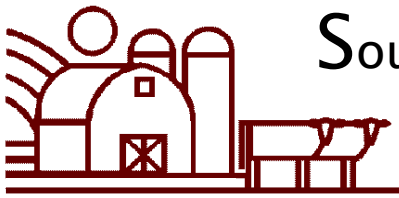
Development of a Methodology for Assessing the Effect of a Lay Home Visitation Program for Rural High-Risk Women and Infants



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Development of a Methodology for Assessing the Effect of a Lay Home Visitation Program for Rural High-Risk Women and Infants

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TABLE OF CONTENTS

Page

EXECUTIVE SUMMARY 1

CHAPTER ONE: Background and Significance 3

CHAPTER TWO: The Resource Mothers Program 9

CHAPTER THREE: Analysis and Interpretation of Results 14

CHAPTER FOUR: Conclusions and Policy Implications 19

APPENDIX A: Methods 26

APPENDIX B: Detailed Tables 37

REFERENCES 44

EXECUTIVE SUMMARY

Case management is a community-focused approach to augmenting prenatal and well child care which incorporates health education and social support. Lay health care workers from the clients' community are thought to be influential in modifying behavioral and environmental determinants because of their common social, cultural, and environmental milieu. The positive impact of paraprofessional support programs on use of services was consistently documented in the literature. However, their effects on pregnancy and birth outcomes among low-income, rural women were less clear.

This small pilot study tested a linked data set approach for evaluating the effectiveness of a community health worker program for women at risk for poor pregnancy and birth outcomes. We applied the method to a home visitation program that uses lay health workers to provide health education, referral, and social support to rural, low-income pregnant African American women and their infants receiving Medicaid. Adequacy of preventive services and health outcomes were compared across three groups of mother-infant pairs: (a) participants in the Resource Mothers Program during its first year of operation (n = 39), (b) a comparison group from similar counties in which the program was not offered (n = 243), and (c) a comparison group from the same counties 2 years prior to program implementation (n = 283). Analysis was performed using de-identified data elements from Vital Records Birth Certificates, Medicaid, and Low Country Healthy Start.

Readers are advised to interpret the statistical results with caution. Given that (a) the purpose of the pilot study was to test feasibility of the design and procedures, (b) generation of data occurred during first year of operation of the home visitation program, and (c) the small Study Group sample size (39 mother-infant pairs), results may be biased.

Key Findings

- The pilot study successfully demonstrated that a retrospective, population-based, comparative design is a feasible method for evaluating the effect of a maternal-infant home visitation program on adequacy of preventive services and health outcomes.
- Subjects in our sample, comprised of pregnant Medicaid women and their resulting infants from rural, African American communities, shared many characteristics that increased the risk of poor pregnancy and birth outcomes, including age (below 18 or over 34 years, 18%), less than a high school education (30%), and first pregnancy (46%).
- Approximately half of mothers obtained adequate prenatal and post partum care. Adequacy of maternal preventive services was similar among the three comparison groups.
- Adequate well child care was obtained by 37% of infants. However, infants in the Study Group (47%) were nearly 3 times as likely as those in the Same Counties Comparison Group (18%) to obtain adequate preventive care ($p < .0001$).
- Fewer infants (8%) in the Study Group than in Similar (25%) or Same Counties (22%) Comparison Groups recorded any visits for preventable conditions, a finding that approached statistical significance (p=.0589). On the other hand, Study Group infants averaged more medical encounters for nonpreventable conditions (M = 19) than Comparison Group infants (Similar, M = 14; Same, M = 12). .

- Initial program data collection methods failed to control adequately for completeness and accuracy, impacting program evaluation. For example, 10% of Medicaid recipient numbers for program participants were inaccurate. This resulted in loss of 17 mother-infant pairs from the Study Group. Immunization data were frequently missing from client records.

Recommendations for Further Research

To address the racial disparities in the health of African American pregnant women and their infants in rural communities with scarce financial resources, cost effective interventions must be identified. It is critical to dispel the ambiguity surrounding the cost effectiveness of home visitation programs using lay health workers to improve pregnancy/birth outcomes and infant health and decrease the cost of medical care

We recommend that:

- further investigation of the effectiveness of maternal-infant home visitation programs should be conducted among rural, minority populations in underserved areas. Studies should include measurement of cost effectiveness.
- research efforts extend the monitoring of effects of care coordination on children past the 60-day period following birth, as the greatest effects of the intervention are likely to be on infant care and health. We recommend evaluation through the first 2 years of life.
- particular attention to systematic measurement of the impact of a lay home visitation program on health-related behaviors. Our preliminary findings indicated the possible positive impact of lay health workers on increasing adequacy of well child visits and decreasing encounters for preventable illness and injury among infants.
- process evaluation should be incorporated into the research design to monitor the quality of program implementation and data reporting.
- data included in formal program evaluation should be drawn from the period when the program is at full strength, with all staff and systems operational.

