be implemented in each site (RA2). In some sites, participants would be randomly assigned to the high-cost intervention *versus* standard site practice; in other sites, to the low-cost intervention *versus* standard site practice.

The advantage of RA3 is that it is the only way to answer with scientific rigor the questions:

- Is the high-cost intervention more *effective* than the low-cost intervention in the selected sites?
- Is the high-cost intervention more *cost-effective* than the low-cost intervention in the selected sites?

If the two interventions are implemented in different sets of sites, then the answers to those two questions must be based on what amounts to a comparison group design. We can only ascertain that the high-cost intervention was (or was not) more effective in one set of sites than the low-cost intervention was in a different set of sites. It is highly likely that site differences would swamp the differences in effectiveness between the two interventions, so that such a comparison would be an unreliable guide for policy. Randomly assigning sites to the two interventions gives little protection, because we assume the number of sites will be small—perhaps 3 for each treatment.

Using RA2, we *can* rigorously answer the questions:

- Is the high-cost intervention effective/cost-effective in the sites in which it was implemented?
- Is the low-cost intervention effective/cost-effective in the sites in which it was implemented?

and these may be deemed sufficient. It may be argued that the primary goal of this study is to establish the feasibility of increasing breastfeeding rates and duration *via* an intervention, and the secondary goal is to determine if this can also be done by a less expensive intervention. Those goals can be met by RA2.¹⁷ We note, however, that the expert consultants for this project argued strongly that FNS needs to know the relative effectiveness of the high-cost *versus* the low-cost intervention for planning breastfeeding promotion in WIC.

If RA2 is chosen, we must be prepared for the possibility of a confusing set of findings, comprising significant positive impacts of the low-cost but not of the high-cost intervention. This could come about because the interventions are being tested in different sites, in which the standard site practices and other conditions are different. Alternatively, it could be because implementation failed in the high-cost sites. (It is hard to imagine that the result would be due to the low-cost intervention actually being more effective.) The conclusion we would have to draw from such an outcome is that there is

¹⁷ In fact, they can also be met by a two-step procedure: first testing the high-cost intervention for effectiveness, and only if it passes that test going on to test the low-cost intervention.

evidence that the low-cost intervention works, and no evidence that the high-cost intervention works. In any event, with the RA2 design, it would not be possible to draw conclusions on the relative cost-effectiveness of the two interventions.¹⁸

The disadvantages of RA3 are in the realm of feasibility. Depending on the nature of the interventions, it may be difficult to calibrate the services offered to individuals within a site, making sure that all individuals in one group receive the more expensive package and all individuals in the other group receive the less expensive package. The logistical considerations of training staff to offer two levels of intervention in a site may still be of concern.

Another potential drawback of three-way random assignment is the increased difficulty of measuring the separate costs of the high- and low-cost treatments. The costs of activities in the demonstration sites that serve both interventions are joint costs for the two treatments. These costs would need to be clearly identified and allotted to the two interventions. On the other hand, the costs of the two interventions cannot be compared to each other even in principle if RA2 is selected.

A final difference between RA2 and RA3, which is not necessarily an advantage or disadvantage, is that RA2 by its nature requires more sites, but fewer participants per site (because the sample only needs to be split two ways instead of three). Sites that might be too small to support an RA3 design might be sufficiently large to participate under an RA2 design.

Summary

Three alternative designs that achieve internal validity for answering at least some of the research questions have been described and compared. These designs are:

- ***SRA (Site-level Random Assignment): Sites are randomly assigned to three groups: a high-cost intervention, a low-cost intervention, or standard site practice.***
- ***RA2: In half of the selected sites, individuals are randomly assigned to the high-cost intervention versus standard site practice, and in the remaining sites they are randomly assigned to the low-cost intervention versus standard site practice.***

¹⁸ We also considered, but ultimately rejected, a compromise between RA2 and RA3. Suppose that each site randomly assigned clients for the first six months between the low-cost treatment and standard site practice, and for the second six months between the high-cost treatment and standard site practice. The two treatments might not overlap for very long in each site if the low-cost treatment ended, say, six weeks postpartum. While this approach has the advantage of controlling for site differences, it has several drawbacks that render it unattractive. First, sites would still have to implement two interventions, and might find it more difficult to do so in sequence than in parallel. Second, any startup effects would fall on the low-cost treatment, biasing the relative results in favor of the high-intensity treatment. Furthermore, if the low-cost treatment was effective, women enrolling in the second half-year would see more women in the WIC waiting room who were breastfeeding. This shift in the cultural norm could itself make breastfeeding more acceptable. Finally, the same difficulties with regard to allocating costs between the interventions (discussed below) would occur as in the RA3 design.

- **RA3: In all of the selected sites, individuals are randomly assigned to the high-cost intervention, the low-cost intervention, or standard site practice.**

Their features are summarized and compared in Exhibit 3.1. The columns in this exhibit correspond to the three alternative designs, while the rows correspond to various dimensions of the designs: the suitability of each design for addressing Implementation and Impact Study research questions, the number of sites required (based on calculations presented in Chapter Four), generalizability of findings, acceptability of design to sites, threat of control group contamination, fidelity of treatment models, and consistency of “standard site practice.”

While potentially more attractive to program staff, we believe that SRA is infeasible on grounds of cost, as a very large number of sites would be required for this design to yield acceptably precise estimates. RA3 is preferred to RA2 if it is desired to gain information on the relative effectiveness and cost-effectiveness of two distinct interventions. The panel of experts convened for this study and Abt staff believe that the answers provided by RA3 are critical for the WIC program administrators and policymakers to have in planning for future WIC breastfeeding promotion and support. We therefore strongly recommend the RA3 design.

Exhibit 3.1 Features of Proposed Alternative Designs			
Feature	Design Alternative		
	SRA	RA2	RA3
Description	Sites are randomly assigned to high-cost intervention, low-cost intervention, or standard site practice.	Individuals in some sites are randomly assigned to high-cost intervention or standard site practice. Individuals in remaining sites are randomly assigned to low-cost intervention or standard site practice.	Individuals in all sites are randomly assigned to high-cost intervention, low-cost intervention, or standard site practice.
Suitability for addressing Implementation Study research questions	Best design. Implementation can be related to site characteristics.	Third best design. Cannot compare costs of high- and low-cost interventions.	Second best design.
Suitability for addressing Impact Study research questions	Best design. Achieves internal validity. Can address all questions. Impacts can be related to site characteristics.	Third best design. Achieves internal validity. Cannot compare high- and low-cost interventions. Impacts cannot be related to site characteristics.	Second best design. Achieves internal validity. Can address all questions overall and for subgroups of participants, but impacts cannot be related to site characteristics.
Recommended number of sites (see Chapter Four)	Around 140.	Minimally, 6 to 10.	Minimally, 3 to 6.
Generalizability	Not nationally representative, but covers a broad array of sites.	Not nationally representative, covers a small range of sites.	Not nationally representative, covers a small range of sites.

Exhibit 3.1 Features of Proposed Alternative Designs			
Feature	Design Alternative		
	SRA	RA2	RA3
Likely acceptability to sites	Most acceptable, because all participants in site are treated the same.	May be unacceptable because some participants within a site (control group) are not given peer counseling services.	May be unacceptable because some participants within a site (control group) are not given peer counseling services and because site has to manage both high- and low-cost services.
Threat of control group contamination	Minimal.	Some, because control group may see treatment group members breastfeeding.	May occur between the two treatment groups as well as between each treatment group and the control group.
Control over fidelity of treatment models	Relatively low, because of large number of sites.	Relatively high.	Relatively high.
Consistency of “standard site practice”	Low, because of large number of sites.	Can be high if sites with similar standard practices are selected.	Can be high if sites with similar standard practices are selected.

Chapter Four

Site Selection, Sample Sizes, and Statistical Power

This chapter provides details on the site selection process for this evaluation, and discusses the statistical power of the proposed evaluation design. The site selection process will most likely begin with a grant notice from FNS inviting local WIC agencies to participate in the demonstration. As detailed below, sites should be selected based on geographic location, demographic characteristics, number of eligible clients, willingness to participate in a random assignment study, and a lack of existing peer counseling breastfeeding support activities. Under the recommended three-way person-level random assignment design, we suggest that a minimum of three to six sites be included, although the study could in principle be implemented in a single large site or more than six sites. Similarly, if the two-way person-level random assignment design is chosen, we suggest that six to ten sites be included, although, minimally, two large sites would also serve. We suggest that site-level random assignment will require about 140 sites.

Site Selection

For purposes of this demonstration, sites will be local WIC agencies, rather than state WIC agencies or individual WIC clinics. Local agencies can be defined as the administrative unit one level below state WIC agencies. The number of local agencies per state varies from five (Nevada) to 128 (Louisiana); nationwide there are about 2,200 local WIC agencies (Bartlett et al., 2002).¹⁹ Many local agencies typically include more than one office or clinic.

Local agencies are best suited as the unit of analysis because the decision whether to participate in the demonstration needs to be made at the local agency level. Local agencies operate fairly independently from state agencies. Individual clinics are not autonomous, and could not decide to participate independently of the agency to which they are subordinate. Participating local agencies may choose to include only one clinic (provided it serves a sufficient number of women eligible for random assignment), or more than one clinic in the demonstration.

We assume that sites will volunteer to participate in the demonstration, by responding to an FNS grant announcement. FNS will publish a notice of funding availability inviting local WIC agencies to apply to participate in the demonstration, and specifying the requirements for participating.

An alternative is to select a nationally representative sample of sites, and then to recruit sites in the sample. The primary advantage of this approach, compared to selecting only among sites that volunteer, is that it can provide findings that are more generalizable. This advantage holds only to the extent that a large proportion of the selected sites agree to participate. The main disadvantages are the additional evaluation costs for site recruitment, and the fact that sites that agree to participate are likely to feel a greater burden of participating (on average) compared to sites that volunteer.

¹⁹ Washington D.C. has four local agencies; Puerto Rico has seven; the Virgin Islands, American Samoa, Guam, and a number of Indian tribal organizations have one local agency each.

On balance, for purposes of this demonstration, we believe it is best to reduce the burden and costs of the evaluation by using a volunteer approach rather than recruiting sites. The members of the expert panel agree with this approach. The relatively small number of sites needed for the evaluation (under a person-level random assignment design) means that the recruiting approach would not lead to a meaningfully nationally representative sample anyway, despite the higher cost and burden.

Among the local WIC agencies that volunteer for the demonstration, a sample will be selected to participate. Key selection criteria will be determined in consultation with FNS, but it will likely be desirable to have some *variation across sites in geographic location, and race or ethnicity of clients*, broadly reflecting the diversity of the national WIC population. This type of variation is likely to arise naturally if the Site-level Random Assignment (SRA) design is chosen, given the large number of sites. As discussed below, under individual-level random assignment a *minimum size requirement for sites* (in terms of the number of eligible clients) is also necessary. It furthermore seems desirable to select *sites that do not already use peer counseling extensively*, because such sites may find it less problematic to exclude control group members from peer counseling, and may be more willing to implement the intervention as intended (rather than a modified version based on their own peer counseling process). This may be especially important under SRA, because sites that currently use peer counseling would have to forgo it entirely if assigned to the control group. While it is desirable that “standard site practice” be similar across control group members, this may not be practical to achieve under SRA, given the large number of sites needed for the evaluation. A final but important criterion for sites to participate in the demonstration is a *willingness to take part in a random assignment study*. This requirement should be explicit in the notice of funding availability.

Abt recommends that site selection be done in consultation with FNS. Independence of the evaluation, however, may best be maintained if the evaluation contractor—not FNS—selects the sites from a pool of volunteer sites.

Whatever criteria are used to select sites, the evaluation should include an analysis comparing the selected sites to all WIC agencies nationwide. The comparison should include information on demographic composition (mothers’ age and race/ethnicity), size of site (number of women participating), and breastfeeding prevalence (numbers of breastfeeding women relative to pregnant women and all participating women). Data from the biennial Study of WIC Participant and Program Characteristics can be used for this analysis.²⁰

Criteria for Determining Numbers of Participants and Sites

The criteria to be considered in determining the numbers of participants and the numbers of sites include the following:

- Statistical precision. The numbers of participants and sites must be sufficient to detect meaningful effects for each intervention, using the conventional five percent significance level (one-tailed tests) and 80 percent power.

²⁰ Detailed information on breastfeeding initiation and duration for WIC infants is currently not available for all sites in the Study of WIC Participant and Program Characteristics Study.

- Cost. Given the total number of participants, it is cheaper to conduct the evaluation in fewer sites.
- Face validity. While the minimum-cost designs for RA3 and RA2 would comprise a single large site and two large sites, respectively, policy makers may not deem the minimum-cost designs to be optimal. Testing each intervention in several sites, so that one could get a sense of the effectiveness under a variety of conditions would seem safer, even if the results are not reported separately by site.

We suggest that the criterion for statistical precision be *the ability to detect a five-percentage point difference on a control group mean of 50 percent*. Our rationale for this suggestion is as follows. The study will examine impacts on a variety of breastfeeding outcomes, including initiation, status at two months postpartum, and status at six months postpartum. The dichotomous outcomes with the largest variances, and requiring the largest sample sizes for detecting given percentage point effects, are those with means around 50 percent. The overall breastfeeding initiation rate for WIC mothers is around this value,²¹ and it seems reasonable to assume conservatively that we will need to estimate impacts on an event with about a 50 percent frequency.

Five percentage points may be deemed on the small side for a minimum detectable effect. We recommend basing the calculations on this value, however, because it is likely that effects will be sought for subgroups as well. A minimum detectable effect of 10 percentage points on a 50 percent control group mean requires a sample size one-fourth as large. Hence we will be able to detect effects of 10 percentage points on subgroups that comprise at least one-quarter of the sample—e.g. women of a particular race/ethnicity, or of participants in a particular site.

If individuals are randomly assigned, the criterion for statistical precision described above implies a minimum of 1,273 individuals per group. That is, under RA3, a total of about 3,800 study participants would be required (about 1,270 in the control group and in each treatment group – high- and low-cost). Under RA2, a total of about 5,100 participants would be required—because two separate sets of control group members would be needed, one for evaluating each intervention.

We suggested above that policymakers might prefer not to put all their evaluation eggs in one basket. While there are some sites that are large enough to support the entire evaluation, spreading the study over several sites allows the inclusion of some small and medium local agencies. Exhibit 4.1 tabulates the distribution of site size, measured by number of pregnant women served in April 2002, based on the Study of WIC Participant and Program Characteristics. Note that site size is highly skewed. While 37 percent of sites serve 100 pregnant women or fewer, only 4 percent of pregnant

²¹ For example, WIC administrative data show that 45.7 percent of WIC infants aged 7 to 11 months were ever breastfed (in states reporting breastfeeding information for at least 75 percent of infants). It must be noted that this statistic differs from the outcome of interest in two ways: it excludes non-WIC infants of mothers who received WIC while pregnant; and it includes WIC infants whose mothers did not receive WIC while pregnant. We are not aware of recent data on the dynamics of women’s WIC participation. A study based on 20-year-old data (Merrell and Burstein, 1989) found that 30 percent of women receiving WIC while pregnant did not receive WIC in the postpartum period; while they may have enrolled their infants in WIC, given their own non-participation it seems unlikely that they were breastfeeding. In addition to these maternal dropouts, some fraction of WIC infants also drop out of the program before reaching age 7 to 11 months.

women are served in sites this small. Conversely, while only 2 percent of offices serve more than 2,400 pregnant women, these comprise 29 percent of all pregnant women served.

Exhibit 4.1			
Distribution of Local Agencies by Number of Pregnant Women Served, April 2002			
Number of pregnant women served	Number of agencies	Percent of agencies	Percent of pregnant women
Less than 100	803	37.1	4.3
101-200	455	21.0	7.5
201-300	235	10.9	6.7
301-400	150	6.9	5.9
401-800	282	13.0	17.7
801-1200	86	4.0	9.5
1201-1600	53	2.4	8.3
1601-2400	48	2.2	10.6
Over 2400	53	2.4	29.4
TOTAL	2165	100.0	100.0

How Many Participants, How Many Sites: RA3

The least costly way to implement the RA3 design is to draw participants from a single large site. As suggested above, let us assume that we wish to be able to detect a five-percentage point difference between the control group and each of the two treatment groups for an outcome such as breastfeeding initiation, which has a control group mean of around 0.50, using a one-tailed test with a 5 percent significance level and 80 percent power. This would require a total of some 3,800 study participants—about 1,270 each in the control, high-cost, and low-cost groups.

Assuming that intake occurs over a 12-month period, and that pregnant women receive WIC on average for six months, we would need to select a single site that was serving at least 1,900 women at a point in time to achieve an annual flow of 3,800 women. Allowing for refusal to participate, loss to follow-up, etc., we might seek a site that served at least 2,400 pregnant women at a point in time. There were 53 such sites out of the 2,200 local agencies nationwide: five in Florida, five in Puerto Rico, 13 in California, 11 in Texas, and 19 others in 12 other states. These sites together serve about a quarter of pregnant WIC recipients.

While such a design is possible, it is not necessarily attractive, as it would provide information on only a single large WIC site. For face validity, and to lower the risk of demonstration failure, we suggest a minimum of three sites. Apportioning the sample equally among the three would require using sites that serve about 800 pregnant women, of which there are 240. This broadens the spectrum of participating sites somewhat. These 240 sites serve nearly 60 percent of pregnant WIC participants. If six sites were used, so that the size cutoff was about 400, sites could be chosen from the top quartile of the size distribution. These 522 sites cover about 80 percent of pregnant WIC participants.

It may be thought troubling that smaller sites should be excluded from the study. This concern could be addressed by, for example, taking four small sites which together served at least 800 women, and two larger sites that served at least 800 women each. FNS will need to decide how many sites they can fund, with the concomitant increase in representativeness. Exhibit 4.2 shows the alternative combinations described here of the number of sites, and participants per site. Other combinations could be calculated, for example two small sites, two medium-size and one large site, adding up to a caseload size of 2,400 at a point-in-time.

Exhibit 4.2 Numbers of Sites, Numbers of Participants for RA3			
Participants per group	Required point-in-time caseload	Criterion for site selection	Outcome for site selection
1273	2400	Minimize cost	Take one of the 50 largest WIC sites
1273	2400	Compromise between cost and representativeness by choosing three sites	Choose 3 sites each with caseload of at least 800
1273	2400	Include some smaller sites, no more than six sites total to constrain costs	For example, take four sites with caseload under 800, one site with caseload 801-2500, one site with caseload 2500+

NOTE: Assumptions for all scenarios are a control group mean of 0.50, a one-tailed test at a 5 percent significance level, and 80 percent power.

How Many Participants, How Many Sites: RA2

The RA2 design requires a greater total number of study participants, because the control group individuals do not do “double duty.” That is, one control group *each* is paired with the high- and low-cost peer counseling interventions. It also requires more sites, but fewer participants per site (because they are only split two ways). If 1,273 participants were required in each group, as in the example in the previous section, one would need four times this many individuals in total, i.e., around 5,100 participants, spread out over at least two sites. This corresponds to a total caseload of about 3,200, which could be accomplished by choosing two sites to test the two interventions with caseloads of at least 1,600 each. There are 101 such local agencies, and they serve 40 percent of all pregnant WIC women.

Again, for face validity, we recommend at least three sites per intervention, i.e., a minimum of six sites. Eight or ten sites might be preferable to allow for inclusion of small sites and an array of site characteristics.

Exhibit 4.3 Numbers of Sites, Numbers of Participants for RA2			
Participants per group	Required point-in-time caseload	Criterion for site selection	Outcome for site selection
1273	3200	Minimize cost	Take two of the 101 largest WIC sites
1273	3200	Compromise between cost and representativeness by choosing three sites for each intervention	Choose 6 sites each with caseload of at least 533
1273	3200	Include some smaller sites, no more than eight sites total to constrain costs	For example, for testing each intervention take two sites with caseload of 1200 or less, one site with caseload 1200-2400, one site with caseload 2400+
1273	3200	Include some very small sites, no more than 10 sites total to constrain costs	For example, for testing each intervention take two sites with caseload under 400, one site with caseload 401-1200, one site with caseload 1201-2400, one site with caseload 2400+

NOTE: Assumptions for all scenarios are a control group mean of 0.50, a one-tailed test at a 5 percent significance level, and 80 percent power.

How Many Participants, How Many Sites: SRA

As suggested in Chapter Three, site-level random assignment has major implications for the required numbers of sites and participants. If all of the WIC sites were similar in their breastfeeding experiences, one could draw a sample from multiple sites without any increase in variance. In fact, intersite variability adds hugely to the sample requirements.

While exact information on intersite variability in breastfeeding outcomes is not available, the WIC Participant Characteristics data give an idea of its scope. A rough proxy for the breastfeeding rate that is readily available for all WIC sites is the ratio of breastfeeding women to the number of pregnant women participating at a point in time. Because breastfeeding women participate longer on average than pregnant women—they are eligible for 12 rather than 9 months of benefits—this ratio is an overestimate of the breastfeeding rate. This measure is also imperfect because intersite variations can reflect not only breastfeeding behavior, but also the fraction of the pregnancy during which women participate in WIC, and the proportions of women who receive WIC only while pregnant or only while breastfeeding. Other rough measures of breastfeeding are the proportion of WIC infants aged 7 to 11 months who were ever breastfed, and the proportion of such infants who were breastfed for at least 2 months. These latter two measures are only available in some states.

Exhibit 4.4 shows the very high intersite variation in these three ratios. For example, if a site were chosen at random, there is one chance in four that the proportion of infants aged 7 to 11 months who were breastfed for 2 months or more would be less than 9 percent, and another chance in four that the proportion would be greater than 28 percent. If two sites were chosen, there would only be one chance in four that the proportion in *both* sites would fall between 9 and 28 percent. This suggests

that if sites were going to be compared to each other (as in site-level random assignment), one would want to use a large number of sites to avoid a bad draw.

Exhibit 4.4 Means and Standard Deviations of Site-Level Breastfeeding Measures			
Measure	Mean	Standard deviation	N (Number of sites)
Breastfeeding women / pregnant women	0.485	0.367	2135
Proportion of infants aged 7-11 months ever breastfed	0.276	0.145	1889
Proportion of infants aged 7-11 months breastfed 2+ months	0.199	0.144	1874

Source: WIC Participant and Program Characteristics, 2002 (unpublished data)

Part of this variability might be due to bad data in some sites. If we restrict the samples to those in which the denominators for the ratios are at least 100 participants and the proportions and ratios are at least 0.05, we would eliminate many sites but still have very high variability, as shown in Exhibit 4.5.

Exhibit 4.5 Means and Standard Deviations of Site-Level Breastfeeding Measures, Restricted Sample			
Measure	Mean	Standard deviation	N (Number of sites)
Breastfeeding women / pregnant women	0.466	0.264	1354
Proportion of infants aged 7-11 months ever breastfed	0.281	0.122	1176
Proportion of infants aged 7-11 months breastfed 2+ months	0.221	0.120	1062

Source: WIC Participant and Program Characteristics, 2002 (unpublished data)

The sample sizes required to achieve a given minimum detectable effect (MDE) under site-level random assignment depend on how much of the total variation in the outcome of interest is between rather than within sites, a measure referred to as the *intraclass correlation coefficient*. The greater the proportion of variance that is between sites, the greater the number of sites that must be sampled to achieve a given MDE.

Based on the truncated sample of 1,176 sites with “reasonable” data on proportion of infants aged 7 to 11 months who were ever breastfed, the intraclass correlation coefficient is 0.067.²² The design effect is given by the formula:

$$deff = 1 + (m - 1) \rho$$

²² If the uncensored sample of 1,889 sites is used, the intraclass correlation is even higher, 0.093.

where m is the sample size per cluster (i.e., WIC site) and ρ is the intraclass correlation coefficient. For example, if we sampled 100 women per site, the design effect would be

$$1 + (99 \times (0.067)) = 7.6.$$

That is, we would require nearly 8 times the total sample size as in individual-level random assignment.²³

This design effect can be reduced to a more reasonable level if we can stratify sites effectively before randomly assigning them. Arguably this can be done based on state. In the truncated WIC data, state alone accounts for 60 percent of the intersite variation in “proportion of infants ever breastfed” and for 65 percent of the intersite variation in “infants breastfeeding at least 2 months.” If we can reduce the intraclass correlation by 60 percent, to 0.027, then the design effect with 100 women per site is only

$$1 + (99 \times (0.027)) = 3.7.$$

This would imply a total of **141 sites** ($3.7 \times 1273 \times 3 / 100$)—coincidentally, very similar to the number chosen in an ongoing study of the School Breakfast Program funded by FNS in which site-level random assignment was essential to the research questions.²⁴ Possibly the intraclass correlation could be reduced further by using information on site-level demographics as well as state to stratify the sample. It seems unlikely, however, that the required number of sites under the SRA design could fall below 100.

²³ To achieve the same level of precision with SRA as we could get with RA3, assigning 1,273 individuals per treatment group, we would need to assign some 9,700 women, i.e., go to 97 sites per group. The total number of sites required would be 291.

²⁴ Note that the required number of sites cannot be reduced much by raising the number of women per site. For example, if we take 200 women per site, the design effect becomes

$$1 + (199 \times (0.027)) = 6.4,$$

and the number of sites required per group is 122 instead of 141 (while the sample of individuals is 1.7 times as large as with 100 women per site).

Chapter Five

Implementation Study

This chapter describes the objectives of the Implementation Study, the research questions, the data requirements for the three components of the Implementation Study (i.e., background contextual factors, implementation outcomes, and intervention costs), and the implementation analysis plan. The discussion in this chapter is based on the assumption that the peer counseling evaluation will use a within-site random assignment of participants to treatment or control groups. In line with the discussion in Chapter Three, this design also implies that relatively few local agencies would be involved in the evaluation. Therefore, the Implementation Study analysis would focus on 1) description of peer counseling implementation across the study sites (with no analyses by subgroups of programs) and 2) the cost of implementing peer counseling. At the end of the chapter, there is a general discussion of how the analysis plans may differ from the proposed plan if the evaluation is based on a design with site-level random assignment of approximately 140 local agencies.

Objectives of the Implementation Study

Under the recommended evaluation plan using within-site random assignment, the Implementation Study would focus on three objectives. First, by providing detailed descriptions of how the peer counseling intervention is implemented in participating WIC sites, it would help in understanding the Impact Study results. Further, the detailed implementation process descriptions, based on multiple sources of data (e.g., WIC program administrative data, staff interviews, and study participant interviews) would provide possible explanations and hypotheses in sites that fail to produce positive impacts of the intervention. Assuming that FNS uses the most rigorous and efficient evaluation design to assess the impact of peer counseling (i.e., within-site random assignment of participants), this evaluation would be conducted in only a small number of WIC agencies. In this case, the numerous ways in which the sites could differ would not be included in the statistical impact analyses. Nonetheless, information on how the intervention is implemented and its programmatic context would be critical in interpreting the results of these analyses.

Second, the study would generate estimates of the costs of high- and low-cost interventions to inform policy decisions regarding the absolute and relative cost-effectiveness of these interventions. Finally, the comprehensive implementation data would inform WIC policy makers and program administrators whether it is feasible to implement peer counseling in additional WIC agencies, what aspects work well, and what aspects need to be improved. The implementation data should also be valuable for other WIC programs that are considering implementing breastfeeding support services using peer counselors.

Research Questions

The major research questions for the Implementation Study have been stated in Chapter One, and the key measures (data elements) to be collected to address these questions and the sources of these data are presented in Chapter Seven. Exhibit 5.1 lists detailed questions for each major research question.

Exhibit 5.1
Implementation Study Research Questions

1. What are the characteristics of WIC agencies participating in the evaluation?

1. How are they similar to or different from WIC agencies nationally?

2. What are the characteristics of WIC mothers participating in the study (treatment and control groups) in each site?

1. How do they compare with WIC mothers nationally?
2. How do the treatment and control groups of participants compare to each other in demographic and other background characteristics?

3. What breastfeeding promotion services (other than the peer counseling intervention) are provided by participating agencies?

1. What is the history of breastfeeding promotion activities in the local agencies included in the evaluation? What initiatives and methods have been implemented to date? Is there evidence to suggest that they have any effect on breastfeeding initiation or duration?
2. What breastfeeding promotion services (besides the peer counseling to be evaluated) are being offered to WIC mothers now?
 - What staff members or external consultants are involved in these activities?
 - When are these services being offered (e.g., during pregnancy, postpartum)?
 - To what extent are these services being used by WIC mothers?
 - What is the agency budget that supports these activities?
 - Are any hospitals and other community organizations involved in these activities?
 - Does the agency have data on breastfeeding initiation and duration among WIC mothers receiving services from this agency?

4. How is the peer counseling intervention implemented at participating WIC agencies?**4a. What changes are made in local WIC program staffing and operations to implement the peer counseling intervention?**

1. What changes are made in program staffing to accommodate the peer counseling intervention? Are new staff positions/responsibilities created for the intervention? Are responsibilities of existing staff modified for the intervention?
2. What are the general reactions of existing staff to these changes?
3. Is special staff training conducted for the implementation of the peer counseling intervention? What is the content of the WIC staff training regarding the peer counseling intervention? When is the training conducted, by whom?
4. Do local agencies need to purchase additional equipment or supplies to implement the intervention?
5. Do local agencies need to modify client service schedules to accommodate peer counseling?
6. Are any additions or modifications made to program's administrative record keeping procedures or systems to support the peer counseling intervention?
7. What measures are implemented by local agencies to ensure that peer counseling services are provided ONLY to participants assigned to the experimental group?

Exhibit 5.1**Implementation Study Research Questions**

4b. How are the peer counselors recruited, trained, assigned to WIC mothers, and monitored in each site?

1. How are peer counselors recruited? How are they selected?
2. What are the demographic characteristics of peer counselors (e.g., age, education, marital status, race/ethnicity, primary language, WIC experience, breastfeeding experience)?
3. How is the training of peer counselors planned and conducted? Who are the trainers? How long is the training?
4. What are peer counselors paid? Do they receive employee benefits?
5. What are peer counselors' work hours, schedule, and caseload?
6. How are peer counselors assigned to a WIC mother? What factors are considered in peer counselor assignment?
7. How do agencies monitor peer counselor performance and provide feedback to peer counselors?
8. What supports and continuing education are provided to peer counselors?
9. What is the turnover rate among peer counselors? How are peer counselors' caseloads handled when they leave the demonstration?

4c. What activities and services are involved in peer counseling? How closely do they conform to the intended intervention models? How does the implementation fidelity vary across study sites?

1. Where do peer counselors work with WIC mothers? Where do they make their phone calls to WIC mothers?
2. What types of counseling methods do peer counselors use: telephone, individual counseling at WIC site, home visits, group sessions?
3. What sources of additional professional expertise and counseling are available for peer counselors to refer WIC mothers to (e.g., peer counselor supervisor, hospital lactation consultant, hospital nutritionist, pediatricians)?
4. What procedures are used by peer counselors to refer WIC mothers to these sources of professional counseling?
5. How do local agencies assess the presence of contraindications for breastfeeding (e.g., AIDS) to exclude some WIC participants from the study participant sample?

4d. How do participating WIC agencies coordinate activities and services with area hospitals and other organizations to implement the peer counseling intervention?

1. Are there other community agencies that are involved in implementing the intervention? If so, who are they and what are their responsibilities or contributions?
2. Has there been coordination with area hospitals to implement the peer counseling intervention? What type of arrangements and coordination are put in place with area hospitals in implementing the peer counseling intervention? What hospital staff are involved in establishing the arrangements?
3. What hospital staff are involved in carrying out the intervention?
4. Are regular meetings or other methods of communication scheduled to maintain coordination with hospitals and other community collaborators?
5. What protocol does the hospital follow in support of early infant feeding (e.g., rooming-in, provision of formula)? What breastfeeding promotion education and support services do the collaborating hospitals provide to WIC mothers? In what ways do these services complement, overlap, or interfere with the peer counseling intervention services?

Exhibit 5.1**Implementation Study Research Questions**

5. *To what extent do WIC mothers participate in the peer counseling intervention in each site?*

1. What percent of the total WIC enrollees are selected to participate in this evaluation?
2. What percent are contacted for prenatal breastfeeding intention verification?
3. What percent are randomly assigned to the treatment and control groups?
4. What percent receive prenatal education and support services? How much and what type of prenatal services do study participants receive?
5. What percent of treatment group participants receive a prenatal peer counselor visit/meeting? How much and what type of prenatal peer counseling do treatment group participants receive?
6. What percent of treatment group participants receive postpartum peer counseling services/contacts? How much and what type of postpartum peer counseling do treatment group participants receive?
7. How many participants call peer counselors (average per month) for assistance?
8. How many high-cost treatment group participants attend postpartum group support sessions?

6. *What are the responses of WIC mothers, WIC staff, and collaborating organization staff to the peer counseling intervention in each site?*

1. What aspects of implementing peer counseling are the most challenging?
2. What changes do local agencies suggest to improve the implementation and operations of the peer counseling intervention?
3. What comments do the treatment group participants report about the peer counseling services offered to them?
4. What comments are reported by peer counselors and peer counselor supervisors about various aspects of the peer counseling intervention?
5. What comments are reported by WIC program staff about various aspects of the peer counseling intervention?
6. What comments do the control group participants report about the breastfeeding promotion and support services they receive from WIC?

7. *What is the cost of the peer counseling intervention(s) in each site?*

1. What are the costs of starting the intervention(s) at a site, apart from the cost of peer counseling services provided to participants?
2. What are the costs of peer counselor training and supervision?
3. What is the cost of the peer counseling services provided, per participant?
4. How are the total and per-participant costs of peer counseling affected by site characteristics such as caseload and prevailing wages?

8. *What are the prospects for continuing peer counseling at the participating WIC agencies?*

1. Do local agencies that implement peer counseling for this evaluation plan to continue all or portions of the peer counseling beyond the demonstration phase? What portions are likely to be continued? What portions will be changed or eliminated?
 2. How will local agencies fund the continuation of peer counseling?
-

This list of implementation questions should be used to define the content of implementation data collection and guide the data analysis.

Implementation Study Analysis

Addressing the research questions listed in Exhibit 5.1 would be facilitated by organizing implementation data and analysis into three components: 1) the background contextual factors, 2) implementation outcomes, and 3) the cost of the intervention. The key topics and issues included in each of these components and their use in analysis are discussed below.

Background Contextual Factors

The contextual factors pertain to the setting and context in which the peer counseling intervention is implemented, including:

- WIC program characteristics (e.g., geographic location, urbanicity, enrollment size, demographic composition of the participants);
- Characteristics of clients enrolled in the participating WIC agencies;
- Characteristics of WIC mothers assigned to the treatment and control groups (e.g., age, race/ethnicity, household income, immigrant status, education, marital status, parity, breastfeeding experience, attitude toward breastfeeding);
- Breastfeeding promotion and support activities (other than peer counseling) provided by the participating WIC agencies;
- Breastfeeding promotion services available in the community; and
- Breastfeeding promotion and support services and infant feeding policies in the area hospital(s) where study participants deliver their babies.

The program and participant characteristics and the contextual factors are highly relevant to addressing the key objectives of the Implementation Study. The content and extent of peer counseling activities that are actually provided to treatment participants may vary by contextual factors such as urban and rural community setting, race and ethnicity of WIC mothers, and level of breastfeeding support provided by area hospitals. Under the recommended within-site randomization design using few study sites, it will not be possible to analyze systematically potential relationships between implementation outcome data (e.g., rates of participation in the demonstration) or participant impact data and these contextual factors. However, the context in which the peer counseling demonstration takes place will be described fully as part of the comprehensive documentation of the intervention.

These descriptions may also be useful when interpreting the results of the impact analyses. For example, if the study yields very different impact results from two WIC sites that are fairly similar in intervention implementation, participant demographic characteristics, and program characteristics, then additional Implementation Study data (e.g., differences in availability of breastfeeding support in the area hospitals and in the community) may help to explain the observed impact differences.

In addition, if the implementation of peer counseling is affected by some of the contextual factors, then these factors would need to be considered in determining the feasibility of implementing the intervention in the broader WIC community. The peer counseling models examined in this evaluation may be feasible in WIC agencies with certain characteristics (e.g., small rural agencies) but less so in agencies with other characteristics (e.g., large urban agencies).

Implementation Outcomes

A comprehensive documentation of the peer counseling interventions that are implemented should include:

- Changes made to local WIC program staffing and operations to support the intervention;
- Process of peer counselor recruitment, selection, training, assignment to WIC mothers, and supervision;
- Activities involved in peer counseling and the fidelity of the high- and low-intensity peer counseling implementation according to the intended design;
- Coordination of activities between WIC programs and area hospitals and other organizations;
- The extent of participation by treatment group mothers in the intervention;
- The extent of participation by the control group mothers in any breastfeeding support services other than the peer counseling intervention; and
- Reactions of WIC mothers, WIC and collaborating organization staff, and peer counselors to the intervention.

A careful examination of these factors would be necessary for assessing the intervention fidelity, elements of the intervention that need to be revised or improved in future interventions, and the feasibility of expanding the peer counseling approach to other WIC programs. In addition, documentation of these factors will provide valuable guidance to other WIC program administrators in the process of adopting the intervention.

Cost of the Intervention

The intervention cost analysis would constitute the third component of the Implementation Study. The resource cost of the peer counseling intervention is an important consideration for policymakers and program administrators. The overall cost of implementing peer counseling, and the difference in costs between the high- and low-cost models, would need to be weighed against the breastfeeding impacts in considering the desirability of further implementation of these interventions.

Descriptive Analysis of Peer Counseling Demonstration

The Implementation Study will generate qualitative and quantitative data, collected from multiple sources (e.g., WIC staff, WIC participants, peer counselors, and WIC program administrative database). Under the recommended evaluation design (within-site random assignment of participants), the primary purpose of the Implementation Study would be to describe the peer counseling implementation at the relatively small number of WIC sites participating in the study. The quantitative implementation study data (e.g., percent of participants who receive in-hospital peer contact, percent of participants who initiate breastfeeding, number of peer counselor contacts participants receive of various types) would be analyzed by univariate descriptive statistical analysis (e.g., means, frequencies, and percentages). The results would document peer counseling demonstration carried out at each study site in terms of the program context, implementation process, implementation outcomes, and intervention cost. These descriptive data, combined with qualitative data from interviews with WIC staff, peer counselors, and WIC participants, would be used to

generate narrative case studies of how the high- and low-cost peer counseling is implemented in each study site.

Analysis of Program Costs

The primary purpose of the cost analysis is to measure the cost of the peer counseling interventions in the demonstration sites, to support the cost-effectiveness analysis. By documenting the individual cost elements and showing how they fit together, the analysis can also provide guidance on the likely cost of implementing peer counseling in new sites under different circumstances—e.g., with varying caseload sizes or prevailing wage rates. For both purposes, it is essential to distinguish between those costs in the demonstration sites that are incurred only because of the evaluation (e.g., random assignment within sites and data collection) and those that are associated with the intervention *per se* and would be incurred by all sites implementing the initiative.

A new initiative leads staff to substitute some activities for others, and it may be hard to identify and measure these tradeoffs. In this case, a design that randomly assigns sites is better suited for analyzing the cost of an intervention than a design that randomly assigns individuals within sites. If sites are randomly assigned, one can measure and compare the total administrative costs in the three groups of sites. At the same time, one must consider how other outcomes may be affected. For example, supervisor time might be freed up for a new breastfeeding promotion initiative by decreasing the amount of time spent on nutrition education initiatives for children.

Most of the costs of the intervention are *variable*, proportional to the number of participants served (conditional on high- *versus* low-cost treatment). Two types of fixed costs that must be broken out are start-up costs, incurred once per site, and ongoing fixed costs, related to the minimal scale of operation.

Start-up costs include time needed by the WIC director and/or other supervisory personnel to understand the peer counseling intervention, to develop appropriate policies and procedures, and to recruit and hire staff specifically for the intervention (e.g., a board-certified lactation consultant to be the peer counseling supervisor). WIC staff members' training in their peer counseling-related activities is also a start-up cost. (While this training would have to be repeated for new WIC staff as turnover occurs, this cost is probably small relative to the cost of initially training the entire staff.) Another category of start-up costs is the higher expenditure for ongoing activities occurring during the first few months as sites work out the kinks, e.g., determine how best to recruit successful peer counselors, coordinate the stream of participants with the available peer counselors, address issues of transportation and logistics, and so on. Even after the start-up period *ongoing fixed costs* arise because even the smallest office needs to employ one peer counselor one peer counselor supervisor.

The high expected turnover of peer counselors relative to WIC staff and peer counselor supervisors, argues for treating their recruitment, selection, and training as variable costs. If, for example, it is found that on average peer counselors remain in the job for X months, then the annual cost of peer counselor recruitment, selection, and training for a site is equal to those costs per peer counselor hired times the number of counselors at a point in time times $12/X$. In addition, of course, the service-related costs of peer counselors' salaries, materials used, and so on, are variable costs, as are the corresponding costs for supervisors.

Measuring the costs associated with WIC staff activities will be difficult. These are not out-of-pocket costs for the demonstration, but represent displacement of other WIC activities. They should be estimated based on WIC staff reports of how much time they spend on these activities and their loaded hourly salaries. With the high- and low-cost intervention models presented in Chapter Two as illustrative examples, WIC staff's direct labor costs to support the interventions are expected to be a very small percentage of the total, so that some inaccuracy in measurement will not seriously affect the conclusions. The intervention would require little from WIC staff—only informing participants about peer counseling services, and referring them if appropriate. Activities by WIC staff that are required only because of the evaluation rather than the peer counseling intervention (e.g., obtaining contact information and signed consent forms from WIC participants) should be excluded from the cost calculations.

Costs should be expressed in two metrics: annual costs for a site as function of size (e.g., number of pregnant women enrolling per year), and costs per participant served, also as a function of site size. It is the latter form of costs that is compared with impacts in the cost-effectiveness calculation. Policymakers will assess the attractiveness of one or both peer counseling models based on the estimated impacts (e.g., a 3 percentage point increase in the breastfeeding rate at six months postpartum) relative to dollar cost per participant served.

In summary, costs will be measured in each site in the following categories:

- Start-up costs
 - Salaries, benefits, and overhead associated with WIC director activities
 - Salaries, benefits, and overhead associated with WIC staff training
 - Excess variable costs during the start-up period (difference between variable costs measured in early months and later months of operation)
- Ongoing costs after the start-up period
 - Referrals of participants to peer counselors by WIC workers
 - Peer counselor salaries
 - Peer counselor supervisor salaries and benefits
 - Peer counselor and supervisor local travel
 - Peer counselor and supervisor telephone usage
 - Peer counselor and supervisor use of office equipment, supplies
 - Office space used for individual and group counseling
 - Breastfeeding support equipment (e.g., breast pumps, practice dolls)
 - Breastfeeding education materials (e.g., books, video tapes)

A clear explanation of the components of costs will allow inferences with regard to potential variations. This is illustrated for the ongoing costs of peer counselor salaries in Exhibit 5.2. (This example excludes the costs of peer counselor selection, recruitment, and training.) It would be simple to calculate the dollar cost per site of peer counselors' salaries, based on checks written. It is more illuminating, however, to show how this cost is built up from, and varies with, such components as peer counselor caseload size, hours spent serving clients *versus* administrative tasks and downtime, and hourly pay rates. The raw data required from each site are:

- Number of months covered by the cost data
- Number of participants served during those months

- Average number of active peer counselors on the payroll over those months
- Average hours per week that active peer counselors were employed
- Average number of months that individual participants were served by peer counselors
- Average number of hours spent directly on participants by peer counselors
- Peer counselors' hourly wage

From these pieces, we can build up estimates of

- Annualized participants served by site
- Average caseload of active peer counselors
- Case-related costs of peer counselor services per participant
- Annualized total site case-related costs of peer counselor services
- Annualized amount of administrative and down time per peer counselor
- Total annual site cost for peer counselors' salaries

A new site could estimate its own likely costs in this domain by considering the hourly wage it would have to pay, the size of its caseload, and its ability to minimize peer counselors' downtime and administrative activities. For example, a larger site would have to scale the operations up, increasing costs; but would have a smoother flow of clients, which could reduce the proportion of downtime. Or a site in which peer counselors worked more hours per week could reduce the proportion of counselors' time spent on administrative tasks such as periodic meetings with supervisors.

Exhibit 5.2 Components of Annualized Ongoing Costs Associated with Peer Counselor Salaries After the Start-Up Period			
	Site A	Site B	Site C
Participation			
(a) Number of months covered by cost data			
(b) Number of participants served in those months			
(c) Annualized participants served ($= 12 \times (b) \div (a)$)			
Peer counselor caseload			
(d) Average number of peer counselors			
(e) Average hours per week worked by peer counselors			
(f) Average number of months participants were served			
(g) Average caseload per peer counselor ($= \{(c) \times (f) \div 12\} \div (d)$)			
Case-related costs for peer counselors			
(h) Average number of hours per participant			
(i) Hourly wage of peer counselors			
(j) Average case-related cost per participant ($= (h) \times (i)$)			
(k) Annualized hours per peer counselor on case-related activities ($= (g) \times (h) \times 12 \div (f)$)			
(l) Total annual case-related costs for peer counselors for site ($= (j) \times (c)$)			
Non-case-related costs for peer counselors			
(m) Annualized average number of hours per active peer counselor spent on administrative activities and downtime ($= \{(e) \times 52\} - (k)$)			
(n) Total annual non-case-related costs for per counselors for site ($= (m) \times (i) \times (d)$)			
Total ongoing costs for peer counselors after startup period			
(o) Total annual site cost for peer counselors' salaries ($= (e) \times 52 \times (i) \times (d)$)			
(p) Cost per participant of ongoing peer counselor salaries ($= (o) \div (d)$)			

Analysis of Implementation Process and Outcomes by Site Characteristics

A useful question to address in the Implementation Study would be: Do the peer counseling intervention process and outcomes vary depending on local WIC agency characteristics, e.g., the number and demographic characteristics of participants, staff and other program resources, availability of baby-friendly hospitals in the community, and urban vs. rural community setting? As described earlier, if the evaluation is based on the recommended, within-site randomization of participants, the small number of sites that would be involved in the study would preclude conducting descriptive analyses of implementation process and outcomes by site characteristics.

However, if a site-level randomization design with a large number of sites is used, then it would be possible to analyze the Implementation Study data by subgroups of sites. This would be the key difference in the implementation analysis approach between the within-site randomization and site-level randomization designs. Randomly assigning a large number of sites to treatment or control groups would allow systematic analysis of variations in implementation outcomes and participant impacts by site characteristics. Such analyses would provide policy makers and program administrators additional information regarding the feasibility of implementing, expanding, and refining the peer counseling interventions in certain types of WIC agencies.

Integrative Analysis of Quantitative and Qualitative Data

While the differences in the types of data and the level of analysis call for the use of different analytic methods, the ultimate purpose of the Implementation Study is to address its objectives by integrating the results of all analyses. For example, the discussion of “how peer counseling is implemented” should weave together the quantitative data analysis results concerning the number of peer counselors recruited and trained, number of hours and weeks of training, types of professionals who conduct training, number of hours of hands-on practice and mentoring provided for peer counselors, coupled with qualitative descriptions of the types of changes programs made in staffing and program procedures, and the types of arrangements WIC agencies make with area hospitals and other collaborating organizations. Similarly, a discussion of the feasibility of implementing similar interventions in additional WIC agencies would clearly involve integrating quantitative findings about the cost of intervention, comparisons of program and participant characteristics between the study sites and WIC national data, and assessments of the benefits and challenges of peer counseling strategy as reported by WIC staff, peer counselors, and WIC participants.

Chapter Six

Impact Study

This chapter discusses the proposed Impact Study: the conceptual model of the effects of peer counseling, the research questions and outcome measures, models for estimating overall effects, and approaches for estimating variations in effects associated with client and site characteristics.

Conceptual Model

Exhibit 6.1 illustrates major factors that may influence a woman's decision to initiate breastfeeding, as well as the intensity and duration of breastfeeding, and whether or not she breastfeeds on demand. Articulating influential factors is helpful to identify (a) the specific pathways through which the peer counseling interventions may influence breastfeeding outcomes, (b) key variables that need to be taken into account in assessing intervention impacts, and (c) the hypothetical relationships that will need to be explored in the analyses.

Exhibit 6.1 illustrates the peer counseling intervention, factors that are not directly influenced by the intervention ("Baseline and Other Fixed Factors"), and outcomes that a peer counseling intervention is intended to change, including proximal or mediating outcomes and distal outcomes. The intervention's influence can vary depending on its characteristics, for example, timing of peer counselor support, number of contacts, and accessibility of peer counselors. Factors that will not be directly affected by the intervention include maternal socio-demographic characteristics, characteristics of the birth, characteristics of the infant, the hospital environment, and support provided by WIC and non-WIC healthcare providers. Although these factors are not amenable to change through the intervention, it is important that they be considered in the design and implementation of the intervention and in impact analyses.

Peer counseling is intended to work through proximal outcomes, including: a woman's knowledge of and perceptions and attitudes about breastfeeding; and the level of social support (or discouragement) a woman receives for breastfeeding, including the extent to which a woman has one or more positive role models of successful breastfeeding. In addition, peer counseling could affect the amount of breastfeeding promotion services (other than peer counseling) that a woman may access. For example, the extent to which peer counselors can provide access to professional services, such as referral to a certified lactation consultant, is also an important factor in influencing positive breastfeeding outcomes. Peer counselors could influence a woman's decisions about returning to work or effect how she addresses health problems that could, in turn, affect her breastfeeding outcomes.

Exhibit 6.1
Model for Understanding the Effect of Peer Counseling on Breastfeeding Outcomes

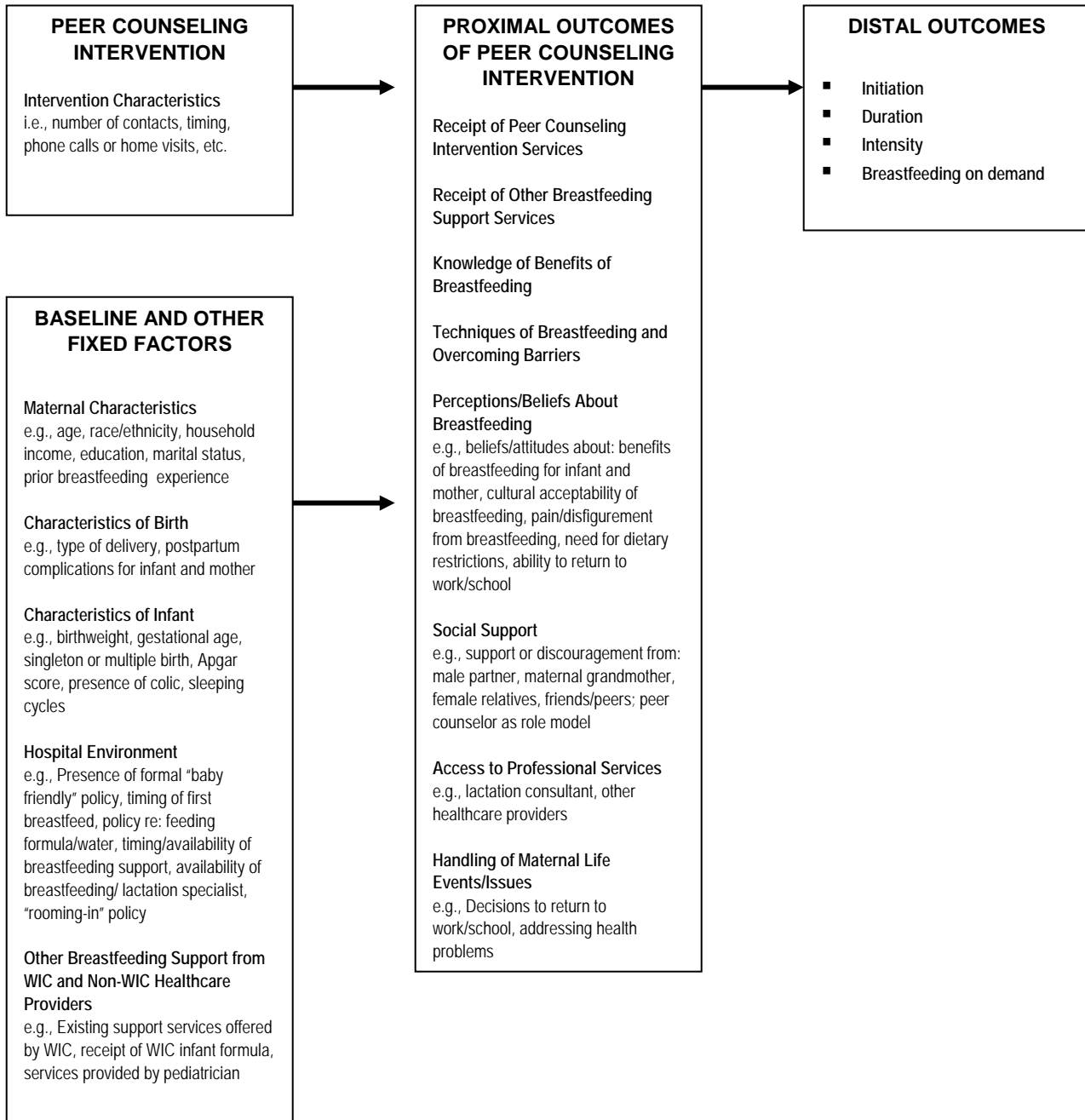
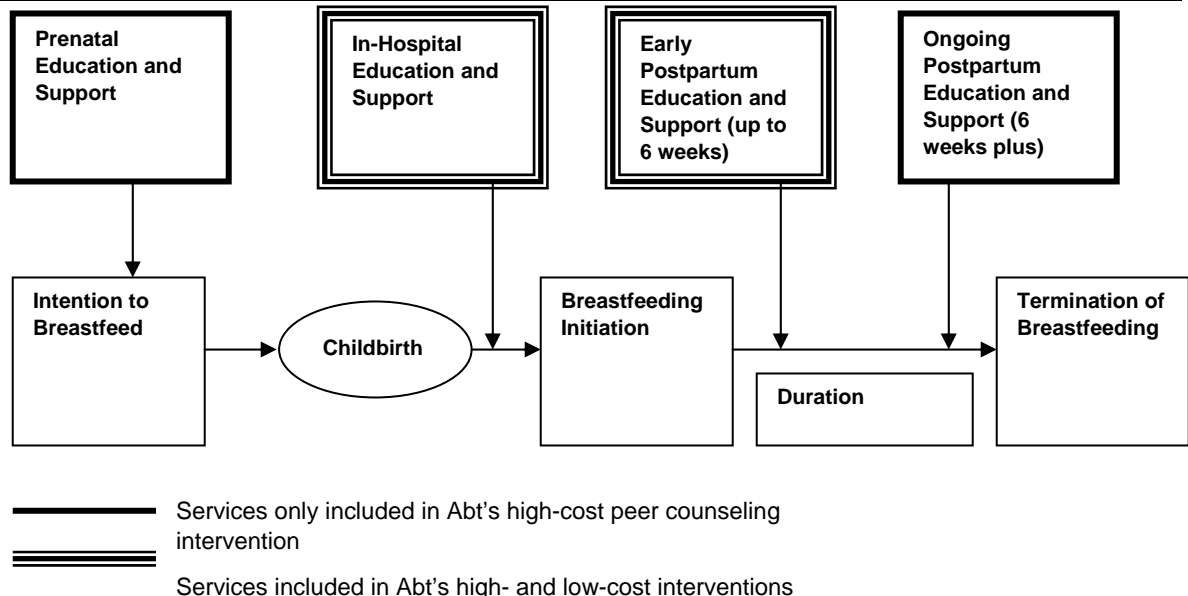


Exhibit 6.2 presents a timeline of the breastfeeding process and key points at which interventions can influence this process. The intervention points on the breastfeeding continuum represent times when women need targeted support to initiate breastfeeding in an optimal fashion or to maintain breastfeeding. These key points include the early prenatal period, the late prenatal period – shortly before delivery – and the early postnatal period, both in and out of the hospital, as well as the later postnatal period. After breastfeeding has been established successfully, women may need continued support to deal with emerging concerns, such as worries about continued adequacy of their milk supply, scheduling time away from the baby, returning to work or school, breastfeeding in public, and introducing solid foods. Note that while breastfeeding termination is visually depicted at a distance away from breastfeeding initiation, it could come at any point along the continuum. That is, mothers could stop breastfeeding after the first breastfeeding experience, after two weeks, after two months or after a year or more.

Exhibit 6.2
The Breastfeeding Process and Key Intervention Points



The services included in Abt's high- and low-cost intervention models described in Chapter Two are also depicted in Exhibit 6.2. Abt's high-cost intervention is designed to target all key intervention points during the breastfeeding process, from prenatal through six months postpartum. The low-cost intervention targets the early postpartum period, including in the hospital and up through six weeks. The focus of other peer counseling interventions FNS considers may be different (e.g., both high and low cost might offer prenatal education and support).

Key Research Questions

The conceptual model of the peer counseling intervention and its effects presented above posits a process in which maternal and infant characteristics, WIC program context, and how much

intervention is received by study participants would affect the proximal breastfeeding outcomes (e.g., knowledge of benefits of breastfeeding, level of social support for breastfeeding), which, in turn, would lead to the final breastfeeding outcomes (e.g., duration and intensity of breastfeeding). The impact analysis involves estimating impacts of the intervention not just on breastfeeding outcomes, but also on services received and proximal or intermediate outcomes. Together, results from these analyses will not only show the impacts of the intervention on sample members' breastfeeding, but should also provide some understanding of how those impacts came about. In Chapter Seven we list the research topics and outcomes for the Impact Study, the measures corresponding to each outcome, and the data sources.

Services Received and Proximal Outcomes

Any statistically significant differences between the treatment and control groups in the breastfeeding outcomes are likely to have come about because of differences in receipt of peer counseling and other breastfeeding services. The intervention is intended to produce substantial treatment-control differences in peer counseling receipt. Peer counseling receipt among the control group might not be zero, because of contamination within WIC or services received outside of WIC, e.g., from the local hospital or the La Leche League, and to some extent peer counseling services may simply substitute for these.

For purposes of understanding the existence and size of impacts, the key research questions relating to breastfeeding support services received are:

- Does each of the two peer counseling interventions increase the receipt of peer counseling services?
- Do the interventions affect the receipt of other types of breastfeeding support services?

The outcome measures used should include receipt of support (yes/no), duration of support (weeks or months), and intensity of support (contacts per month).

The Implementation Study also includes some participation analyses, as described in Chapter Five. A key difference is that the focus for the Impact Study is on accurately measuring *impacts* on inputs (that is, treatment-control differences in services received), whereas the Implementation Study is concerned with a broader assessment of participants' experiences, and focuses more on the treatment groups.

Other proximal outcomes are those that mediate the relationship between peer counseling and breastfeeding. The three most likely pathways by which peer counseling may be hypothesized to increase breastfeeding are by providing increased knowledge about the benefits of breastfeeding, improved breastfeeding techniques and solutions to overcome barriers, and social support for breastfeeding. Specific research questions are:

- Do the interventions increase sample members' knowledge about breastfeeding?
- Do the interventions improve sample members' breastfeeding techniques and solutions, as seen in lower incidence of such barriers to breastfeeding as perceived insufficient milk and nipple soreness?

- Do the interventions increase sample members' perceptions of social support for breastfeeding, and the availability of breastfeeding role models?

These mediating outcomes can be measured through participant survey data. For example, a positive impact of peer counseling on social support without an impact on participants' knowledge about the benefits of breastfeeding could be interpreted as evidence that the intervention was effective more for the former than the latter reason. Although examining impacts on potential mediators can *suggest* causal mechanisms and rule out others, such an analysis cannot *prove* causality. Causes of impacts other than the hypothesized pathways are possible.

In addition to the outcomes above, all of which involve estimating experimental impacts, the Impact Study will include descriptive analyses of baseline and other characteristics that are fixed or exogenous to the intervention. Such analyses will provide a more detailed picture of sample members, including their breastfeeding intentions and role models at baseline, and will detail the circumstances pertaining to the infant's birth. Exhibit 7.2 lists specific measures for these descriptive analyses.

Distal Outcomes of Breastfeeding

The heart of the impact analysis is estimating experimental impacts on four key breastfeeding outcomes. The specific outcome research questions are:

- Does each of the two peer counseling interventions increase breastfeeding *initiation rates*?
- Do the interventions increase breastfeeding *duration*?
- Do the interventions increase the *intensity* of breastfeeding?
- Do the interventions increase the rates of women breastfeeding *on demand*?

The peer counseling interventions are intended to increase each of these dimensions of breastfeeding, by providing social support to participants, increasing their knowledge about the benefits of breastfeeding, and improving their breastfeeding techniques and solutions.

Models to Be Estimated

Random assignment ensures that simple comparisons of raw mean outcomes between treatment and control groups will provide unbiased estimates of impacts. Typically, however, regression analysis is used to improve the precision of the estimates by adjusting for any chance differences between the treatment and control groups on a number of characteristics measured at baseline. The specific impact models to be estimated depend on the random assignment design selected: two-way (person level), three way (person-level) or site level. Chapter Three discusses the merits of each of these designs. We begin with RA3, our preferred design.

The basic impact model for *three-way random assignment* is:

$$\log[p_{ij}/(1-p_{ij})] = \beta_0 + \sum_{s=1}^S \beta_s^L T_{is}^L + \sum_{s=1}^S \beta_s^H T_{is}^H + \sum_{s=1}^{S-1} \beta_s^{Site} Site_{is} + \sum_{k=1}^K \beta_k^X X_{kij} + \varepsilon_{ij}$$

where

- p_{ij} is the outcome of interest (e.g., whether breastfeeding at four weeks) for sample member i in site j ;²⁵
- T_{is}^L is equal to 1 if sample member i is in site s and belongs to the low-cost treatment group, 0 otherwise;
- T_{is}^H is equal to 1 if sample member i is in site s and belongs to the high-cost treatment group, 0 otherwise;
- $Site_{is}$ is an indicator that individual i is in site s , where S is the total number of sites (and one site is excluded to avoid collinearity);
- X_{kij} are a set of K baseline characteristics for sample member i in site j ;
- ε_{ij} is a random error term; and
- the β 's are coefficients to be estimated—in particular, β_s^L is the effect of the low-cost treatment in site s and β_s^H is the effect of the high-cost treatment in site s .

Because it is likely that effects will vary among sites, this model allows for separate site impact estimates. Nonetheless, the parameters of interest are the estimated *overall* effects, and the hypothesis of interest is whether each is greater than zero; that is, whether the high-cost treatment improves breastfeeding outcomes compared to standard site practice, and analogously for the low-cost treatment, in all sites combined. The overall impact for each treatment (high- and low-cost) is calculated as a weighted average of the site impacts, where the weights are based on the relative number of eligible individuals at that site. Similarly, the variance of the overall impact of each treatment is a weighted sum of the variances of the site-level impacts, where the weights are the squares of those used in calculating the average effect.

The three-way random assignment approach makes three sets of comparisons possible: high-cost versus control, low-cost versus control, and high-cost versus low-cost. Comparison of the high- and low-cost interventions would be based on a statistical test of the equality of the weighted sums of the site-level coefficients. The three two-way comparisons are not independent; any one of the comparisons can be derived from the other two.

The basic model under a *two-way random assignment* design differs from the model above in that the treatment-site interactions are indexed separately for low-cost and high-cost treatment groups.²⁶ We assume that the total of S sites are numbered such that the first half are used for the low-cost intervention and the second half are used for the high-cost intervention.

$$\log[p_{ij}/(1-p_{ij})] = \beta_0 + \sum_{s=1}^{S/2} \beta_s^L T_{is}^L + \sum_{s=(S/2)+1}^S \beta_s^H T_{is}^H + \sum_{s=1}^{S-1} \beta_s^{Site} Site_{is} + \sum_{k=1}^K \beta_k^X X_{kij} + \varepsilon_{ij}$$

²⁵ The basic model is specified as logit because most of the outcomes of interest are binary. For any continuous outcomes, an ordinary least squares model would be estimated.

²⁶ Alternatively, one could estimate two models, one for high-cost sites and another for low-cost sites. The single equation approach is more efficient because it constrains the coefficients on the baseline characteristics to be the same in the low- and high-cost sites.

where

T_{is}^L is equal to 1 if sample member i is in (low-cost) site s and belongs to the low-cost treatment group, 0 otherwise;

T_{is}^H is equal to 1 if sample member i is in (high-cost) site s and belongs to the high-cost treatment group, 0 otherwise.

As in the three-way design above, the overall impact of the low-cost intervention is a weighted average of the low-cost impacts at individual sites, and analogously for the overall impact of the high-cost intervention. Variances are also calculated analogously.

The high- and low-cost impact estimates in the two-way model are based on different sets of sites, and therefore on different sets of control group members. Because of this, as discussed in Chapter Three, a comparison of impacts between the high- and low-cost interventions is not experimental.

Under either the two-way or three-way approach, the site-specific impact estimates β_s^L and β_s^H are unbiased estimates of the average impact of each treatment on all sample members assigned to the respective treatment group. These estimates include what we expect will be a small proportion of treatment group members who do not receive peer counseling services for whatever reason. This type of estimate is referred to as the “intent to treat” (ITT) estimate, because it represents the effect of the treatment on all those to whom it was offered, whether or not they actually received it.

In both models, site-specific “fixed effects” (the *Site* terms) are included to control for variation in average outcomes at the site level. Because the sites are not a probability sample, they are treated as having fixed rather than random effects. The statistical software used needs to take account the clustering of individuals within sites, which results in intrasite correlation of residuals.

The covariates (the *X* terms) would include a range of measures available from the baseline participant survey and from WIC administrative data. The most important covariates, in terms of improving precision of the impact estimates, are pre-program measures of breastfeeding intentions and history. Covariates must either be time-invariant (such as race) or measured at or before random assignment, because variables measured after random assignment could mistakenly incorporate the real effect of the intervention.

The third approach, *site-level random assignment*, requires a different estimating equation. Treatment effects are calculated directly for all sites combined, and site-level characteristics as well as individual characteristics can be included in the equation:

$$\log[p_{ij}/(1-p_{ij})] = \beta_0 + \beta^L Site_j^L + \beta^H Site_j^H + \sum_{h=1}^H \beta_h^Z Z_{hj} + \sum_{k=1}^K \beta_k^X X_{kij} + \varepsilon_{ij}$$

where

$Site_j^L$ is equal to 1 if Site j is in the low-cost treatment group, 0 otherwise;

$Site_j^H$ is equal to 1 if Site j is in the high-cost treatment group, 0 otherwise; and

Z_{hj} are a set of H site characteristics for Site j .

Examples of site characteristics that could be included in the model are regional indicators, urban/suburban/rural indicators, availability of breastfeeding services from other sources such as the La Leche League, breastfeeding-supportive hospitals, and baseline measures of breastfeeding outcomes.

Because the sites are randomly assigned to treatment groups, i.e. they comprise a probability sample from the set of sites that were selected to participate in the study, it is appropriate to treat residual site effects as random rather than fixed. Statistical software incorporating this feature is readily available.

Variations in Impacts

Subgroup analyses will show whether the peer counseling interventions were effective for particular types of sites or participants, and whether they were more effective for some types of sites or participants than others. The participant subgroup categorization of primary interest for this study is race/ethnicity. Because black women and some subgroups of Hispanic women (such as Puerto Ricans) have substantially lower breastfeeding rates than non-Hispanic white women, FNS may be especially interested to learn if peer counseling can increase breastfeeding among those groups.

Other possible subgroup categorizations include prior exposure to breastfeeding, strength of intentions to breastfeed, employment status, and household composition and size. Whatever the specific subgroup categories, they must be defined based on characteristics that are time invariant or determined at or prior to random assignment. Furthermore, some theory should guide the selection of a small number of subgroups because the analysis of a large number of subgroups is bound to yield at least some false positive findings. Also, note that the power calculations in Chapter Four pertained to all participants combined. Statistical power will be proportionately less for subgroups.

If individual-level random assignment is used, subgroup effects should be measured within site, then combined across sites. Because the sites are not a nationally representative sample, the average of the effects does not have a generalizable meaning. The best we can do is assume that the demonstration sites comprise their own world, and calculate overall effects within that world. The site effects for each subgroup should be combined using weights that reflect the number of participants in the subgroup. For example, a site that served twice as many black participants as another site (regardless of the proportion of participants that were black in each site) would be weighted twice as heavily in determining effects for black women.

Subgroup effects can be estimated by two distinct methods, corresponding to assumptions of other things equal (*ceteris paribus*) and other things varying (*mutatis mutandis*). The first approach, which is more common, is to interact the treatment indicator(s) with subgroup indicators. This answers the conceptual question:

- If two women were identical in their characteristics that affected breastfeeding outcomes (e.g., age, parity, education, household income, marital status, etc.) other than race/ethnicity, how would the fact that one was (say) black and the other non-Hispanic white affect the expected impact of peer counseling?

If indeed the effect of peer counseling varies *only* with race/ethnicity then this is an unobjectionable approach. But suppose that peer counseling is more effective for women with some college education, and that black WIC participants are less likely than non-Hispanic white participants to have any college education. Then this approach would tell us the difference in effectiveness of peer counseling between a black woman and a non-Hispanic white woman with the same amount of

formal education—not between the average black woman (with less formal education) and the average non-Hispanic white woman (with more formal education).

To find the difference in effects between the average black woman and the average non-Hispanic white woman requires a *mutatis mutandis* approach (letting other things vary naturally, rather than holding them constant). This is done by estimating *separate regressions* for the subgroups (from which of course the subgroup indicators and subgroup-treatment interactions are dropped). This is the approach we recommend, for both individual- and site-level random assignment designs.

If site-level random assignment is chosen, it will also be possible to determine the relationship between impacts and site characteristics, such as urban/suburban/rural location or availability of other breastfeeding support services. Again, this can be done either by interacting site characteristics with the treatment indicator, or by estimating separate models for different types of sites. We recommend the latter approach. Policymakers will find it more useful to know, for example, whether the intervention works better in urban than in rural sites *as they are currently constituted* (e.g. with particular caseload demographics, geographic distribution, and availability of other breastfeeding services), than to know whether the intervention would have worked better if a particular rural site was urban, with all its other characteristics unchanged.

Chapter Seven

Data Collection: Measures

This chapter presents the details of data collection for the evaluation of the peer counseling interventions. The data elements, sources and methods of data collection are discussed for the Implementation and Impact Studies, respectively. The discussion about data collection measures is based on the assumption that the evaluation uses within-site random assignment of participants. Under this design, all local agencies in the study would implement the peer counseling interventions, and participants within each agency would be randomly assigned to either receive the high- or low-cost peer counseling (treatment) or not to receive peer counseling (control). However, the information in this chapter would generally apply to an evaluation based on a design that randomly assigns some agencies to use peer counseling with all of their participants and other agencies to provide no peer counseling to any of their participants (i.e., site-level random assignment). Measurement issues that would differ depending on the choice of evaluation design are noted in the text.

Implementation Study

Exhibit 7.1 presents the required data elements, sources, and data collection methods for the key research topic areas addressed in the Implementation Study.

Sources of Data

For the Implementation Study, Abt recommends that data be collected from relevant WIC staff, including the local agency WIC Director, peer counselor coordinator or supervisor, and peer counselors. Staff from the hospital and other organizations (e.g., pediatric practice) that may collaborate with WIC on the peer counseling interventions should also be interviewed. WIC study participants should also be an important source for implementation data, through interviews conducted as part of the Impact Study and through focus groups. WIC administrative data and data specifically collected during the evaluation (i.e., cost data, peer counselor activity logs, records of study contacts and random assignment) could also provide important implementation information.

Data Collection Methods

Baseline WIC Agency Survey

Local WIC agencies that are selected for the evaluation would be asked to provide baseline program information as part of the preliminary steps in their involvement in this study. Information on the characteristics of the local agency, the clients served, and on current breastfeeding promotion and support activities should be gathered through this survey.

Interviews with WIC Staff

Interviews need to be conducted with the local WIC agency program directors, peer counselor coordinators, and the peer counselors. As described in Exhibit 7.1, these interviews should cover a variety of topics, including questions about the local agency and its operations, breastfeeding

promotion activities (other than peer counseling) that are offered to WIC participants, the details of how the peer counseling intervention has been implemented, and their perceptions of the intervention. It is recommended that these interviews be conducted in person during site visits in the early months of the intervention and again after a year of implementation. As an interim check on how implementation is going, it is recommended that phone interviews be conducted with the local WIC agency director and peer counselor coordinator. Given the competing demands on the time of these staff, data collection instruments should be as brief as possible.

Interviews with Hospital and Collaborating Organizations

Abt recommends that interviews be conducted with staff within the local hospital(s) and any other agencies or organizations that are collaborating on the peer counseling interventions with WIC. Staff can provide a description of breastfeeding promotion and support services offered to WIC participants by the hospital and provide insight into the coordination of services with WIC, especially as this relates to the peer counseling intervention. For example, if a local pediatric practice serving WIC clients refers mothers to the peer counselors or requests peer counselors to do some in-office support groups, then these efforts can be documented. Hospital and other agency staff should also be asked about their perceptions of the peer counselor intervention and for input on improvements to the program.

Survey of WIC Participants

Questions related to the implementation of the peer counseling intervention will be asked as part of the interviews with WIC participants planned for the Impact Study, as further described later in this chapter. In particular, these questions relate to treatment group members' perceptions of the benefits and challenges of peer counseling, and the treatment and control members' perceptions of other WIC breastfeeding promotion and support activities.

Focus Groups of WIC Participants

Focus groups should be planned for each participating WIC agency during the Implementation Study site visits. Three focus groups need to be held per site, with about 8-12 participants in each. One group should consist of study participants receiving the high-cost peer counseling intervention; another group for participants receiving the low-cost intervention; and the third group for those receiving the standard breastfeeding promotion practice (control group members). The focus should be on the benefits and challenges of breastfeeding promotion and support in WIC, with particular attention to the peer counseling intervention for the treatment groups. These same topics need to be addressed to some extent in the Participant Surveys; however, the context of the focus group often provides an environment in which participants express their opinions more candidly. It also allows facilitators to probe for clarification or for more depth to a response.

Exhibit 7.1**Implementation Study: Required Data Elements, Sources of Data, and Data Collection Methods**

Research Topic	Required Data Elements	Source of Data	Data Collection Method
1. Characteristics of participating local WIC agencies	Type of agency (health, social service, etc.) Number of service sites Number of staff Number of WIC clients served Geographical region and urbanicity Breastfeeding coordinator or lactation consultant on staff Staff training on breastfeeding promotion Percent of WIC Nutrition Services and Administrative (NSA) funds devoted to breastfeeding promotion/support	Participating local WIC agency staff	Administrative data extraction Baseline WIC Agency Survey Baseline site visit [Baseline implementation data collection]
2. Characteristics of agency clients	Age Marital/living status Education Employment status Race/ethnic origin Household income Participation in other food assistance programs Type of health insurance (Medicaid, private, etc.) Prior WIC participation	WIC administrative database, e.g., for WIC Program Characteristics Studies, supplemented by study participant survey data	Administrative data extraction [Baseline implementation data collection]
3. Breastfeeding (BF) promotion services provided by WIC agency (previously and current)	BF promotion services provided historically and currently Evidence of service effectiveness Staff members involved in BF support services Time of service delivery vis a vis WIC mothers' pregnancy Extent of services received by WIC mothers Cost of BF promotion and support services Involvement of hospitals and other collaborating agencies Availability of data on BF initiation and duration rates	Participating local WIC agency staff Area hospital and other collaborating agency staff	WIC staff interview Interviews with collaborating hospital and other agency staff [Baseline implementation data collection]

Exhibit 7.1**Implementation Study: Required Data Elements, Sources of Data, and Data Collection Methods**

Research Topic	Required Data Elements	Source of Data	Data Collection Method
4. Peer counseling implemented at participating WIC agencies			
4a. Changes made in program staffing and operations	Staffing changes: new hires, changes in responsibilities and assigned tasks Staff reactions to staffing changes Staff training to support the peer counseling intervention (content, timing, trainer) Purchase of new equipment and supplies for the intervention Changes in agency's client service schedule and procedures Changes in agency's administrative record keeping process/system Rules and processes implemented to provide peer counseling exclusively to the treatment group participants	Participating local agency staff (WIC director, BF coordinator)	WIC staff interview [Baseline and Follow-up implementation data collection]
4b. Peer counselor recruitment, training, assignment, supervision	Peer counselor recruitment and selection process Demographic characteristics of peer counselors (e.g., age, education, marital status, race/ethnicity, primary language, WIC experience, breastfeeding experience) Recruitment and selection of peer counselor trainer Training: content, schedule, attendance, number of peer counselors trained Peer counselor pay, benefits Peer counselor work schedule and caseload Process of matching and assigning peer counselor to WIC mothers (include: factors considered in matching) Process of monitoring and supervising peer counselor performance Continuing training and supports provided to peer counselors Turnover rate of peer counselors Process of training additional peer counselors (frequency, timing, number of peer counselors trained, trainer)	Participating local agency staff (WIC director, BF coordinator, peer counselor supervisor, peer counselors)	WIC staff interview Peer counselor interview [Baseline and Follow-up implementation data collection]

Exhibit 7.1**Implementation Study: Required Data Elements, Sources of Data, and Data Collection Methods**

Research Topic	Required Data Elements	Source of Data	Data Collection Method
4c. Services offered in peer counseling	Places where peer counseling is conducted (e.g., WIC site, participant home, hospital) Methods of counseling contacts (individual meeting, phone, home visit, group meeting) Professional supports available for peer counselors to refer participants (type of professionals involved, support provided) Procedures used by peer counselors to refer WIC mothers for additional professional services Process of assessing the presence of BF contraindications	Participating local agency staff (WIC director, BF coordinator, peer counselor supervisor, peer counselors)	WIC staff interview Peer counselor interview [Baseline and Follow-up implementation data collection]
4d. Coordination of peer counseling activities with area hospitals and other collaborating organizations	Number and type of collaborating organizations Responsibilities and contributions of each organization Type of coordination made with area hospital Hospital staff involved in the administrative coordination (type and number of staff) Infant feeding policies and practices of area hospital BF promotion/support services provided by area hospital (content, timing, frequency) Hospital staff involved in hospital's BF promotion/support services (type and number of staff, type of service provided) Mechanisms for maintaining collaborative relationship between WIC agency and collaborating organizations	Participating local agency staff (WIC director, BF coordinator) Area hospital and other collaborating agency staff	WIC staff interview Interviews with collaborating hospital and other agency staff [Baseline and Follow-up implementation data collection]
5. Extent of participation by WIC mothers in peer counseling	Percent of total WIC enrollees selected for the evaluation at enrollment Percent of WIC enrollees contacted for BF intention verification Percent of WIC enrollees randomly assigned to treatment or control groups Percent of WIC enrollees that receive the standard prenatal BF education Extent of prenatal BF education received by study participants Percent of treatment group participants who receive prenatal peer counseling contact Number and type of postpartum peer counseling contacts received by treatment group participants Number of calls peer counselors receive from treatment group participants and timing of the calls	Evaluation activity record Peer counselor activity log	Evaluation activity record maintained by Site Coordinators Peer counselor activity log completed by peer counselors and reviewed by peer counselor supervisor [Follow-up implementation data collection]

Exhibit 7.1**Implementation Study: Required Data Elements, Sources of Data, and Data Collection Methods**

Research Topic	Required Data Elements	Source of Data	Data Collection Method
6. Reactions and perceptions of WIC participants, staff, and collaborating agency staff to the intervention	Treatment group participants' perception of benefits and challenges to peer counseling WIC staff's perception of benefits and challenges to peer counseling Hospital and collaborating agency staff's perception of benefits and challenges to peer counseling Peer counselors' and their supervisors' perception of benefits and challenges to peer counseling Control group participants' perception of benefits and challenges of available BF promotion and support services Areas for improving peer counseling BF support method	Participating local agency staff (WIC director, BF coordinator, peer counselor supervisor) Area hospital and other collaborating agency staff Treatment and control group participants	WIC staff interview Interviews with collaborating hospital and other agency staff Participant interview and focus groups [Follow-up implementation data collection]
7. Cost of peer counseling demonstration	Start-up expenditures Training costs Costs of WIC staff's involvement in the intervention Costs of peer counselors	Participating local agency WIC director Administrative records on expenditures	WIC staff interview (Director) Administrative data extraction [Follow-up implementation data collection]
8. Prospects of continuing peer counseling	Participating agencies' plans for continuing peer counseling Changes and modifications anticipated Reasons for discontinuing the intervention Plans for funding peer counseling	Participating local agency staff (WIC director, BF coordinator)	WIC staff interview [12-month Follow-up implementation data collection]

WIC Administrative Data

State WIC programs are required to maintain management information systems, which have some standard data items across agencies as well as those that are specific to a state. Of note are the data that are required as part of the Minimum Data Set (MDS) of items provided to the biennial WIC Participant and Program Characteristics studies. The MDS includes demographic information about participants (e.g., family income, number of family members, race/ethnicity), their pregnancy and health (e.g., expected date of delivery, height and weight), and WIC status (e.g., nutrition risks present at certification, prescribed food package). The MDS also contains data items related to breastfeeding, including whether infants between seven and eleven months are currently receiving breast milk, whether they were ever breastfed, the duration of breastfeeding, and the date the breastfeeding information was collected.

A state may also collect information in a standardized format for the Supplemental Data Set (SDS) for the biennial WIC Participant and Program Characteristics studies. These additional data, while not required, provide some useful information about WIC participants, including more demographic information (e.g., educational level), data about pregnancy and birth (e.g., total number of live births for WIC women, birth weight for infants), and WIC participation (e.g., number in household on WIC, length of time on WIC during pregnancy).

Other records that could potentially be used in evaluation of the peer counseling interventions are:

- **WIC certification records.** These records include participants' identifying information (name, address, phone), which are needed to contact study participants, and, depending on the state, can include information on certification category, eligibility (income, household size, nutrition risks), demographics (age, race, language, employment status, marital status), pregnancy history, and prescribed food package.
- **WIC appointment records.** Clinic visits and missed appointments are recorded in the management information system of most state WIC agencies. In addition, some information systems maintain a record of the types of nutrition education services received by each participant. This information could be used as an alternative, or to validate, survey responses.
- **WIC food package codes or voucher records.** WIC food package codes provide a record of the food prescription of individual WIC participants. These codes are therefore indicative of whether an infant is enrolled as a non-breastfeeding infant or a mother is enrolled as a breastfeeding mother.

Data extracted from WIC administrative files can be used as sources of information to supplement or verify the survey and interview data collected for the study.

Intervention Records

Abt recommends that two types of records be developed specifically for the peer counseling intervention and the Implementation Study. The first is the intervention activity record that would be used to document all study activities and contacts for each study participant throughout the evaluation. Staff would document each step of the recruitment and intervention process, including WIC enrollment and the completion of the Intention Screener, the outcome of the random assignment process, and all attempts at interviews (and whether they were successful or not). These records will

form the basis of a tracking system and can then be analyzed to document the outcomes of this process, including the number of women who are selected for the evaluation at enrollment, the number who are contacted for breastfeeding intention in later pregnancy, those assigned to the treatment and control groups, and so on.

As a way of monitoring the progress of counseling activities for each participant, Abt recommends that peer counselors be asked to provide weekly activity logs documenting all of the peer counseling activities (e.g., phone calls, in-person contacts at WIC, hospital visits). These logs can then be used to determine the numbers and types of contacts received by each study participant.

Impact Study

Exhibit 7.2 presents the required data elements, sources, and methods of data collection for the Impact Study by research topic area, grouped into three categories: 1) the baseline and other fixed characteristics of participants; 2) the proximal outcomes; and 3) the distal outcomes of the intervention.

Exhibit 7.2**Impact Study: Required Data Elements, Sources of Data, and Data Collection Methods**

Research Topic	Data Elements	Source of Data	Data Collection Method
BASELINE AND OTHER FIXED CHARACTERISTICS OF STUDY PARTICIPANTS			
1. Demographic characteristics	Age Marital/living status Education Employment status Race/ethnic origin Primary language Household composition and size Presence and ages of other children in household Household income Receipt of Temporary Assistance for Needy Families (TANF) Participation in other food assistance programs Type of health insurance (Medicaid, private, etc.)	Study participants WIC administrative data	Baseline Survey of WIC participants, with changes identified in follow-up surveys Case record abstraction
2. Pregnancy and health status of study participants	Expected date of delivery or weeks gestation Parity Whether breastfed other children Contraindications to breastfeeding Health status and behaviors (cigarette smoking, alcohol, drugs, etc.) Any prenatal care When prenatal care began Number of prenatal care visits Prior and current WIC participation	Study participants	Baseline Survey of WIC participants
3. Characteristics of the birth	Type of delivery Difficulty/complications Use of general anesthesia Post-delivery medical complications for mother	Study participants	Surveys of WIC participants at 2 weeks

Exhibit 7.2**Impact Study: Required Data Elements, Sources of Data, and Data Collection Methods**

Research Topic	Data Elements	Source of Data	Data Collection Method
4. Characteristics of the infant at birth	Birth weight Gestational age Singleton or multiple birth Apgar score Need for neonatal intensive care Medical/physical complications that affect ability to breastfeed	Study participants	Survey of WIC participants at 2 weeks
5. Characteristics of the infant after birth	General disposition/"fussiness" Alertness Presence or absence of colic Sleeping cycles, particularly at night Health	Study participants	Follow-up Surveys of WIC participants
PROXIMAL OUTCOMES			
1. Receipt of peer counseling services	Proportion receiving peer counseling services, by type of service Amount of peer counseling services received, by type (e.g., number and type of contacts with peer counselor)	Study participants Peer counselor activity log	Follow-up Surveys of WIC participants Peer counselor activity log completed by peer counselors and reviewed by supervisor
2. Receipt of other breastfeeding services	Type and content of breastfeeding services received Source of services Timing of services Frequency of services Duration of services	Study participants	Baseline and Follow-up Surveys of WIC participants
3. Infant feeding intentions of study participants	Intention to breastfeed, formula-feed, both, undecided Reasons for/most important factor in feeding decision Length of time planning to breastfeed	Study participants	Intention Screener Baseline and Follow-up Surveys of WIC participants

Exhibit 7.2**Impact Study: Required Data Elements, Sources of Data, and Data Collection Methods**

Research Topic	Data Elements	Source of Data	Data Collection Method
4. Knowledge, perceptions and attitudes of study participants regarding breastfeeding	Knowledge of health/other benefits of breastfeeding to mother and infant Belief in health/other benefits of breastfeeding Knowledge of dietary recommendations for breastfeeding mothers Importance of dietary practices for breastfeeding mothers Perceived enhancers/barriers to breastfeeding	Study participants	Baseline and Follow-up Surveys of WIC participants
5. Availability of social support	Support or discouragement from: Male partner Maternal grandmother Female relatives Friends/peers	Study participants	Baseline and Follow-up Surveys of WIC participants
6. Availability of breastfeeding role models	Personal prior breastfeeding experience Was breastfed as infant Mother breastfed other infants Female relative or friend breastfeed successfully	Study participants	Baseline and Follow-up Surveys of WIC participants
7. Potential barriers to breastfeeding and reasons for discontinuing breastfeeding	Perceived insufficient milk Problems with positioning/latching on Nipple soreness Difficulties with the use of breast pump Formula supplementation Introduction of solid foods Need to schedule time away from baby Return to work Maternal health issues	Study participants	Survey of WIC participants at 2 weeks Follow-up Surveys of WIC participants

Exhibit 7.2**Impact Study: Required Data Elements, Sources of Data, and Data Collection Methods**

Research Topic	Data Elements	Source of Data	Data Collection Method
DISTAL OUTCOMES			
1. Breastfeeding <i>duration</i>	Breastfeeding at hospital discharge Breastfeeding at 2 weeks Breastfeeding at 4 weeks Breastfeeding at 8 weeks Breastfeeding at 6 months Median duration of breastfeeding	Study participants	Follow-up Surveys of WIC participants
2. Breastfeeding <i>intensity</i>	Exclusivity of breastfeeding	Study participants	Follow-up Surveys of WIC participants
3. Breastfeeding <i>initiation</i>	Ever breastfed	Study participants	Survey of WIC participants at 2 weeks
4. Breastfeeding <i>frequency</i>	Whether infant is breastfed on demand	Study participants	Follow-up Surveys of WIC participants
5. Subgroup differences in breastfeeding outcomes (e.g., race/ethnicity, employment status)	Same data elements as above	Study participants	Baseline and Follow-up Surveys of WIC participants

There are four key outcome measures for the study of peer counseling interventions:

- Initiation, defined as whether or not a mother *ever* breastfed her infant;
- Duration, or the length of time a mother continued to breastfeed her infant;
- Intensity, defined as whether a mother breastfeeds exclusively or partially with some infant formula supplementation; and
- Whether a mother breastfeeds the infant on demand.

As described in Chapter Two, the reason for choosing peer counseling as an intervention strategy is that prior research has suggested that it has an effect on breastfeeding duration, a particular concern for the WIC program. Thus, breastfeeding duration should be a critical focus and Abt recommends that breastfeeding at hospital discharge, at 2, 4 and 8 weeks and at 6 months be analyzed.

While duration is a focus, other outcomes of importance are initiation and intensity (or exclusivity). Peer counseling is generally not associated with increasing rates of breastfeeding initiation, but it is possible that meeting a peer counselor in the prenatal period or knowing that one will receive peer support for breastfeeding will increase the incidence of breastfeeding initiation. It is also possible that peer counselors will influence the intensity of breastfeeding. Through education or support, peer counselors may help WIC women to either delay the onset of formula supplementation or limit the amount of supplementation.

In its original request for this study, FNS expressed interest in looking at frequency of breastfeeding as an outcome. The Institute of Medicine (1991) has developed recommendations for breastfeeding frequency, which state that mothers breastfeed at least eight to 15 times per day for the first month, then five to 12 times per day on demand after the first month. However, while it would be possible to ask mothers how many times they breastfeed in a day and compare the results to these recommendations, our expert panel advised against this approach. Frequency of breastfeeding can vary markedly, depending on a variety of things including infant's feeding style, illness, or colic. The expert panelists recommended instead that we measure whether mothers feed their children "on-demand," in response to their infants' hunger cues. The panel believed that this would be a better measure of a mother keeping up her milk supply to meet the infants needs than simple counts of breastfeeds. Having some indication of a mother keeping up her milk supply is important as "insufficient milk" is often cited as the reason for breastfeeding termination. In the WIC Infant Feeding Practices Study, over one-third of WIC mothers indicated they stopped breastfeeding in the first month after birth due to insufficient milk (Baydar *et al.*, 1997).

Sources of Data

The primary source for information for the Impact Study should be from WIC study participants. Abt also recommends considering a limited use of the extant data from existing WIC administrative management information systems (described in the previous section) in cases where basic demographic data from participants are missing (e.g., when there is item nonresponse or a missed survey). Note, however, that there may only be a few variables of interest from the extant data, and they might not be in the same format as the survey questions (e.g., income may be reported for a different economic unit or for a different timeframe).

Data Collection Methods

Surveys of WIC Participants

It is recommended that WIC Participants be surveyed several times throughout the study, starting with the Intention Screener when women enroll in the WIC program during pregnancy. Follow-up interviews will be conducted to gather information on study outcomes and to assess changes in knowledge and attitudes about breastfeeding, changes in feeding practices, and reasons for these changes as described below. Follow-up interviews are recommended at roughly 2, 8, and 26 weeks.

To the extent possible, questions from existing surveys should be used in developing data collection instruments. This will allow comparisons with national surveys or other demonstration studies, and takes advantage of the testing and validation of survey items done in these other studies. Particularly relevant to this survey is the WIC Infant Feeding Practices Study, which surveyed a nationally representative sample of WIC mothers at short intervals (including monthly from birth to seven months) on breastfeeding and other feeding practices, and the new study of infant feeding being done by the Food and Drug Administration. Other surveys that should be reviewed are the data sets for the WIC Participant and Program Characteristic Studies, the National Survey of Family Growth (NSFG) and the National Health and Nutrition Examination Survey (NHANES).

Breastfeeding Intention Screener and Baseline Participant Survey. As stated above, Abt recommends that the evaluation focus on those who intend to breastfeed or are undecided on their method of infant feeding. At the time of enrollment in WIC, Abt recommends that an “Intention Screener” be administered to all pregnant women enrolling in the selected local WIC agencies to ask whether they intend to breastfeed. The next step depends upon the nature of the interventions FNS chooses to implement. If they choose to implement the peer counseling intervention as soon as women enroll in WIC, then those who intend to breastfeed or are undecided will need to be immediately recruited into the study and a Baseline Participant Survey should be administered. Random assignment can then be performed to determine whether women receive peer counselor support or the standard practice for the site (control). If FNS chooses peer counseling interventions that do not begin at WIC enrollment, such as those described in Chapter Two of this document, then Abt recommends that the Intention Screener be repeated at the time of recruitment (at 6 weeks prior to delivery in the Abt interventions), and the Baseline Participant Survey will be administered to all women who still intend to breastfeed or who are undecided. The Baseline Participant Survey should collect background information on the recruited women, including demographic characteristics, pregnancy and health status, participation in other public assistance programs, and prior WIC participation. Questions related to breastfeeding should include their breastfeeding intentions (e.g., how long they plan on breastfeeding), knowledge of and attitudes towards breastfeeding, receipt of other breastfeeding services (e.g., through an obstetrician’s office), social support for breastfeeding (e.g., mother, partner), and the presence of role models.

Postpartum follow-up. Abt recommends that study participants be surveyed three times postpartum (at roughly 2, 8 and 26 weeks postpartum) to gather information on breastfeeding outcomes and related issues. At the first follow up (2 weeks), participants should be asked about changes in their circumstances (e.g., employment status, participation in other programs) or to their breastfeeding intentions, the outcome of their pregnancy and delivery characteristics, their own and infant health status, and their knowledge and attitudes regarding breastfeeding. They should also be asked whether they initiated breastfeeding, whether they are still breastfeeding, what problems, if any, they have experienced, how frequently they breastfeed, and whether they use any supplementation. They

should also be asked about support for breastfeeding (including sources other than the peer counselors and WIC), social support, and role models. Information should be gathered on the characteristics of the infant after birth that may affect breastfeeding (e.g., fussiness, colic). Study participants who have opted not to breastfeed or have stopped breastfeeding by the time of the interview should be asked their reasons for doing so. Subsequent follow up interviews should request updates on these issues. As noted above, Abt recommends these interviews be conducted through six months of age.

WIC Administrative Data

The types and sources of WIC administrative data that may be used for this study were discussed in the previous section. For the Impact Study, the primary purpose of accessing the WIC administrative data for the few relevant variables would be to check the basic demographic information provided by survey respondents or to fill in any missing data (for example, age or income).

Chapter Eight

Data Collection: Procedures

This chapter describes data collection schedules and procedures for both the Implementation and Impact Studies Abt has recommended in Chapter Three. As with previous chapters, this chapter focuses on a study of high- and low-cost interventions using the recommended experimental design. However, the procedures described here can be considered no matter which interventions and evaluation design are ultimately chosen by FNS.

Implementation Study

Under Abt's plan for this study, evaluation contractor staff, including local site coordinators hired by the contractor, would collect the Implementation Study data. Local WIC staff, peer counselors, WIC participants, and local breastfeeding collaborators would participate in the data collection process as interview respondents or focus group participants. Peer counselors would also provide records of client contacts for analysis. Exhibit 8.1 lists the Implementation Study data collection components, as described earlier, and provides information on timing, respondents, and mode of data collection.

Baseline Site Survey

The local WIC agency director should complete the Baseline Site Survey shortly after their participation in the study has been confirmed. The survey should collect information needed for the implementation data analyses (as described in Chapter Seven, Exhibit 7.1), as well as information needed to plan site-specific data collection activities. This would include information on the characteristics of the local WIC program, such as the location of WIC clinics, hours of operation, anticipated monthly caseload of newly enrolling pregnant women, and scheduling practices for prenatal certification and recertification.

To ease response burden, information that is available in the WIC agency application forms submitted to FNS should be transferred to the Baseline Site Survey forms, and directors should be asked to edit only if anything has changed or the information is incorrect. In addition, local WIC agency directors should be advised that they can submit reports or other documents that include the requested information, rather than transcribing sections of the documents to the survey form. An example of such a document is a description of the agency's service delivery sites. Respondents should be asked to ensure that supplementary reports include all the requested information and, if not, to add the missing information. For example, a respondent might pencil in the days and hours of operation on the list of service delivery sites.

Exhibit 8.1
Schedule for Implementation Study Data Collection Activities

Activity	Timing	Respondents	Mode
Baseline site survey	At point of site selection	Local WIC agency director	Self-administered paper survey
Baseline site visits	3 months after implementation start-up ¹	<i>Baseline staff interviews:</i> Local WIC agency director Peer counselor coordinator All peer counselors Breastfeeding coordinator Hospital staff <i>Focus groups with WIC participants:</i> 3 separate groups of treatment (high- and low-cost) and control participants	In-person interviews Structured, moderated group discussion
Interim staff interviews	6 months after implementation start-up	Local WIC agency director Peer counselor coordinator Hospital staff	Telephone interviews
Follow-up site visits	12-15 months after implementation start-up	<i>Follow-up staff interviews:</i> Local WIC agency director Peer counselor coordinator All peer counselors Breastfeeding coordinator Hospital staff <i>Focus groups with WIC participants:</i> 3 separate groups of treatment (high- and low-cost) and control participants	In-person interviews Structured, moderated group discussion
Evaluation activity records	Ongoing, from start-up of enrollment (3 months after implementation start-up)	Evaluation staff site coordinator	Computerized data collection tracking system
Peer counselor records	Ongoing, from time of random assignment (as early as 3 months after implementation start up)	Peer counselors	Paper records

¹ As discussed in the previous chapters, the timing of the visits may vary, depending on how long it takes for a site to get the basic intervention components in place (e.g., to hire and train peer counselors, coordinate with the local hospital).

Baseline Site Visits

Approximately three months after implementation start-up, evaluation staff will visit each site. As described earlier, Abt recommends that the site visit be conducted only after a site has met a set of criteria for start-up, which would include such things as completion of the hiring and training of peer counselors and WIC staff training. For collection of baseline data at the site level, on-site visits are

preferable to other modes of data collection. On-site visits allow evaluation staff to gain a more complete and detailed view of how the interventions are being implemented in study sites. In addition, operating “on the ground” provides an opportunity to triangulate and reconcile information sources. That is, it provides an opportunity to crosscheck information from different sources and to double back to prior sources as discrepancies or missing elements become apparent. It also allows project staff to check on the implementation of random assignment procedures, a critical evaluation component.

Advance communication and overall scheduling of site visits should be coordinated by the evaluation staff for the Implementation Study. The time window for each site visit will need to be negotiated with the local WIC director. She should be asked to check on availability of key respondents before setting a firm date for the visit to ensure that all respondents will be available.

After the site visit dates have been scheduled, a confirmation letter, including an overview of site visit activities, should be sent to the local agency. In addition, letters should be sent to each of the targeted respondents (see Exhibit 8.1). These letters should inform respondents about the site visit and request their participation in an interview. The letter should also cover the topics to be discussed and inform respondents that site visitors will contact them by phone shortly before the visit to schedule a specific time for the interview.

During site visits, baseline interviews should be completed with the individuals listed in Exhibit 8.1 and focus groups need to be conducted with WIC participants enrolled in the evaluation of the peer counselor interventions. It is recommended that two evaluation staff members visit each site for 2-3 days to complete all of the data collection activities. Conducting the focus groups will take the better part of a day and, given the number of respondents, at least two days may be needed to complete the interviews. The actual number of interviews to be conducted will vary depending on how many peer counselors the site has and whether the site has both a peer counselor coordinator/supervisor and a breastfeeding coordinator (in some sites, these functions may be performed by the same person).

Hiring Site Coordinators

Abt recommends that site coordinators be hired in each site to assist with both the Implementation and Impact Study components. For the Implementation Study, the responsibilities of the site coordinators would include: assisting with the scheduling of the baseline site visits, helping with the selection and the logistics for the participant focus groups, and the management of a tracking system which records contacts for the evaluation.

Site coordinators need to be hired in each of the cities included in the demonstration. At this point, the assumption is that one evaluation staff member will be needed for each local WIC agency, as study participant recruitment will take place over a year’s time. However, this assumption may need to be adjusted based on the interventions and particular sites selected by FNS. For example, it may be necessary to hire an additional evaluation staff person for local agencies that enroll large numbers of pregnant women each month. In such sites, more field staff are needed for a shorter period of time.

Site coordinators should be selected carefully. A major qualification for all field staff should be a proven ability to work independently. They should also be organized and have good communication skills. In sites with large Hispanic populations, site coordinators must also be bilingual.

The training for site coordinators is described more fully under the Impact Study.

Selecting and Training Site Visitors

All site visitors should be senior evaluation staff with experience conducting in-person interviews of program staff, preferably in the WIC program. At least one site visitor on each team should be an experienced focus group moderator. All site visitors should complete a training program prior to field visits. Training should include an introduction to the study, including a detailed description of the interventions being studied, a thorough review of all study instruments and field procedures, and a discussion of the anticipated schedule and “what ifs.”

Baseline Site Visit Interviews

Baseline interview respondents are identified in Exhibit 8.1. The hospital staff interview should be with the person who coordinates with WIC to allow the peer counselors to conduct in-hospital contact and/or the person who can best describe the hospital’s policies on infant feeding. Respondents should be contacted by telephone, in advance of the visit, to schedule times for the interviews and to briefly describe the topics that will be discussed. Interviews should be limited to approximately 45 minutes per respondent.

Participant Focus Groups

Focus groups are a cost-effective way of getting WIC participants’ perspectives on breastfeeding and on the WIC services they are receiving relative to breastfeeding. As noted above, three focus groups are recommended for each site. One group would consist of study participants receiving the high-cost peer counseling intervention; a second group of those receiving the low-cost intervention, and the third would consist of those receiving the standard WIC breastfeeding promotion practice (control group members).

Site coordinators should assemble a list of all study participants in their sites and forward the list to the evaluation contractor. The contractor can then randomly select 15 women to be recruited for each of the three focus groups. Allowing for absences, this will yield a group of 8-12 women per group.

Focus groups must be conducted by staff who are experienced focus group moderators. Each session should be audiotaped and last from 45 to 60 minutes. Focus groups can be held at the WIC clinic if an appropriate facility is available, or at a location near the WIC sites, e.g., a conference room in a local hotel. Light refreshments should be provided. The site coordinator will need to make arrangements for focus group sites and recruit focus group participants. Transportation should be offered to participants who may need it. Women should receive a monetary incentive for participating in focus groups.

Interim Staff Interviews

Abt recommends that approximately six months after the intervention is underway, key respondents in each site (the local agency director, the peer counselor coordinator, and a key hospital staff member) be interviewed again. As described above, these interim interviews provide an opportunity for a mid-course assessment of implementation. Interim staff interviews can be completed by phone by evaluation staff who visited each site.

Follow-up Site Visits

Approximately 12 to 15 months after intervention start-up, a final follow-up site visit should be completed in each site. The activities included in these site visits and the protocols for arranging and implementing them should be identical to those described for the baseline site visits. Interviews need to be modified from those used in the baseline visits to capture information on experiences during the implementation phase, plans for continuing the interventions, and perceptions about the feasibility of implementing the interventions in other WIC sites.

Evaluation Activity Records

Local site coordinators will need to be responsible for maintaining records of all study activities and contacts for every woman referred to the study. These records will include initial enrollment in WIC and completion of the Breastfeeding Intention Screener, follow-up contacts for the Baseline Participant Survey, date and result of the random assignment process, and attempted phone and/or in-person contacts for data collection (and whether or not they were successfully completed). These records should be part of the tracking system described in the description of the Impact Study. Information on group assignment, data collection contacts, and attrition from the study can be monitored throughout the course of the evaluation.

Peer Counselor Records

Peer counselors should be required to maintain detailed records of all peer-counseling contacts with treatment group participants. Each day, peer counselors can record on a form information about every contact they have with study participants. This information should include, at a minimum:

- Participant name;
- Study (or WIC) ID;
- Date of contact;
- Type of contact (in-person WIC, in-person hospital, home visit, telephone, group, mailing);
- Recipient of peer counseling (WIC mother, spouse/partner, maternal grandmother, other);
- Length of contact, as appropriate;
- Major topics discussed, activities conducted; and
- Referrals made (medical, social service, WIC staff).

Peer counselors should also record attempted contacts that do not actually occur and the reasons, for example, no-show for a scheduled class or attempted telephone contact that got no answer. The site coordinator should collect peer counselor records on a weekly basis and forward them to the project team.

Impact Study

Data collection for the Impact Study will begin approximately three months after intervention start-up, depending on the time required by each site to get the intervention components implemented. As previously described, Abt recommends that locally hired evaluation site coordinators collect data. The site coordinators will be essential to ensure that study enrollment, random assignment, and data

collection are handled in an efficient manner. Their work will contribute toward minimizing burden on the local WIC staff and protecting the independence of evaluation activities from the local WIC operations. Achieving sample size objectives will require diligence on the part of WIC staff. Having a local evaluation staff member work with WIC staff during the enrollment period will increase the likelihood that all potentially eligible women are recruited. In addition, having local evaluation staff communicate information on random assignments to WIC site staff will decrease the potential for confusion and errors related to this critical study component.

Abt recommends that the participant survey data be collected using Computer Assisted Telephone Interview (CATI) software for telephone interviews and Computer Assisted Personal Interview (CAPI) for those that need to be done in person. Follow-up surveys should build on previous survey waves to avoid unnecessary repetition of questions from one wave to the next and to ensure consistency between the waves. Surveys should be translated into Spanish for sites that have a high proportion of Spanish speakers.

Training of Site Coordinators

For the Implementation Study, site coordinators need to be trained to assist with site visit scheduling, gathering and sending the names of participating WIC women for focus group selection, and maintenance of the study tracking system for WIC participants. For the Impact Study, site coordinators need to be trained to administer the participant surveys, handle random assignment, coordinate delivery dates with hospital staff, and complete WIC record abstractions.

It would be optimal for site coordinators from all sites to be trained in a centralized location. Under this scenario, training would be expected to last 2-3 days and would take place approximately 1-2 weeks before the study participant enrollment is scheduled to begin. However, there may be one or more sites that have a delayed start-up schedule, and these site coordinators may need to be trained at their local site. These site coordinators would have a training tailored to their sites, and it would probably take less time to review the training material. However, for cost reasons, this on-site training might need to be coordinated with the first set of site visits, and thus the site coordinators in these sites would provide minimal, if any, assistance in setting up the first site visit for the Implementation Study.

Topics covered in the training (and included in a procedures manual) should include the following:

- **Overview of the study.** Site coordinators need to understand the goals of the study and the study design, particularly the importance and the process of random assignment. They need to have their roles in the evaluation clearly presented to them, along with the timeline for each task. Site coordinators also need to be familiar with the WIC program and the roles that USDA, FNS, local WIC staff, and contractor staff play in the study.
- **Principles of field data collection.** This segment of the training should address issues such as confidentiality, the need for consistency in methods and reporting, appropriate dress and behavior, and dealing with contingencies. It should also touch on techniques for building rapport with women, and other interviewing skills (e.g., refusal conversion techniques), which should be covered in more depth during the specific training for conducting the various interviews. Even for experienced field staff, a review of field data collection principles is helpful.

- **Background information about local WIC agencies.** Each site coordinator should receive a “backgrounder” on the local WIC agency with which they will be working. This should include contact information about key staff, location and hours of operation of service-delivery sites, scheduling practices, and anticipated weekly caseload.
- **Use of CAPI and administering each of the survey instruments.** This session should include question-by-question reviews of the instruments and response options and practice sessions in which staff administer surveys to other site coordinators or to trainers.
- **Data management and reporting requirements.** This session should include procedures for submitting data to the evaluation contractor, using the random assignment program (discussed below), communicating random assignments to WIC staff, and procedures for tracking and documenting data collection activities for each study participant.

Enrolling Subjects

Abt recommends that study enrollment begin approximately three months after a site begins implementing the intervention (e.g., hiring and training the peer counselors, training WIC staff on the intervention). In line with previous discussions, all pregnant women (less than eight months pregnant) enrolling in WIC who either intend to breastfeed or have not made a firm decision should be eligible to participate in the study. WIC staff will need to be trained to follow a standard protocol developed for study enrollment. The protocol would include such things as an explanation of the study and the nature of random assignment. In addition staff would assure women that: participation is voluntary, their status in the program will not be affected by whether or not they participate in the study, all women will be able to receive the standard breastfeeding support services offered by the WIC clinic, and information collected will be kept confidential. Women who agree to be involved in the study will need to sign a consent form and fill out the Intention Screener. WIC staff will also need to inform women that evaluation staff will contact them at a later date.

Site coordinators will need to collect signed consent forms and Intention Screeners from WIC sites on a regular basis. A schedule for pick-ups should be developed for each site, taking into account their scheduling practices for prenatal certification and recertification. In sites that do not have structured scheduling policies or that see clients on a walk-in basis, site coordinators will need to check with WIC staff daily to see if there are any new Intention Screeners and consent forms.

Abt recommends that enrolling women complete Intention Screener while they are filling out their other paperwork. The Screener will be short—asking for only the breastfeeding intention and contact information—and can be done efficiently during the enrollment process. WIC staff will have to make sure that the women have been given the questionnaire and that it is completed. This procedure can be included in the WIC staff training on explaining the study to enrolling women. Evaluation site coordinators can also work with staff to make sure that they are following the procedures correctly.

Completing Participant Surveys

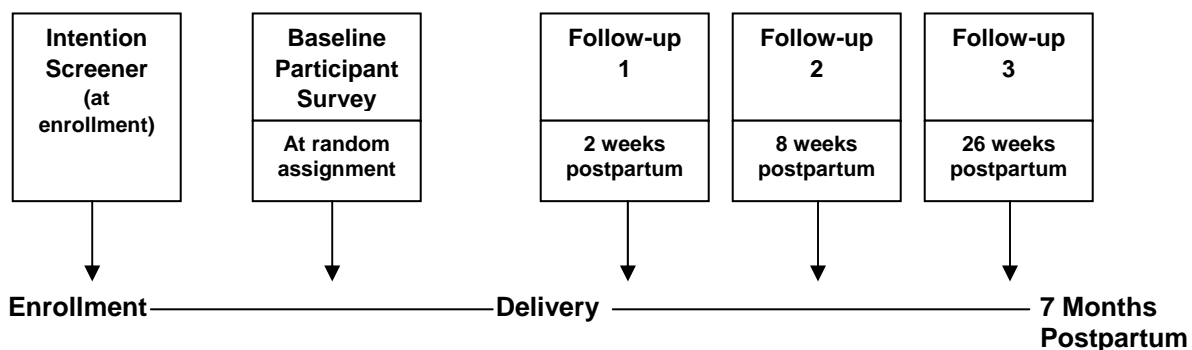
The schedule for the surveys of WIC participants depends on the peer counselor interventions chosen by FNS. If the interventions focus on the prenatal period, then the evaluation contractor will need to

do the Baseline Participant Survey and random assignment shortly after the woman has enrolled in WIC. If the focus is on the postpartum period, as in the Abt intervention models described in Chapter Two, then the Baseline Survey and random assignment will take place later in the pregnancy, about six weeks prior to the expected date of delivery (EDD). A schematic of the timing is shown in Exhibit 8.2.

Abt recommends that study participants be contacted a total of four times after the Intention Screener. The first follow-up contact needs to be for the Baseline Survey. This Survey should be used to verify that women are still pregnant and to confirm their breastfeeding intentions. Information on socio-demographic characteristics and the pregnancy and health of the WIC participants should also be collected. Abt recommends that the remaining three contacts take place at approximately 2, 8, and 26 weeks postpartum. To the extent possible, these contacts should be made by phone from a central data collection office. This will ensure that women can be contacted at times that are most convenient for them. For those women without phones, the local site coordinators should conduct in-person interviews.

A critical task for both the peer counselor interventions and for the evaluation is to determine when the study participants deliver their infants. How this will be done may depend upon the site, and what the local hospital staff will allow. Local WIC staff may already have a procedure in place or find it fairly easy to work with hospital staff to set one up. One strategy is for local site coordinators to send to the hospitals bi-weekly lists of study participants that are about to deliver. Site coordinators could then call the hospital on a daily basis to see if any of the women have delivered. Some success has also been reported for having new parents call health providers following the birth of their baby (personal communication, Dr. Mary Blankson, 2003). This could be attempted as an alternative if there is a problem working out a system with hospital staff in this study.

Exhibit 8.2
Timing of Impact Study Participant Surveys



The data collection tracking system for the study will need to include the EDD, the actual delivery date, treatment or control status, and the target interview dates based on when the participants deliver.

Random Assignment

As described in Chapter Three, random assignment should take place immediately after the Baseline Participant Survey has been completed. Abt recommends that women who have made a firm decision to bottle feed not be included in the study. Women who continue to be interested in breastfeeding or who have not made a decision about feeding choice should remain in the study and be randomly assigned.

Careful consideration should be given to the optimal timing of random assignment, once the peer counseling interventions have been chosen for implementation in WIC and the evaluation design tailored to the interventions. Women should be randomly assigned as close to study enrollment as possible, to minimize them dropping out once the assignment has been made. Thus, in a within-site experimental design of Abt's illustrative peer counseling interventions, we recommend enrolling women into the study and immediately assigning them to their treatment status at 6 weeks before their delivery date, at the point when peer counseling would begin for the high-cost intervention. If the assignment were made when the Intention Screener was filled out during their enrollment in WIC weeks or even months earlier, there would no doubt be a higher rate of attrition, even before the intervention could begin.

Abt recommends that random assignment be completed via a centralized random assignment program (e.g., a web-based application). Ideally, site coordinators would access the random assignment program on a study web site. They would then be able to enter each woman's name and local agency and the program would randomly assign each woman to treatment or control conditions.

Results of random assignments will need to be communicated to WIC staff on a regular basis. To maintain the integrity of random assignments, a system will be developed for each site to ensure that only the treatment group receives peer-counseling services. Assignments must be documented and readily apparent to WIC staff, as well as the peer counselor coordinator, peer counselors, and those who might be called upon to make referrals for breastfeeding support (e.g., those delivering nutrition education, and those answering phone calls from WIC participants).

Record Abstractions

Record abstraction from WIC administrative data can be used as a back-up data source, if this information is not obtained from participant surveys. The site coordinator would need to arrange to gather this information at one time, after all surveys are completed, so as to minimize the burden on local WIC staff.

Minimizing Data Collection Challenges

The goals of any data collection effort are to collect high quality data and to maximize the number of respondents. The context for this evaluation provides some challenges to meeting these goals. Specifically, the evaluation will be conducted over the course of several months, during a major life event for the WIC participants (i.e., pregnancy and child birth). Mothers may be overwhelmed by the experience and it may bring on other stresses (e.g., loss of employment and income) that they have to deal with as well. Data collection from WIC staff will take place amid all the competing demands on their time. It will be important in designing and implementing this data collection that

care is taken to make the effort as easy as possible for the respondents. Below are strategies to help reach the goals of high data quality and response rates in the context of this evaluation.

- **Keep the participant surveys and staff interviews as brief as possible.** Minimizing respondent burden will be critical to ensure high response rates in this study. Keeping the data collection instruments focused on critical questions and pretesting should be key goals in the early study development phase. In some cases, such as for Implementation Study data, it may be possible to use extant sources (e.g., WIC administrative data). The use of available data will allow focusing most of the surveys and interviews on information that cannot be obtained from other sources.
- **Instruments should be thoroughly reviewed and tested to avoid ambiguity or misunderstandings.** Even when using questions that have been used in other studies, it will be important to pretest them on a group of WIC women in the context of the entire interview. Probing directions should be standardized for interviewers and any clarifications that interviewers are allowed to make (e.g., defining a word or concept) should be provided as standard guidance.
- **Use computer-assisted interviewing (CATI or CAPI) to complete the interviews.** This is especially important with WIC participant surveys. Follow-up surveys will build on one another, and CATI and CAPI can easily track the information from one survey to another. For example, a follow-up interview would include information already obtained from the respondent, such as the name and age of the child, whether a mother was exclusively breastfeeding during the last interview or whether formula supplementation had begun. Time would thus not be wasted with the participant in reviewing this information.
- **Provide comprehensive training for data collection staff.** A critical component of successful data collection is the use of experienced and trained staff. Funds should be allocated for a 2-3-day training session, which will provide an overview of the project and the WIC program, general guidelines for data collection (e.g., probing, gaining cooperation and avoiding refusals), and the specifics of the instruments and computer-assisted technology for in-person as well as telephone interviews. Experienced and well-trained staff can help ensure high quality data and address specific problems in a way that minimizes data loss. In addition to thorough training, data collection managers should closely monitor work performance of all data collectors on a regular basis, and corrective feedback should be provided as appropriate.
- **Use translated data collection instruments and bilingual interviewers if possible.** Depending on the sites chosen for the intervention, it may be necessary to translate some of the survey instruments into other languages. Most likely a Spanish-language version of the instrument will be necessary. It will also be important for bilingual interviewers to be hired to conduct the telephone or in-person interviews for this population.
- **Use strategies to minimize survey non-response and dropouts.** The WIC Infant Feeding Practices Study (Baydar *et al.*, 1997) interviewed mothers they recruited in pregnancy nine times in the first year of their infants' lives. Response rates were relatively high, ranging from 87 to 95 percent, except in the first month when the response rate was 75 percent. This

suggests that it is feasible to obtain good response rates, even during this busy time for mothers. However, extra effort will have to be made to obtain information in the first month. Perhaps key questions could be included in the second postpartum follow-up survey for those that missed the one-month survey so that critical information can be obtained (e.g., on breastfeeding initiation) or extending the window beyond one month for completing the first postpartum survey.

When women are recruited into the study, the study requirements and time commitment should be made clear to them. Providing participants with clear expectations and minimizing their survey burden will go a long way in helping them to stay in the study. Having experienced and trained data collection staff that can handle potential barriers to study participation will also be important (e.g., offering to call back if the time is not convenient, talking to “gatekeepers”).

Use of incentives for completing surveys should also be considered. Incentives have proven helpful in increasing response rates in several studies (e.g., Abreu and Winters, 1999) and have been shown effective in studies with low-income and minority participants (Singer and Kulka, 2002).

- **Use strategies to minimize item non-response.** Every effort should be made to minimize the number of sensitive questions and to work on the way in which these questions are asked (e.g., training study interviewers, putting sensitive questions last in the survey). In addition, certain traditionally sensitive questions, such as those about income, can be obtained from WIC administrative records, either as the main source of information or as backup should respondents not want to provide the information.
- **Provide quality control.** Using computer-assisted technology (i.e., CAPI and CATI) assures a high degree of data quality (e.g., the interviewer cannot proceed until a response is keyed in correctly), but other levels of quality control are also recommended for the study. A ten percent sample of respondents should be contacted to verify that they have been interviewed (by checking responses to certain questions) and to ensure that appropriate procedures were followed.
- **Keep contact information up to date.** WIC participants may move one or more times during the course of the evaluation. In addition, it is not uncommon for a new mother to stay with a friend or relative during the first weeks after the birth of her baby. Thus, the contact information collected at enrollment may be outdated by the time of study contact. The evaluation site coordinator will need to maintain close contact with a liaison at the WIC clinic to update participant contact information throughout the evaluation period for each study participant.²⁷ The Baseline Survey and participant follow-up instruments should also include questions on plans to move, change of address or phone information, and a collateral contact person (e.g., mother) in case of loss of contact. If these strategies fail, then standard data collection strategies should be used to try to locate respondents (e.g., sending letters to respondents that will be forwarded to their new address). Note that even if a respondent

²⁷ Given the need for women to pick up their WIC vouchers on a regular basis, it is likely that updated contact information can be obtained, unless the women move out of the WIC local agency catchment area (in which case they will not be followed up for the study).

cannot be located for one of the follow-up contacts, efforts should continue so that they may be contacted for subsequent follow-ups.

- **Develop methods for tracking the estimated delivery date of study participants.** It is critical for the postpartum data collection to track the delivery dates for study participants, and to try to make the first postpartum assessment as close as possible to two weeks after the birth of the infant. Otherwise, the responses of the mothers in the immediate postpartum period will be with retrospective recall of varying lengths of time. At the time of random assignment and the Baseline Participant Survey, the expected date of delivery should be checked. As described above, procedures will be needed to determine the actual date of birth. How this is worked out may vary by site. Some sites may have a strong link with the hospital's labor and delivery staff or lactation consultant, who may provide the delivery dates to WIC to pass on to evaluation site coordinator. In others, the evaluation staff might need to make phone calls to mothers to determine when infants are born or have the mothers call staff.
- **Provide in-person as well as telephone survey options.** Another challenge that will be faced in certain areas is the lack of phones in low-income households. Although nationwide the estimate of those not having telephones is fairly low (6 percent), it is estimated that the proportion of poor households *with children* that lacked a regular, cell, or car phone in mid-1998 was 15 percent (unpublished analyses of data from the Survey of Income and Program Participation conducted by Abt, currently in draft). Baydar and her colleagues (1997) report that bias could be introduced in a study of infant feeding if only participants with telephones were included. In particular, they present data from the 1985 National Health Interview Survey that show that children in households with telephones were more likely to ever have been breastfed than children living in non-telephone households (56 versus 32 percent). To address this issue in the WIC Infant Feeding Practices Study, researchers included some in-person interviewing along with the primary mode of data collection, CATI. In-person interviewing should be an option for those without phones in the evaluation outlined in this document as well.

Appendix A
Expert Panel Members

Expert Panel Members

Kimarie Bibbs Bugg

Coan Middle School
Emory University School of Medicine

Mary Blankson

Department of Health
Jefferson County, Alabama

Jacqueline Grant

Department of Obstetrics & Gynecology
University of Missouri-Columbia

Laurence Grummer-Strawn

Maternal and Child Nutrition Branch
Centers for Disease Control and Prevention

Gail Harrison

Center for Health Policy Research
University of California – Los Angeles

Rafael Perez-Escamilla

Department of Nutritional Sciences
University of Connecticut

Kathleen Rasmussen

Division of Nutritional Sciences
Cornell University

Linda Smith

Bright Future Lactation Resource Centre
Dayton, Ohio

Holly Szcodronski

Bureau of Nutrition and WIC
Iowa Department of Public Health

Appendix B

Current Federal Requirements for Breastfeeding Promotion in WIC

Current Federal Requirements for Breastfeeding Promotion In WIC

The current federal WIC regulations contain provisions to encourage women to breastfeed and to provide appropriate nutritional support for breastfeeding participants.

CITATION	PROVISION
246.2	<p>Definitions</p> <p><i>Breastfeeding</i> means the practice of feeding a mother's breast milk to her infant(s) on the average of at least once a day.</p> <p><i>Breastfeeding women</i> means women up to one year postpartum who are breastfeeding their infants.</p>
246.3(e)(4)	<p>State staffing standards</p> <p>Each State agency shall designate a breastfeeding promotion coordinator, to coordinate breastfeeding promotion efforts identified in the State plan in accordance with the requirement of 246.4(a)(9). The person to whom the State agency assigns this responsibility may perform other duties as well.</p>
246.4(a)(9)	<p>State Plan</p> <p>The State Plan must include the State agency's nutrition education goals and action plans, including a description of the methods that will be used to promote breastfeeding.</p>
246.7(e)(1)(iii)	<p>Certification of Participants</p> <p>Breastfeeding Dyads. A breastfeeding mother and her infant shall be placed in the highest priority level for which either is qualified.</p>
246.7 (e)(4)(i)	<p>Nutritional risk priority system. Priority I: pregnant women, breastfeeding women and infants at nutritional risk as demonstrated by hematological or anthropometric measurements or other documented nutritionally related medical conditions which demonstrate the need for supplemental foods.</p>
246.7(g)(1)(iii)	<p>Certification Periods</p> <p>Breastfeeding women shall be certified at intervals of approximately six months and ending with the breastfed infant's first birthday.</p>
246.10(c)(7)	<p>Supplemental Foods</p> <p>Food Package VII-Breastfeeding Women (Enhanced) contains additional amounts of juice, cheese and legumes, plus carrots and canned tuna.</p>

CITATION	PROVISION
246.11(c)	<p>Nutrition Education State agencies shall perform the following activities in carrying out nutrition education responsibilities:</p>
246.11(c)(2)	Provide training on the promotion and management of breastfeeding to staff at local agencies who will provide information and assistance on this subject to participants.
246.11(c)(3)	Identify or develop resources and educational materials for use in local agencies, including breastfeeding promotion and instruction materials; taking reasonable steps to include materials in languages other than English in areas where a significant number of or proportion of the populations needs the information in a language other than English.
246.11(c)(7)	<p>Establish standards for breastfeeding promotion and support which include, at a minimum, the following:</p> <ul style="list-style-type: none"> (i) A policy that creates a positive clinic environment which endorses breastfeeding as the preferred method of infant feeding; (ii) A requirement that each local agency designate a staff person to coordinate breastfeeding promotion and support activities; (iii) A requirement that each local agency incorporate task-appropriate breastfeeding promotion and support training into orientation programs for new staff involved in direct contact with WIC clients; and (iv) A plan to ensure that women have access to breastfeeding promotion and support activities during the prenatal and postpartum periods.
246.11(e)(1)	<p>Participant Contacts All pregnant participants shall be encouraged to breastfeed unless contraindicated for health reasons.</p>
246.14(b)(1)(iii)	<p>Program Costs The State agency may use food funds to purchase or rent breast pumps.</p>
246.14(c)(1)	Specified allowable nutrition services and administration (NSA) costs. Each fiscal year, each state agency must spend, for nutrition education activities and breastfeeding promotion and support activities, an aggregate amount that is not less than the sum of one-sixth of the amount expended by the State agency for costs of NSA and an amount equal to its proportionate share of the national minimum expenditure for breastfeeding promotion and support activities. The national minimum expenditure for breastfeeding promotion and support activities shall be equal to \$21 multiplied by the number of pregnant and breastfeeding women in the Program, based on the average of the last three months for which USDA has final data. On October 1, 1996 and each October 1 thereafter, the \$21 will be adjusted annually using the same inflation percentage used to determine the national administrative grant per person.
246.14(c)(10)	Costs of breastfeeding aids which directly support the initiation and continuation of breastfeeding are allowable.

Source: Food and Nutrition Service (2003). *Breastfeeding Promotion In WIC: Current Federal Requirements*.
<http://www.fns.usda.gov/wic/Breastfeeding/bfrequirements.HTM>

Appendix C

Studies of WIC Peer Counseling Interventions Reviewed by Abt Associates Inc.

Studies of WIC Peer Counseling Interventions Reviewed by Abt Associates Inc.¹

Arlotti, J.P., Cottrell, B.H., Lee, S.H., and Curtin, J.J. (1998). Breastfeeding among low-income women with and without peer support. *Journal of Community Health Nursing* 15(3): 163-178.

Caulfield, L.E., Gross, S.M., Bentley, M.E., Bronner, Y., Kessler, L., Jensen, J., Weathers, B., and Paige, D. (1998). MWIC-based interventions to promote breastfeeding among African-American Women in Baltimore: Effects on breastfeeding initiation and continuation. *Journal of Human Lactation* 14(1): 15-22.

Grummer-Strawn, L.M., Rice, S.P., Dugas, K., Clark, L.D., and Benton-Davis, S. (1997). An evaluation of breastfeeding promotion through peer counseling in Mississippi WIC clinics. *Maternal and Child Health Journal* 1(1): 35-42.

Long, D.G., Funk-Archuleta, M.A., Geiger, C.J., Mozar, A.J., and Heins, J.N. (1995). Peer counselor program increases breastfeeding rates in Utah Native American WIC population. *Journal of Human Lactation* 11(4): 279-284.

Lovelady, C.A., Rasmussen, G., Dunn, P.C., van Eck, N., Britt-Smith, S., and Jones, R. (1996). Peer counseling of lactating women in the women, infants and children supplemental feeding (WIC) program: A cost-effective analysis. *Journal of American Dietetic Association* 96: 64. (abstract).

Mutch, B., and McKay, C. (1996). Michigan's ES/WIC Nutrition Education Initiative: Breastfeeding Peer Counselor Initiative (BFI). Unpublished final report for ES/WIC Nutrition Education Initiative, Michigan State University Extension, E. Lansing, MI.

Paige, D.M. (1994). Breastfeeding strategies for urban WIC women, MCJ-240609. Prepared for the Maternal and Child Health Research Program, Maternal and Child Health Bureau, Rockville, MD.

Schafer, E., Vogel, M.K., Viegas, S., and Hausafus, C. (1998). Volunteer peer counselors increase breastfeeding duration among rural low-income women. *Birth* 25(2): 101-106.

Shaw, E., and Kaczorowski, J. (1999). The effect of a peer counseling program on breastfeeding initiation and longevity in a low-income rural population. *Journal of Human Lactation* 15(1): 19-25.

Siu-Norman, A. (1996). Breastfeeding peer counseling program in Missouri. ASTSPND newsletter.

Tuttle, C.R., and Dewey, K.G. (1995). Impact of a breastfeeding promotion program for Hmong women at selected WIC sites in northern California. *Journal of Nutrition Education* 27(2): 69-74.

¹ These results of this review are presented in McLaughlin et al., 2003, cited in the reference section of this document.

Part 2:

**Review of Literature on Breastfeeding Promotion
and Support Interventions**

Contents

Chapter 1: Introduction	1
1.1 Previous Reviews of the Literature	2
1.2 Organization of This Report.....	4
Chapter 2: Literature Review Methods	7
2.1 Search Methods	7
2.2 Screening, Categorizing, and Reviewing Published Items.....	8
Chapter 3: Results of the Literature Review	11
3.1 Prenatal Interventions.....	11
Types of Prenatal Interventions	11
Evaluation Methodologies	12
Outcome Measures and Findings	13
Summary.....	15
3.2 Postpartum Education Interventions	17
Types of Postpartum Education Interventions.....	17
Evaluation Methodologies	19
Outcome Measures and Findings	21
Costs of Interventions	21
Summary.....	22
3.3 Postpartum Support Interventions.....	23
Types of Postpartum Support Interventions	23
Evaluation Methodologies	26
Outcome Measures and Findings	28
Costs of Interventions.....	30
Summary.....	31
3.4 Peer Counselors.....	33
Types of Peer Counselor Interventions	33
Characteristics and Qualifications of Peer Counselors.....	36
Evaluation Methodologies	37
Outcome Measures and Findings	39
Cost Information.....	41
Summary.....	41
3.5 Other Prenatal and Postpartum Interventions.....	43
Printed Materials	43
Discharge Packs.....	44
Incentive Programs	45
Programs for Working Mothers.....	46
3.6 Hospital Interventions	49
Breastfeeding Policy Change.....	50
Staff Training.....	52
Change in Hospital Service Structure.....	54
Cost of Hospital Interventions	55
Summary of Hospital Interventions.....	55
3.7 Multifaceted Interventions	57
Types of Multifaceted Interventions.....	57

Evaluation Methodologies	62
Outcome Measures and Findings	63
Results	64
Cost of Interventions	66
Summary of Multifaceted Interventions	66
Chapter 4: Summary and Conclusions	69
4.1 Summary of Findings	69
Prenatal Education	69
Postpartum Education	69
Postpartum Support	69
Peer Counselor	70
Other Prenatal and Postpartum Interventions	70
Hospital Interventions	70
Multifaceted Interventions	71
Summary	71
4.2 Limitations of the Evidence	71
Gaps in Evidence and Intervention Details	71
Methodological Issues	72
Implementation Issues	72
Bibliography	75
Appendix A: Summary Information for Reviewed Interventions.....	A-1
Table A-1: Prenatal Interventions.....	A-2
Table A-2: Postpartum Education Only Interventions	A-4
Table A-3: Postpartum Support Interventions.....	A-5
Table A-4: Peer Counselor Interventions	A-10
Table A-5: Other Prenatal and Postpartum Interventions.....	A-14
Table A-6: Hospital Interventions	A-17
Table A-7: Multifaceted Interventions	A-22
Appendix B: Profiles of Innovative and Successful Interventions.....	B-1
Prenatal Education Profile	B-1
Peer Counselor Profile: Telephone Support	B-2
Peer Counselor Profile: Home Visit Support.....	B-4
Prenatal and Postpartum Profile: Prenatal Education and Postpartum Support	B-7
Hospital Intervention Profile: The Baby-Friendly Hospital Initiative.....	B-9

Chapter 1

Introduction

Breastfeeding is recommended as the preferred infant feeding method because of the nutritional value and health benefits of human milk. Benefits of human breast milk, relative to formula feeding, have been established through considerable research, and include fewer cases of infectious and noninfectious diseases for breastfed infants, as well as less severe cases of diarrhea, respiratory infections, and ear infections. Women who breastfeed also benefit, with the evidence suggesting they experience less postpartum bleeding, earlier return to pre-pregnancy weight, and a reduced risk of ovarian cancer and premenopausal breast cancer (US DHHS, 2000). Current recommendations of the American Academy of Pediatrics, the American Dietetic Association, the World Health Organization, and the U.S. government's Healthy People 2010 goals all call for increases in the proportion of U.S. mothers who breastfeed their babies. The goals for breastfeeding, as outlined in Healthy People 2010, are to (1) increase to 75 percent the proportion of mothers who breastfeed their babies in the early postpartum period; (2) increase to 50 percent the proportion of mothers who breastfeed their babies through five to six months of age; (3) increase to 25 percent the proportion of mothers who breastfeed their babies through the end of the first year; and (4) close the racial and ethnic disparities in breastfeeding.

The U.S. Department of Agriculture's (USDA) Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) provides supplemental foods, nutrition education, and health and social service referrals to eligible pregnant and postpartum women, infants, and children up to five years of age. The program is designed to prevent the occurrence of health problems and improve the health status of children by intervening with nutritional benefits during the early childhood years, beginning with the prenatal period. WIC currently enrolls approximately one-third of all pregnant women in the United States and half of all infants, and as such WIC has the opportunity to provide leadership in meeting the national agenda for increased breastfeeding.¹

The WIC program, however, faces particular challenges in breastfeeding promotion and support. This is due in part to the fact that WIC serves populations that are least likely to breastfeed, including women with low income levels and those from racial and ethnic minorities. In addition, throughout its history, WIC has balanced the seemingly competing goals of encouraging new mothers to breastfeed their infants, while at the same time providing access to infant formula for non-breastfeeding infants. Although WIC recognizes the importance of breastfeeding, the provision of infant formula ensures adequate nutrition for all infants participating in the program.² Breastfeeding rates for WIC are well below the national average. For example, data from the Ross Laboratories Mothers' Survey showed that, in 1989, only 34 percent of WIC newborns were breastfed, compared to 63 percent of non-WIC newborns. This difference had narrowed somewhat but still persisted in 1995, when 47 percent of WIC newborns were breastfed, compared to 71 percent of non-WIC newborns (US DHHS, 2001).

¹ WIC enrollment in the year 2000 was 898,210 pregnant women and 2,062,759 infants (PC2000, unpublished). The total number of infants born in the U.S. in that year was 4,058,814 (Martin *et al.*, 2002). The total number of pregnant women at a point in time is estimated at two-thirds the annual number of births.

² Over half of all infant formula consumed in the United States is purchased through the WIC program (Oliveira *et al.*, 2001).

WIC currently earmarks funds for breastfeeding promotion and support activities; good information on the effectiveness of its current activities, however, is limited (Ryan, 1997). Furthermore, although there are many interventions that have been or are being implemented in various sites across this country and internationally, there has been no systematic effort to review and evaluate these efforts for their applications to the WIC setting. This literature review was undertaken as part of a larger effort by the USDA to identify promising breastfeeding promotion and support interventions for the WIC setting, and to develop a plan to evaluate these interventions.

1.1 Previous Reviews of the Literature

The results of four recent reviews of the breastfeeding literature are relevant to this literature review.³ Table 1.1 summarizes the findings from three of these reviews.

In one review of breastfeeding initiation and duration from 1990 to 2000, Dennis discusses two kinds of interventions, those providing “professional” and “lay” (peer) support (Dennis, 2002). Her discussion of professional support is taken exclusively from a review of interventions focused on breastfeeding duration by Sikorski and Renfrew (2001). Thirteen random controlled trials from seven countries were included. Meta-analysis performed on the data showed that professional support interventions may add a small overall beneficial effect on the duration of breastfeeding. The authors reported additional analyses that indicated the following: (1) duration was positively influenced by face-to-face interventions, but not by those relying primarily on phone contacts; (2) no benefit was found to adding an antenatal component when compared with postnatal support only; (3) no significant benefit was achieved by providing professional support to low-income populations; and (4) professional interventions have a positive effect at two months postpartum, but by three months there were no significant benefits noted.

Dennis reviewed ten studies offering peer (mother-to-mother) support, four of which used random controlled studies. She concluded that peer support interventions are promising in increasing breastfeeding duration, especially among low-income women. Unlike the health care professional interventions reviewed above, Dennis notes that telephone support from peers does appear effective.

A comprehensive review was conducted by Fairbanks and colleagues on the literature through 1998 (Fairbanks *et al.*, 2000). A primary goal of the review was to identify effective interventions for increasing the initiation of breastfeeding, with a secondary goal of reporting on the duration and/or exclusivity of these interventions. Fifty-nine studies were reviewed, of which 14 were random controlled trials. The studies fell into nine categories:

- **Health education interventions.** Included in this category were interventions that provided factual or technical information to a specific target group in a hospital or community setting, and include the provision of literature or group education classes for pregnant women.
- **Baby-Friendly Hospital Initiative (BFHI).** Studies included in this group specifically stated that they used the initiative developed by the World Health Organization (WHO)

³ A fifth review of breastfeeding promotion strategies is not included because it is limited to interventions in developing countries (Witmoth and Elder, 1995).

and United Nations Children’s Fund (UNICEF) in developing and planning their interventions.

- **WIC initiatives.** Interventions are those that are delivered at the local level targeting WIC participants.
- **General health sector initiatives.** These interventions do not have a particular framework or contextual setting (BFHI or WIC).
- **Training of health professionals.** Interventions included here provide professional training to health care staff as a single intervention.
- **Social support from health professionals.** This type of intervention is defined by a health professional working within the health sector to provide one-to-one advice and support on breastfeeding.
- **Peer support.** Interventions here include those that use trained non-professionals, usually mothers who have successfully breastfed, to provide breastfeeding support to women with newborns in their community.
- **Media campaigns.** These interventions are commonly received by a wide audience and use public media to reach a target group or community.
- **Multi-faceted interventions.** These were defined as initiatives that had more than one component delivered to the same target group at the same time (e.g., media campaign and social support).

The results for each category are presented in Table 1.1. In general, the reviewers conclude that three stand-alone interventions are associated with increased breastfeeding outcomes in developed countries. These include informal, small group education sessions delivered during the prenatal period. This type of intervention has been associated with increased initiation rates among different income and minority groups. The reviewers also conclude that breastfeeding initiation among minority women may benefit from one-to-one health education sessions. Peer support initiatives also seem effective at increasing both initiation and duration among poor women, particularly those who have expressed an interest in breastfeeding.

The reviewers report that combined or “packages” of interventions also show promise in increasing the initiation and, in most cases, duration of breastfeeding. Effective combinations include peer support and/or media campaigns combined with structural changes to health services and/or health education. Structural changes to hospital practices, including the BFHI, were related to increases in both initiation and duration.

A review by Perez-Escamilla and his colleagues focused on maternity ward practices associated with positive breastfeeding outcomes (Perez-Escamilla *et al.*, 1994). The review included articles in English or Spanish between 1951 and 1991. They identified 18 valid studies (16 random controlled trials and two quasi-experimental designs) that formed the basis of their review of five maternity ward practices: providing commercial discharge packs; rooming-in and breastfeeding guidance to mothers (these practices were combined in the interventions); early mother-infant contact; breastfeeding on demand; and in-hospital formula supplementation.

A meta-analysis on the six studies that addressed commercial discharge packs suggested a significant detrimental effect of the packs on full breastfeeding (breastfeeding as the only source of milk) at one

month and on any breastfeeding at four months. The reviewers noted that discharge packs were particularly problematic for “vulnerable” mothers, including first time mothers and poor women in developing countries. Two studies that considered rooming-in and breastfeeding guidance together found they had a positive impact on breastfeeding outcomes for first-time mothers. The meta-analysis of early mother-infant contact suggested that there was a beneficial effect on breastfeeding at two to three months, but the meta-analysis was somewhat weakened by heterogeneity of the seven studies included in the analysis.

The studies in Perez-Escamilla and colleagues’ review of breastfeeding on demand suffered from methodological problems, and there was only one study identified for in-hospital supplementation. Therefore, no definitive statements could be drawn for these practices.

A review by de Oliveira and colleagues is of interest, but is not reported in the table because they structure their review by timeframe (e.g., prenatal, hospital, and postpartum) rather than by intervention type (de Oliveira *et al.*, 2001). Their findings of the characteristics of successful interventions are worth discussion, however, and there are differences from findings reported in other reviews. From their review of 37 internally valid studies, they found that the most effective interventions were those that combined face-to-face information, guidance, and support and were long-term and intensive. The interventions that spanned the prenatal and postpartum period were generally more effective than postpartum interventions only. The most effective strategies were group sessions during the prenatal period, home visits postpartum or both prenatal and postpartum, and individual sessions in both these periods. Of particular note is the fact that this review team found the effectiveness of the intervention was unrelated to the type of personnel (health care professional or peer) involved. Interventions that did not make a difference in breastfeeding duration included those with no face-to-face interaction, small-scale interventions (e.g., limited to short time periods), and those with practices contradicting the intervention message (e.g., advising breastfeeding while also providing formula discharge packs).

1.2 Organization of This Report

The scope and methodology of this review is presented in Chapter 2. The results of the review are presented in Chapter 3, followed by the overall Summary and Conclusions in Chapter 4. Appendix A includes tables with summary information for all interventions reviewed in Chapter 3, and Appendix B provides short profiles of successful interventions identified in the review.

Table 1.1**Summary of Findings from Previous Reviews**

Author/Review Year Years Covered Purpose	Types of Interventions	Number of Studies^a	Positive Effect on Breastfeeding Outcomes?
C. Dennis (2002) 1990-2000 Review literature on breastfeeding initiation and duration	Professional support	1 ^b	Yes. Meta-analysis indicated a small overall beneficial effect on any breastfeeding.
	Peer support	13	Yes. Associated with increased duration, especially among “socially disadvantaged” women.
Fairbanks <i>et al.</i> (2000) Start of databases – 9/98 Review literature for effective interventions on initiation of breastfeeding. Secondary goal to assess impact of interventions on duration and exclusivity.	Health education interventions	19	Yes. Small, informal group education classes that occur in the prenatal period are associated with significant increases in initiation and, in some cases, duration of breastfeeding among women of different income levels and ethnic groups. No differences were found among those interventions providing literature alone or more formal, non-interactive sessions.
	BFHI and general ^c	9	Yes. Effective in increasing both the initiation and duration of breastfeeding, particularly in developing countries. Interventions may include stand-alone practice (e.g., rooming-in) or combination of practices.
	WIC initiatives	10	Yes. Interventions effective in the WIC setting including one-to-one education sessions in the prenatal period, peer counseling in the pre- and post-natal periods, or a combination of these approaches.
	Training of health professionals	5	No. Knowledge was shown to increase, but not breastfeeding outcomes.
	Social support from health professionals	1	No. More than one study is needed for a definitive answer on this.
	Peer support	2	Yes. Shown to be effective in increasing initiation and duration among low-income groups among those who expressed a wish to breastfeed.

Table 1.1**Summary of Findings from Previous Reviews**

Author/Review Year Years Covered Purpose	Types of Interventions	Number of Studies^a	Positive Effect on Breastfeeding Outcomes?
	Media campaigns	2	Yes. Stand-alone interventions, and particularly television commercials, may increase initiation rates.
	Multi-faceted interventions	11	Yes. Evidence that these interventions improve initiations rates, exclusivity, and duration of breastfeeding. Those most effective were found to combine a media campaign and/or peer support intervention with structural changes to the health sector or, in a smaller number of cases, an education program.
Perez-Escamilla <i>et al.</i> (1994) 1951-1991 Review maternity ward practices effect on breastfeeding success	Commercial discharge packs	6	No. Discharge packs are significantly detrimental to full ^d breastfeeding at 1 month, and any breastfeeding at 4 months, particularly among vulnerable groups (primiparae and the poor)
	Rooming-in and breastfeeding guidance	2	Yes. Found positive impact on short (less than 4 months) and longer term (4+ months).
	Early mother-infant contact	7	Cannot be determined. Meta-analysis indicated a beneficial effect, but analysis was weakened by heterogeneity of studies.
	Breastfeeding on demand	3	Cannot be determined. Studies were flawed.
	In-hospital formula supplementation	1	Cannot be determined. One intervention found no difference, but supplementation was limited. More studies needed.

^a All review teams screened the studies reviewed on internal validity. The numbers reported here are those articles on which they base their findings.

^b Cites a Cochrane systematic review by Sikorski and Renfrew (2001), which included 13 controlled trials of approximately 3,600 women in seven countries.

^c Results from the general health sector initiatives are combined with the BFHI results, because those in the general category typically were one or more of the BFHI components or “steps.”

^d “Full breastfeeding” refers to breast milk as the only source of milk.

Chapter 2

Literature Review Methods

This chapter describes the methods used to identify, categorize, and review studies of breastfeeding interventions included in this report.

2.1 Search Methods

Studies of breastfeeding interventions were identified for this review through a systematic search of published and unpublished research. Studies were included regardless of whether the intervention described was evaluated for effectiveness. The primary search strategy was a search of nine electronic databases (listed in Table 2.1); most of these contain only published literature, but Federal Research in Progress (FEDRIP) and Inside Conferences include listings of unpublished work.

Two limits were put on the electronic search. The time span was limited to items published/dated from January 1990 to November 2001, and only English-language items were searched, though no restriction was placed on country of origin. The following search terms were used in searching the electronic databases:

(breastfeeding OR lactation) AND (intervention OR promotion OR education OR evaluation OR program OR trial OR demonstration)¹

Table 2.1 lists the electronic databases, the number of initial hits from each database, and the number of items requested for retrieval. A total of over 8,000 items were identified from the electronic search. These initial hits were reviewed to identify items that described or evaluated breastfeeding interventions. Items were reviewed based on their abstracts, when available, and based on title alone when abstracts were not available.² The review of titles was conservative in the sense that any item that was potentially relevant was requested, even if it could not be determined that a breastfeeding intervention was the subject of the study. As shown in Table 2.1, PubMed provided the most productive search, in terms of the number of initial hits and the number of requested items.

From over 8,000 listings returned from the search of electronic databases, approximately 450 were identified as potentially relevant to this study, and those items were obtained from libraries and government repositories.³ Items were requested for retrieval if the subject matter was in one of the categories listed below. In addition, a number of general background articles were requested.

- Breastfeeding promotion or intervention
- Critique of or editorial about breastfeeding promotion

¹ The term “support” was not included in the citation search because it doubled the number of hits and retrieved general breastfeeding articles that “supported” some hypothesis. It is possible that some breastfeeding support studies were missed as a result.

² Eighty-three percent of PubMed citations were accompanied by abstracts.

³ The difference between the number of hits and the number of requested items reflects a large number of studies of animal lactation and a large number of studies concerning determinants of breastfeeding.

- WIC and breastfeeding, regardless of whether there was an intervention
- Review articles related to breastfeeding
- Measurement issues related to breastfeeding (e.g., instrumentation)

Of the nearly 450 items requested, 408 were successfully retrieved in time for the preparation of this report. Items that could not be obtained include ten dissertation theses, eight books, two grant reports, and 22 journal articles.

In addition to the search of electronic databases, two other search strategies were employed. First, government web sites and conference proceedings were searched online. This search failed to yield any items not already obtained from the search of electronic databases.⁴ Second, contact was made with 19 authors of three or more studies that screened into this review (screening procedures are described below). Two authors forwarded to us the drafts of unpublished studies of breastfeeding interventions, which are included in this review.

Table 2.1

Electronic Databases Searched for Breastfeeding Intervention Publications

Database	Initial Hits	Items Requested
PubMed – National Library of Medicine	5,024	360
NTIS – National Technical Information Service, U.S. Dept. of Commerce	171	18
AGRICOLA – Agricultural Online Database, National Agricultural Library	253	14
Dissertation Abstracts	1,370	11
Social SciSearch	617	3
Gale Group Health and Wellness Newsletter	462	14
CINAHL – Cumulative Index to Nursing and Allied Health Literature	144	9
FEDRIP – Federal Research in Progress	102	2
Inside Conferences (2000 to present only)	110	13
Total	8,151	446

The Dialog databases (Social SciSearch, Gale, and CINAHL) overlapped significantly with PubMed listings.

Three studies were obtained in other ways: two unpublished papers were received from authors, and one study was found in the MCH Projects database.

2.2 Screening, Categorizing, and Reviewing Published Items

The items that were requested and retrieved from libraries were screened for inclusion in this literature review. All items were categorized as “breastfeeding intervention” or “no intervention,” and the interventions were categorized by type.⁵ The initial screening was completed by research assistants,

⁴ The search of government websites disclosed the MCH Projects Database at the Maternal and Child Health Library, National Center for Education in Maternal and Child Health at Georgetown University. A search of this database, however, yielded only one item not already identified through the NTIS database.

⁵ The “no intervention” category included background articles and review articles referenced by project staff. Only a few of those are reflected in the bibliography of this report.

and all items determined to be “no intervention” were reviewed by senior staff and reclassified as necessary. Publications were screened into the following categories, corresponding to the planned organization of this report:

- Prenatal interventions –Intervention is delivered exclusively in the prenatal period
- Postpartum education-only –Short term postpartum intervention (one to three contacts with mother), designed primarily as an education intervention
- Postpartum support –More than three contacts with mother; may begin in the prenatal or postpartum period; excludes postpartum support by peer counselors
- Peer counselors –Peer counselors are the main focus of the intervention
- Other prenatal and postpartum –Interventions that do not fit in other categories
- Hospital interventions –Intervention involves changes in hospital policies and practices or training of health care professionals
- Multifaceted interventions –Intervention involves three or more of the categories listed above (interventions with two strategies were classified according to the dominant strategy); strategies not in other categories such as mass media campaigns and community-based activities also appear here

The initial screening identified 174 items for review. The authors of this report systematically reviewed and coded these items. The coding process used a web-based data entry form and was designed to ensure that all authors of this report reviewed studies in a consistent and systematic fashion. The coding form included sections addressing the intervention design, study design, sample characteristics, data collection methods, and results.

The review process resulted in some reclassification of items between categories and exclusion of 21 items. Items were excluded primarily because they were originally misclassified and did not, in fact, describe an intervention, or because insufficient detail was provided to describe the nature of the breastfeeding intervention.

Table 2.2 shows the final count of interventions reviewed for this report. The final count of 141 breastfeeding interventions corresponds to 153 published or unpublished items (some interventions were described in multiple reports). Table 2.2 shows the number of interventions by category of intervention and study design. Three broad categories of study design were used to classify breastfeeding interventions for this report: randomized treatment-control (RTC) design, quasi-experimental design, and descriptive study.

For the most part, interventions were categorized as RTC if the intervention used random allocation, or a quasi-random method of allocation, to treatment and control groups. Often it was not possible to determine whether a reported randomized study met the formal criteria for randomized controlled trial (RCT). An RCT requires that the allocation of sample to treatment and control be made by mathematical techniques such as a random numbers table (Dickersin and Larson, 1996). It was clear, however, that many breastfeeding interventions recruited sample in hospitals and allocated sample to

treatment and control using quasi-random methods such as coin toss, day of week, or other method that does not meet the formal criteria of a randomized controlled trial.

The category of quasi-experimental studies contains all evaluated studies that did not use randomization to allocate sample to treatment and control groups. As described in Chapter 3, quasi-experimental studies include pre-post designs (breastfeeding outcomes were measured before and after the implementation of the intervention), and contemporaneous treatment and comparison groups.

Descriptive studies are defined for this review as studies that did not report breastfeeding outcomes, or studies that reported outcomes for the group subject to the intervention, but did not provide data for a comparison group.

Table 2.2

Breastfeeding Interventions, by Category and Study Design

Category of Interventions	Study Design			Total*
	Randomized Treatment-Control	Quasi-Experimental	Descriptive	
1. Prenatal	10	6	1	17
2. Postpartum education only	7	3	1	11
3. Postpartum support	15	14	5	34
4. Peer counselors	4	13	2	19
5. Other prenatal and postpartum	8	3	2	13
6. Hospital	5	19	0	24
7. Multifaceted (and Media only)	0	18	5	23
Total	47	78	16	141

Some interventions were described in multiple reports: 153 reports correspond to these 141 interventions.

Chapter 3

Results of the Literature Review

The chapter is organized in seven sections, corresponding to the seven groups of breastfeeding interventions defined in Chapter 2: prenatal education, postpartum education, postpartum support, peer counselors, other prenatal and postpartum interventions, hospital interventions, and multifaceted interventions. For each group of intervention studies, this chapter presents a summary of the nature and timing of intervention services, evaluation methods, sample characteristics, data collection methods, breastfeeding outcome measures, and study results. Tables summarizing the breastfeeding interventions are presented by group in Appendix A.

3.1 Prenatal Interventions

This section describes 17 prenatal-only interventions. This group of interventions is defined by the timing of subject contacts, which took place exclusively or primarily during the prenatal period. Three interventions (3, 7, 17)¹ included some postpartum contact, but this contact was not significant enough to be considered a postpartum education intervention or a postpartum support intervention. Interventions that included prenatal contact followed by significant postpartum intervention are discussed in subsequent sections.

Table A.1 provides an overview of the 17 interventions reviewed in this section. Twelve of the 17 interventions were implemented in the United States, including four WIC interventions. The five non-US interventions include three implemented in Australia, one in Chile, and one in China.

Three of the 12 US interventions focused on specific subgroups of women. These included African-Americans (8), Latinos (9), and teenagers (17). In addition, one of the Australian interventions was specifically designed for Vietnamese immigrants (13).

Seven of the 17 interventions were implemented in the early 1990s (3, 5, 6, 7, 12, 13, 15). Three interventions, including one published in 1997, were implemented in the late 1980s (4, 8, 11), and two were in the late 1990s (14, 17). Information on the timing of the remaining interventions (1, 2, 10, 16) was not reported.

Types of Prenatal Interventions

The prenatal-only interventions reviewed here can be divided into three broad categories based on the content or focus of the intervention. Four of the 17 interventions (4, 5, 12, 15) can be considered information dissemination or education-only interventions. These interventions focused on providing participants with information, e.g., information about the advantages of breastfeeding, the anatomy and physiology of breastfeeding, and/or factors that influence breastfeeding success for the mother and /or child, without specifically assessing individual attitudes or barriers to breastfeeding, providing support/motivation for breastfeeding, or assisting the mother-to-be in developing skills necessary for successful breastfeeding.

¹ The numbers in parentheses correspond to the interventions listed by group in Appendix A.

Eight of the interventions included more specific attention to motivation/support, with or without the sort of background information provided in the education-only interventions (2, 3, 6, 7, 9, 13, 14, 17). The manner in which support and motivation were addressed and/or provided varied and included assessing individual barriers and providing tailored guidance (6, 7, 8, 14), involving trained peer counselors or training other providers in motivational support (6, 17), offering incentives (2), addressing specific cultural issues and barriers (9, 13), and providing breastfeeding-supportive hospital discharge packs (3).

Finally, five interventions focused on skills development (1, 8, 10, 11, 16). This included providing guidance on proper breastfeeding techniques and nipple care (1, 11), breastfeeding demonstrations with live infants (8, 16), and practice with breastfeeding positions and techniques using a life-size baby doll (1, 10). Two of these interventions were fairly narrowly focused on breastfeeding skills (1, 10). The others incorporated general education and/or support and motivational elements (8, 11, 16).

Non-WIC interventions were generally provided as part of routine prenatal care and delivered by physicians, nurses, or nurse midwives. Exceptions to this rule included interventions that were delivered by pediatricians (17), a culture-specific health educator and interpreter (13), and a lactation consultant (1, 12). In addition, two interventions were incorporated into childbirth/prenatal education classes (5, 16); one of these was delivered by members of a breastfeeding advocacy group and their partners (16). One intervention was implemented in a high school for pregnant teenagers, and was delivered by a nurse and WIC peer counselors (17).

Three of the four WIC interventions were delivered by WIC nutritionists or educators (2, 3, 9), and one was delivered by nurses (11).

Most papers provided no information on the timing of the prenatal intervention relative to a woman's due date. Among papers that did provide some information, there was wide variation. One study recruited women who were at least 12 weeks pregnant (13), another focused on women who were less than 24 weeks pregnant (8),² two studies focused on women who were in their third trimester (10, 12), and one study indicated that the intervention was delivered between 32 and 36 weeks gestation (15).

Nine of the prenatal-only interventions were limited to one contact with the expectant mother. Five of these interventions involved a single individual counseling session (1, 7, 8, 12, 15), and four involved a single class or group discussion (2, 5, 9, 16).

Of the eight prenatal-only interventions that included more than one contact, one used four individual counseling sessions (14) and one used an individual counseling session followed up by five motivational letters and reinforcement at however many follow-up visits the women had at WIC (3). (The latter study also provided breastfeeding-supportive discharge packs to half of the women who received the intervention). The remainder used classes or small group discussions (8, 10, 11, 13, 17) or a combination of individual and group contacts (4, 16, 12).

² This study involved both individual and group treatments. The individual treatment focused on women who were at least 24 weeks pregnant. Comparable information was not provided for the group treatment.

Evaluation Methodologies

As noted in Table A.1, nine of the prenatal-only interventions were evaluated with randomized treatment-control (RTC) designs. Seven interventions were evaluated in studies using quasi-experimental designs, and all but one of these used unmatched treatment and comparison groups. One intervention was not evaluated. The paper described the intervention and provided some information on an ongoing randomized trial. It was included in this summary because the intervention was developed for Hispanic WIC participants.

All of the studies included samples of treatment and control women drawn from the same institutional populations. In several cases, providers involved in delivering the interventions were also involved in delivering “standard or routine care” to comparison group subjects (2, 3, 4, 8, 15). Four studies used historical controls, i.e., the researchers compared outcomes for women in the treatment group to women who had received care in the same institution prior to the implementation of the intervention (6, 7, 10, 17).

Samples

Three interventions were implemented in WIC clinics. Of the eight US studies that were not done specifically with WIC participants, five were conducted with low-income women (4, 6, 8, 14, 15), one was conducted with higher-income women (12), and information on participants’ income is not available for two interventions (5, 17). Three of the five non-US studies were conducted with low-income populations (1, 7, 13). The other two included middle- and upper income women (10, 16).

Eight evaluations included small samples of fewer than 50 subjects in each group. Three of these included samples of less than 25 per group. None of the studies included samples of 100 or more in both treatment and control/comparison groups.

Seven of the 16 evaluations of prenatal-only interventions used samples that were restricted on the basis of a woman’s stated feeding intentions and/or on her pregnancy history or prior breastfeeding exposure and experience. Three studies were limited to women who planned to breastfeed (1, 10, 12). One study was limited to women who were undecided about breastfeeding or reported an intention to bottle feed (14). Five studies restricted enrollment to women who were first-time mothers or to women who had no prior breastfeeding experience (1, 5, 12, 15, 16).

Other sample restrictions related to maternal characteristics included a focus on women who were married (5) and women who had at least a high school education (12). Some studies restricted the sample used for analysis on the basis of subsequent pregnancy outcomes, excluding women who had multiple births (6, 15) or who had given birth to infants who were premature, low birthweight, or had congenital anomalies (1, 3, 5, 11, 16) or low APGAR scores (5). In addition, one study excluded women who had not had vaginal deliveries (5), and one excluded women who had postpartum depression that required medication (16).

Outcome Measures and Findings

As noted in Table A.1, all but one of the evaluations of prenatal-only interventions examined impacts on the initiation and/or duration of breastfeeding. That study collected data on breastfeeding initiation but did not report it (4). Of the studies that did examine impacts on breastfeeding behaviors, one limited its focus to breastfeeding initiation (17). Eight studies looked at both initiation and duration

(2, 3, 6, 8, 11, 13, 15, 16) and six studies looked only at duration (1, 5, 7, 12, 10, 14). Duration was measured at a number of different time points. Endpoints included one week (14), two weeks (6), one month (5), six weeks (1), two months (2, 15), four months (7, 8, 16), and six months postpartum (3, 10, 11, 12, 13). Five studies looked at the incidence of and/or duration of exclusive breastfeeding (1, 2, 10, 14, 16).

In addition to breastfeeding behaviors, the available research examined the impact of prenatal-only interventions on knowledge (4, 8, 12, 13), attitudes and/or perceptions (2, 5, 13, 14, 16), social support (14), and nipple pain, trauma, and “latch scores,” a measure of how well the infant attaches to the breast (1). Results for these outcomes are not discussed in this report.

Results

Four of the nine studies that examined impacts on breastfeeding initiation reported significant results (6, 8, 13, 17). The size of the effect was greatest for the intervention that focused on teenagers (17). This quasi-experimental study that used historical controls reported a rate of breastfeeding initiation from the treatment group of 65 percent, compared with a rate of 15 percent for the comparison group (students enrolled in the same high school the preceding year who did not receive the intervention). Unfortunately, the study did not examine impacts on breastfeeding duration.

Two of the randomized experiments that looked at breastfeeding initiation reported significant effects. Kistin *et al.* (8) found that both group and individual interventions increased initiation of breastfeeding among low-income African-American women. Unfortunately, this impact was not maintained over time. Although differences remained at two weeks postpartum, they had largely dissipated by six weeks postpartum. A significant difference persisted to 12 weeks postpartum for the group intervention; the number of women who were still breastfeeding at this point, however, was quite small.

Rossiter (13) reported a significant improvement in the initiation of breastfeeding among low-income Vietnamese women in Australia after participation in a prenatal intervention (70 percent vs. 38 percent). This difference persisted through four weeks postpartum (50 percent vs. 26 percent), but disappeared by six months postpartum.

The remaining study that looked at breastfeeding initiation involved incorporation of materials and guidelines from the Best Start program into prenatal care in an inner-city prenatal clinic (6). Using an historical control group, the authors reported a significant difference in breastfeeding initiation of 31 percent vs. 15 percent. Information on breastfeeding duration was available only up to two weeks postpartum and, at that point, the difference between the two groups had already disappeared.

Four studies reported favorable impacts on the use of exclusive breastfeeding (1, 7, 10, 14). The most relevant of these studies is an RTC study (1) that focused specifically on the impact of a skill-based intervention primarily among low-income Australian women. At six weeks postpartum, 92 percent of the women who completed the intervention—which included detailed discussion of appropriate breastfeeding techniques, information on ways to avoid nipple pain and trauma, and hands-on practice with proper breastfeeding techniques such as using baby dolls—were exclusively breastfeeding, compared to 29 percent of the women who had not received the intervention.

Pugin *et al.* (10) evaluated a skills-based program that was similar to the one described above but was delivered over three to five sessions, and included breastfeeding demonstrations with live infants.

The intervention was delivered as an addition to an ongoing breastfeeding promotion program. Women who received the additional skill-based intervention were compared with women who received only the existing program. At six-months postpartum, 80 percent of the middle-and-upper-income Chilean women who participated in the additional skill-based intervention were exclusively breastfeeding, compared with 65 percent of women who had not received the additional intervention.

Finally, Ryser (14) found that low-income women who received four individual counseling sessions based on the Best Start program were more likely to be exclusively breastfeeding at one week postpartum than women who had not received the intervention (61 percent vs. 15 percent). Information on the retention of this effect over time was not collected.

Summary

All of the studies reviewed in this section have design limitations, particularly with regard to sample size, that may have affected their ability to detect differences. Nonetheless, taken as a whole, the body of research suggests that prenatal interventions are more likely to influence breastfeeding initiation than breastfeeding duration. Moreover, the evidence suggests that interventions targeted at developing breastfeeding skills may be more successful than other interventions at maintaining breastfeeding over time.

3.2 Postpartum Education Interventions

For this review, postpartum interventions are divided in two categories: education-only and support.¹ Education-only interventions provide breastfeeding education to new mothers following delivery, with no significant postpartum follow up. In contrast, postpartum support interventions (summarized in the next section) provide ongoing breastfeeding support to new mothers, sometimes beginning in the prenatal period and continuing up to 12 months postpartum or until weaning.

This section describes 11 postpartum education-only interventions.² These interventions differ from prenatal education interventions in the timing and location of the intervention, and some of the content of instruction. Postpartum education is often provided in the hospital following delivery, or during home visits soon after hospital discharge. Education sessions provide general breastfeeding information (similar to prenatal education), and may include instruction in breastfeeding technique while the mother is breastfeeding her baby.

Four of the 11 education-only interventions were conducted in the United States; four were in other developed countries (Australia (2), Canada, Turkey), two in developing countries (Brazil, South Africa), and one in a least-developed country (Nepal).

In contrast to prenatal education interventions, postpartum interventions generally enroll new mothers who are breastfeeding or intend to do so, with the goal of increasing breastfeeding duration. This was an explicit sample inclusion criterion for seven studies, and implicitly defined the sample in three studies with populations that normally breastfeed following birth (Nepal, South Africa, and Turkey).³ In the latter three studies, the goal of the intervention was to increase rates of exclusive breastfeeding.

Types of Postpartum Education Interventions

Breastfeeding education typically provides mothers with information about the advantages of breastfeeding, proper technique, and problem management. The educational content of interventions, however, is described with varying amounts of detail. Some studies provide only a general description of the intervention content, for example: “infant care, infant feeding, maternal physical care, and maternal emotional changes” (2); “usual care similar to the literature on early postpartum care” (3); “a video film discussing basic topics of breastfeeding, an explanatory leaflet handed to parents immediately after seeing the film, and a free discussion on the topic with parents” (11).

Detailed descriptions of education sessions include: “visual, written, and verbal information covering simple breast anatomy, various positions of infant at the breast, principles of correct attachment, and the 3 stages of suckling” (4); instruction on correct positioning, hand expression of milk, and how to assess the infant’s suck and swallow, milk intake, and urine and stool output (5); instruction on “breast changes during pregnancy and lactation, maturational changes of breast milk, maternal nutrition during lactation, breastfeeding positions, normal feeding patterns, evaluating the adequacy of

¹ Support interventions may or may not include a structured education component.

² These studies are listed in Table A.2 along with their primary characteristics, and are referenced in this section by the numbering provided in Table A.2.

³ The only study without this sample criterion was (2).

breastfeeding in the newborn, pumping and storing breastmilk, bottle supplementation, and problem solving” (10).

One study provided instruction on correct positioning and the basic physiology of lactation to both treatment and control groups, but the treatment group received additional specific advice for establishing easier patterns of breastfeeding, including stimulating milk production by expressing milk between feeds, avoiding non-nutritive sucking, and encouraging baby to stay alert (9). The family planning advantages of breastfeeding were discussed as part of the intervention in Nepal (1), and the value of colostrum was stressed in the intervention in South Africa (6).⁴

In addition to breastfeeding education, treatment of diarrhea was a topic of interventions in Nepal and Turkey; the Nepal intervention also included instruction on recognizing the symptoms of acute respiratory infection and the importance of full immunization;⁵ general nutrition (preparation of nutritious meals) was an additional topic of the intervention in South Africa.

Teaching aids were part of four interventions. These include a “cloth flip chart with large pictures, developed by local artists from health materials supplied by UNICEF” (1); printed materials (leaflet, booklet) on breastfeeding (7,11); a cloth breast model (4); and video/film on the advantages and practice of breastfeeding (7,11).

Nine of the 11 postpartum education-only interventions provided individual in-person instruction, one provided group education sessions, and one provided only instructional videos. Only one intervention specifically delivered education to someone other than the mother, in this case the father or partner (11). Among the in-person interventions, one specifically cited use of “hands-off” advice to teach mothers proper breastfeeding technique (4), whereas others did not indicate teaching methods. One study indicated use of a clinical protocol for home visits to ensure a consistent, structured message to all mothers (2), another study used a standard curriculum for in-hospital education sessions (11), whereas another study stressed individualized instruction for each mother and infant (5).

The educator and the number, timing, and location of contacts varied among interventions. Six interventions provided education in the hospital following delivery: two of these involved a single session by a midwife (1, 4); one was a single education session by a physician (11); and one involved a hospital session and home visit (five to seven days after discharge) by a dietician (7). Lactation consultants delivered breastfeeding education in two interventions; one intervention provided an unspecified number of visits by a lactation consultant in the hospital (8), whereas another provided a single 30 to 60 minute education session that followed a standard curriculum (11). The latter study provided both treatment and control groups access to a breastfeeding telephone hotline staffed by

⁴ Colostrum is produced during the first few days after delivery. It is a yellowish liquid that is rich in antibodies and precedes the production of true milk.

⁵ The Nepal intervention included three treatment groups for different combinations of two education sessions: in the hospital prior to discharge; in the hospital and at three months postpartum; and at three months only. The two education sessions covered the same general health topics but “more emphasis was placed on the importance of breastfeeding in the first session and on the need for family planning in the second session.” Much of the analysis combined the first two treatment groups to analyze the impact of breastfeeding education, and this review considers only those analyses.

lactation consultants, but only the treatment group received the structured education session (no significant impacts were found in this study).

Five interventions provided education outside the hospital setting. A single home visit was the setting for the education provided by nurses in three interventions (2, 3, 5). These visits occurred within three days of birth, and in two cases, additional visits were scheduled if needed. One intervention provided three group education sessions in a clinic, over a four-week period, after mothers were enrolled at five to nine weeks postpartum (12). Another intervention enrolled two treatment groups (individual education at home, or group sessions at a clinic), but the number and timing of sessions was not specified (6).

Evaluation Methodologies

Seven of the postpartum education-only interventions were designed as randomized treatment-control (RTC) trials, three were quasi-experimental, and one was descriptive. All but one of the RTC trials randomized individual mothers; the other randomly selected two wards in a ten-ward hospital on four days each week, and assigned the selected wards to treatment on days 1 and 2 and control on days 3 and 4 (7).⁶ Sample sizes for RTC trials are shown in Table A.2. Sample sizes ranged from 58 mothers (29 treatment and 29 control) to over 1,000 mothers. All RTC trials reported intervention impacts as the difference in outcomes for treatment and control groups after the intervention.

Two of the three quasi-experimental designs assigned organizational units, rather than mothers, to treatment and comparison groups. A U.S. study included one treatment hospital (education provided by a lactation consultant) and one comparison hospital (no lactation consultant), with both hospitals recruiting mothers into the study following delivery (2). This study enrolled unequal samples (46 treatment; 115 comparison) and comparison of treatment and comparison group outcomes was limited by the disparity in sample characteristics between sites.

A quasi-experimental study in South Africa assigned three study villages and three comparison villages, with all mothers in the study villages exposed to postpartum breastfeeding education (6).⁷ The intervention was evaluated by comparing pre-post changes in the study villages to pre-post changes in the comparison villages; retrospective household surveys were conducted in all six villages prior to implementation and again two years after implementation, with a total of over 1,000 households surveyed pre and post.

The third quasi-experimental study recruited women, following delivery, in a single hospital in Brazil. A control group and two alternate treatment groups were defined based on the sequential enrollment of nearly 600 mothers into the study during three time periods (11). Education was not provided to the control group (first time period); education was provided to mothers in the first treatment group (second time period); and both mothers and fathers received education in the second

⁶ In four of five trials that randomized individuals, randomization occurred after mothers were recruited in the hospital following delivery; the fifth RTC recruited mothers who attended a health clinic at five to nine weeks postpartum.

⁷ This intervention probably provided prenatal breastfeeding education as well, but the nature of the intervention was only vaguely described, with the study population was defined as “female caregivers of infants.”

treatment group (third time period). This study did not directly evaluate the impact of the intervention on breastfeeding outcomes.⁸

One descriptive study is included in this review because it was the only postpartum education-only intervention designed for a population similar to the WIC population. The intervention was a breastfeeding education program designed for an Illinois hospital serving a population that was 40 percent Medicaid-eligible (5). After the intervention began, however, the percentage of patients covered by Medicaid decreased. This intervention provided breastfeeding education to mothers in an early discharge program (discharged within 48 hours of delivery). The standard of care for the early discharge program included breastfeeding education in the hospital and a nurse home visit. The intervention provided an additional home visit (treatment) or phone follow-up (comparison), depending on assessment of breastfeeding at the time of discharge. The study provides a description of breastfeeding education topics and the allocation of home visits based on assessed need; breastfeeding outcomes, however, were not evaluated.

Samples

With the exception of the descriptive study (5), none of the postpartum education-only interventions were designed or evaluated with populations similar to the WIC population. The studies in the U.S., Canada, and Australia enrolled samples characterized by high socio-economic status; Nepal and South Africa are characterized by very low socio-economic status.⁹ In addition, the populations of Nepal, Turkey, and South Africa differ from the U.S. in their traditionally high rates of breastfeeding.

Sample sizes for each study are shown in Table A.2. Samples for postpartum education interventions, as mentioned above, generally include mothers who are breastfeeding or intend to do so. In addition, six of the studies enrolled only full-term, healthy infants. Samples were further limited in four studies: two were designed to measure intervention impacts among mothers in an early discharge program (2,3), and two were designed to measure intervention impacts among first-time mothers (4,7).

Six of the seven RTC trials reported similar socio-demographic characteristics for treatment and control groups, although one study reached this conclusion based on only two characteristics: maternal age and intended breastfeeding duration.¹⁰ All other studies compared groups on maternal age, education, and parity. In addition, one or more RTC studies compared treatment and control groups with respect to maternal race, marital status, employment status prior to birth, income, intended breastfeeding duration, smoking status, receipt of prenatal care, mode of delivery, postpartum hospital length of stay, and prior breastfeeding experience. Infant characteristics (gender, birthweight, and weeks gestation) were also examined by three RTC studies, with no significant differences found between treatment and control groups.

⁸ Breastfeeding knowledge of all study participants was measured in the hospital (prior to education) and again at one month postpartum. A statistically significant relationship was found between breastfeeding outcomes and both mothers' and fathers' breastfeeding knowledge, but the relationship between the intervention and breastfeeding outcomes was not directly tested.

⁹ Nepal is one of the least developed countries with high infant mortality and adult literacy of only 26 percent (1). The South African villages were described as rural villages with untarred roads, communal taps, and little electricity.

¹⁰ The RTC trial with non-comparable treatment and control groups found that women in the control group were less likely to be married, and less likely to have previous pregnancies and other live children. Groups were comparable with respect to maternal age, education, and employment status.

Two of the three quasi-experimental studies compared treatment and comparison groups on a large number of characteristics: one found similar characteristics except for ethnic group (11); the other found that treatment group mothers were significantly older, with higher education and higher income than the comparison group (8).¹¹ For the study in South Africa (6)—with three study villages and three control villages—it is unknown if treatment and comparison groups were comparable; sample characteristics before and after the intervention were not reported.

Outcome Measures and Findings

The outcome measures reported for postpartum education interventions have little consistency across studies. Three studies (1, 3, 9) measured intervention success only by rates of exclusive breastfeeding (measured at three months, two weeks, and four months, respectively). Other studies provided a variety of measures; comparability in outcome measurement is limited to three studies reporting rates of breastfeeding at six months postpartum. In addition to reported rates of breastfeeding, two of the 11 studies reported breastfeeding frequency and several studies reported non-breastfeeding outcomes such as maternal satisfaction with postpartum care (2, 3), satisfaction with breastfeeding (4), breastfeeding knowledge (1, 11), and hospital readmissions for infants (2, 5).

Parallel to the reported outcome measures, final data collection for these studies ranged from two weeks postpartum in one study (2) to six months postpartum in four studies (1, 4, 7, 11). Of the nine RTC and quasi-experimental studies, six collected post-intervention data in-person and three used telephone follow-up.

Results

Only two of the six RTC trials found that breastfeeding intervention activities were successful in improving breastfeeding outcomes (7, 9). One successful trial, conducted in Turkey, was described as “an educational model to promote exclusive breastfeeding” (7). This intervention provided in-hospital education (40 minute education session, two films, booklet on breastfeeding) and one 20- to 30-minute home visit between five and seven days postpartum. The study found that rates of exclusive breastfeeding were significantly greater for the treatment group in the first two months postpartum, but differences between treatment and comparison did not persist beyond two months.

The second trial yielding statistically significant improvements in breastfeeding outcomes was conducted in Australia, and was designed to increase breastfeeding duration by making breastfeeding more comfortable for the mother (9). The study enrolled mothers at three maternal and child health centers when infants were five to nine weeks old. Mothers were randomized to two groups, and received breastfeeding education during three group meetings conducted over a four-week period. Both treatment and control groups received standard lactation management advice; the treatment group received additional instruction to make breastfeeding easier. The treatment group had a significantly higher rate of exclusive breastfeeding at four months compared to the control group (25 versus 4 percent). These findings should be viewed with caution, however, because mothers and researchers were not blind to group assignment.

¹¹ This study used multivariate analyses to control for sample differences, but was limited by a treatment group size of only 46 women.

Costs of Interventions

The cost of postpartum education interventions was documented by only one study (2). This study enrolled women from an early discharge program in a single hospital in California. The intervention provided a single 60- to 90-minute home visit for treatment group members within 48 hours of discharge, compared with standard care (control group) of a hospital-based group education session lasting one-and-a-half to two hours for new mothers, or a 15-minute individual session for women with previous children. The 1998 intervention reported costs of \$265 per mother for the home visit, \$22 per mother for group education, and \$52 per mother for an individual 15-minute visit. The study enrolled over 1,000 middle-class mothers over a 17-month period, and found no difference in breastfeeding outcomes for treatment and control groups to warrant the additional expense of home visits.

Summary

The 11 studies reviewed in this section fail to provide convincing evidence that postpartum educational instruction, without follow-up support, yields significant increases in breastfeeding duration or rates of exclusive breastfeeding.

These 11 studies provide some insight, however, for designing breastfeeding interventions. The studies vary in study design, populations, and details of the interventions. This variation highlights the many elements of education programs: delivery person, location and timing of contacts, number and length of sessions, teaching methods (hands-on or hands-off; structured or individualized), educational content, and teaching aids. Evaluation design elements also varied across studies, including location and timing of recruitment, sample inclusion criteria, randomization methods, and length of data collection period. These issues appear again in the next section on postpartum support interventions, where they are discussed in more detail.

3.3 Postpartum Support Interventions

Postpartum support interventions are characterized by ongoing support during the postpartum period, sometimes lasting until 12 months postpartum or until the infant weans. These interventions provide multiple contacts between the mother and a professional or trained layperson, and focus on motivating the mother to maintain breastfeeding and solving problems that threaten continued breastfeeding. This section describes postpartum support interventions, excluding those delivered primarily by peer counselors; peer counselor interventions are discussed in the next section.

This section summarizes 34 postpartum support interventions.¹ Most of these interventions combined structured education and follow-up support, but eight were characterized as support without structured education. Just over half (20 of 34) of these interventions were limited to the postpartum period, whereas the others provided some intervention services in the prenatal period.

Nearly half of the interventions in this category were conducted in the United States (15 of 34). Six interventions were in other developed countries (Australia, Canada, Turkey, and the UK); 13 were in developing countries (Brazil, Chile, Iran, Mexico, Nigeria, Pakistan, Philippines, Slovenia, and Taiwan), with two each in Brazil and Nigeria, and three in Chile.

Three US interventions were implemented in WIC clinics. A North Carolina WIC intervention provided hospital and home visits by trained paraprofessionals from the Cooperative Extension Service to WIC participants planning to breastfeed (33);² a WIC intervention in Pennsylvania provided telephone support (but lacked a comparison group) (30); and an intervention in Guam delivered breastfeeding education to teenagers in high schools and WIC clinics (23).

Types of Postpartum Support Interventions

The distinguishing characteristics of postpartum support interventions are the number and type of contacts, the length of the intervention period, and the delivery person (person providing education and support to new mothers). Nearly all postpartum support interventions included in-person individual contact (Figure 3.1), and more than half of these also include telephone support (2, 6, 8, 13, 15, 17, 20, 24-28, 32-35). Group sessions were an addition to individual support in eight interventions (4, 7, 10, 16, 22, 28, 32, 35) (not shown in figure). Of the five interventions without in-person individual contact, two provided group sessions (3, 9), one provided group sessions and telephone support (23), and two provided only telephone support (18, 30).

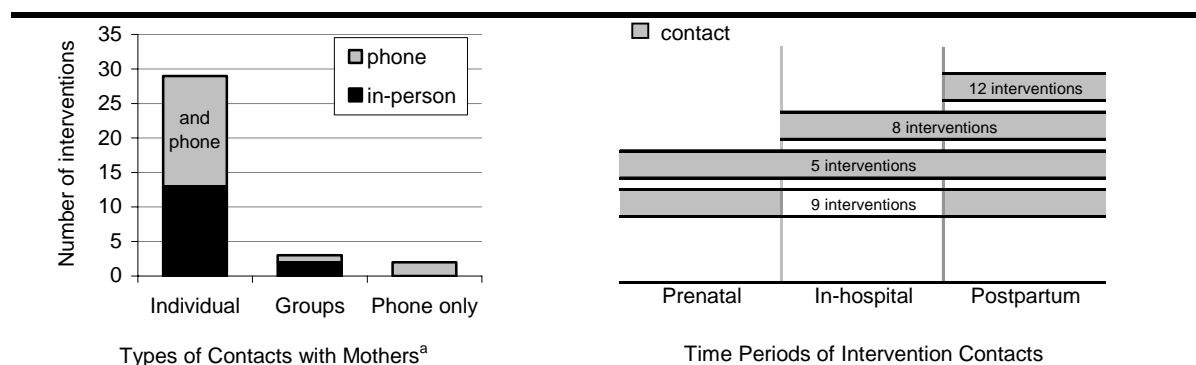
Figure 3.1 also shows the timing of intervention contacts: prenatal, in-hospital, and postpartum. The most common model included intervention services only in the postpartum period **after** hospital discharge (12 interventions). The second most common model included services in the prenatal and postpartum periods, but did not include hospital visits (this is the most common model for peer counselor interventions). Overall, initial services were delivered prenatal in 14 interventions, in-hospital in eight interventions, and postpartum in 12 interventions. Only five interventions provided continuity of care through all three periods.

¹ Table A.3 lists 35 reports; two reports describe the same intervention (16, 29).

² Paraprofessionals were from the Expanded Food and Nutrition Education Program (EFNEP) within the North Carolina Cooperative Extension Service (ES). This intervention was a North Carolina ES/WIC Nutrition Education Initiative.

Figure 3.1

Postpartum Support Interventions



^a Eight interventions with individual and group contacts are shown as individual.

Fourteen interventions began in the prenatal period (1, 4-7, 10, 14, 16, 22, 23, 28, 30, 32, 35). These interventions generally provided prenatal education in clinics.³ Five of these interventions included in-hospital services (5, 6, 22, 28, 32). Following hospital discharge, postpartum support was provided through home visits (nine interventions), telephone follow-up (one intervention), or clinic visits (four interventions). These interventions usually involved nurses (five interventions) or lactation consultants (five interventions), and nurses were sometimes supplemented by other professionals (physicians or midwives). Postpartum support was provided for two weeks postpartum (one intervention), four months (four interventions), six months (three interventions), and 12 months or until weaned (three interventions).

Eight interventions began in the hospital (2, 13, 17, 24, 26, 27, 33, 34). Five of these interventions provided structured education (2, 13, 26, 27, 33) and two provided systematic assessment of breastfeeding technique (24, 34). In all but one case, postpartum support was provided through home visits following hospital discharge; one intervention provided telephone follow-up (13) with clinic visits if problems were not resolved by phone. Half of these interventions involved nurses and two involved lactation consultants (in one case working with a nurse); other delivery persons were midwives, paraprofessionals (Cooperative Extension Service), and study investigators. Postpartum support was provided for one month or less (four interventions), five to six months (three interventions), and 12 months or until weaned (one intervention).

Twelve interventions provided initial services to new mothers after hospital discharge (3, 8, 9, 11, 12, 15, 18-21, 25, 31). Half of these interventions recruited mothers into the study during their hospital stays (3, 8, 12, 15, 20, 25), three interventions recruited in the prenatal period (9, 19, 31), and two recruited during postpartum clinic visits (11, 21).⁴ Half of the interventions included home visits (8, 11, 15, 19, 25, 31); four interventions provided services at a clinic or lactation center (3, 12, 20, 21); one provided only telephone contact (18); and one intervention directed new mothers to La Leche

³ The location of the prenatal contacts for these 14 interventions was in clinics (ten interventions), during home visits (three interventions), and over the phone (one intervention).

⁴ One observational study did not recruit women into a sample, but initial contact was made in the hospital (18).

support groups (9). Half of the postpartum-only interventions involved either nurses, lactation consultants, or both; three involved laypersons; and a physician and nutritionist were each the provider in one intervention. The postpartum support period was one month or less (five interventions), six to eight weeks (two interventions), four months (three interventions), and five to six months (two interventions).

Regardless of the timing of the initial contact, postpartum support interventions are characterized by multiple contacts with expectant/new mothers. Support interventions differ from education-only interventions because multiple contacts allow education to be delivered as needed over time, and to be reinforced over time. These interventions sometimes refer to “counseling” rather than “education,” and stress continuity of care. One study described postpartum support as providing ongoing assessment, establishing a therapeutic relationship, reinforcing the importance of breastfeeding, and relieving the mother of the burden of remembering large amounts of information (18).

Problem solving, motivation, and ongoing assessment were frequently mentioned as the content for postpartum contacts. For example, one study stated: “the objective of the (home) visits and phone calls is to talk with mothers about their experience with breastfeeding, their worries, difficulties, and also to give positive feedback to those who are breastfeeding successfully” (2). Another study described support as “anticipatory guidance of expected occurrences and responsive reaction to cues provided by the mother defining her needs ... also involved ego-strengthening ... and development of multiple coping mechanisms” (8). Group sessions were described as a place “where problems with breastfeeding are presented by the mothers and solutions are offered by the group based on their own experience, supervised by a pediatrician” (3).

The problem-solving nature of postpartum support interventions results in highly individualized “treatment” to women in the intervention groups. Only a small number of postpartum support studies mentioned that interventions were designed to deliver specific messages and/or abide by specific protocols. In one intervention, specific protocols specified topics for the early weeks (management of engorgement, frequency of feeding, confidence and relaxation, stool patterns, and determining adequate intake by infant) and additional topics for later weeks (expression and storage, nursing in public, dealing with fatigue, and supplementation of breast milk with formula, water, or solid foods) (31). One study talked of systematic follow-up (32) and another said that specific protocols were followed in response to various breastfeeding problems (7).

Although most support interventions are designed to test the theory that individualized breastfeeding support will improve breastfeeding duration, others were designed to test the impact of specific messages. One intervention specifically addressed the problem of perceived insufficient milk supply (15), and another specifically focused on ameliorating maternal fatigue and decreasing breastfeeding difficulty (25). The latter intervention provided flexible nursing support, which could include housework. Studies in Nigeria and Pakistan were designed to address the lack of acceptance by new mothers of colostrum, which is associated with delayed breastfeeding initiation.

Teaching aides were part of several interventions. One-third of the postpartum support interventions distributed print materials (2, 5, 10, 12-14, 16, 20, 28, 32, 33, 35). Additional teaching aides include videotapes (2, 23, 28, 32, 35), dolls to teach breastfeeding positions (23, 28), and demonstration breast pumps (20). One intervention distributed free breast pumps (5) and one distributed breastfeeding discharge packs (bilingual pamphlet, washable nursing pads, T-shirt with breastfeeding message, refrigerator magnet with immunization schedule, and safety plugs with clinic logo) (35).

The number of intervention contacts varied considerably in the 34 postpartum support interventions reviewed here. The number of prenatal contacts ranged from one to six; more contacts are generally associated with interventions provided through clinics where breastfeeding classes/counseling is integrated with prenatal care.⁵ Most interventions with hospital contacts specified one hospital visit, although three of the 13 interventions with hospital contacts specified daily hospital visits (6, 24, 27).

Postpartum contacts ranged from one to over 30, with most of the variation due to phone calls; the number of home visits ranged from one to ten. Many studies mentioned the importance of a schedule of contacts initiated by the provider to ensure that all intervention participants get the same treatment. For example, one intervention included 35 contacts: one hospital visit, three home visits, and 32 phone calls (twice per week for eight weeks, then monthly until month six) (27). Perhaps because of the intensity of services, this RTC study did not include a sample with sufficient power to evaluate the intervention (20 women in each of the treatment and control groups).

Evaluation Methodologies

Most of the studies of postpartum support interventions were designed to support evaluation of the impact of intervention activities: 15 had a randomized treatment-control (RTC) design and 14 were quasi-experimental. In addition, five studies were descriptive and did not provide evaluation of the intervention, and two studies were ongoing.⁶ Intervention activities were reported to be successful in 17 of the 27 evaluations: 11 of the 14 quasi-experimental studies, and six of the 15 RTC studies.

All of the 15 RTC studies randomized individual women from the same hospital. Sample sizes for RTC studies ranged from 40 mothers (20 treatment and 20 control) to 623 (311 treatment and 312 control), although two studies with samples of 40 and 51 women did not perform statistical tests due to the small sample sizes. (Sample sizes for all studies are shown in Table A.3). Twelve of the 15 studies had sample sizes below 200, including all nine US RTC studies. All RTC trials reported intervention impacts as the difference in outcomes for treatment and control groups after the intervention.

The 14 quasi-experimental studies consisted primarily of pre-post designs and contemporaneous treatment-comparison groups. In addition, one quasi-experimental study matched individuals to treatment and comparison groups (26). Only one compared pre-post changes for the treatment group with pre-post changes for the comparison group (16).

Three types of pre-post designs were used. Four studies used pre- and post-intervention samples from the same institution (clinic, hospital, WIC local agency) (7, 32, 33, 35). Three studies used historic data for the pre-intervention group (extant data or baseline survey more than one year prior to intervention implementation) (2, 14, 22), and one pre-post study collected pre-intervention comparison group data using a retrospective survey of mothers of children age 18 to 30 months (17).

Five studies used contemporaneous treatment-comparison groups defined by region or organization (1, 10, 20, 23). For example, two regions or communities were assigned to treatment and comparison

⁵ Six prenatal contacts were provided by an intervention in Guam that provided prenatal classes for teenagers in high schools and WIC clinics

⁶ One RTC study is currently ongoing (5); one quasi-experimental study was ongoing at the time of publication and the report on evaluation results could not be located in time for this review (22).

groups. The WIC intervention in Guam obtained a comparison group from WIC offices where the intervention was not provided.

Sample sizes for quasi-experimental studies were generally larger than for RTC studies, with a range of 120 to 2,382 (total of treatment and comparison), excluding one study with matched treatment and comparison groups with ten women per group. In all studies, sample sizes depended on the sample frame (hospital or geographic area), the flow of new births within that sample frame, and the time period for recruitment to the study.

The five descriptive studies include a client satisfaction study of a breastfeeding drop-in center in Canada (21), descriptions of telephone support programs provided by lactation consultants (18, 30), and two studies without valid comparison groups (because the treatment group was defined as mothers choosing to attend breastfeeding group support sessions) (3, 9).

Samples

Nearly two-thirds of the US postpartum support interventions targeted WIC populations (five interventions) or low-income women (four interventions). Other special populations targeted by US interventions include teenagers (33, the Guam intervention), women planning to return to work (9), African-Americans (18, 35), and Armed Forces members (34). Studies in other countries were not targeted to specific populations.

The use of sample inclusion criteria depended on the timing of recruitment into the studies. Ten of 25 interventions beginning after delivery enrolled only mothers of full-term, healthy infants. One of the nine studies beginning in the prenatal period excluded women from the study after delivery if their babies were born prematurely or with low birth weight (1). Samples were sometimes limited to particular subgroups of interest: women with husbands or regular partners (4, 32), women who had prenatal breastfeeding instruction or at least one prenatal care visit (31, 35), first-time mothers (6, 12, 20, 28, 34), first-time breast-feeders (12, 31), and women with no other breastfeeding support (24, 28).⁷

Studies of postpartum support interventions did not necessarily restrict samples to women intending to breastfeed, although this was true of eight of the 15 US interventions (9, 13, 25-27, 31, 33, 34).⁸ Only five of 19 non-US studies used breastfeeding intention as a sample inclusion criteria, but nearly one-third of non-US studies were with populations for which breastfeeding is the norm (and the goal was to increase exclusive breastfeeding and feeding of colostrum to newborns).

In all but three of the 15 RTC trials, randomization resulted in comparable sample characteristics for treatment and control groups. The studies with non-comparable samples were biased in different ways: two were biased toward finding intervention success (the treatment group had higher education than the control) (4, 34); the other was biased against finding intervention success (the treatment group had more low-income and minority women than the control group) (15). Six of the quasi-

⁷ Samples restricted to first-time mothers avoid bias from prior breastfeeding experience. Studies restricted only to first-time breast-feeders include mothers biased by prior breastfeeding failures, but more closely resemble the real-world sample encountered by a breastfeeding support program. Previously successful breast-feeders are excluded from treatment and comparison groups because they would dampen estimates of intervention impacts.

⁸ The descriptive study of telephone support for WIC participants in Pennsylvania recruited women who planned to breastfeed or who were undecided (30).

experimental studies provided no information about the comparability of treatment and comparison samples. Of the eight reporting sample characteristics, three found statistically significant differences between treatment and comparison groups for at least some characteristics. Studies varied considerably, however, in the number of maternal and infant characteristics examined to determine sample comparability.

Of the 29 studies with valid comparison groups (excluding descriptive studies), 16 indicated that the control or comparison group received some breastfeeding services, usually defined as “usual care.” Four studies specified that no services were received, and nine studies did not specify.

Outcome Measures and Findings

Evaluation outcomes were reported for 27 postpartum support studies (excluding five descriptive studies and two ongoing studies). All studies reported measures of breastfeeding duration. Breastfeeding initiation was not universally reported, consistent with the goal of postpartum support interventions and the sample criteria that often excluded women not planning to breastfeed.⁹

Breastfeeding duration was measured by rates of any breastfeeding (12 studies), rates of exclusive breastfeeding (six studies), or both (nine studies), although most US studies (eight of 11) did not report rates of exclusive breastfeeding. Seven studies also reported breastfeeding duration in terms of mean or median weeks. Generally speaking, rates of breastfeeding were reported for multiple time points (four and eight weeks, three and six months). One study surveyed intervention participants every two weeks for 20 weeks, and reported changes in breastfeeding rates for each two-week interval (26). Most studies examined proportions of women still breastfeeding at specific time points and evaluated statistical significance with a chi-square test.¹⁰

Outcome measures reflected the variation in the length of intervention periods (from less than one month to 12 months), although some studies reported that data collection extended beyond the time period when postpartum support ended. Only about half (five of 11) of US studies, however, reported the percent of women breastfeeding at six months, even though breastfeeding rates at six months were a priority of Healthy People 2000 (USDHHS, 1991).

Results

Intervention activities were reported to be successful in five of the 13 RTC studies, including two in the United States (6, 15). One successful US trial was one of the few to provide continuity of care through the prenatal, hospital, and postpartum periods. Intervention services included prenatal education sessions, hospital visit, telephone follow-up, and visits to a lactation clinic (6). Breastfeeding initiation was found to be significantly higher in the treatment group (61 percent versus 32 percent) and significantly more treatment group mothers were breastfeeding at two months (37 percent versus 9 percent).¹¹

⁹ Twenty-one studies either excluded women who did not plan to breastfeed, or involved populations where breastfeeding initiation was the norm.

¹⁰ Other analysis methods were life-table analysis (4), survival analysis (14), and adjusted odds ratios (16).

¹¹ The study dropped women from the treatment group if they failed to attend at least two prenatal classes, but a reanalysis of the data on an intention-to-treat basis found similar statistically significant results (61 percent versus 40 percent).

The second successful US trial was a 20-week postpartum intervention providing six home visits and follow-up phone calls (15).¹² The intervention targeted resources to women at risk of early weaning due to perceived insufficient milk supply (IMS). Mothers were assessed for risk of perceived IMS at one week postpartum. High-risk mothers were randomly assigned to treatment and control groups, whereas low-risk mothers were retained as a low-risk comparison group. Among mothers inexperienced at breastfeeding, the intervention was associated with a lower rate of weaning due to IMS (22 percent versus 38 percent in treatment and control groups; 13 percent in the low-risk comparison group). The intervention had no impact on mothers with previous breastfeeding experience, which the authors attributed to the inability of their risk assessment tool to predict risk for experienced breast-feeders.

The three successful non-US randomized trials were conducted in countries where breastfeeding is the norm, and the goal was to increase optimal breastfeeding practices (Philippines, Iran, Nigeria (4, 11, 12)). These studies have limited relevance for the US.

Nearly all quasi-experimental studies were reported to be a success. Many of these studies had design limitations such as small sample sizes, historic comparison groups without control for secular trends, or estimation methods that did not control for the lack of comparability between treatment and comparison groups. Only two studies are discussed in detail here. One study had the strongest quasi-experimental design, examining pre-post changes for treatment and comparison groups (16). The second study used a pre-post design that might easily be modified for examining pre-post changes for treatment and comparison.

The pre-post treatment versus comparison design was used to evaluate a community-based breastfeeding promotion intervention in Mexico (16). Four sites were selected to test individual breastfeeding instruction (T1), group instruction (T2), and both (T3), with a fourth site serving as control. In each site, sample participants were pregnant women with at least one child who lived at least six months prior to the intervention. The study compared the pre-post changes for the groups, where pre-intervention data refers to the breastfeeding of the last child born before the intervention, and post-intervention data refers to the child born after the intervention. Comparisons between sites were based on adjusted odds ratios, which correct for differences in demographics and pre-intervention breastfeeding prevalence across sites. The group model produced the strongest results. Relative to the control site, women in T2 had about four times the odds of any breastfeeding at six months, and almost five times the odds of exclusive breastfeeding for at least three months. Estimates for T1 were 3.4 times the odds of any breastfeeding at six months and no significant increase in exclusive breastfeeding.

A pre-post design was used to evaluate a breastfeeding intervention in a New Jersey health center affiliated with a university hospital and serving low-income women (35). This intervention provided prenatal education, a discharge package, and telephone support. Evaluation was based on data collected from hospital records (breastfeeding at discharge) and clinic records (breastfeeding at first well-baby visit at two weeks). Data were collected for all women seen at the clinic during the year prior to the intervention (pre-intervention) and all women seen at the clinic for two years after the start of the intervention (post-intervention, years 1 and 2). The intervention was associated with an

¹² This unpublished study was funded by a grant from the National Institutes of Health. The sample was recruited at ten hospitals in four states (Colorado, Illinois, Iowa, and Wyoming).

increase in the rate of exclusive breastfeeding at hospital discharge from 36 percent to 51 and 55 percent (years 1 and 2), and at two weeks from 20 percent to 24 and 30 percent.

Costs of Interventions

Four studies of postpartum support interventions included some cost information (19, 27, 33, 35).¹³ One study documented some of the costs incurred in a 1993 intervention providing breastfeeding support to all women seen for prenatal care in a New Jersey neighborhood health center (35). Material costs relating to publicity and support groups (refreshments and small gifts) totaled approximately \$1,000 per year, and discharge packs costing \$8 each were distributed to 549 women.

The North Carolina ES/WIC intervention began in 1993 with federal grant funds totaling \$455,357 (33). The project tested replication of an earlier pilot program and therefore did not incur all of the normal startup costs. In each of five counties, a paraprofessional was hired on a 0.75 FTE basis and trained to provide breastfeeding support home visits. The project ran for 36 months in three counties, and for 12 and 18 months in the other counties. Project expenditures included \$288,000 for personnel (salary and fringe), \$6,800 for materials and supplies, \$48,000 for travel, \$86,000 for services (clerical services, pager rentals, telephone charges), and \$21,000 for publications and shipping.¹⁴

Two studies included cost-benefit analysis (19, 27).¹⁵ A study in the UK found no health benefits, including no difference in breastfeeding rates, from an increased level of postpartum support (19). The study has limited relevance, however, because usual postpartum care included a high level of support (home visits from midwives), and the additional support from the intervention aimed to relieve maternal fatigue rather than support maternal motivation to breastfeed.¹⁶

The second cost-benefit analysis weighed the costs of postpartum support (community health nurse and peer counselor) against the savings on formula. Through six months postpartum, intervention costs for breastfeeding support were \$301 per mother (excluding fixed costs of training), and treatment group mothers spent \$247 less on formula than control group mothers, on average, for a net cost of breastfeeding support equal to \$54.¹⁷ Sample sizes, however, were too small to detect statistically significant differences in breastfeeding outcomes or costs (40 women total).

¹³ In addition, one ongoing study indicated use of incentive payments. Women recruited in the prenatal period are paid \$20 incentives for completing the baseline interview and attending at least two prenatal sessions.

¹⁴ Federal funds from this project were also used to distribute manuals to all states when the project was completed in 1997. Two manuals were distributed: (1) a package for training paraprofessionals in breastfeeding education and support; and (2) a guide for implementing, managing, and supervising paraprofessionals in in-home breastfeeding support programs.

¹⁵ An additional study assessed savings resulting from the hospital rooming-in portion of a larger intervention (32). Rooming-in was found to yield 14 percent savings in personnel costs, after accounting for the capital costs needed for physical space changes.

¹⁶ Support workers provided flexible services, including housework and childcare.

¹⁷ This study also considered the time costs involved with infant feeding, and found this cost to be significantly higher for women who breastfed.

Summary

The 34 postpartum support interventions reviewed in this section were designed to provide multiple contacts with new mothers in the immediate postpartum period. Multiple contacts allow breastfeeding education to be delivered as needed over time, and to be reinforced over time.

Most of the 34 studies were designed to support evaluation of the intervention activities. Intervention activities were reported to be successful in 12 of the 15 quasi-experimental studies and five of the 13 RTC studies. Interventions in the US were reported to be successful in four of six quasi-experimental studies and two of five RTC studies. These studies differed significantly in study design, content of the interventions, and demographic composition of study samples, so it is not possible (without a structured meta-analysis) to point to the components of interventions that lead to success (although it is clear that small sample sizes were a limiting factor in several RTC studies). The large number of studies finding some evidence of an impact of breastfeeding support on breastfeeding outcomes is encouraging.

3.4 Peer Counselor Interventions

Peer counselor interventions are designed to increase breastfeeding initiation and/or duration by assigning community peers to provide breastfeeding education and motivational support to women during pregnancy and/or the postpartum period. Peer counselors are not health care professionals, but typically have personal breastfeeding experience and are trained to provide counseling. Peers are also generally similar to the women they serve in terms of residence and demographics. Peer counselors are frequently used in WIC programs, and WIC participants are the target population in over half of the peer counselor studies reviewed here.

This section summarizes 25 reports describing 19 peer counselor interventions.¹ These reports are listed in Table A.4.² (In the following discussion, only the first reference is usually listed for interventions with more than one reference.) Peer counselors were the primary promotional strategy in these interventions. Two interventions, however, combined peer counselors with another promotional strategy: a peer counselor intervention in WIC clinics (3, 6, 19) used motivational videos, and a peer counselor program in a First Nation community in Canada (13, 14) coincided with community-wide prenatal breastfeeding education delivered by a community health nurse.³

Twelve of the 19 peer counselor interventions were conducted in 12 different states in the U.S. (2, 7, 10-12, 18, 19, 21-25), two were in Canada (5, 13), and one each was in Bangladesh (8), Chile (1), Mexico (17), and Scotland (15). One intervention began in the late 1980s (10), ten during 1990 to 1994 (1, 2, 7, 11, 13, 15, 18, 19, 21, 24), and five during 1995 to 1997 (5, 8, 17, 22, 23); two reports (12, 25) did not specify intervention start dates.

Most of the U.S. studies (11 of 13) involved WIC participants, or a retrospective evaluation of WIC data (see Table A.4). Of the two remaining U.S. studies, one targeted low-income women who were likely to be WIC-eligible (10); the other targeted participants in a teen mother and child program (TMCP) and provided peer counselors trained through WIC (25). Five of the six non-U.S. studies targeted low-income women.⁴

Types of Peer Counselor Interventions

Nearly all peer counselor interventions enrolled women with personal breastfeeding experience to provide education and support to pregnant women and new mothers. The content of peer counseling sessions is usually described in general terms, indicating that peer counselors informed women about the benefits and techniques of breastfeeding, and about what could go wrong and how to handle it. Peers also provided women with encouragement and support based on personal experience. Peer

¹ In two cases, initial and follow-up reports on the same study were included (3, 6; 13, 14), and in five cases two separate papers described different aspects of the same interventions (3, 4; 5, 8, 9, 15, 16, 19, 20). For example, one report described implementation (16), and another presented outcome data (15).

² Although nearly all the reports provide full-length summaries of studies, three were brief abstracts (12, 23, 25) that lacked detailed information.

³ For the WIC intervention, the breastfeeding outcomes of the combined intervention were compared with those for each intervention separately and with a control group.

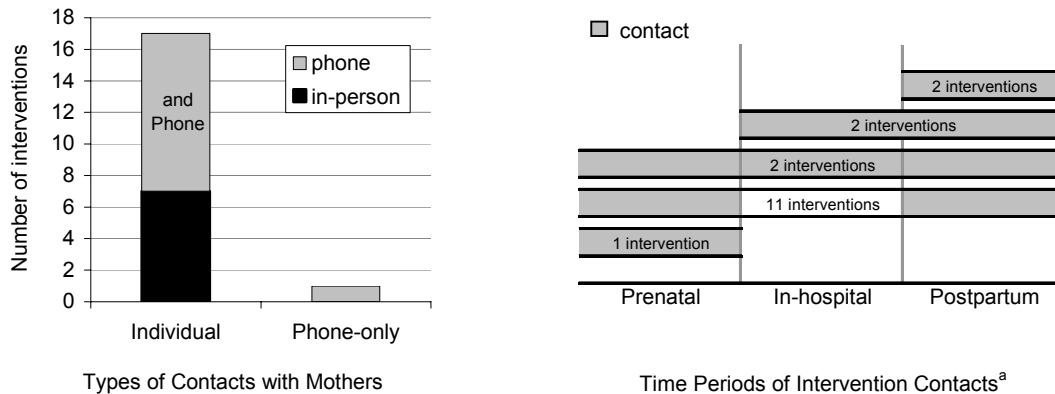
⁴ One Canadian study (5) was not targeted to low-income women; 75 percent of participants had completed more than 12 years of education.

counselor interventions varied along a number of dimensions, however, including the timing, intensity, and duration of contacts.

Most peer counselor interventions involved in-person contact between peers and mothers; one involved telephone contacts only (4), and ten involved a combination of in-person and telephone contacts (2, 3, 7, 10, 11, 14, 18, 20, 22, 25). The type and timing of contacts is summarized in Figure 3.2. Peer counselors almost always worked individually with mothers, but they worked in pairs in an intervention in Glasgow, Scotland (15). (The counselors made home visits together, and the pairs were rotated every two weeks.)⁵ Although the core of the peer counseling intervention is the one-on-one contact between the peer counselor and participating woman, some interventions included additional interactions. Interventions in Bangladesh (8) and Mexico (17) included peer counselor contact with key family members who were likely to give the mother support. In some interventions, mothers also had contact with health care professionals who supported the message of the peer counselor. These included a physician and midwife (1), a community health nurse (13), a nutritionist (2, 22), and WIC staff (19); some interventions (1, 24) included prenatal and postpartum group sessions led by peer counselors.

Figure 3.2

Peer Counselor Interventions



a Six interventions with individual and group contacts are shown as individual (four included phone contact). One intervention did not specify the type of contact, and one did not specify the timing of contacts.

In-person meetings between peer counselors and mothers were typically held at the WIC or health clinic during the prenatal period, and at the mother’s home during the postpartum period (1, 11, 13, 18, 19, 21, 22, 24). Some reports, though, described meetings only at the health clinic (25) or WIC clinic (2), and others described only home visits (8, 15, 17). Peer counselors in a WIC program in

⁵ This arrangement seems inconsistent with development of a close peer-mother relationship, presumed to be a factor in successful programs. Perhaps coincidentally, this intervention was one of the few not found to be associated with significant increases in breastfeeding outcomes.

Iowa said that in addition to meeting with mothers in their homes and at the WIC clinic, they also met in the peer counselors' homes and at other convenient locations.

Prenatal contact was described as part of nearly all peer counselor interventions. The number of prenatal contacts varied from one (22, 25) to three or more (2, 19). In WIC-based interventions the number and timing of prenatal contacts was usually tied to WIC prenatal visits, which varied across mothers (7, 11, 19).

Some interventions reported prenatal contacts but focused on postpartum support (10, 13). In two WIC-based interventions (2, 13) women did not have contact with their peer counselor until after delivery, but infant feeding was discussed during a prenatal meeting with either a community health nurse (13) or nutritionist (2). Only one intervention did not include any prenatal contact (5). In this intervention, Canadian mothers were randomly assigned to the peer counselor group while in the hospital, and peer counselors contacted them by telephone within 48 hours of hospital discharge. This effective intervention was provided to women who gave birth in a hospital with a high level of breastfeeding support.

Five interventions included meetings between peer counselors and mothers in the hospital (1, 10, 18, 22, 24). These contacts may be especially important because the immediate postpartum period is a crucial time for new mothers to learn basic breastfeeding skills. In an intervention in Chile (1), peer counselors (called "health promoters") visited women in the hospital to provide support and strengthen the mothers' determination to breastfeed. A Chicago study (10) reports that peer counselors were in the hospital's maternity wards five days a week. The intervention in Mississippi (18) included peer counselor hospital visits if the mother requested them. The intervention serving Hmong women in California (24) included peer counselor visits within one to three days after birth, and depending on the timing, this visit would occur either in the hospital or at the mother's home.

Postpartum contacts were initiated by peer counselors in some interventions (2, 13), and by mothers in other interventions (15, 22). In some cases the schedule and content of visits was highly specified (8, 17), whereas in others peer counselors were encouraged to adapt their contact to each mother's particular needs (5, 15). Most often the descriptions of the interventions included guidelines for scheduling postpartum contacts between peer counselors and mothers. The most common schedule of contact after the first postpartum month was either weekly or bi-weekly (8, 10, 11, 13, 17, 19, 25), but two interventions recommended only monthly contacts (1, 2).

Peer counselors typically continued to support mothers either for a specified length of time, or until the mothers stopped breastfeeding. Specified lengths of time ranged from three days (24) to six months (5, 8). Peer counseling was provided only until the third day postpartum in an intervention aimed to increase breastfeeding initiation among Hmong women in a California WIC clinic (24). Longer intervention periods were used when the goal was to establish breastfeeding or increase duration. Two WIC interventions (11, 22) and an intervention in Glasgow, Scotland (15) provided peer support for up to six weeks; other interventions followed women through two (17), three (2, 5, 10, 13, 21), and four months (3).

The content of peer counseling sessions depended in part on their timing. Prenatal visits typically informed pregnant women of the benefits of breastfeeding and educated them on what to expect. Postpartum visits focused on teaching specific breastfeeding techniques, helping mothers deal with problems, and encouraging mothers to continue breastfeeding and, in some cases, to continue

exclusive breastfeeding. Postpartum sessions were often more individualized to the needs of the particular mother than prenatal sessions. Ten reports (2, 5, 7, 10-13, 15, 23, 25) did not describe any particular materials used in peer counseling or specify the main message of the intervention beyond the two general goals of providing education and support.

A few reports mentioned specific materials that were used with mothers or given to them. The intervention in Mexico City (17) developed a set of visual aids based on La Leche League materials; an intervention in rural Iowa (21) developed educational flip charts and brochures; and a Michigan program provided booklets called *Eating Right for Two* and *Feeding Your New Baby (0-4 months)* (18). One program (22) used a standardized assessment tool to determine each mother's particular breastfeeding problems and tailored peer support based on that information. Several interventions developed materials to be culturally sensitive to group attitudes based on ethnographic studies. This was true of interventions with Mexican (17), urban African American (19), and Hmong (24) mothers.

Only one peer counselor intervention reported use of incentives. The Baltimore WIC intervention (3, 6, 19) gave breastfeeding promotional gift packages to treatment group women after delivery. Both treatment and control group participants were also paid for each stage of data collection.

Characteristics and Qualifications of Peer Counselors

As noted earlier, peer counselors are not health professionals, but typically have personal breastfeeding experience and are trained to provide peer counseling. Personal breastfeeding experience was a requirement for peer counselors in all but one (17) of the interventions reviewed.⁶ Other commonly cited criteria for peer counselors were to live in the same geographic area and/or community as the women served (1, 8, 15, 17, 21); to be similar to the participating women by being low-income (2, 10, 18) or a former WIC participant (19, 22); and to want to help other women breastfeed (2, 8, 10, 15). In one study, women were matched with peer counselors of the same race whenever possible (10).⁷

Thirteen reports provided at least a brief description of peer counselor training (2, 5, 8, 10, 11, 13, 15-22, 25). The time allotted for training ranged from a 2.5-hour orientation program (5) to over 40 hours of class with supervised training (8, 17), although formal training typically lasted no more than 25 hours (2, 10, 11, 13, 15, 21). Peer counselor programs in Bangladesh (8) and Mexico (17) had extensive training and supervision requirements; for example, peer counselors in Mexico worked under supervision for up to six months before beginning the intervention program that was evaluated. The numbers of peer counselors trained for the specific interventions ranged from two to 94.

Training topics were quite consistent across programs, typically focusing on content specifically related to breastfeeding (e.g., its value, how to do it, when to refer for medical consultation) and on listening and communication skills (2, 8, 10, 13, 15, 21). Specific curricula varied. Three interventions, one each in the U.S. (2), Canada (13), and Mexico (17), relied on La Leche League training curricula. Three other programs, all in the U.S., used training materials developed by state WIC programs (11, 19) or trained with a WIC program (25). Other specific training curricula included the

⁶ Peer counselors in the Mexican intervention (17) were not required to have personal breastfeeding experience, but they had to be committed to helping other women breastfeed.

⁷ The Chicago study (10) noted that peer counselors usually worked for little if any money and, because they were selected from the same population as the women being served, were likely to have stressful lives that sometimes interfered with their roles as peer counselors.

WHO/UNICEF breastfeeding counseling course (8) and the BEST Breastfeeding Course developed by Warren (15). The curricula used with peer counselors in Chicago (10) focused on typical breastfeeding topics, but used training methods that were aimed at motivating and empowering the participating peer counselors.

Training approaches, when described, included a combination of group discussions, lectures, role-playing exercises (2, 8, 10) and, in several cases, supervised practice experience (8, 17). Several training programs included written exams that the peer counselors were required to pass (11, 15, 19).

Evaluation Methodologies

Table 3.1 provides summary counts of peer counselor interventions by country and study design. Only four studies used a randomized treatment control design (5, 8, 17, 25). Among the quasi-experimental designs, ten used unmatched treatment comparisons (1, 2, 10, 12, 15, 18-23), and four used pre-post comparisons (7, 11, 13, 24). Some of the unmatched treatment comparison studies assigned WIC clinics (19) or sections of a city (1, 15) to intervention or control groups. Others (2, 10) recruited women who intended to breastfeed and assigned them to intervention or control groups based on availability of peer counselors. Two of the pre-post studies compared WIC participants in a new peer counseling program with the breastfeeding behavior of women at the same clinic(s) before the intervention began (11, 24). The most common design for the WIC studies was an unmatched treatment control comparison (2, 12, 18-23); none of the ten WIC studies used a randomized treatment control design.

Table 3.1

Peer Counselor Interventions: Study Designs and Results

	Number of Interventions	Study Design		Significant Impacts	
		RTC	Quasi-Experimental	RTC	Quasi-Experimental
Goal: Increase any breastfeeding					
US–WIC	11	—	11	—	8
US–WIC	2	1	1	—	1
Canada, Scotland	3	1	2	—	1
Goal: Increase exclusive breastfeeding					
Bangladesh, Chile, Mexico	3	2	1	2	1
Total	19	4	15	2	11

Peer counselor studies that did not use random assignment often suffered from a number of limitations, the most serious being selection bias. In some non-RTC studies, the treatment group members (18, 21) or treatment clinics (7) self-selected into the intervention (i.e., women choose peer counselor support). In addition, several non-RTC studies lacked comparability across treatment and control groups on influential variables (11, 12, 18, 20-22, 24), especially on intention to breastfeed. One researcher stated the data in her study indicated that “intention to breastfeed is the most significant

factor influencing breastfeeding initiation and early duration” (3). As a result, studies suffer from selection bias when the treatment group contains women intending to breastfeed and the comparison group is not similarly selected. Some studies avoided this problem by explicitly selecting both treatment and comparison groups from among only these women intending to breastfeed (2, 10, 18, 21, 25) or already breastfeeding (2, 5, 13, 23). In nine studies, treatment and control groups were comparable on these dimensions, either through random assignment (5, 8, 17, 25) or other means (1, 2, 10, 15, 23), and the main outcome of interest was breastfeeding duration.

Another limitation of many peer counselor studies is that data collectors were usually more or less aware of the treatment group assignment of the women participants, though most studies did not address this as a concern. In a study of an intervention in Mexico (17), however, the researchers attempted to control for possible bias by carefully standardizing the data collection procedures across treatment and control groups.

Samples used to evaluate peer counselor interventions ranged from general (all mothers of infants born within a certain time period in a community (13)) to specific. Specific sample inclusion criteria were singleton births (5, 8, 19, 24) and absence of serious maternal or infant health problems that would interfere with breastfeeding (5, 8, 11, 19). Three studies limited the sample to women who started prenatal care before 24 weeks gestation (3, 6, 19), and one study included only African-American women (3).

Sample sizes varied across studies and types of analyses. An evaluation of a peer counselor program in Mississippi WIC clinics used statewide WIC records collected before and after the introduction of peer counselors. The study examined the pre-post change in breastfeeding initiation for WIC clinics with and without peer counselors, using an overall sample of more than 18,000 women (7), and found that peer counselors were associated with greater increases in breastfeeding initiation.

Among the 16 studies analyzing breastfeeding outcomes at the level of individual women, sample sizes ranged from 36 in a study of a peer counseling in WIC clinics in Florida (2) to 995 in the community-based study of poor areas of Glasgow, Scotland (15). Overall sample sizes for nine studies (1, 3, 5, 6, 10, 11, 13, 17, 19, 21, 22) were in the range of 100 to 300. Among the WIC studies that used new data collection (2, 11, 19, 21, 22, 24) rather than WIC records, sample sizes for the treatment groups ranged from 18 (2) to 156 (22).

Data from peer counselor interventions were most frequently collected through pre- and post-intervention surveys—in-person (2, 8, 15, 17), by telephone (25), or by a combination of methods (5, 10, 19). Other studies collected new data from treatment groups for comparison with existing records (11, 18, 21, 24). Four studies used extant data entirely (7, 12, 13, 23). Three studies of WIC participants drew entirely on extant data. Two of these studies (7, 23) used WIC clinic data from the Pediatric Nutrition Surveillance System from the Centers for Disease Control (CDC) to analyze the impact of peer counselor interventions statewide (7) and at the level of WIC clinics (23). The third study (12) drew entirely on records from a single WIC clinic. Other WIC-based interventions used a combination of in-person surveys and record reviews (11, 21, 22, 24) or collected all data, either by in-person surveys (2) or a combination of in-person and telephone surveys (3, 6, 19).

Outcome Measures and Findings

Peer counselor studies reported breastfeeding outcomes in terms of breastfeeding initiation, duration of any breastfeeding, and duration of exclusive breastfeeding. Initiation of breastfeeding was defined in a number of ways, including “ever to breastfeed” (21) and “any attempt at breastfeeding” (22). Duration was examined as the percentage of women breastfeeding at the following intervals: at hospital discharge (15, 22), and at two, four, six, eight and/or twelve weeks (3, 5, 6, 10, 12, 15, 18, 24, 25). Some studies collected data on any breastfeeding through the fourth (6) and fifth months postpartum (1, 11, 13, 17), and one study (13) reported breastfeeding duration to one year postpartum. Studies focusing on exclusive breastfeeding reported this outcome at one week (25), four through 12 weeks (12, 15, 17), and at six months postpartum (1, 8). Some studies examined changes in breastfeeding outcomes over time (7, 23).

Several reports included outcomes in addition to initiation and duration of breastfeeding. Studies conducted in Mexico (17) and Chile (1) examined the impact of increased breastfeeding on aspects of infant health, specifically incidence of infant diarrhea (17) and measures of infant growth (1). Increases in treatment group mothers’ knowledge of breastfeeding facts and of nutrition were assessed by tests as part of an intervention in rural Iowa (21). A Canadian study reported on the impact of the peer counselor intervention on whether mothers expressed dissatisfaction with their infant feeding experience.

Results

The peer counselor studies included in this review provide positive endorsements of the peer counselor method of breastfeeding promotion. Only 4 of the 18 interventions, however, were evaluated with a randomized treatment-control design needed to provide results free from selection bias and other limitations. Table 3.1 showed the number of studies by study design, and findings of significant impacts on breastfeeding outcomes.

Three of the four RTC trials found that intervention activities resulted in statistically significant impacts on breastfeeding outcomes. These interventions were in Bangladesh, Mexico, and Canada; the one US RTC study (25) had small samples and did not have statistically significant results. The Bangladesh and Mexico interventions have limited relevance for the US because of population differences in the prevalence of breastfeeding (both studies aimed to improve exclusive breastfeeding among populations with high rates of any breastfeeding).

The Canadian RTC study (4) was unusual in that all peer counselor contact was intended to be through postpartum telephone calls. Women were randomly assigned to treatment and control groups in the hospital, and peer counselors were to contact them by telephone within 48 hours of discharge and as frequently as the mother needed afterwards. This intervention, however, made use of volunteers in a community breastfeeding organization—so that the group of peer counselors was less similar to the mothers than in other interventions. This relatively low-intensity intervention was effective: 81 percent of mothers in the treatment group were breastfeeding at three months, compared to 67 percent of the comparison group. The success of this intervention, however, may have depended on the fact that the women were all in a hospital that was especially supportive of breastfeeding, and therefore the peer counselors met a receptive audience.

The results of quasi-experimental studies suggest that peer counseling is effective at increasing breastfeeding initiation and duration—nearly all of these studies reported significant, positive impacts

on one or more breastfeeding outcomes. Peer counselor interventions were associated with increases in breastfeeding initiation (3, 6, 7, 10, 11, 19, 23, 24), duration of any breastfeeding (3, 5, 6, 10, 12, 13, 19, 21-23), and duration of exclusive breastfeeding (1, 2, 5, 8, 10, 12, 17, 25). These studies, however, must be viewed with caution. All of these studies were limited by their study design, but in addition, the most serious limitation of the quasi-experimental studies was the failure to match treatment and comparison groups with regard to intention to breastfeed.

Three quasi-experimental studies are discussed in detail here. One intervention, in Chicago (10), points to the importance of providing support in the immediate postpartum period, whether as part of the peer counselor intervention or through a supportive hospital program. The second intervention was conducted with a large sample (995) in Glasgow, Scotland (15), and is unusual in that it failed to have any effect on prevalence of breastfeeding at six weeks postpartum. Consideration of this intervention's failure to have an impact might be instructive in planning an effective intervention. The third study is one of the few examples of a dose-response study, in which multiple treatment groups received different types of treatment.

The Chicago program (10) targeted low-income women giving birth at Chicago's largest public hospital. The treatment and comparison groups were roughly matched because both groups intended to breastfeed and asked to have peer counselors. Initial contact was made in the hospital in the immediate postpartum period, and subsequent contacts were made by telephone. A strength of this intervention is that it begins with in-person contact with the participating women at an opportune time, the immediate postpartum, and then provided less labor-intensive telephone contact to follow up. This intervention also attempted to match counselors and women by race. A limitation of this program in terms of its generalizability is that the entire sample may be atypical because they were low-income women intending to breastfeed and asking for a peer counselor. This intervention was associated with greater prevalence of breastfeeding at six weeks: 64 versus 28 percent for treatment and comparison groups, respectively. The difference between groups persisted to 12 weeks postpartum.

The intervention in Glasgow, Scotland (15) was the only intervention in which peer counselors worked in pairs. This arrangement may have diluted the strength and effectiveness of the counselor-mother relationship. Possible reasons suggested by the researchers for the intervention's ineffectiveness were its very low level of intensity. Although the planned intervention called for a minimum of four contacts, two prenatal and two postpartum, only 71 percent of the women actually received at least one prenatal visit, and of the women who decided to breastfeed, only 76 percent received at least one postpartum visit. Other possible weaknesses mentioned by the authors were the failure to involve influential members of the mother's family and relying on mothers to initiate postpartum visits. Intention to breastfeed may also have been a factor in this intervention, because only one in five of the original sample reported intending to breastfeed.

One of the few interventions that tested alternate treatments—thereby highlighting the relevance of the intensity of intervention activities—is the Baltimore WIC clinic intervention (3). This intervention had three treatment groups in which both peer counselor and motivational videotape interventions were provided, and the effectiveness of each was assessed, both separately and combined. The videotape condition alone was as effective as the peer counselor intervention alone or the combined interventions. The videotape condition consisted of the continuous playing of a motivational breastfeeding videotape in WIC clinics and providing motivational pamphlets and informal breastfeeding support from WIC staff. All the apparent treatment outcomes, however, may have been confounded

by the greater number of treatment group women who intended to breastfeed, compared to the comparison group.

Cost Information

Very little information on the cost of peer counselor interventions was provided in the reports reviewed. One conclusion that can be drawn, however, is that peer counselors should be paid if they are expected to provide consistent contact with participating women. Because the peer counselors are expected to come from the same low-income group as the mothers involved, they are unlikely to be able to volunteer their time.

One variable factor related to cost effectiveness is whether peer counseling sessions are held in person or by telephone. Three effective interventions (5, 10, 25) relied primarily on telephone calls as the primary means of contact between the counselor and woman. Two of these interventions (10, 25) included in-person contact between the counselor and woman before the postpartum telephone calls began.

Summary

The studies reviewed here presented a variety of models for implementing a peer counselor intervention. The various interventions present lessons to be learned about aspects of peer counselor interventions to include and those to avoid. Several researchers mentioned the following as potentially important characteristics of peer counselor interventions: whether peer counselors also talk with key family members who might provide the mother support (2, 25); whether local hospitals provided support for breastfeeding and/or collaborated with peer counselors (3, 6, 15, 19, 23); and whether peer counselors address the problems mothers will face in continuing to breastfeed after returning to work or school (2). One intervention thought it was important to match peers and mothers by race (10), but most studies did not specify criteria for matching peers and mothers.

It is important to note, however, that although these studies described the design of peer counselor interventions, only a few reported on actual implementation. Actual contacts between peers and mothers may include more or fewer contacts than originally intended. For example, in one study (4) designed to have peer counselors contact mothers by telephone within 48 hours after hospital discharge, it was noted that 33 percent of the peer counselor volunteers contacted mothers while they were still in the hospital. In other studies (10, 15) reporting on implementation, peer counselors were found to be less consistent in contacting mothers than intended. These variations from study design make the results of prior studies difficult to interpret.

3.5 Other Prenatal and Postpartum Interventions

This section summarizes four types of breastfeeding interventions that did not fit in previous categories: (1) printed materials (without in-person contacts); (2) discharge packs (unaccompanied by ongoing support); (3) incentive programs (evaluated separately from other support components); and (4) programs for working mothers (corporate programs; workplace changes). These interventions are listed in Table A.5, and are discussed separately by category in this section.

Printed Materials

Four breastfeeding interventions consisted solely of the distribution of printed information (1-4).¹ One intervention was conducted in the United States (Alabama), and three in foreign countries (Italy, Australia, and Ireland). All four took place in the mid-nineties (1994 to 1998) and were evaluated in randomized controlled trials. Although no specific cost information was provided, all authors alluded to this method of disseminating information as time- and cost-efficient.

Printed materials ranged from a one-page information sheet distributed to pregnant women just prior to birth (4), to booklets mailed or handed to new mothers intending to breastfeed (2, 3), to a comprehensive self-help manual given to pregnant women, with information for both the prenatal and postpartum periods (1). Each was intended to motivate and educate mothers about breastfeeding and, in the latter three cases, to serve as a reference when health care providers were not accessible. The self-help manual was targeted specifically to low-income women, but none of the printed materials was tested in a WIC setting.

The one-page information sheet conveyed eight positive aspects of breastfeeding, with the objective of increasing breastfeeding initiation (4). The booklets, on the other hand, focused on issues related to the exclusivity and duration of breastfeeding. One booklet contained information about the advantages of breastfeeding for at least the first six months, feeding positions, mother's diet, feeding schedules, care of nipples, and common concerns and beliefs (2). The second booklet contained information on common problems, principles of supply and demand, and expression of breast milk (3). The self-help manual included a prenatal education/motivation section, postnatal steps to initiation and maintenance, and a section on managing common problems. The manual was written at the fifth-grade reading level, and was intended to increase initiation and duration among clients of a public health clinic in an urban area of Alabama (1).²

Two of these four studies collected data on use of the printed materials, in addition to breastfeeding outcomes. The booklet promoting six months of exclusive breastfeeding was used at least once by all treatment mothers, with 82 percent of them reporting it to be "useful" (2). Ninety percent of breastfeeding women rated the self-help manual as "very" or "somewhat helpful" for initiation, and 60 percent gave this rating for maintenance (1). Two studies also collected information about additional sources of breastfeeding information (3, 4).

¹ These interventions represent a small fraction of the interventions using printed educational and support materials, but these four were specifically evaluated as add-ons to usual care or as the only strategy for influencing breastfeeding rates.

² This three-part self-help manual was developed after conducting focus groups and interviews with low-income women, and consulting with breastfeeding experts and health professionals.

Results from these studies suggest the printed materials were more successful at increasing breastfeeding initiation than duration. The one-page fact sheet was associated with an almost 40 percent higher rate of initiation, but the difference was not statistically significant due to small sample size (4). The self-help manual was associated with a higher initiation rate that was statistically significant (60.3 versus 43.6 percent for treatment versus control group) (1). Knowledge of study group assignment in the latter study, however, may have reinforced use of the manual among the treatment group. In spite of this, authors noted that the positive outcome and relatively low level of time, effort, and money involved were sufficient to justify revising the manual and testing it in different settings and populations (1).

None of the four studies found impacts on breastfeeding duration. Authors noted limitations in their study designs, as well as the limitations of print materials, in explaining the lack of impact on duration. A commentary published with one study pointed out that use of the information in print materials depends on its availability at the time the information is needed, the mother's literacy skills, and her interpretation of the information (2).

Discharge Packs

Three interventions consisted solely of the distribution of alternative or “nursing” discharge packs. These discharge packs are alternatives to the regular hospital discharge pack containing infant formula. The nursing discharge pack generally does not include formula, but includes items of potential benefit to a nursing mother, such as breast pads and breast pumps.³

Three studies of nursing discharge packs were located; one was described in two separate reports (7, 8). All three studies took place in the United States—one in California and two in Iowa—in the early nineties (1990 to 1993). Randomized controlled trials were used for each. Mothers in all three studies were predominantly white, married, educated, and middle-income.

The discharge packs used in the interventions were provided free of charge to new mothers who initiated breastfeeding or planned to breastfeed. The California study used a four-cell model, where mothers were assigned to receive a discharge pack containing either (a) a pump, (b) formula, (c) a pump and formula, or (d) neither (printed materials only) (5). These discharge packs were assembled in commercial diaper bags, and included breastfeeding pamphlets written by hospital staff.

The Iowa studies distributed nursing discharge packs with manual breast pumps (one also included breast pads and breast cream), but included no infant formula samples or promotional materials. The control group for one Iowa study received discharge packs with commercially available infant formula (6); the control groups in the other Iowa study received either (a) infant formula or (b) infant formula and a breast pump (8).

Cost information was provided for the two Iowa studies. Discharge packs containing manual breast pumps, breast pads, and cream were \$15 each in 1990, \$11.75 of which was for the pump (6). The cost of each pack containing a manual breast pump only was \$13.25 in 1993 (8).

³ A number of studies have examined the effects on breastfeeding duration of hospital discharge packs containing infant formula. Two reviews of the research concluded that the distribution of commercial hospital discharge packs has a detrimental effect on exclusive breastfeeding, but reached different conclusions with respect to non-exclusive breastfeeding (Donnelly *et al.*, 2002; Perez-Escamilla *et al.*, 1994).

Results were mixed. The earlier Iowa study with the smallest sample size found that the nursing discharge packs were associated with longer duration of exclusive breastfeeding (4.18 versus 2.78 mean weeks duration). Conversely, results from the two studies with larger samples indicated that the content of discharge packs had no significant effect on feeding method (any versus exclusive breastfeeding) up to six months after birth, after controlling for predictor variables (5, 8). In addition, neither of the larger studies found any differences in the duration of any breastfeeding.

The California study was the only study to compare mothers receiving breast pump packs with a group that received no discharge packs (thereby eliminating the effect of formula). This comparison showed a small impact of the nursing discharge packs among mothers who had intended to breastfeed at least six months and those who had not yet returned to work or school. In both cases, the results did not persist past six weeks postpartum.

Incentive Programs

Three studies examined the effects of incentive gifts on breastfeeding rates (9-12). The incentive interventions took place in Arizona and North Carolina beginning in 1992, and in Kansas during the year 2000. The Kansas study was described only in an abstract (10); the Arizona study was described in two full publications (11, 12).

The three programs provided incentives for participating in breastfeeding intervention activities (classes, peer counselor visits, WIC visits), or for demonstrating breastfeeding initiation and continuance, or both. Incentives were provided in the form of gifts, raffled prizes, or coupons redeemable for personal or baby items. For example, participation in educational activities and the ongoing support of partners were important goals of the “Caring Connection” program in Arizona (12). This program gave mothers a gift bag with diapers, baby wipes, and a breast pump, plus tickets to a local college football game for their partners. This program also raffled prizes such as gift certificates, infant carriers, and stuffed animals. In the North Carolina program, participating mothers earned coupons (“BabyBucks”) as an incentive for participating in breastfeeding education activities;⁴ the coupons were redeemable for personal or baby items (nightgowns, diaper bags, bibs, car seats, strollers). (No information was provided on the nature of the incentives provided in the Kansas study.)

All three incentive programs were targeted to low-income women and, in Arizona and Kansas, to the WIC population in particular (10, 12). The BabyBucks program in North Carolina was designed specifically to improve breastfeeding and a host of other health outcomes in rural, medically underserved areas (9). WIC staff were involved in the incentive programs in all three locations. For example, WIC peer counselors provided an incentive gift to new mothers in the Caring Connection program at the initial and three-month visits.

All three incentive programs were evaluated. The Arizona and Kansas incentive programs recruited eligible participants from selected WIC clinics and assigned them (randomly, in Arizona) to the intervention or control group. For the BabyBucks evaluation, a retrospective comparison group was used. The intervention group consisted of all 417 women who sought prenatal care through a regional health department for a two-year period after BabyBucks was implemented. The comparison group

⁴ Coupons were also earned for participating in other perinatal health services.

was a random sample of 519 women who received care at the same health department during a four-year period prior to the BabyBucks program.

The Arizona evaluation relied on in-person interviews with mothers at several points during the postpartum period. Data for the Kansas program were obtained through “questionnaires.” Data on breastfeeding outcomes for the BabyBucks study were obtained exclusively through record review.

Results from the Arizona Caring Connection program showed that the proportion of women who breastfed exclusively up to three months postpartum was significantly greater in the intervention than in the control group. They also showed increases in knowledge, positive attitudes, and partner support for breastfeeding, and authors felt the incentives attracted women and their partners from lower socioeconomic groups to the educational programs. Although the study utilized a randomized controlled design, the sample size was quite small (68 mothers). The Kansas program, which provided “gifts” for initiation and continued breastfeeding at one and three months postpartum, reported partial success. Breastfeeding rates were significantly higher among treatment compared with control women at one month, but not at three months postpartum. In addition, the BabyBucks evaluation noted “nearly a three-fold increase” in the proportion of infants who were breastfed after implementing the program. Unfortunately, these studies suffer from a lack of information about the comparability of intervention and comparison groups. In addition, the BabyBucks findings were highly susceptible to bias, given the upward trend in breastfeeding rates among the target population during the five years prior to introducing the program.

All three studies of incentive programs reported statistically significant improvements in breastfeeding rates. Unfortunately, lack of information and limitations of the study designs preclude drawing strong conclusions about the effectiveness and generalizability of these findings. Another potential issue is cost. The Caring Connection program indicated that the community donated the incentives, but this is not likely to be feasible on a larger scale. The BabyBucks program received \$11,000 in grant funds, but it is unclear what period of time or how many participants this covered.

Programs for Working Mothers

Mothers returning to work within the first year postpartum face unique challenges in their efforts to continue breastfeeding. To maintain an adequate milk supply, mothers may need to pump breast milk as often as two or three times during an eight-hour workday (13). This requires a supportive employer, a private place, time to pump, and the equipment to do so at the workplace. Social and clinical support may also be important factors in a working mother’s ability to continue breastfeeding successfully. This review identified three breastfeeding promotion and support programs specially designed to meet the needs of working mothers (13-15). Two were conducted in the United States (California and Minnesota), and one in Chile (Santiago). The programs began between 1989 and 1995, and appear to be ongoing.

The two US interventions were workplace programs: a Corporate Lactation Program at two corporations in California (13), and a nursing mothers room at a large university in Minnesota (14). The California programs were comprehensive, spanning the prenatal and postpartum periods. In addition to the availability of a special on-site pumping room equipped with an electric breast pump, a lactation consultant offered prenatal classes for female employees and their partners, and provided prenatal and ongoing counseling and support regarding lactation, nutrition, and balancing work and family issues. Participants were charged a fee, which covered the entire service.

The Minnesota program was available to all female students, staff, and faculty who were breastfeeding. A private room, centrally located within the academic health center complex, was furnished and equipped with a hospital-grade electric pump and educational books, pamphlets, and flyers. Lactation clinical nurse specialists were available for telephone consultation and support. These nurses promoted breastfeeding throughout the university, and published a quarterly newsletter featuring resources for new parents making the transition back to work or school.

The program for working mothers in Chile was part of a larger hospital- and clinic-based breastfeeding promotion program for urban women delivering at a large university hospital (Valdes *et al.*, 1993) (15). The treatment and comparison groups consisted of breastfeeding women who planned to return to work before 120 days postpartum. Beginning 30 days after delivery, women in the treatment group were seen in the lactation clinic, initially by a nurse, and then monthly by a physician and nurse-midwife. Mothers were taught hand-expression techniques (rather than the use of a breast pump). They were also provided with ongoing, individualized breastfeeding support and assistance with problem management, and they received information about the benefits of exclusive breastfeeding for six months and information about legislation that protects working mothers. Fathers and other relatives were encouraged to participate in clinic visits.

The California and Minnesota interventions were not evaluated—these studies reported only the post-intervention outcomes for the self-selected groups of women who participated in the programs (187 and 46 women in the California and Minnesota studies, respectively).

A prospective follow-up design was used to evaluate the lactation clinic in Chile. Group assignment was not random, but there were few significant differences on measured characteristics and the comparison group did not have access to the lactation clinic. Data on breastfeeding outcomes were obtained through interviews with mothers. The evaluation found that this clinical breastfeeding support intervention was associated with significantly higher rates of exclusive breastfeeding at six months (53 versus 6 percent for treatment versus comparison).

The three studies reviewed here provide little information about the effectiveness of workplace breastfeeding support programs. It is important to note, however, that the proportion of WIC participants who are employed is not trivial (32 percent of pregnant women, 18 to 20 percent of breastfeeding and postpartum women), but none of the programs for working women reviewed here could be easily implemented by the WIC program.

3.6 Hospital Interventions

Several interventions focused on promoting breastfeeding within the hospital setting. The interventions reviewed here are those that typically occurred around the time of delivery through hospital discharge, although interventions were included if they were hospital-based even if they included a prenatal or postpartum component to accompany the core hospital intervention surrounding birth.¹

This section reviews 24 interventions, as listed in Table A.6 in Appendix A. Seven of them were interventions in U.S. hospitals. The other 17 were done in other countries, and many were in hospitals with practices that differed in potentially important ways from those in the U.S. For example, the length of hospital stays for delivery were often longer, midwives were part of the hospital staff, and national campaigns or legislation, such as one that prevented the use of formula discharge packs in Brazil (4), may have played a role in the intervention findings. These differences, in addition to some of the cultural differences and traditions—for example, the already relatively high rate of breastfeeding in some countries such as Sweden (23) or the practice of using prelacteal feeds (e.g., sugar water, tea) as the first feed in India (14)—warrant consideration when the findings are assessed for relevance for U.S. hospitals.

The interventions were implemented from 1982 to 2000. Seven of them began in the 1980s, six in the early 1990s, nine in the late 1990s, and the timing of two interventions are unspecified.

There were three types of hospital interventions:

- **Breastfeeding policy change.** Generally these included interventions that were aimed at initiating one or more of the steps identified in the BFHI, an international movement launched in 1991 by WHO and UNICEF to ensure hospital environments are optimally supportive of breastfeeding.
- **Staff training.** These interventions consisted of providing breastfeeding education and/or promotion training to all or one group (e.g., nurses) of hospital staff.
- **Changes in service structure.** These types of interventions included an overhaul in how perinatal services were provided, and the opening of an in-hospital community breastfeeding center.

The interventions are described separately below, by type. In general, the hospital interventions took place in the hospital setting and lasted only during the in-hospital stay for mothers (which was typically somewhat longer in other countries than the U.S., and longer for caesarean section than vaginal deliveries). The women in the interventions were typically those in the hospital service area; those serving a special population (e.g., mostly middle income with health insurance, or low-income) are noted in the discussion. There was no discussion of WIC in any of the reports. Eighteen of the 24 interventions had some criteria for sample inclusion, which typically specified that neither mother nor infant had any conditions that would contraindicate breastfeeding or make breastfeeding difficult (e.g., no maternal substance abuse, infants were of normal birthweight). Two of the 24 interventions focused on women who initiated or planned to initiate breastfeeding.

¹ Education sessions that were located in the hospital or had a hospital component (e.g., hospital visit) are included in the Education Intervention section.

Breastfeeding Policy Change

There were ten studies in this category (1-10). Four of the studies tried to promote and support breastfeeding through a fairly major overhaul of the maternity services, using the BFHI's *Ten Steps to Successful Breastfeeding* (see Table 3.2) (1, 2, 7, 10). The goal of these steps is to emphasize hospital staff assistance with initiating and maintaining breastfeeding, with referrals to post-discharge community support. As described above, these steps were developed in a joint effort of WHO and UNICEF as guidelines for maternity facilities that wanted to be designated as "baby-friendly". Support for the ten steps and the Baby-Friendly designation has been strong internationally, but progress on the initiative has been slow in the United States (with only 33 U.S. hospitals being designated as baby-friendly by the end of 2002, compared with over 16,000 internationally) (DiGirolamo *et al.*, 2001; www.babyfriendlyusa.org).

Table 3.2

The Ten Steps to Successful Breastfeeding

-
1. Have a written breastfeeding policy that is routinely communicated to all health care staff.
 2. Train all health care staff in skills necessary to implement this policy.
 3. Inform all pregnant women about the benefits and management of breastfeeding.
 4. Help mothers initiate breastfeeding within an hour of birth.
 5. Show mothers how to breastfeed and how to maintain lactation, even if they should be separated from their infants.
 6. Give newborn infants no food or drink other than breast milk, unless medically indicated.
 7. Practice "rooming-in" by allowing mothers and infants to remain together 24 hours a day.
 8. Encourage breastfeeding on demand.
 9. Give no artificial teats, pacifiers, dummies, or soothers to breastfeeding infants.
 10. Foster the establishment of breastfeeding support groups and refer mothers to them on discharge from the hospital or birthing center.
-

Sources: <http://home.onemain.com/~ct1008688/bfusa.htm>, website for Baby-Friendly Hospital Initiative, USA.

Two of the four studies attempting to change hospital policy to conform to all Ten Steps of the BFHI were conducted in the U.S. (7, 10). The others were in the Republic of Belarus and Italy (1, 2). Of the four studies, one used random assignment of hospitals to treatment and control conditions (2), and the other three use before-and-after designs.² Two of the studies used hospital record reviews (2, 7), whereas the other two used surveys and in-person and phone interviews with the sampled mothers to gather outcome data. The sample sizes ranged from about 600 to over 17,000. None of them targeted a specific population, but one served primarily low-income, immigrant and minority women (about 50 percent Black and 25 percent Hispanic) (7).

² Kramer *et al.* (2) randomly assigned 34 hospitals in the Republic of Belarus. Two hospitals refused their random assignment (one treatment and one control), and one hospital was dropped for falsifying data, resulting in a sample of 31 hospitals.

Three of the four studies, including the one with an experimental evaluation design, found increases in breastfeeding outcomes (1, 2, 7). One of the U.S. studies found an increase in breastfeeding initiation (any breastfeeding while in the hospital after birth) from about 58 to 87 percent, and exclusive breastfeeding at hospital discharge to increase from about 6 to 34 percent following the BFHI intervention. This was the study that had a target population of low-income immigrant and minority women. In a subgroup analysis, these researchers also found breastfeeding among U.S.-born Blacks to increase from 34 to 74 percent as a result of the BFHI intervention (7). In the other U.S. study (10), breastfeeding initiation after the intervention was not significantly different than before the intervention. Duration was not studied, although there was a significant change in the number of babies that were breastfed earlier, within the first hour after birth (in compliance with one of the Ten Steps) (10). In the study in the Republic of Belarus, where women who intended to breastfeed were included in the sample, the intervention is associated with significant differences in exclusive breastfeeding at three and six months, and any breastfeeding at 12 months. Other positive health outcomes associated with breastfeeding were observed in this study, including a lower risk for gastrointestinal tract infections and lower incidence of atopic eczema (2). The study in Italy found significant differences in exclusive breastfeeding at hospital discharge, “full” breastfeeding (exclusive breastfeeding plus non-nutritive fluids such as water and tea) at three months, and any breastfeeding at six months.

The six other studies included in this section (3-6, 8, 9) include one or more components of the Ten Steps as a major component of the intervention, including rooming-in and breastfeeding within the first hour after birth, and assisting mothers with breastfeeding. All of these studies were done outside the U.S., including Mexico (6), Central America (3, 9), Brazil (4), Norway (5), and Thailand (8). Two of these studies, done in Honduran and Thai hospitals, did not include any tests of significance on the data, and are not discussed further here (8, 9). Of the remaining four studies, one used a before-and-after design within the same hospital (5); two compared treatment and control hospitals, matched on similar characteristics (4, 6); and one randomly assigned two groups of mothers to treatment and control groups and used a third convenience sample as a second treatment group (3). Sample sizes in these studies ranged from about 150 to 450 mothers.

The Norwegian study focusing on early and frequent breastfeeds with no supplementation found that the intervention was associated with longer period of exclusive (up through six months) and any breastfeeding (up through nine months) (5). A study in Brazil included an intervention with rooming-in, early breastfeeding initiation, breastfeeding assistance for mothers, and education with postpartum referrals, found significantly increased mean duration for exclusively breastfeeding, from 22 to 75 days (4). Another research team found an increase in initiation of breastfeeding through early mother-infant contact and “standard” breastfeeding guidance, and an increase in duration at four months associated with rooming-in and standard guidance among poor women in Nicaragua (3).

In a study of rooming-in in Mexico, the authors found that rooming-in was enough to make a short-term difference in breastfeeding rates in primiparous women. Breastfeeding guidance to mothers in addition to rooming-in was required, however, in order to make a longer-term difference (more than four months) (6). Breastfeeding guidance had no effect on women with other children. The studies in Brazil, Nicaragua, and Mexico were of primarily poor women (3, 4, 6).

Many of the studies reported above have methodological or implementation issues that should be noted. For example, in the study of the BFHI changes in Italy, researchers note that the hospitals volunteered for the study (1). Observers of outcomes in the Belarussian study are those who were key to implementing the intervention (2). In one of the U.S. BFHI studies, the medical record review

was not blinded, and researchers noted that over the course of the three years of data collection, the nurses who recorded information into the medical records could have changed the rigor with which they recorded breastfeeding data as a result of the intervention. In the U.S. intervention of the full BFHI steps that did not find differences in initiation of breastfeeding, researchers noted that the intervention was not a priority of the administrative staff and that the nurses were not required to attend training sessions. Thus, implementation was not as it had been planned.

Issues associated with quasi-experimental designs are applicable here as well. For example, in the study of the intervention in Brazil, the authors defended the comparability of the treatment and control hospitals, although the women in the study did differ on some characteristics associated with increased rates of breastfeeding (e.g., planned duration of breastfeeding) (4). The intervention in Nicaragua may have been affected by some national breastfeeding promotion on the treatment as well as control group members.

Of note in the findings for implementing parts or all of the BFHI is the length of time required for full implementation of this intervention, and the differences in the level of difficulty in implementing the various steps. The research team in Belarus reported that full implementation of the BFHI took a year in their study, and noted that the health care system there is highly centralized so the intervention was fairly easy to implement (2). Another research team in Italy reported different levels of difficulty in implementing the Ten Steps, with written guidelines, staff training, and community support referrals being the most difficult (1). Another team, reporting on a U.S. hospital intervention, found that getting newborns to the breast within the first hour, decreasing the provision of formula to breastfeeding infants, and providing assistance to mothers were relatively easy to implement. Rooming-in and doing away with infant formula discharge packs were more difficult changes (7).

It cannot be determined from these interventions if there are particular steps or a combination of steps that are critical to influencing breastfeeding outcomes. There is some evidence from the studies reported above that improved breastfeeding outcomes can be achieved with somewhat less than the full complement of the ten steps, but no systematic review of this has been undertaken. One recent analysis of a longitudinal mail survey in the U.S. suggests a dose-response relationship between the number of steps and breastfeeding termination before six weeks. The survey collected data on implementation of five of the steps. The mothers who experienced none of the steps included in the survey were eight times more likely to stop breastfeeding before six weeks. Those who experienced some of the steps were at decreased risk for termination, but the risk was higher than those who experienced all five steps (DiGirolamo *et al.*, 2001).

Staff Training

This type of intervention included the education of some or all staff dealing with maternity services in target hospitals. The education curriculum, the trainees (nursing or all maternity service staff), and length of time spent in training varied, thus making it difficult to summarize across interventions. There were no structural or policy changes made as part of the intervention, only education of staff.

There are five interventions included in this category (11, 12, 14-16), with only one in the U.S. (16). There were two in Canada by the same researcher (11, 12), one in India (14), and one in Brazil (15). The intervention in Brazil included an experimental design, with random assignment at the hospital-level (15). The other four studies used before-and-after designs; two of these compared treatment and control hospitals before and after the intervention period (11, 12), and the other two compared

outcomes for women before and after the intervention in the same hospital (14, 16). Two were done in the early 1990s (14, 15) and the others from 1995 to 2000. All of the interventions were conducted with the general population served by the hospital, although in one case this included a low-income, mostly illiterate, rural sample of women (14), and in another included a large proportion of Native Americans in the treatment (about 75 percent) and control (about 27 percent) groups (11). There were no significance tests done on the data from the study in India (14), and so the intervention but not the results are reported here. There was an additional intervention conducted in the U.S. that encouraged medical staff to inform patients about breastfeeding, provided lectures to maternity services staff, and included lactation consultants to support mothers in daily rounds. There was no description of what the control group was receiving, however (which may have been substantial, because the hospital was moving towards BFHI status), nor any statistical comparisons of the descriptive data. Thus, this study is not included further in this discussion (13).

The focus of the staff training included the Wellstart International curriculum³ or a customized version of it, the ten steps of the BFHI, and a program developed specifically for the target hospital. In the study with an experimental design, two physicians and one nurse from each of the eight Brazilian hospitals in the study were trained full-time for three weeks in a course modeled after Wellstart (15). Based on data from over 950 mothers interviewed at one and six months postpartum, survival analysis were conducted on the duration of breastfeeding for the before and after cohorts. An effect of the training of the hospital staff was found for both exclusive and full (no use of other milk or formula). The researchers report increases in the estimated adjusted rates for infants in the treatment hospitals were 29 percent (hazard rate = 0.71) and 20 percent (hazard rate = 0.80) for exclusive and full breastfeeding, respectively (15).

The training in the other intervention studies included a baby-friendly education program that was conducted over ten days for doctors, nurses, and midwives in a hospital in India (14); a one-and-a-half hour mandated in-service training for all nursing staff in a Canadian hospital, intended to increase BFHI compliance (11); a one-day, BFHI-focused workshop mandated for all nursing staff in another Canadian hospital (12); and a breastfeeding education program mandated for all health care providers in one U.S. hospital that included breastfeeding seminars, yearly grand rounds, and bedside teaching seminars (16). Sample sizes ranged from 75 (11) to over 13,000 (16). Data collection methods included pre and post in-person surveys (15) and medical record data (11, 12, 16).

The results from these studies were mixed. In the intervention with a one-and-a-half-hour mandated session for nurses on baby-friendly hospital practices, there was a significant increase in exclusive breastfeeding at hospital discharge but not in breastfeeding initiation (11). No significant difference was found in initiation or exclusivity of breastfeeding in a similar but slightly longer staff training of nurses in an intervention by the same researcher (12). In both studies, there was an increase in measures of BFHI compliance to the ten steps.

The U.S. study found significant increases of initiation and breastfeeding at hospital discharge for the treatment group. The effect of the intervention was most dramatic for mothers of low birthweight babies, who also received prenatal counseling on breastfeeding from their physicians. Results from a qualitative component of this study suggest that follow-up support is needed for hospital education

³ Wellstart International is a non-profit corporation that promotes and supports breastfeeding through the education of medical, nursing and nutrition students. Their curriculum has been used widely internationally, and includes training for health professionals in the fundamentals of breastfeeding management and support.

interventions to promote more permanent change (16). This is echoed in the researchers reporting on the intervention in India, who found dramatic drop in breastfeeding gains six months after the intervention ended (14).

Change in Hospital Service Structure

Interventions under this heading were those that made a change in the structure of maternity care or nursing care, opened a breastfeeding center, or allocated staff resources specifically to support breastfeeding in hospital. Three of the eight interventions under this heading were done in the U.S. (19, 21, 22), one in Sweden (23), two in Canada (17,24), one in the England (18), and one in South Africa (20). Of those in the U.S., one was a change in the model of perinatal services, shifting education to the prenatal period, opening a postpartum care center for newborn follow up after hospital discharge, and increasing lactation consultant hours (22). Another was a change in nursing practices to support early breastfeeding support, and included in-service education sessions, changing the standard protocol for assisting mothers in breastfeeding, providing nurses with teaching aids, establishing mechanisms for monitoring breastfeeding success (e.g., serum bilirubin levels), and tying breastfeeding management into nurses' performance appraisals (21). The third U.S. study looked at breastfeeding outcomes associated with the provision of doulas, laywomen who provide emotional support during labor and delivery (19). This latter study included an experimental design with random assignment of women to the intervention or control conditions. The other two studies used before-and-after designs within the same hospital.

Other interventions included perinatal care in a birth center rather than standard hospital maternity care (23), an in-hospital breastfeeding center (17), combined mother-infant postnatal care (24), and the provision of a "baby-feeding advisor" along with the elimination of dextrose supplementation (but not water or formula) and reduction in night-only shifts for nurses (18). One study was similar to the U.S. study on doulas, in that it provided non-professional companion through labor, in this case for poor women without other family or partner support. The study of the birth center used an experimental design with random assignment of women who expressed interest in participating in the clinical trial (23). The study of labor companions also used an experimental design with random assignment (20). The other studies used before-and-after designs with in the same hospital. The intervention of the hospital breastfeeding center did not include clear comparisons between treatment and control nor tests of significance (17), and thus is not included in the discussion below.

The sample sizes among all the studies ranged from 188 to over 1200 mothers. Seven of them targeted the general population served by the hospital; the labor companion intervention targeted low-income women without other supportive companions. In two of the U.S. studies, the hospitals were associated with HMOs, which serve women who are typically middle class (19, 22). Three interventions were conducted in the late 1980s (18, 23, 24), two in the 1990s (19, 22), one in the late 1990s, and the timing of one (published in 1999) was unspecified (21).

Overall, there was only one significant difference on breastfeeding outcomes associated with these interventions. In the study of labor companions in the low-income sample in South Africa, there was a significant difference in exclusive breastfeeding at six weeks (20).

The interventions included in this section vary considerably, and it is thus hard to draw overall conclusions from their review. Some did not explicitly focus on breastfeeding promotion, but expected positive changes to breastfeeding outcomes nonetheless (e.g., changing the model of peri-

natal services). It may also be that changing the structure of service provision alone is not enough to improve breastfeeding outcomes, and is secondary to or must be combined with policy or education/training changes. The information needed to assess this is still lacking. The only two studies replicating an intervention are the provision of lay support companions during labor in an HMO hospital in the U.S. and in a South African hospital. The results suggest that provision of a supportive companion may have a positive effect in low-income populations when a supportive partner or family member is unavailable.

Cost of Hospital Interventions

There was very little cost information provided in the reports reviewed in this section. One BFHI intervention in the U.S. reported that a significant cost was payment for infant formula use as required by the intervention, which added \$20,000 per year to the budget. Prior to the BFHI, infant formula companies provided formula free (7). Other costs mentioned included the staff training for in-service trainers and staff time, videos, etc. (\$18,000 in one study (12), \$33,000 in another (16)) for those interventions that included staff training. Two of the research teams reported no to minimal costs, using on-duty staff, hospital space, and existing opportunities for training staff (16, 17).

Summary of Hospital Interventions

There were a wide variety of interventions that were undertaken in the hospital setting. For simplicity, these were grouped based on the main focus of the intervention: breastfeeding policy change, staff training, education sessions for mothers, and change in service structure. The interventions that as a group appeared most promising are those that supported all or parts of the WHO/UNICEF ten steps of the BFHI. Evidence from technically sound randomized trial of all ten steps (2), supported by the results of well-conducted, though less technically sound, before-and-after studies of the full ten steps or a smaller subset, suggests positive association with breastfeeding initiation, exclusive breastfeeding, and any breastfeeding. Results were obtained across varying income groups, including low-income, immigrant, and minority women.

Given the results of the BFHI interventions, it appears that not all ten steps have to be administered to see changes in breastfeeding outcomes. It cannot be determined at this time, however, which step or set of steps are critical to producing successful breastfeeding outcomes. There is some evidence, however, of a dose-response relationship between number of steps and longer breastfeeding duration (DiGirolamo *et al.*, 2001). The intervention reports also suggest that full implementation of the ten steps is a long process (2), and that implementation of these steps can have a range of difficulties (1). Nonetheless, the ten steps do hold promise for improving breastfeeding outcomes in the U.S., and the BFHI is profiled separately at the end of this report.

Interventions focused on hospital staff training have shown mixed results. Studies that included education of physicians, nurses, and other health professionals (including one using an experimental design) showed positive results on breastfeeding initiation and duration (15, 16). Those that focused on education of nurses only showed improvement in exclusive breastfeeding at hospital discharge in one study (11), with no difference in another (12). Of note is that even when successful, researchers saw evidence of the need for continued follow up support after the education sessions.

Only one significant finding came out of the studies grouped as changes to hospital service structure. It may be that the interventions in this grouping are so disparate, with little replication, that the effects

of changing the structure have not been well tested. Alternatively, it may suggest that a change in service structure alone is not enough to improve breastfeeding outcomes. A more targeted focus on breastfeeding through policy or education and training in the hospital setting may more directly link to breastfeeding outcomes.

3.7 Multifaceted Interventions

Multifaceted interventions were defined for this review as a combination of three or more categories of breastfeeding interventions discussed earlier in this chapter. For example, a multifaceted intervention might consist of a prenatal education program, changes to hospital policies, and a peer counselor program—all delivered to the target population during the same time period. Multifaceted interventions may also involve strategies not previously discussed, such as training of health care workers, mass media campaigns, community-based activities, and others.

Twenty-three publications reporting on 21 multifaceted breastfeeding interventions were identified for this review. These are listed in Table A.7 in Appendix A. Two interventions were described in multiple publications (17, 18, 22, 23). Of the 21 multifaceted interventions, 17 were in the United States, three were in developing countries (Belize, Panama, and Brazil; 10, 17, 18, 20), and one was in Canada (9). Six multifaceted interventions were implemented in the 1980s (7, 10, 12, 17-20) and most of the remaining (13 of 15) in the early 1990s. Seven comprehensive interventions were implemented in the 1980s to early 1990s, funded by grants from the Maternal and Child Health Bureau of the Department of Health and Human Services (2, 5, 6, 8, 12, 16, 19).¹ The most recent multifaceted breastfeeding promotion was the Mississippi Breastfeeding Promotion Program, a pilot project of the Loving Support Makes Breastfeeding Work campaign sponsored by USDA (11).² Fifteen interventions involved WIC clinics or WIC participants.

Sixteen of the 21 multifaceted interventions included some evaluation of breastfeeding outcomes. None of the interventions was a randomized experiment. The most common study design was a pre-post comparison of cross-sectional samples of the target population—used by 15 of the 16 evaluations (1-5, 8-10, 12, 13, 15, 16, 18, 19, 22). The one remaining evaluation used a quasi-experimental design comparing outcomes between two groups with different levels of exposure to the breastfeeding interventions (11). Three studies were descriptive, providing outcomes for the group receiving the intervention, but no evaluation of outcomes relative to a comparison group (7, 14, 20).

Types of Multifaceted Interventions

Ten of the 17 multifaceted interventions conducted in the U.S. were state efforts, and seven were local.³ Most U.S. interventions targeted low-income women (12 of the 17), including two that focused on women in rural communities (12, 21) and one that was a culturally sensitive intervention to promote breastfeeding among low-income African-American women receiving prenatal care at a teaching hospital in Philadelphia (3).⁴ Five interventions did not specifically target low-income women: three provided breastfeeding promotion to WIC and non-WIC mothers (6, 16, 19); one

¹ Nine other state-based breastfeeding promotion initiatives were funded by the Maternal and Child Health Bureau (MCHB), but reports for those interventions could not be located. These projects were conducted in Colorado, Connecticut, Georgia, Illinois, Maryland, Missouri, New Mexico, New York, and North Carolina (NCEMCH, 1996).

² Loving Support was a social marketing campaign developed cooperatively by Best Start Social Marketing and the Food and Consumer Service (FCS) of USDA. Ten states and Indian Tribal Organizations were selected to pilot the project. Project goals were to increase breastfeeding initiation and duration rates among WIC participants, increase referrals to WIC for breastfeeding support, and increase public acceptance and support of breastfeeding. Two reports of evaluations of Loving Support were located and are included in this review (11, 26).

³ Local interventions operated in selected counties (12), a single WIC agency (14, 15), and a single hospital or hospital-based clinic (3, 7, 22).

⁴ Data collected for mothers participating in this intervention showed a large proportion were WIC participants.

promoted breastfeeding to mothers eligible for a hospital-based “Nursing Mothers Service” in New York State (7); and one promoted breastfeeding among Navajo mothers in New Mexico (22, 23). The latter intervention was designed to incorporate traditional beliefs about infant feeding, emphasizing its health and psychological benefits.⁵

Three of the four non-U.S. interventions—Belize, Panama, and Brazil—were national in scope, promoting breastfeeding to the general population and health care professionals, as well as pregnant women and mothers (10, 17, 18, 20). The fourth non-US intervention was in Canada, and promoted breastfeeding to mothers and health care professionals in an economically disadvantaged region of Nova Scotia where very low rates of breastfeeding prevailed (9).

Table 3.3 summarizes the major types of breastfeeding promotion and support activities included in the interventions reviewed here. In just over half of the cases, a national, statewide and/or community-based coalition or task force was formed to direct, plan, and facilitate coordination of the intervention components. Task forces were typically interdisciplinary, interagency groups of health care professionals; in two states, the WIC State Breastfeeding Coordinator led these groups (4, 5). Coalitions, such as those formed as part of Georgia’s breastfeeding promotion program, developed breastfeeding resource guides or directories (1, 11). The Mississippi Breastfeeding Coalition encourages work sites, childcare centers, churches, and health care clinics to create “breastfeeding-friendly” environments (11).

Virtually all of the multifaceted interventions included the following three components: (1) training of health care professionals, (2) prenatal education or counseling, and (3) dissemination of educational materials (brochures, pamphlets, booklets, videos). Interventions differed in terms of the type of health care staff trained: 15 interventions trained WIC and/or other maternal and child health clinic staff (2-6, 8, 10-14, 16, 18, 19, 21), 11 interventions trained hospital workers (1-3, 6, 8, 10, 15, 16, 18-20), and six included breastfeeding in the curricula of medical or nursing schools (6, 8, 9, 16, 18, 20).

Prenatal breastfeeding education and counseling were delivered in at least 16 of the 21 multifaceted interventions.⁶ Some interventions included prenatal group classes, but others did not indicate whether education was provided in groups or individually. The Tennessee Breastfeeding Promotion Project was the only multifaceted intervention to initiate prenatal peer group discussions about infant feeding. These “rap sessions” were held regularly (one to three times per month), and were facilitated by health department clients who had successfully breastfed (12).

⁵ Unlike some cultural beliefs that negatively influence breastfeeding behaviors, among the Navajo population, breastfeeding is regarded as the proper way to feed an infant. It is felt to model the sharing of food, pass on maternal attributes, promote growth, and make the child feed loved and secure (22).

⁶ Georgia WIC, the Florida Breastfeeding Promotion Initiative, and the Navajo Breastfeeding Promotion Program did not specifically mention the availability of prenatal breastfeeding education or counseling (1, 2, 22); this was likely available to WIC participants but was not part of the intervention being evaluated. The interventions in Panama and Brazil did not appear to involve prenatal breastfeeding education (10, 18).

Table 3.3

Major Components of Multi-Faceted Interventions

Component	Georgia WIC (1)	Florida (2)	Philadelphia Hospital (3)	Alabama WIC (4)	Kentucky (5)	Arkansas (6)	Upstate NY Hospital (7)	W. Virginia (8)	Nova Scotia (9)	Panama (10)	Mississippi WIC (11)	Tennessee (12)	Utah WIC (13)	Los Angeles WIC (14)	Passaic, NJ WIC (15)	Kansas (16)	Brazil (17, 18)	Indiana (19)	Belize (20)	Harrison County, IN WIC (21)	Navajo IHS, NM (22, 23)	Number of Interventions
Multidisciplinary task force, committee or coalitions	✓	✓				✓		✓		✓	✓	✓	✓			✓	✓	✓			✓	12
Breastfeeding education or training for health care professionals	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	20
Prenatal education or counseling			✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓		✓	✓	✓		16
Dissemination of education materials (pamphlets, brochures, booklets, videotapes)		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	20
Peer counselors	✓	✓	✓			✓		✓	✓		✓	✓	✓	✓	✓	✓			✓	✓	✓	15
Mass media campaign		✓			✓			✓		✓	✓	✓				✓	✓	✓	✓		✓	11
Changes in hospital policies or practices		✓	✓				✓	✓		✓						✓	✓	✓	✓		✓	10
Postpartum follow-up or support (excluding peer counselors)	✓		✓		✓	✓	✓	✓	✓			✓		✓	✓	✓			✓	✓	✓	14
Provision/loan of breast pumps	✓			✓		✓	✓					✓	✓	✓	✓	✓			✓	✓	✓	11
Breastfeeding “friendly” health care environment			✓			✓		✓	✓		✓	✓		✓			✓			✓		9
Breastfeeding education in workplace or day care settings		✓			✓						✓			✓		✓	✓	✓				7
Incentive program			✓	✓		✓						✓			✓				✓	✓	✓	8

A wide variety of educational/motivational print materials were disseminated in the multifaceted interventions, including brochures, pamphlets, booklets, posters, and training modules. Printed materials were developed locally and/or obtained from Best Start, Wellstart, or Loving Support. These materials were provided to women, their families, and healthcare workers. Several projects developed educational materials for day care providers and employers (2, 16, 19). For example, *Breastfed Babies and You: Information for Daycare Providers* (Florida), *Worksite Support for the Breastfeeding Employee: A Guide for Business* (Florida), and *What Does Your Business Have in Common with a Breastfed Baby?* (Indiana).

More than half of all multifaceted interventions used videotapes to disseminate information and motivate and support nursing mothers and their families (3-6, 8, 11, 12-14, 19, 21, 22). Videos were typically 10 to 15 minutes in length (range was 8 to 25 minutes) and were intended as a supplement or reinforcement, rather than replacement, for in-person contacts. Videos were usually viewed by expectant mothers in WIC offices or prenatal clinics, or were made available through a clinic lending library. Hospital-based interventions showed instructional videos in the hospital maternity ward shortly after delivery, and included them as part of a discharge package (3, 8). Videotapes conveyed messages about the benefits of breastfeeding (health, cost savings, convenience, and getting back in shape); the diversity of women who breastfeed (various ages, races, employment, and marital status); that breastfeeding is not embarrassing; and that family and friends can be supportive. The Arkansas Best Start Promotion Project developed a video about working and breastfeeding called *You Can Do It: Working and Breastfeeding, How Seven Mothers Coped* (6). Videotapes were also used to train health care professionals in a number of interventions.

In addition to the components of multifaceted interventions discussed above, 15 interventions incorporated peer support activities, 11 implemented a mass media campaign, ten involved changes to (or efforts to change) hospital practices or policies, and 14 had postpartum follow-up or support.

Most peer support was provided through telephone and in-hospital contact by women who had successfully breastfed at least one child. Only one intervention provided peer home visits (the Tennessee intervention included up to seven home visits by peer counselors during the first year of the infant's life). The Navajo Breastfeeding Intervention Program implemented a unique, peer support-like activity: a bilingual "foster grandmother" visited new mothers in the maternity ward of the Indian Health Service hospital five days a week to talk about her breastfeeding experiences, answer questions, and help with positioning if needed. Nine of the 14 interventions with peer support programs described formal training for peer counselors (3, 6, 8, 12-15, 20, 21).

Media campaigns typically involved some combination of radio, television and newspaper ads, posters, and printed materials. Press releases, billboards, and a bus sign campaign were also mentioned. A common message/image portrayed in the media campaigns is that breastfeeding is an "up-to-date," positive activity done by a variety of women. Other messages were aimed at fathers ("The healthy breastfed baby of today may be the star athlete of tomorrow") and other family members. Materials for the Loving Support campaign were designed to address three barriers to breastfeeding: embarrassment, competing demands on mother's time, and the need for social support. In Mississippi, the Loving Support campaign included educational posters; flyers; brochures; signs for WIC clinics; table-top display units for health fairs; TV, radio and newspaper ads; billboards in

larger communities; and staff support kits (11).⁷ The success of media campaigns in reaching target populations, however, appears to have varied across interventions.

Five of the 11 reports of interventions involving hospital practices mentioned the WHO/UNICEF Baby Friendly Hospital Initiative or the Wellstart training program. The Florida Breastfeeding Promotion Initiative worked to formally adopt the Healthy Mothers Healthy Babies policies and protocols. The remaining interventions did not specify a particular set of breastfeeding support policies.

Two-thirds of the multifaceted interventions provided some type of postpartum follow-up or support other than peer counselors. Telephone support was part of 12 interventions, and in-hospital visits were part of eight interventions; postpartum home visits were the least common (five interventions). Telephone support was generally provided through regular follow-up calls to breastfeeding mothers by health care professionals, and/or hot/help lines for mothers to call in with questions. One intervention established a “nursing mothers service” to provide care after discharge through ongoing, individualized telephone and in-person counseling by a certified lactation consultant⁸ (this service also distributed breastfeeding aids such as pumps, shells, shields and feeding tubes)⁹ (7).

Other postpartum support efforts included the provision or loan of breast pumps (in about half of the multifaceted interventions), mothers’ support groups (5, 6, 12, 15, 18, 21), and incentive programs (3, 4, 6, 12, 15, 20-22). Hospital milk banks were established in one intervention (Panama Breastfeeding Promotion Project, 10).

Two multifaceted interventions offered a fairly intensive mix of postpartum support strategies. In addition to home visits and telephone follow-up by peer counselors or lactation consultants, the rural Indiana WIC clinic offered monthly support group meetings, breast pumps and a pumping station at the clinic, T-shirts for infants certified as breastfeeding, and telephone numbers of WIC and La Leche League staff (21). The Tennessee Breastfeeding Promotion Project’s peer counselors provided follow-up to new mothers in the hospital, at home for up to one year by telephone, and in the WIC and maternal and child health clinics. Incentives were provided for attendance at discussion groups with a friend or family member (diapers), and for continued breastfeeding (diapers, infant T-shirts, pads, nursing bras).

Other breastfeeding promotion activities included in one or more multifaceted interventions were education of employers/day care providers, changes to WIC clinics or other health care environments (reduce exposure to infant formula advertising; provide appropriate facilities for nursing), and community-based breastfeeding promotion activities (exhibits at health fairs and in malls; talks to community groups and schools).

⁷ The Loving Support media campaign was also implemented by the Iowa WIC program, although it did not meet our criteria as a multifaceted intervention since other breastfeeding promotion activities were already in place prior to introducing the media campaign (26). A report of a mass media campaign in Jordan was also reviewed (24). Results of both of these interventions are mentioned briefly later in this section.

⁸ Lactation consultants were utilized in a variety of ways in ten of the 21 multifaceted interventions. WIC programs in several states hired lactation consultants to train health professionals, peer counselors and other staff, provide inpatient counseling for breastfeeding mothers, make home visits, and answer telephone helplines (4, 5, 8, 15, 21).

⁹ Breast shells are used to protect sore nipples; breast shields are used to help with latch-on difficulties.

Evaluation Methodologies

As noted previously, 15 of the 16 evaluated interventions used a pre-post study design (1-5, 8-10, 12, 13, 15, 16, 18, 19, 22). In all cases, outcome data were obtained for all or a sample of the target population at a time point before the breastfeeding promotion interventions were implemented, and again after the interventions were implemented. Results were generally reported (or could be interpreted) as a change in population or study sample rates of breastfeeding.

The remaining evaluated intervention employed a quasi-experimental design that relied on comparisons of breastfeeding outcomes between women in purposively selected intervention and control districts (11). The evaluation of the Mississippi Breastfeeding Promotion Program reported a two-group, post-intervention design.¹⁰ This evaluation might be more accurately described as a “natural variation” or “dose-response” study (Hamilton and Rossi, 2002). Intervention districts fully participated in Loving Support campaign activities, whereas comparison districts partially participated in the campaign.

The majority (14 of the 16 evaluated) of multifaceted interventions relied on existing data sources to assess the major outcomes of interest. WIC records and hospital or physician records were the most common sources of extant data on breastfeeding initiation and duration. Other U.S. data sources included state-level and national results of the Ross Mothers Survey (2, 19), the Pregnancy Risk Assessment Monitoring System (PRAMS) and Pregnancy Nutrition Surveillance Survey (PNSS) (1), and the CDC/Pediatric Nutrition Surveillance Survey (PedNSS) (4). National health surveys were a source of data in Panama and Belize (10, 20).

Five studies used primary data collection exclusively (3, 5, 11, 12, 18), and two studies used a combination of primary and extant data (3, 8). Specific methods of primary data collection included in-person interviews, self-administered surveys, and telephone surveys with sampled mothers. Random sampling was used in two of the five studies using primary data collection. The pre- and post-intervention and comparison groups for the evaluation of the Best Start-Kentucky program were randomly selected from among all WIC mothers with infants presenting for a WIC appointment during the two-week study period (5). (No information on sample size was provided.) In the Mississippi evaluation of Loving Support, a random sample of postpartum women with Medicaid insurance (a proxy for WIC eligibility) was selected in both the intervention and control strata, from a common sampling frame (11).

Sample inclusion criteria were specified for ten of the 16 evaluated interventions (applied to extant or primary data). Five explicitly noted WIC enrollment as a criterion for inclusion in the evaluation sample.¹¹ Other sample inclusion criteria were unique to only one or two multifaceted interventions. They included the timing of delivery, infant age, and all mothers of children born at a particular hospital. Exclusion criteria were rarely reported. In one study, multiparous women and those who had moved, miscarried, or delivered stillborns during the study period were excluded (12). In another, newly postpartum mothers who were unregistered, abusing drugs/alcohol, or with psychiatric problems were dropped from the sample (3).

¹⁰ The Mississippi intervention was also evaluated qualitatively, through focus groups with WIC clients and WIC staff.

¹¹ One study sampled WIC mothers with infants up to 12 months of age who presented for a WIC appointment during the two-week study period (5), another limited the sample to postpartum mothers receiving the WIC breastfeeding food package (4); the remaining three did not further specify eligible WIC certification categories (2, 13, 16).

Seven of the 16 reports of evaluated interventions provided information on sample size, but only four provided response rates. One case stood out as having particularly inadequate samples for assessing the effectiveness of the intervention (12). The Tennessee project reported main outcome results by county and by year. Subgroups ranged from 24 to 234 women, with sample sizes for three of the four intervention counties consistently below 100.¹² Of the nine studies that omitted sample size information, all were pre-post studies and most relied on available regional or statewide data rather than a sample of the target population.

Because the information was rarely provided, it is not possible to summarize the response rates for multifaceted interventions. Two interventions with low response rates were identified, however. The evaluation of Georgia's WIC breastfeeding program relied partly on data from the Pregnancy Nutrition Surveillance Survey (PNSS); 48 percent missing data on breastfeeding initiation could have biased the results (1). In addition, outcome measures reported for the Mississippi intervention were based on only 61 percent of the original sample (11).

Outcome Measures and Findings

Eleven of the 16 evaluated studies measured breastfeeding initiation and duration (1, 2, 8, 9, 11-13, 16, 18, 19, 22), four measured initiation only (3-5, 15), and one reported only duration (10).¹³ Initiation and duration were assessed differently across studies. Seven studies defined initiation as breastfeeding at hospital discharge, and four studies defined it as ever having breastfed. Other studies defined initiation as breastfeeding at birth, exclusive or any breastfeeding at the first WIC or other postpartum clinic visit, and ever breastfed exclusively. Four studies did not define or specify a point of measurement for breastfeeding initiation rates.

The most common measure of breastfeeding duration, used in seven studies, was the rate of any breastfeeding at six months postpartum. Other measures included: percent breastfeeding at six weeks, eight weeks, three months, and four months, and the mean number of days/weeks/months an infant was breastfed. Duration of exclusive breastfeeding was assessed in terms of rates at three months and at four months, and the mean number of weeks of exclusive breastfeeding. One study reported exclusive breastfeeding at one year postpartum (22).

Many of the studies of multifaceted interventions assessed outcomes other than breastfeeding initiation and duration. Three assessed changes in knowledge and attitudes about breastfeeding (11-13, 18); three conducted focus groups to measure experience and satisfaction with breastfeeding services, breastfeeding knowledge, and perceived barriers (1, 5, 11); three measured changes in hospital practices (10, 16, 18); and one assessed the effectiveness of health professional training (19). The study of the Navajo Breastfeeding Promotion Program also examined the incidence of illness (e.g., otitis media, gastroenteritis, pneumonia, croup, and fevers) among infants up to one year of age (23). Although there was no evidence of standard qualitative analytical methods, more than half of the studies collected some process data to examine the degree to which the intervention was implemented and received as intended (3, 5, 8, 10-12, 16, 18, 19).

¹² Three of the four counties were pooled for analyses of some breastfeeding outcomes, but significant differences in demographics prevent pooling all counties.

¹³ One study assessed the frequency of breastfeeding by measuring the mean daily number of times an infant was breastfed at two weeks and six months postpartum (12).

Results

An assessment of the effectiveness of the multifaceted interventions reviewed here is limited by variability in the components implemented, weaknesses in the study design, and the lack of tests of statistical significance.¹⁴ Three studies reported a significant increase in rates of breastfeeding initiation and duration (11, 18, 22), and one (18) found a significant increase in breastfeeding duration. All but one of the remaining interventions (19) reported to have positive impacts, but study designs were weak and no evidence of statistical significance was provided.

The three studies reporting statistically significant results were the Brazilian National Breastfeeding Program (18), the Mississippi Breastfeeding Promotion Program (the pilot test of the national WIC Loving Support campaign) (11), and the Navajo Breastfeeding Promotion Program (22).¹⁵

The Brazilian intervention was implemented over several years, beginning in 1981. It relied heavily on mass media, but also included training of health professionals, implementation of “rooming in,” preparation of a code of marketing for breast milk substitutes, enforcement of laws that protect the rights of working women during pregnancy and lactation, and incentives for participation in mothers support groups. The main media messages were to “nurse your child for at least the first 6 months,” and “every woman can do it—insist on it.” Interviews were conducted in two metropolitan areas (Recife and Sao Paulo) in 1981 and 1987 with mothers of infants aged zero to eight months. Breastfeeding initiation increased from 88.0 to 93.8 percent and from 91.3 to 94.7 percent in Recife and Sao Paulo, respectively. Only the Recife results, however, were statistically significant. In addition, the proportion of children breastfed for more than six months rose significantly from 18.9 percent to 26.6 percent in Sao Paulo (Recife results not reported).

The major components of the Mississippi intervention were client and family education (using Loving Support materials), a public awareness campaign (using Loving Support mass media ads), health professional outreach, and partnerships within the community. Based on a mail survey (with telephone follow-up) of 736 postpartum women,¹⁶ rates of breastfeeding at hospital discharge were significantly higher for women in intervention districts than for women in comparison districts (44.8 vs. 30.8). At four months postpartum, rates were also significantly higher for the intervention group for any breastfeeding (30.9 vs. 18.9 percent) and exclusive breastfeeding (10 vs. 6 percent). Additional evidence from Ross Mothers Survey for the state (1995, 1997, 1999) showed increases for initiation and duration for both WIC infants and all infants, consistent with the timing of the Loving Support campaign. The authors interpret these trends as positive effects of Loving Support, suggesting that the intervention may have reached the non-WIC as well as the WIC population.¹⁷

¹⁴ Only one study (1) used a design that allowed assessment of the effects of individual program components by implementing separate components in different geographic areas, but response rates were quite low (52 percent).

¹⁵ The two mass media campaigns included in Table A.7 were evaluated but did not provide conclusive evidence. The Jordan study found a significant increase in initiation and “timely initiation” of breastfeeding (within six hours of delivery), but problems related to the use of independent samples, lack of a control group, and the high rates of breastfeeding (90 to 97 percent) were recognized as limiting the generalizability of findings (24).

¹⁶ An original sample of 1200 mothers with Medicaid insurance was drawn to approximate the WIC population.

¹⁷ Alternatively, the Ross Mothers Survey may be evidence of a general secular trend. One has to wonder how Loving Support could be responsible for increased breastfeeding among non-WIC mothers but not among comparison group WIC mothers who, as noted previously, were exposed to Loving Support ads, print materials, posters, and billboards.

The Navajo Breastfeeding Promotion Program incorporated culturally appropriate social marketing and community participation in a comprehensive intervention to promote breastfeeding among Navajo mothers in New Mexico. The intervention included training of health care providers, changes in hospital policies, a mass media campaign addressing barriers specific to the Navajo Indian pregnant woman, breastfeeding education using culturally specific materials, and postpartum support through a tribal foster grandparent program. An evaluation of the intervention compared cohorts of mothers who gave birth at the Indian Health Service hospital, before and after the 11-month intervention. Based on data collected from hospital and physician records (and occasional home visits) for 1,814 infants, authors reported a statistically significant increase in both initiation and duration as a result of the intervention. Initiation, defined as ever beginning breastfeeding, increased from 71.1 to 81.1 percent; the mean age at which formula was introduced increased from 12 days to 48 days; and the mean days breastfed increased from 100.6 days to 131.6 days.¹⁸ Response rates for this study were reasonably high (98 percent for initiation and 76 percent for measures of duration), treatment and comparison groups were comparable on measured characteristics (age, parity, WIC enrollment), and potential bias from secular trends was probably minimal due to the short duration of the study. The authors attributed success, in part, to the involvement of local Navajos, collaboration with local institutions/programs, incorporation of traditional beliefs into education and support messages, and the multifaceted approach.

Of the remaining studies of multifaceted interventions, the majority reported improvements in rates of breastfeeding initiation (11 of 12 that measured initiation) and duration (seven of nine that measured duration). These studies all had pre-post designs without control for secular trends, and lacked tests of statistical significance.

In pre-post studies, outcomes may be influenced by factors occurring during the intervention period, other than the intervention.¹⁹ For example, one study reported possible exposure of the post-intervention group to other breastfeeding support activities (3). In this study, during two months of the intervention, WIC sponsored public service announcements on six radio and TV stations. The author acknowledges that this activity may have affected the rates of breastfeeding in the post-intervention sample separate from the intervention being studied.

Another potential source of bias arises when the pre- and post-intervention samples differ on characteristics that may be related to outcomes of interest—for example, as a result of changing demographics. All 13 pre-post studies selected pre-intervention and post-intervention comparison groups from the same sampling frame, which would maximize comparability. Only three reported significant differences between the pre- and post-intervention samples (1, 22), but sample characteristics were provided for ten of the other 11 interventions that used this design. There was no mention of adjustments for any shifts in measured characteristics of the study populations for any of the pre-post studies.

Finally, only three of the studies of multifaceted interventions reported results of tests of statistical significance on their outcome data (11, 18, 22). This makes it difficult to determine objectively how

¹⁸ Number of days breastfed was measured by infant age on last day breastfed.

¹⁹ Both the Iowa and Jordanian studies of mass media interventions utilized before-after study designs and suffered from this same limitation.

successful this category of interventions has been, even though the great majority of authors describe their evaluation findings as positive.

Cost of Interventions

Information on the total costs of multifaceted interventions is limited. Five of the seven MCHB-funded breastfeeding promotion projects reported grant amounts of approximately \$150,000 over three years (2, 5, 6, 8, 16), although in most cases additional funds were required. Grant activities in most sites were enhanced by WIC breastfeeding promotion funds, ranging from \$45,000 for specific supplemental breastfeeding projects in Florida to \$661,490 for a variety of project expenses (office space, telephone, fax, help line beeper, some staff salaries, education materials, office supplies, equipment, medical supplies, and travel) in Arkansas. (Absolute dollar amounts reflect costs from 1990 to 1995.) Most MCHB-funded projects, however, did include some information on the types of resources needed to replicate various components of the projects.

No information was available on the costs of “enhancements” to existing WIC breastfeeding promotion activities in the Utah, Georgia, South Central Los Angeles, or Passaic New Jersey programs. The Mississippi Breastfeeding Promotion Program reported costs only for health clinic environment projects (11).²⁰ Fourteen sites reported costs ranging from \$907 for converting a storage room into a bright and attractive nursing mothers’ room to \$4,239 for the construction of walls within a large waiting area to create a private nursing area (electric pump available). The Iowa evaluation of Loving Support reported a media budget for 1997 of approximately \$84,600, and for 1998 of \$90,000. This included print materials, billboards, and media ads running for two to eight weeks in three media markets of the state (26).

Costs for setting up the Nursing Mothers Service in Johnson City, New York included salary support for two secretaries, three registered nurses, and one lactation consultant, as well as office supplies, brochures, and equipment/supplies (7). This program, however, generated revenue through rental of electric breast pumps, sale of manual pumps, shields, shells, special feeding tubes, and fees charged for prenatal breastfeeding classes.

Summary of Multifaceted Interventions

Twenty-one interventions incorporating multiple strategies for promoting and supporting breastfeeding were identified for this review. Almost three-quarters of these interventions were specifically designed for the WIC or WIC-eligible population, and aimed to address barriers to breastfeeding that are known to be common among low-income women. There is considerable variation in the nature and length of multifaceted interventions, as well as the degree to which the target populations are reached. Pre-post study designs were the most common method of evaluation.

²⁰ In addition to the Loving Support campaign, the Mississippi Breastfeeding Promotion Program included a clinic environment project and a video project. The purpose of the clinic environment project was to fund and evaluate a staff training program (How to Support A Breastfeeding Mother) and permanent changes in the physical environments of WIC clinics, such as private nursing areas and breastfeeding visual images in key traffic areas. The objective of the video project (Breastfeeding: Another Way of Saying I Love You) was to address three identified barriers to breastfeeding: embarrassment, time and social constraints, and lack of social support. These projects were evaluated, but breastfeeding rates were not among the outcomes measured.

Most of the multifaceted interventions were supported by government agency funds as “special projects.” In most cases there was some indication that the full costs exceeded the funded amounts. Additional support was often provided by WIC program funds and/or the institutions sponsoring the intervention activities. A few authors noted that the mass media campaigns required a large proportion of their budget, but using existing materials could help defray the costs. One intervention generated revenue through fees for breastfeeding classes and the rental or sale of breast pumps and other aids. Others charged for seminars and conferences for health care professionals. These sources of revenue may not be available for interventions with the WIC population.

Reports on most of the interventions reviewed here attempted to provide evidence of their “success,” but almost all of the studies were methodologically weak. Drawing conclusions about the effectiveness of these interventions is hindered by the limitations of pre-post and observational study designs, variability in the interventions and outcome measures, and the paucity of quantitative analytic methods. For this reason, it is difficult to identify a particular multifaceted intervention that stands out as a model for future implementation and evaluation.

One evaluation difficulty common to several multifaceted interventions is that some intervention components saturate the community with information (media and outreach campaigns; posters and brochures in health care facilities) without guaranteeing that the target population is reached. As a result, the effects of multifaceted interventions may be “diluted” by treatment group members never exposed or minimally exposed, and by comparison group members with exposure. Several studies attempted to measure exposure. For example, based on survey data, the Mississippi Breastfeeding Promotion Program found that there were no differences between treatment and comparison groups in exposure to Loving Support ads, print materials, posters, and billboards, but significantly more women in the treatment group were exposed to other parts of the intervention in that state (11).

The literature on multifaceted interventions, however, does provide information—both anecdotal and quantitative—about some of the barriers and facilitators of multifaceted interventions. Table 3.4 summarizes this information on “lessons learned.”

Table 3.4

Summary of Information Learned from Multifaceted Interventions

Barriers to Implementation of Multifaceted Interventions

Hospital administrator and physician resistance
Lack of support among hospital staff and private physicians
Formula company marketing
No cost-effective approach to training large body of health professionals
Lack of sufficient social support for mothers and for using breast pumps
Infant formula provided by WIC perceived to be of greater worth than food received as exclusively breastfeeding participant
Too few peer counselors
Lack of in-hospital or community steering committee for ongoing communication

Facilitators to Implementation of Multifaceted Interventions

Physician buy-in
Multidisciplinary task forces and/or community coalitions
Coordination with WIC program
Incentives (to get support groups going, to help provide clear message to mother, and to balance the perceived financial “loss” of WIC formula)
Best Start materials (well received by practitioners and messages focus on most important issues for low income women and their families)
Cooperation between hospitals and public health agencies
Culturally sensitive, accurate and reading level-appropriate educational materials
Peer counselors for cultural groups where female support is valued
Cooperation of voluntary institutions, artists and TV channels (to diminish costs)
Lactation consultants/specialists
Financial support for health professionals to plan, consult and give workshops

Chapter 4

Summary

4.1 Summary of Findings

This review included 141 breastfeeding promotion and support intervention efforts described in articles and reports written since 1990. The interventions represented in this body of work varied across a number of characteristics including the nature of the intervention, the target group, time period in which the intervention was implemented (e.g., prenatal, postpartum), the delivery person or persons, and where the intervention took place. For ease of review, the articles and reports were grouped into seven categories. These are presented below, along with a summary of the results for each category. Overall, this review suggests that there are approaches to promoting and supporting breastfeeding that have improved breastfeeding outcomes of initiation, exclusivity, and duration. In addition, many of these interventions have shown promise across a variety of income and cultural and ethnic groups.

Prenatal Education

There were 17 interventions in this group, which promoted breastfeeding exclusively or primarily during the prenatal period. They included interventions focused on education only, those that included motivation and/or support, and those that focused on skill development. All of the evaluations of these interventions had methodological limitations, with small sample sizes a particular concern. In general, the results suggest that prenatal interventions had more of an effect on initiation than on duration of breastfeeding. Of those that did have an influence on duration, those that targeted breastfeeding skills (e.g., positioning, nipple care) seemed to be more effective at maintaining breastfeeding over time.

Postpartum Education

There were 11 interventions in this category, which dealt with education-only interventions that were provided to mothers following delivery without significant postpartum follow-up. They included in-person or group education sessions or videos covering a wide-array of breastfeeding information. These interventions did not provide significant increases in duration or rates of exclusive breastfeeding.

Postpartum Support

Thirty-four interventions were characterized by ongoing support during the postpartum period. These interventions focused on motivating mothers to maintain breastfeeding and on solving breastfeeding problems. They typically involved multiple contacts between the mother and a professional or trained layperson (not including peer counselors, who were in a stand-alone category). Most of the interventions included education sessions with support, although eight were characterized as support-only interventions. Taken together, the results from this review suggest that postpartum support interventions are associated with positive effects on breastfeeding outcomes, including initiation, duration and exclusivity. Given the wide variation in intervention content, demographics of the study populations, and study designs, it was not possible to define the most promising support intervention components.

Peer Counselor

Peer counselor interventions focused on programs that used laywomen from the community, trained to provide breastfeeding education and motivational support to women during pregnancy and/or the postpartum period. Nineteen separate peer counselor interventions were reviewed in this report. Although the majority of them were evaluated with quasi-experimental designs and some had limited sample sizes, the bulk of the evidence from these studies suggests that this approach is highly effective in increasing breastfeeding outcomes, including initiation, exclusivity, and duration. In addition, because all but one of these interventions targeted low-income women, the results are directly relevant to the WIC population.

Other Prenatal and Postpartum Interventions

A small group of interventions were unique and could not be included within the other categories. These interventions involved (1) printed materials, (2) provision of discharge packs, (3) incentive programs, and (4) programs for working mothers. There were four interventions of print materials that involved no in-person contact or other breastfeeding support. The limited evidence suggests that print materials can influence breastfeeding initiation but not duration, and that they are effective with low-income women.

Three studies examined the impact of nursing discharge packs on breastfeeding outcomes. None of these interventions targeted WIC or low-income populations. The results of these studies do not support an effect of nursing discharge packs on breastfeeding duration.

Three studies of incentives used to increase participation in educational activities and continuation of breastfeeding were reviewed. All three targeted WIC or low-income women. Significant increases in breastfeeding rates were found in each, but the small sample sizes and/or design limitations preclude drawing definitive conclusions without further study.

Three breastfeeding promotion and support programs for working mothers were reviewed, two involved changing the physical environment of the worksite, and all involved ongoing support from lactation specialists. No conclusions can be drawn from the studies of these interventions, as the evaluations were weak.

Hospital Interventions

There were 24 interventions focused on improving breastfeeding outcomes in the hospital setting. These interventions were mostly focused on the delivery period, although some included prenatal or postpartum components to accompany the more targeted intervention component surrounding the birth of a child. Three types of hospital interventions were identified. One type aimed to change hospital breastfeeding policies. The most comprehensive of these interventions, the Baby-Friendly Hospital Initiative (BFHI), developed by WHO and UNICEF, included a ten-step process to creating an optimally supportive breastfeeding environment in hospitals. These interventions or those that changed a smaller set of hospital policies (e.g., rooming-in, breastfeeding within the first half hour) were associated with increases in breastfeeding initiation, exclusivity, and duration. These positive results were found across various income groups and among minority and immigrant women.

A second type of intervention included hospital staff training. The results of these interventions were mixed. The ones most consistently associated with positive findings were those that trained all maternity service staff, including physicians and nurses. Of note was that even when successful, the researchers saw evidence of the need for continued follow-up training.

The third type of intervention included those aimed at changing the structure of the hospital's maternity or breastfeeding services. Examples include reworking the way maternity services are provided, hiring peer labor companions, and setting up a breastfeeding center. As a whole these structural changes were in themselves not successful in increasing breastfeeding outcomes, although the interventions were quite different from one another and there was typically one study per intervention.

Multifaceted Interventions

Multifaceted interventions were defined as a combination of three or more categories of breastfeeding interventions (e.g., prenatal education program, changes to hospital policies, and a peer counselor program) all delivered to the target population during the same time period. Twenty-one multifaceted interventions were identified, most supported by U.S. government agencies. It is of note that the cost of most of these interventions exceeded the federal funds provided, and costs were supplemented from other programs or organizations. For the most part, the reports on these interventions attempted to provide evidence of their success, but the studies were generally methodologically weak and no conclusions can be drawn about their effectiveness.

Summary

In general, the results of this review are fairly consistent with those of other reviewers (Dennis, 2002; Fairbanks *et al.*, 2000; Perez-Escamilla *et al.*, 1994), with two exceptions. Fairbanks *et al.* (2000) concluded that multifaceted interventions were successful at increasing breastfeeding initiation, as well as duration and exclusivity. Their definition of multifaceted interventions, however, included those with more than one component, whereas this review defines multifaceted as three or more components across categories. Second, Fairbanks *et al.* (2000) found no improvements in breastfeeding initiation as a result of hospital staff training; their review, however, did not include two recent studies (Taddei *et al.*, 2000 and Wagner *et al.*, 2002), which served as the basis for the more positive conclusion found here.

4.2 Limitations of the Evidence

There are several considerations that should be taken into account when interpreting the findings of this review, including gaps in evidence, methodological issues, and implementation issues, as discussed below.

Gaps in Evidence and Intervention Details

Only a limited number of studies were found for some categories of intervention, for example in the "other" prenatal and postpartum intervention category, where there are roughly three interventions of each type (e.g., discharge packs, support for working mothers). In the hospital category of interventions there are several types of hospital structure changes reported (e.g., opening of a breastfeeding center), but only one article or report per type. Given the paucity of data, usually coupled with the

methodological weaknesses, no conclusive statements on the effectiveness of these interventions can be made at this time.

There are also gaps in the information provided about many of the interventions reviewed in this report. Details of how the interventions are specifically implemented are sometimes missing, especially in the shorter journal articles where brevity is required. In addition, cost information, which is critical to assessing feasibility, is for the most part unavailable.

Methodological Issues

The gold standard for social science research is the experimental design with random assignment of sample members to a treatment or control group. Because variables that may be related to the outcome measures (e.g., interest in breastfeeding, maternal education) are randomly distributed across the treatment and control groups in this design, one can be assured that differences found between the two groups are due to the intervention alone and not other, sometimes unmeasured factors. There were many studies included in this review with random assignment, and these were highlighted within each category of interventions. Many of the studies reviewed, however, used quasi-experimental designs, which leads to less definitive findings. Often there are differences between the two groups other than the receipt of the intervention. For example, the women in a treatment group might be more educated or intend to breastfeed longer. In the case of the pre-post comparisons, there might be events that occur between data collection for the pre and post groups other than the intervention, such as a national media campaign or economic changes that might make breastfeeding a more attractive option (e.g., Popkin *et al.*, 1991). These factors are likely to influence the results. In the better studies, there was an attempt to identify the differences between treatment and control groups and include them in the analysis. This was not always done, however, and not all differences were measurable.

The control group was not well defined in many studies. In some studies the control group also received breastfeeding promotion and support services, although these services were not always specified. In some studies, the services for controls appeared quite ample (e.g., Waldenstrom and Nilsson, 1994). Thus, the intervention was not tested in a context where little breastfeeding support is the status quo. In some cases, there may have been cross-contamination between treatment and control groups. In the multifaceted interventions, for example, at least one author noted that the control group might have had access to the media campaign that served as one intervention component (Khoury *et al.*, 2001).

Many studies also had small sample sizes, which affected certain categories of interventions (e.g., prenatal) more than others (e.g., hospital). A number of researchers reported other potential problems as well, such as the reliance on mothers' recall for measures of duration, or data collectors who were not blinded to a mother's treatment or control status. These and others are mentioned throughout the review. The better studies typically acknowledged these shortcomings and, when possible, tried to address them (e.g., by not doing certain analyses with small sample sizes).

Implementation Issues

There are a few issues to consider in regard to the implementation of the interventions. First, the articles and reports typically described the planned intervention and it was not always clear if the intervention was implemented as planned. Thus, for example, all members of the treatment group

may not have received all components of the intervention (e.g., all contacts from a peer counselor, all education sessions). Those who did not participate, or who did so minimally, could dilute the results.

In some interventions reported here, participation was voluntary; that is, mothers or organizations volunteered to be in an intervention. Implementation might not lead to the same results if participation is mandatory, for example in a WIC clinic where all women might be part of the intervention, whether or not they expressed an interest in doing so.

An intentional effort was made to include interventions from around the world. The intent was to learn about unique and innovative intervention ideas that might potentially be applied to the WIC setting in the U.S. It is important to note, however, that often the context and the women participating in these interventions is quite different than those in the U.S., or WIC in particular. For example, high rates of breastfeeding already exist in some countries, as do different support systems and cultural beliefs. These must be considered when interpreting whether the findings are relevant to the WIC population and setting.

As noted earlier in this review, there were often multiple components to a successful intervention. For example, breastfeeding outcomes generally improved when hospitals adopted the full Ten Steps of the BFHI. Improvements were also seen, however, when a smaller number of the steps were adopted. It is unclear from much of the research whether all components have to be adopted or whether there is a critical component or set of components. Similarly, even when only one component is involved (e.g., peer counselor contacts), it is unclear what the intensity of the intervention needs to be in order for it to be effective. For example, different studies showed success with varying amounts of peer counselor contact. Just how many contacts are necessary to optimize breastfeeding outcomes is not clear.

Bibliography

- Adams, C., Berger, R., Conning, P., Cruikshank, L., and Dore, K. Breastfeeding trends at a Community Breastfeeding Center: An evaluative survey. *Journal of Obstetrics and Gynecology Neonatal Nursing* 30(4): 392-400, 2001.
- Ahluwalia, I.B., Tessaro, I., Grummer-Strawn, L.M., MacGowan, C., and Benton-Davis, S. Georgia's breastfeeding promotion program for low-income women. *Pediatrics* 105(6): E85, 2000.
- Akram, D.S., Agboatwalla, M., and Shamshad, S. Effect of intervention on promotion of exclusive breast feeding. *Journal of Pakistan Medical Association* 47(2): 46-48, 1997.
- Albernaz, E., Giugliani, E.R., and Victora, C.G. Supporting breastfeeding: A successful experience. *Journal of Human Lactation* 14(4): 283-285, 1998.
- Alvarado, R.M., Atalah, E.S., Díaz, S.F., Rivero, S.V., Labbé, M.D., and Escudero, Y.P. Evaluation of a breastfeeding-support programme with health promoters' participation. *Food Nutrition Bulletin* 17: 49-53, 1996.
- Arlotti, J.P., Cottrell, B.H., Lee, S.H., and Curtin, J.J. Breastfeeding among low-income women with and without peer support. *Journal of Community Health Nursing* 15(3): 163-178, 1998.
- Barros, F.C., Semer, T.C., Tonioli Filho, S., Tomasi, E., and Victora, C.G. The impact of lactation centres on breastfeeding patterns, morbidity and growth: A birth cohort study. *Acta Paediatrica* 84(11): 1221-1226, 1995.
- Benitez, I., de la Cruz, J., Suplido, A., Oblepias, V., Kennedy, K., and Visness, C. Extending lactational amenorrhoea in Manila: A successful breast-feeding education programme. *Journal of Biosocial Science* 24(2): 211-231, 1992.
- Bliss, M.C., Wilkie, J., Acredolo, C., Berman, S., and Tebb, K.P. The effect of discharge pack formula and breast pumps on breastfeeding duration and choice of infant feeding method. *Birth* 24(2): 90-97, 1997.
- Bolam, A., Manandhar, D.S., Shrestha, P., Ellis, M., and Costello, A.M. The effects of postnatal health education for mothers on infant care and family planning practices in Nepal: A randomised controlled trial. *British Medical Journal* 316(7134): 805-811, 1998.
- Bonuck, K.A. Economic impact of breast-feeding promotion intervention. Grant from the Agency for Healthcare Research and Quality to Montefiore Medical Center, The Bronx, NY.
- Brady, C. Florida Breastfeeding Promotion Initiative. University of Florida, College of Medicine, Tallahassee, FL, 1995.
- Brent, N.B., Redd, B., Dworetz, A., D'Amico, F., and Greenberg, J.J. Breast-feeding in a low-income population. Program to increase incidence and duration. *Archives of Pediatrics and Adolescent Medicine* 149(7): 798-803, 1995.

- Bretschneider, J.U. An evaluation of a program to promote breast-feeding among low income African American women. Ph.D. thesis, Temple University, Philadelphia, PA, 1995.
- Bruce, N., and Griffioen, A. Usefulness of a non-experimental study design in the evaluation of service developments for infant feeding in a general hospital. *Social Science and Medicine* 40(8): 1109-1116, 1995.
- Burkhalter, B.R., and Marin, P.S. A demonstration of increased exclusive breastfeeding in Chile. *International Journal of Gynaecology and Obstetrics* 34(4): 353-359, 1991.
- Carroll, T.P. Substantially increasing breastfeeding: An accomplishment of the Alabama WIC Program. *Journal of Human Lactation* 10(2): 129-130, 1994.
- Cattaneo, A., and Buzzetti, R. Effect on rates of breast feeding of training for the baby friendly hospital initiative. *British Medical Journal* 323(7325): 1358-1362, 2001.
- Caulfield, L.E., Gross, S.M., Bentley, M.E., Bronner, Y., Kessler, L., Jensen, J., Weathers, B., and Paige, D. MWIC-based interventions to promote breastfeeding among African-American Women in Baltimore: Effects on breastfeeding initiation and continuation. *Journal of Human Lactation* 14(1): 15-22, 1998.
- Chen, C.H. Effects of home visits and telephone contacts on breastfeeding compliance in Taiwan. *Maternal-Child Nursing Journal* 21(3): 82-90, 1993.
- Chezem, J., and Friesen, C. Attendance at breast-feeding support meetings: Relationship to demographic characteristics and duration of lactation in women planning postpartum employment. *Journal of American Dietetic Association* 99(1): 83-85, 1999.
- Coombs, D.W., Reynolds, K., and Blankson, M.A. Self-help program to increase breastfeeding among low-income women. *Journal of Nutrition Education* 30(4): 203-209, 1998.
- Curro, V., Lanni, R., Scipione, F., Grimaldi, V., and Mastroiacovo, P. Randomised controlled trial assessing the effectiveness of a booklet on the duration of breast feeding. *Archives of Disease in Childhood* 76(6): 500-3, 1997; discussion, 503-504.
- Davies-Adetugbo, A.A. Promotion of breast feeding in the community: Impact of health education programme in rural communities in Nigeria. *Journal of Diarrhoeal Disease Research* 14(1): 5-11, 1996.
- Davies-Adetugbo, A.A., Adetugbo, K., Orewole, Y., and Fabiyi, A.K. Breast-feeding promotion in a diarrhoea programme in rural communities. *Journal of Diarrhoeal Disease Research* 15(3): 161-166, 1997.
- de Oliveira, M.I., Camacho, L.A., and Tedstone, A.E. Extending breastfeeding duration through primary care: A systematic review of prenatal and postnatal interventions. *Journal of Human Lactation* 17(4): 326-343, 2001.

Deck, L. Best Start-Kentucky Breastfeeding Implementation Incentive. MCHIP Grant, Title V, MCJ-216035. Prepared for Maternal and Child Health Bureau, U.S. Department of Health and Human Services, Rockville, MD, 1993.

Dennis, C. Breastfeeding initiation and duration: A 1990-2000 literature review. *Journal of Obstetrics and Gynecology Neonatal Nursing* 31(1): 12-32, 2002.

Dennis, C.-L. Breastfeeding peer support: Maternal and volunteer perceptions from a randomized controlled trial. *Birth* 29(3):169-176, 2002.

Dennis, C.-L., Hodnett, E., Gallop, R., and Chalmers, B. The effect of peer support on breast-feeding duration among primiparous women: A randomized controlled trial. *Canadian Medical Association Journal* 166(1): 21-28, 2002.

Dickersin, K., and Larson, K. Establishing and maintaining an international register of RCTs. In: *The Cochrane Collaboration Handbook*. Oxford, Update Software, 1996.

DiGirolamo, A.M., Grummer-Strawn, L.M., and Fein, S. Maternity care practices: Implications for breastfeeding. *Birth* 28(2): 94-100, 2001.

Dodgson, J.E., and Duckett, L. Breastfeeding in the workplace. Building a support program for nursing mothers. *AAOHN Journal* 45(6): 290-298, 1997.

Donnelly A., Snowden H.M., Renfrew M.J., and Woolridge M.W. Commercial hospital discharge packs for breastfeeding women (Cochrane Review). In *The Cochrane Library*, Issue 2. Oxford, U.K.: Update Software Ltd., 2002.

DuBois, J. Arkansas Best Start Promotion Project, MCJ-056036. Prepared for Maternal and Child Health Bureau, U.S. Department of Health and Human Services, Rockville, MD, 1993.

Duffy, E.P., Percival, P., and Kershaw, E. Positive effects of an antenatal group teaching session on postnatal nipple pain, nipple trauma and breast feeding rates. *Midwifery* 13(4): 189-196, 1997.

Dungy, C.I., Christensen-Szalanski, J., Losch, M., and Russell, D. Effect of discharge samples on duration of breast-feeding. *Pediatrics* 90(2, Pt 1): 233-237, 1992.

Dungy, C.I., Losch, M.E., Russell, D.W., Dusdieker, L.B., and Romitti, P.A. To determine the effect of breast pumps on the duration of breastfeeding, MCJ-190624-01-0. Prepared for Maternal and Child Health Bureau, U.S. Dept. of Health and Human Services, Rockville, MD, 1995.

Dungy, C.I., Losch, M.E., Russell, D., Romitti, P., and Dusdieker, L.B. Hospital infant formula discharge packages: Do they affect the duration of breast-feeding? *Archives of Pediatrics and Adolescent Medicine* 151(7): 724-729, 1997.

Escobar, G.J., Braverman, P.A., Ackerson, L., Odouli, R., Coleman-Phox, K., Capra, A.M., Wong, C., and Lieu, T.A. A randomized comparison of home visits and hospital-based group follow-up visits after early postpartum discharge. *Pediatrics* 108(3): 719-727, 2001.

- Fairbank, L., O'Meara, S., Renfrew, M.J., Woolridge, M., Sowden, A.J., and Lister-Sharp, D. A systematic review to evaluate the effectiveness of interventions to promote the initiation of breastfeeding. *Health Technology Assessment*, 4(25): 1-171, 2000.
- Fendrick, S.M., Major, A.L., and Brown, F.R. Nursing mothers service: A community breastfeeding program. *Paediatric Nursing* 20(3): 242-244, 1994.
- Ferris, D. Breastfeeding Promotion Project: Special project of regional and national significance to promote and support breastfeeding in West Virginia, especially among low-income women, MCJ-546037. Prepared for Maternal and Child Health Bureau, U.S. Dept. of Health and Human Services, Rockville, MD, 1993.
- Finch, C., and Daniel, E.L. Breastfeeding education program with incentives increases exclusive breastfeeding among urban WIC participants. *Journal of American Dietetic Association* 102(7): 981-984, 2002.
- Fredrickson, D.D. Breastfeeding promotion among WIC-participating women in North Carolina. Doctoral dissertation, University of North Carolina, Chapel Hill, Dept. of Epidemiology, 1995.
- Frederickson, D. Breastfeeding promotion among WIC-participating women in North Carolina, HS 07523. Prepared for DGGs, Agency for Health Care Policy and Research, Rockville, MD, 1996.
- Froozani, M.D., Permezhadeh, K., Motlagh, A.R., and Golestan, B. Effect of breastfeeding education on the feeding pattern and health of infants in their first 4 months in the Islamic Republic of Iran. *Bulletin of the World Health Organization* 77(5): 381-385, 1999.
- Gagnon, A.J., Dougherty, G., Jimenez, V., and Leduc, N. Randomized trial of postpartum care after hospital discharge. *Pediatrics* 109(6): 1074-1080, 2002.
- Gordon, N.P., Walton, D., McAdam, E., Derman, J., Gallitero, G., and Garrett, L. Effects of providing hospital-based doulas in health maintenance organization hospitals. *Obstetrics and Gynecology* 93(3): 422-426, 1999.
- Gross, S.M., Caulfield, L.E., Bentley, M.E., Bronner, Y., Kessler, L., Jensen, J., and Paige, D. Counseling and motivational videotapes increase duration of breast-feeding in African-American WIC participants who initiate breast-feeding *Journal of American Dietetic Association*. 98: 143-148, 1998.
- Grossman, L.K., Harter, C., and Hasbrouck, C. Testing mothers' knowledge of breastfeeding: Instrument development and implementation and correlation with infant feeding decision. *Journal of Pediatric and Perinatal Nutrition* 2(2): 43-63, 1990.
- Grossman, L.K., Harter, C., Sachs, L., and Kay, A. The effect of postpartum lactation counseling on the duration of breast-feeding in low-income women. *American Journal of Diseases of Children* 144(4): 471-474, 1990.

- Grummer-Strawn, L.M., Rice, S.P., Dugas, K., Clark, L.D., and Benton-Davis, S. An evaluation of breastfeeding promotion through peer counseling in Mississippi WIC clinics. *Maternal and Child Health Journal* 1(1): 35-42, 1997.
- Grunstra, E., and Rowe, S. The effects of a prenatal breast-feeding class on breast-feeding success and maternal perception of the infant: A replication. Master's thesis, Grand Valley State University, College of Nursing, Allendale, MI, 1992.
- Haider, R., Ashworth, A., Kabir, I., and Huttly, S.R. Effect of community-based peer counsellors on exclusive breastfeeding practices in Dhaka, Bangladesh: A randomised controlled trial [see comments]. *Lancet* 356(9242): 1643-1647, 2000.
- Haider, R., Kabir, I., Huttly, S.R.A., and Ashworth, A. Training peer counselors to promote and support exclusive breastfeeding in Bangladesh. *Journal of Human Lactation* 18(1): 7-12, 2002.
- Hartley, B.M., and O'Connor, M.E. Evaluation of the 'Best Start' breast-feeding education program. *Archives of Pediatrics and Adolescent Medicine* 150(8): 868-871, 1996.
- Hauck, Y.L., and Dimmock, J.E. Evaluation of an information booklet on breastfeeding duration: A clinical trial. *Journal of Advanced Nursing* 20(5): 836-843, 1994.
- Henderson, A., Stamp, G., and Pincombe, J. Postpartum positioning and attachment education for increasing breastfeeding: A randomized trial. *Birth* 28(4): 236-242, 2001.
- Hofmeyr, G.J., Nikodem, V.C., Wolman, W.L., Chalmers, B.E., and Kramer, T. Companionship to modify the clinical birth environment: Effects on progress and perceptions of labour and breastfeeding. *British Journal of Obstetrics and Gynaecology* 98(8): 756-764, 1991.
- Hogan, S.E. Overcoming barriers to breastfeeding: Suggested breastfeeding promotion programs for communities in eastern Nova Scotia. *Canadian Journal of Public Health* 92(2): 105-108, 2001.
- Hoyer, S., and Horvat, L. Successful breast-feeding as a result of a health education programme for mothers. *Journal of Advanced Nursing* 32(5): 1158-1167, 2000.
- Huffman, S.L. A historical review of the Panama Breastfeeding Promotion Project, 597-0000-3-7653041. Prepared for Nutrition Communication Project, Academy for Educational Development, Washington, DC, 1991.
- Humenick, S.S., and Hill, P.D. A randomized trial of assessment based nursing intervention and perceived insufficient milk supply. In preparation, 2003.
- Janken, J.K., Blythe, G., Campbell, P.T., and Carter, R.H. Changing nursing practice through research utilization: Consistent support for breastfeeding mothers. *Applied Nursing Research* 12(1): 22-29, 1999.
- Jingheng H., Yindi, X., Yongxin, J., and Jie, X. Evaluation of a health education programme in China to increase breast-feeding rates. *Health Promotion International* 9(2): 95-98, 1994.

- Johnson, T.S., Brennan, R.A., and Flynn-Tymkow, C.D. A home visit program for breastfeeding education and support. *Journal of Obstetrics and Gynecology Neonatal Nursing* 28(5): 480-485, 1999.
- Keane, C.R. Evaluating breastfeeding promotion: A critical review and model study of interventions implemented in Mexico. Unpublished doctorate dissertation, University of Pittsburgh, Graduate School of Public Health, 1993.
- Khoury, A.J., Hinton, A., Mitra, A., Sheil, H., and Moazzem, W. Evaluation of Mississippi's breastfeeding promotion program. Final report to USDA FNS and Mississippi's WIC Program. Center for Community Health, University of Southern Mississippi, 2001.
- Kistin, N., Abramson, R., and Dublin, P. Effect of peer counselors on breastfeeding initiation, exclusivity, and duration among low-income urban women. *Journal of Human Lactation* 10(1): 11-15, 1994.
- Kistin, N., Benton, D., Rao, S., and Sullivan, M. Breast-feeding rates among black urban low-income women: Effect of prenatal education. *Pediatrics* 86(5): 741-746, 1990.
- Kramer, M.S., Chalmers, B., Hodnett, E.D., Sevkovskaya, Z., Dzikovich, I., Shapiro, S., Collet, J.P., Vanilovich, I., Mezen, I., Ducruet, T., Shishko, G., Zubovich, V., Mknuk, D., Gluchanina, E., Dombrovskiy, V., Ustinovitch, A., Kot, T., Bogdanovich, N., Ovchinikova, L., and Helsing, E. Promotion of breastfeeding intervention trial (PROBIT): A cluster-randomized trial in the Republic of Belarus. Design, follow-up, and data validation. *Advances in Experimental Medicine and Biology* 478: 327-345, 2000.
- Kramer, M.S., Chalmers, B., Hodnett, E.D., Sevkovskaya, Z., Dzikovich, I., Shapiro, S., Collet, J.-P., Vanilovich, I., Mezen, I., Ducruet, T., Shishko, G., Zubovich, V., Mknuk, D., Gluchanina, E., Dombrovskiy, V., Ustinovitch, A., Kot, T., Bogdanovich, N., Ovchinikova, L., and Helsing, E. Promotion of breastfeeding intervention trial (PROBIT): A randomized trial in the Republic of Belarus. *Journal of the American Medical Association* 285(4): 413-420, 2001.
- Ladzani, R., Steyn, N.P., and Nel, J.H. An evaluation of the effectiveness of nutrition advisers in three rural areas of northern province. *South African Medical Journal* 90(8): 811-816, 2000.
- Larsen, P.G. Evaluation of the Babybucks incentive program: Utilization of perinatal services (North Carolina). D.N.Sc. thesis, Rush University, College of Nursing, North Carolina, 1995.
- Lawlor-Smith, C., McIntyre, E., and Bruce, J. Effective breastfeeding support in a general practice. *Australian Family Physician* 26(5): 573-5, 578-580, 1997.
- Lawrence, R.A. Promotion of breastfeeding intervention trial (PROBIT): A randomized trial in the Republic of Belarus. *Journal of Pediatrics* 139(1): 164-165, 2001.
- Lazarov, M., and Cohen, C. Tennessee Breastfeeding Promotion Project, MCJ 473813. Prepared for Maternal and Child Health Bureau, U.S. Dept. of Health and Human Services, Rockville, MD, 1991.

Lee, N. Observations based upon multiple telephone contacts with new breastfeeding mothers. *Journal of Human Lactation* 13(2): 147-150, 1997.

Lieu, T.A., Wikler, C., Capra, A.M., Martin, K.E., Escobar, G.J., and Braveman, P.A. Clinical outcomes and maternal perceptions of an updated model of perinatal care. *Pediatrics* 102(6): 1437-1444, 1998.

Lindenberg, C.S., Cabrera Artola, R., and Jimenez, V. The effect of early post-partum mother-infant contact and breast-feeding promotion on the incidence and continuation of breast-feeding. *International Journal of Nursing Studies* 27(3): 179-186, 1990.

Loh, N.R., Kelleher, C.C., Long, S., and Loftus, B.G. Can we increase breast feeding rates? *Irish Medical Journal* 90(3): 100-101, 1997.

Long, D.G., Funk-Archuleta, M.A., Geiger, C.J., Mozar, A.J., and Heins, J.N. Peer counselor program increases breastfeeding rates in Utah Native American WIC population. *Journal of Human Lactation* 11(4): 279-284, 1995.

Lovelady, C.A., Rasmussen, G., Dunn, P.C., van Eck, N., Britt-Smith, S., and Jones, R. Peer counseling of lactating women in the women, infants and children supplemental feeding (WIC) program: A cost-effective analysis. *Journal of American Dietetic Association* 96: 64, 1996 (abstract).

Lutter, C.K., Perez-Escamilla, R., Segall, A., Sanghvi, T., Teruya, K., and Wickham, C. The effectiveness of a hospital-based program to promote exclusive breast-feeding among low-income women in Brazil. *American Journal of Public Health* 87(4): 659-663, 1997.

Martens, P. Sagkeeng First Nation's Breastfeeding Promotion Initiatives: A follow-up study. Unpublished report, University of Manitoba, Canada, 2002.

Martens, P.J. Does breastfeeding education affect nursing staff beliefs, exclusive breastfeeding rates, and Baby-Friendly Hospital Initiative compliance? The experience of a small, rural Canadian hospital. *Journal of Human Lactation* 16(4): 309-318, 2000.

Martens, P.J. Increasing breastfeeding initiation and duration at a community level: An evaluation of Sagkeeng First Nation's community health nurse and peer counselor programs. *Journal of Human Lactation* 18(3): 236-246, 2002.

Martens, P., and Romphf, L. Evaluating the effectiveness of breastfeeding education in Interlake Regional Health Authority. In preparation, 2003.

Martin, J.A., Hamilton, B.E., Ventura, S.J., Menacker, F., and Park, M.M. Births: Final data for 2000. *National Vital Statistics Reports* 50(5). Hyattsville, MD: National Center for Health Statistics, 2002.

McCreath, W.A., Wilcox, S., Laing, V., Crump, D., and Gilles, J. Improving the number of mothers breastfeeding in the postpartum period. *Primary Care Update for Ob/Gyns* 8(1): 40-43, 2001.

- McDivitt, J.A., Zimicki, S., Hornik, R., and Abulaban, A. The impact of the Healthcom mass media campaign on timely initiation of breastfeeding in Jordan. *Studies in Family Planning* 24(5): 295-309, 1993.
- McInnes, R.J., Love, J.G., and Stone, D.H. Evaluation of a community-based intervention to increase breastfeeding prevalence. *Journal of Public Health Medicine* 22(2): 138-145, 2000.
- McInnes, R.J., and Stone, D.H. The process of implementing a community-based peer breast-feeding support programme: The Glasgow experience. *Midwifery* 17(1): 65-73, 2001.
- Michaels, M. Breastfeeding promotion in the Utah WIC program. *Journal of Human Lactation* 9(3): 206-207, 1993.
- Moreland, J.C., Lloyd, L., Braun, S.B., and Heins, J.N. A new teaching model to prolong breast-feeding among Latinos. *Journal of Human Lactation* 16(4): 337-341, 2000.
- Morrell, C.J., Spiby, H., Stewart, P., Walters, S., and Morgan, A. Costs and effectiveness of community postnatal support workers: Randomised controlled trial. *British Medical Journal* 321(7261): 593-598, 2000.
- Morrow, A.L., Guerrero, M.L., Shults, J., Calva, J.J., Lutter, C., Bravo, J., Ruiz-Palacios, G., Morrow, R.C., and Butterfoss, F.D. Efficacy of home-based peer counselling to promote exclusive breastfeeding: A randomised controlled trial. *Lancet* 353(9160): 1226-1231, 1999.
- Mutch, B., and McKay, C. Michigan's ES/WIC Nutrition Education Initiative: Breastfeeding Peer Counselor Initiative (BFI). Unpublished final report for ES/WIC Nutrition Education Initiative, Michigan State University Extension, E. Lansing, MI, 1996.
- Myers, D., Kent, H., and Baranov, S. The joys and challenges of promoting breastfeeding in south central Los Angeles. *Journal of Human Lactation* 9(4): 284-287, 1993.
- Nadel, E.L. Breastfeeding promotion in an urban New Jersey WIC office. *Journal of Human Lactation* 9(2): 140-142, 1993.
- National Center for Education in Maternal and Child Health (NCEMCH). Breastfeeding: Abstracts and products of MCHB-funded projects. National Center for Education in Maternal and Child Health, Arlington, VA, 1996.
- Neyzi, O., Gulecyuz, M., Dincer, Z., Olgun, P., Kutluay, T., Uzel, N., and Saner, G. An educational intervention on promotion of breast feeding complemented by continuing support. *Paediatric and Perinatal Epidemiology* 5(3): 299-303, 1991.
- Neyzi, O., Olgun, P., Kutluay, T., Uzel, N., Saner, G., Gokcay, G., Tasdelen, E., and Akar, U. An educational intervention on promotion of breast feeding. *Paediatric and Perinatal Epidemiology* 5(3): 286-298, 1991.

- Nylander, G., Lindemann, R., Helsing, E., and Bendvold, E. Unsupplemented breastfeeding in the maternity ward. Positive long-term effects. *Acta Obstetrics and Gynecology Scandinavia* 70(3): 205-209, 1991.
- Oliveira, V., Prell, M., Smallwood, D., and Frazao, E. Infant formula prices and availability: Final report to Congress. Washington, DC: USDA, Economic Research Service, 2001.
- Paige, D.M. Breastfeeding strategies for urban WIC women, MCJ-240609. Prepared for the Maternal and Child Health Research Program, Maternal and Child Health Bureau, Rockville, MD, 1994.
- Page-Goertz, S., and McCamman, S. Kansas Breastfeeding Promotion Project. Child Development Unit, Kansas University Affiliated Program and University of Kansas Medical Center, Kansas City, Kansas, 1995.
- Pastore, M.T., and Nelson, A. A breastfeeding drop-in center survey evaluation. *Journal of Human Lactation* 13(4): 291-298, 1997.
- Perez, A. The effect of breastfeeding promotion on the infertile postpartum period. *International Journal of Gynaecology and Obstetrics* 31 (Suppl 1): 29-30, 1990; discussion.
- Perez-Escamilla, R., Pollitt, E., Lonnerdal, B., and Dewey, K.G. Infant feeding policies in maternity wards and their effect on breast-feeding success: An analytic overview. *American Journal of Public Health* 84(1): 89-97, 1994.
- Perez-Escamilla, R., Segura-Millan, S., Pollitt, E., and Dewey, K.G. Effect of the maternity ward system on the lactation success of low-income urban Mexican women. *Early Human Development* 31(1): 25-40, 1992.
- Philipp, B.L., Merewood, A., Miller, L.W., Chawla, N., Murphy-Smith, M.M., Gomes, J.S., Cimo, S., and Cook, J.T. Baby-friendly hospital initiative improves breastfeeding initiation rates in a US hospital setting. *Pediatrics* 108(3): 677-681, 2001.
- Pichaiapat, V., Thanomsingh, P., Pudhapongsiriporn, S., Buranasin, P., Phanidanunt, M., and Monkalasiri, R. An intervention model for breast feeding in Maharat Nakhon Ratchasima Hospital. *Southeast Asian Journal of Tropical Medicine and Public Health* 23(3): 439-443, 1992.
- Pobocik, R. Early experiences and counseling for effective lactation (EXCEL). Unpublished final report for ES/WIC Nutrition Education Initiative, University of Guam, 1996.
- Popkin, B.M., Canahuati, J., Bailey, P.E., and O’Gara, C. An evaluation of a national breast-feeding promotion programme in Honduras. *Journal of Biosocial Science* 23(1): 5-21, 1991.
- Porteous, R., Kaufman, K., and Rush, J. The effect of individualized professional support on duration of breastfeeding: A randomized controlled trial. *Journal of Human Lactation* 16(4): 303-308, 2000.
- Prasad, B., and Costello, A.M. Impact and sustainability of a “baby friendly” health education intervention at a district hospital in Bihar, India. *British Medical Journal* 310(6980): 621-623, 1995.

- Pugh, L.C., and Milligan, R.A. Nursing intervention to increase the duration of breastfeeding. *Applied Nursing Research* 11(4): 190-194, 1998.
- Pugh, L.C., Milligan, R.A., and Brown, L.P. The breastfeeding support team for low-income, predominantly-minority women: A pilot intervention study. *Health Care for Women International* 22(5): 501-515, 2001.
- Pugh, L.C., Milligan, R.A., Frick, K.D., Spatz, D., and Bronner, Y. Breastfeeding duration, costs, and benefits of a support program for low-income breastfeeding women. *Birth* 29(2): 95-100, 2002.
- Pugin, E., Valdes, V., Labbok, M.H., Perez, A., and Aravena, R. Does prenatal breastfeeding skills group education increase the effectiveness of a comprehensive breastfeeding promotion program? *Journal of Human Lactation* 12(1): 15-19, 1996.
- Quarles, A., Williams, P.D., Hoyle, D.A., Brimeyer, M., and Williams, A.R. Mothers' intention, age, education and the duration and management of breastfeeding. *Maternal-Child Nursing Journal* 22(3): 102-108, 1994.
- Rea, M.F. The Brazilian National Breastfeeding Program: A success story. *International Journal of Gynaecology and Obstetrics* 31(Suppl 1): 79-82, 1990; discussion.
- Rea, M.F., and Berquo, E.S. Impact of the Brazilian national breast-feeding programme on mothers in greater Sao Paulo. *Bulletin of the World Health Organization* 68(3): 365-371, 1990.
- Redman, S., Watkins, J., Evans, L., and Lloyd, D. Evaluation of an Australian intervention to encourage breast feeding in primiparous women. *Health Promotion International* 10(2): 101-113, 1995.
- Reifsnider, E., and Eckhart, D. Prenatal breastfeeding education: Its effect on breastfeeding among WIC participants. *Journal of Human Lactation* 13(2): 121-125, 1997.
- Rissler, N.J., and Harris, J.E. The effect of incentive gifts on breastfeeding incidence and duration of selected WIC clinics in Kansas. *Journal of American Dietetic Association* 101: 77, 2001 (abstract).
- Rodriguez-Garcia, R., Aumack, K.J., and Ramos, A. A community-based approach to the promotion of breastfeeding in Mexico. *Journal of Obstetrics and Gynecology Neonatal Nursing* 19(5): 431-438, 1990.
- Roman, C.A.K. The effect of individual and group educational interventions on first time breast-feeding mothers with implications for nursing education. Unpublished doctorate dissertation, Wayne State University, 1992.
- Rossiter, J.C. The effect of a culture-specific education program to promote breastfeeding among Vietnamese women in Sydney. *International Journal of Nursing Studies* 31(4): 369-379, 1994.
- Rowe, L., Cumming, F., King, R., and Mackey, C. A comparison of two methods of breastfeeding management. *Australian Family Physician* 21(3): 286-294, 1992.

- Ryan, A.S. The resurgence of breastfeeding in the United States. *Pediatrics* 99(4): e12, 1997.
- Ryser, F.G. Breastfeeding attitudes, intention and initiation in low-income women: The effect of the "Best Start" program. Ph.D. thesis, Texas Woman's University, College of Nursing, Denton, TX, 1999.
- Schafer, E. Building a peer network of nutrition and breastfeeding support for rural Iowans. Unpublished final report for ES/WIC Nutrition Education Initiative, Iowa State University Extension, 1996.
- Schafer, E., Vogel, M.K., Viegas, S., and Hausafus, C. Volunteer peer counselors increase breastfeeding duration among rural low-income women. *Birth* 1998 25(2): 101-106, 1998.
- Schy, D.S., Maglaya, C.F., Mendelson, S.G., Race, K.E., and Ludwig-Beymer, P. The effects of in-hospital lactation education on breastfeeding practice. *Journal of Human Lactation* 12(2): 117-122, 1996.
- Sciacca, J.P., Dube, D.A., Phipps, B.L., and Ratliff, M.I. A breast feeding education and promotion program: Effects on knowledge, attitudes, and support for breast feeding. *Journal of Community Health* 20(6): 473-490, 1995.
- Sciacca, J.P., Phipps, B.L., Dube, D.A., and Ratliff, M.I. Influences on breast-feeding by lower-income women: an incentive-based, partner-supported educational program. *Journal of American Dietetic Association* 95(3): 323-328, 1995.
- Seidel, M., Dodge, J., and Rossiter, B. Use of lactation consultants in an urban WIC population. *Journal of Nutrition Education* 25(2): 74-76, 1993.
- Serafino Cross, P., and Donovan, P.R. Effectiveness of professional breastfeeding home-support. *Journal of Nutrition Education* 24(3): 117-122, 1992.
- Serwint, J.R., Wilson, M.E., Vogelhut, J.W., Repke, J.T., and Seidel, H.M. A randomized controlled trial of prenatal pediatric visits for urban, low-income families. *Pediatrics* 98(6, Pt 1): 1069-1075, 1996.
- Shaw, E., and Kaczorowski, J. The effect of a peer counseling program on breastfeeding initiation and longevity in a low-income rural population. *Journal of Human Lactation* 15(1): 19-25, 1999.
- Sheehan, A. A comparison of two methods of antenatal breast-feeding education. *Midwifery* 15(4): 274-282, 1999.
- Siu-Norman, A. Breastfeeding peer counseling program in Missouri. ASTSPND newsletter, 1996.
- Smith, C., and Trendell, J. Indiana's Breastfeeding Promotion Project, MCJ 183822. Prepared for: Indiana State Board of Health, Indianapolis, IN, 1993.
- Steel, A., and Huffman, S. Breastfeeding promotion in Belize: A community based integrated approach, PB93180594. Prepared for U.S. Agency for International Development, Washington, DC, 1992.

Stock, C. Breastfeeding promotion in a rural Indiana WIC office. *Journal of Human Lactation* 8(3): 176-178, 1992.

Susin, L.R., Giugliani, E.R., Kummer, S.C., Maciel, M., Simon, C., and da Silveira, L.C. Does parental breastfeeding knowledge increase breastfeeding rates? *Birth* 26(3): 149-156, 1999.

Szcodronski, H., Dobson, B., Losch, M.E., and Bryant, C. Iowa's implementation of the WIC National Breastfeeding Promotion Project: Project report and summary of findings. Prepared for Iowa Dept. of Public Health, Des Moines, IA, 2002.

Szcodronski, H.A., and Dobson, B.L. Evaluating the impact of the WIC National Breastfeeding Promotion Project in Iowa. *Journal of American Dietetic Association* 102: 65, 2002 (abstract).

Taddei, J.A., Westphal, M.F., Venancio, S., Bogus, C., and Souza, S. Breastfeeding training for health professionals and resultant changes in breastfeeding duration. *Sao Paulo Medical Journal* 118(6): 185-191, 2000.

Tuttle, C.R., and Dewey, K.G. Impact of a breastfeeding promotion program for Hmong women at selected WIC sites in northern California. *Journal of Nutrition Education* 27(2): 69-74, 1995.

U.S. Department of Health and Human Services. *Breastfeeding: HHS Blueprint for Action on Breastfeeding*. Washington, DC: DHHS, Office of Women's Health, 2000.

U.S. Department of Health and Human Services. *Healthy People, 2000: National Health Promotion and Disease Prevention objectives*. Hyattsville, MD: National Center for Health Statistics, 1991.

U.S. General Accounting Office. Food assistance: Research provides limited information on the effectiveness of specific WIC nutrition services. Report to Congressional Committees, GAO-01-442, 2001.

Valdes, V., Perez, A., Labbok, M., Pugin, E., Zambrano, I., and Catalan, S. The impact of a hospital and clinic-based breastfeeding promotion programme in a middle class urban environment. *Journal of Tropical Pediatrics* 39(3): 142-151, 1993.

Valdes, V., Pugin, E., Schooley, J., Catalan, S., and Aravena, R. Clinical support can make the difference in exclusive breastfeeding success among working women. *Journal of Tropical Pediatrics* 46(3): 149-154, 2000.

van Eck, N. North Carolina EFNEP/WIC Breastfeeding Support Program. Unpublished final report for ES/WIC Nutrition Education Initiative. North Carolina State University, Cooperative Extension, Raleigh, NC, 1996.

Volpe, E.M., and Bear, M. Enhancing breastfeeding initiation in adolescent mothers through the Breastfeeding Educated and Supported Teen (BEST) Club. *Journal of Human Lactation* 16(3): 196-200, 2000.

Wagner, C.L., Hulsey, T.C., Southgate, W.M., and Annibale, D.J. Breastfeeding rates at an urban medical university after initiation of an educational program. *Southern Medical Journal* 95(8): 909-913, 2002.

Waldenstrom, U., and Nilsson, C.A. No effect of birth centre care on either duration or experience of breast feeding, but more complications: Findings from a randomised controlled trial. *Midwifery* 10(1): 8-17, 1994.

Watters, N.E., and Kristiansen, C.M. Two evaluations of combined mother-infant versus separate postnatal nursing care. *Research in Nursing and Health* 18(1): 17-26, 1995.

Webber, B.G., Elieson, B.E., Gazak, C.E., and Stadler, D.D. Effect of breastfeeding peer counseling on initiation and duration of breastfeeding among adolescent mothers. *Journal of American Dietetic Association* 98: 64, 1998 (abstract).

Wilmoth, T.A., and Elder, J.P. An assessment of research on breastfeeding promotion strategies in developing countries. *Social Science and Medicine* 41(4): 579-594, 1995.

Wrenn, S. Effects of a model-based intervention on breastfeeding attrition. Unpublished doctorate dissertation, University of Texas Graduate School of Biomedical Sciences at San Antonio, TX, 1997.

Wright, A.L., Bauer, M., Naylor, A., Sutcliffe, E., and Clark, L. Increasing breastfeeding rates to reduce infant illness at the community level. *Pediatrics* 101(5): 837-844, 1998.

Wright, A.L., Naylor, A., Wester, R., Bauer, M., and Sutcliffe, E. Using cultural knowledge in health promotion: Breastfeeding among the Navajo. *Health Education and Behavior* 24(5): 625-639, 1997.

Wright, A., Rice, S., and Wells, S. Changing hospital practices to increase the duration of breastfeeding. *Pediatrics* 97(5): 669-675, 1996.

Zimmerman, D.R. You can make a difference: increasing breastfeeding rates in an inner-city clinic. *Journal of Human Lactation* 15(3): 217-220, 1999.

Appendix A
Expert Panel Members

Expert Panel Members

Kimarie Bibbs Bugg

Coan Middle School
Emory University School of Medicine

Mary Blankson

Department of Health
Jefferson County, Alabama

Jacqueline Grant

Department of Obstetrics & Gynecology
University of Missouri-Columbia

Laurence Grummer-Strawn

Maternal and Child Nutrition Branch
Centers for Disease Control and Prevention

Gail Harrison

Center for Health Policy Research
University of California – Los Angeles

Rafael Perez-Escamilla

Department of Nutritional Sciences
University of Connecticut

Kathleen Rasmussen

Division of Nutritional Sciences
Cornell University

Linda Smith

Bright Future Lactation Resource Centre
Dayton, Ohio

Holly Szcodronski

Bureau of Nutrition and WIC
Iowa Department of Public Health

Appendix B

Current Federal Requirements for Breastfeeding Promotion in WIC

Current Federal Requirements for Breastfeeding Promotion In WIC

The current federal WIC regulations contain provisions to encourage women to breastfeed and to provide appropriate nutritional support for breastfeeding participants.

CITATION	PROVISION
246.2	<p>Definitions</p> <p><i>Breastfeeding</i> means the practice of feeding a mother's breast milk to her infant(s) on the average of at least once a day.</p> <p><i>Breastfeeding women</i> means women up to one year postpartum who are breastfeeding their infants.</p>
246.3(e)(4)	<p>State staffing standards</p> <p>Each State agency shall designate a breastfeeding promotion coordinator, to coordinate breastfeeding promotion efforts identified in the State plan in accordance with the requirement of 246.4(a)(9). The person to whom the State agency assigns this responsibility may perform other duties as well.</p>
246.4(a)(9)	<p>State Plan</p> <p>The State Plan must include the State agency's nutrition education goals and action plans, including a description of the methods that will be used to promote breastfeeding.</p>
246.7(e)(1)(iii)	<p>Certification of Participants</p> <p>Breastfeeding Dyads. A breastfeeding mother and her infant shall be placed in the highest priority level for which either is qualified.</p>
246.7 (e)(4)(i)	<p>Nutritional risk priority system. Priority I: pregnant women, breastfeeding women and infants at nutritional risk as demonstrated by hematological or anthropometric measurements or other documented nutritionally related medical conditions which demonstrate the need for supplemental foods.</p>
246.7(g)(1)(iii)	<p>Certification Periods</p> <p>Breastfeeding women shall be certified at intervals of approximately six months and ending with the breastfed infant's first birthday.</p>
246.10(c)(7)	<p>Supplemental Foods</p> <p>Food Package VII-Breastfeeding Women (Enhanced) contains additional amounts of juice, cheese and legumes, plus carrots and canned tuna.</p>

CITATION	PROVISION
246.11(c)	<p>Nutrition Education State agencies shall perform the following activities in carrying out nutrition education responsibilities:</p>
246.11(c)(2)	Provide training on the promotion and management of breastfeeding to staff at local agencies who will provide information and assistance on this subject to participants.
246.11(c)(3)	Identify or develop resources and educational materials for use in local agencies, including breastfeeding promotion and instruction materials; taking reasonable steps to include materials in languages other than English in areas where a significant number of or proportion of the populations needs the information in a language other than English.
246.11(c)(7)	<p>Establish standards for breastfeeding promotion and support which include, at a minimum, the following:</p> <ul style="list-style-type: none"> (i) A policy that creates a positive clinic environment which endorses breastfeeding as the preferred method of infant feeding; (ii) A requirement that each local agency designate a staff person to coordinate breastfeeding promotion and support activities; (iii) A requirement that each local agency incorporate task-appropriate breastfeeding promotion and support training into orientation programs for new staff involved in direct contact with WIC clients; and (iv) A plan to ensure that women have access to breastfeeding promotion and support activities during the prenatal and postpartum periods.
246.11(e)(1)	<p>Participant Contacts All pregnant participants shall be encouraged to breastfeed unless contraindicated for health reasons.</p>
246.14(b)(1)(iii)	<p>Program Costs The State agency may use food funds to purchase or rent breast pumps.</p>
246.14(c)(1)	Specified allowable nutrition services and administration (NSA) costs. Each fiscal year, each state agency must spend, for nutrition education activities and breastfeeding promotion and support activities, an aggregate amount that is not less than the sum of one-sixth of the amount expended by the State agency for costs of NSA and an amount equal to its proportionate share of the national minimum expenditure for breastfeeding promotion and support activities. The national minimum expenditure for breastfeeding promotion and support activities shall be equal to \$21 multiplied by the number of pregnant and breastfeeding women in the Program, based on the average of the last three months for which USDA has final data. On October 1, 1996 and each October 1 thereafter, the \$21 will be adjusted annually using the same inflation percentage used to determine the national administrative grant per person.
246.14(c)(10)	Costs of breastfeeding aids which directly support the initiation and continuation of breastfeeding are allowable.

Source: Food and Nutrition Service (2003). *Breastfeeding Promotion In WIC: Current Federal Requirements*.
<http://www.fns.usda.gov/wic/Breastfeeding/bfrequirements.HTM>

Appendix C

Studies of WIC Peer Counseling Interventions Reviewed by Abt Associates Inc.

Studies of WIC Peer Counseling Interventions Reviewed by Abt Associates Inc.¹

Arlotti, J.P., Cottrell, B.H., Lee, S.H., and Curtin, J.J. (1998). Breastfeeding among low-income women with and without peer support. *Journal of Community Health Nursing* 15(3): 163-178.

Caulfield, L.E., Gross, S.M., Bentley, M.E., Bronner, Y., Kessler, L., Jensen, J., Weathers, B., and Paige, D. (1998). MWIC-based interventions to promote breastfeeding among African-American Women in Baltimore: Effects on breastfeeding initiation and continuation. *Journal of Human Lactation* 14(1): 15-22.

Grummer-Strawn, L.M., Rice, S.P., Dugas, K., Clark, L.D., and Benton-Davis, S. (1997). An evaluation of breastfeeding promotion through peer counseling in Mississippi WIC clinics. *Maternal and Child Health Journal* 1(1): 35-42.

Long, D.G., Funk-Archuleta, M.A., Geiger, C.J., Mozar, A.J., and Heins, J.N. (1995). Peer counselor program increases breastfeeding rates in Utah Native American WIC population. *Journal of Human Lactation* 11(4): 279-284.

Lovelady, C.A., Rasmussen, G., Dunn, P.C., van Eck, N., Britt-Smith, S., and Jones, R. (1996). Peer counseling of lactating women in the women, infants and children supplemental feeding (WIC) program: A cost-effective analysis. *Journal of American Dietetic Association* 96: 64. (abstract).

Mutch, B., and McKay, C. (1996). Michigan's ES/WIC Nutrition Education Initiative: Breastfeeding Peer Counselor Initiative (BFI). Unpublished final report for ES/WIC Nutrition Education Initiative, Michigan State University Extension, E. Lansing, MI.

Paige, D.M. (1994). Breastfeeding strategies for urban WIC women, MCJ-240609. Prepared for the Maternal and Child Health Research Program, Maternal and Child Health Bureau, Rockville, MD.

Schafer, E., Vogel, M.K., Viegas, S., and Hausafus, C. (1998). Volunteer peer counselors increase breastfeeding duration among rural low-income women. *Birth* 25(2): 101-106.

Shaw, E., and Kaczorowski, J. (1999). The effect of a peer counseling program on breastfeeding initiation and longevity in a low-income rural population. *Journal of Human Lactation* 15(1): 19-25.

Siu-Norman, A. (1996). Breastfeeding peer counseling program in Missouri. ASTSPND newsletter.

Tuttle, C.R., and Dewey, K.G. (1995). Impact of a breastfeeding promotion program for Hmong women at selected WIC sites in northern California. *Journal of Nutrition Education* 27(2): 69-74.

¹ These results of this review are presented in McLaughlin et al., 2003, cited in the reference section of this document.