Programmatic Recommendations

As a preliminary evaluation effort primarily designed to assess the feasibility of rigorous study of a lay home visitation program, our research does not yield broad programmatic recommendations regarding provision of services. However, as evaluators, we note that effects of community-based programs will fail to be detected unless efficient data capture procedures are in operation.

- We recommend that all Healthy Start programs apply continuous quality improvement techniques to primary data collection. Without consistent, reliable and timely data collection, program evaluation results are jeopardized and the ability to make future policy recommendations threatened.

CHAPTER ONE

BACKGROUND AND SIGNIFICANCE

1. The Problem: Severe Disparities in Infant Health

Racial disparities in infant health. Nationwide the infant mortality rate (IMR) in 2000 was 6.9 deaths of infants <1 year of age per 1,000 live births. The IMR was lowest in Massachusetts at 4.6 and highest in Mississippi at 10.7. However, the death rate among black infants was 2½ times that among white infants (14.1 vs. 5.7).[1, p. 105] For the nation as a whole, there has been a continuous long-term decline in the IMR since 1915.[2, p. 849] However, in South Carolina the long-term decline ended in 1996. The 3-year average IMR in South Carolina increased 5% from 1994-96 to 1998-00: While deaths among white infants decreased 3%, those among black infants increased 14%.[3, p. 5] Between 1990 and 2000, the black to white IMR ratio in South Carolina increased from 2.1 to 2.5.[3, p. 4]

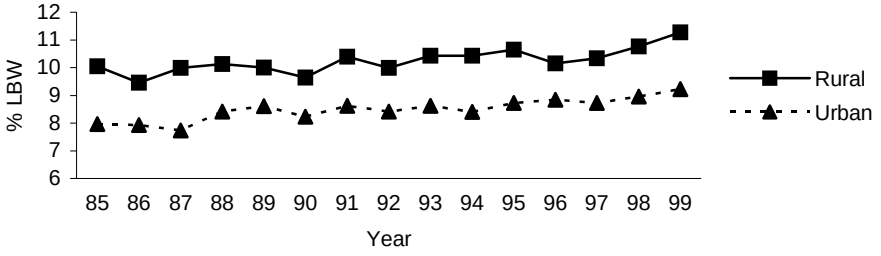
In a study of 10,221 new mothers in South Carolina from 1992 to 1997, Helms, Dillard, Whitehead and Connelly[4] found that women who experienced an infant death within 6 months of delivery, compared to those whose infants lived, were more likely to be black, unmarried, less than 18 years old, have less than a high school education, obtain Medicaid during pregnancy, smoke during pregnancy, obtain inadequate prenatal care, and be hospitalized during pregnancy. Low birth weight babies (< 2,500 g) were much more likely to die than those who were not low birth weight. In 2000 the prevalence of low birth weight in South Carolina was twice as high in black as among white infants (14% versus 7%).[3, p. 8]

Rural-urban disparities in infant health. Rural-urban differences in IMRs vary by geographic region. In the South and West, the 1996-98 average IMR in nonmetropolitan counties was higher than that of metropolitan counties, while the reverse occurred in the Northeast and

Midwest. The death rate per 10,000 among infants in the rural South (8.7) was 20% higher than that (7.2) of the nation as a whole.[5, p. 101] In an analysis of the 1985-87 National Linked Birth Death Data Set, which controlled for known demographic and biologic risk factors, Larson, Hart, and Rosenblatt[6] found that residence in a nonmetropolitan county was independently associated with greater risk of late prenatal care and postneonatal mortality.

The percentage of South Carolina live births which were low birth weight (LBW) (<2,500 g) has increased from 8.6 in 1985 to 9.7% in 2000.[3, p. 8, 7, p. 33] Erkel and Michel[8] examined this trend by rural/urban locality. Both rural and urban counties had statistically significant (p > 0005) increases in the mean LBW rate between 1985 and 1999, but the rate of increase was similar (p = .972) on average. Over the years, however, the mean rates for LBW among rural counties were higher than among urban counties (p < .0005). See Figure 1.

Figure 1
% Low Weight Births, by Locality, South Carolina, 1985-1999



2. The Rural Minority Health Environment: Description and Scholarship

Little is actually known about the impact of the unique interrelationship between rural residence, minority status, and economic circumstance, although racial/ethnic differences and rural/urban differences in health status and health services can be documented.[9, 10, p. 236] Rural residents are particularly vulnerable to preventable health problems and those that can be treated with early, continuing care, as evidenced by more delayed care due to cost,[11, p. 29] less frequent physician and dentist[5, p. 72] visits, increased hospitalization rates for ambulatory-care-sensitive-conditions,[5, p. 74] obesity,[5, p. 38] increased activity limitation from chronic conditions,[5, p. 62] and

increased total tooth loss[5, p. 64] in comparison to urban residents. Availability of care in rural communities is limited by distance and health professional shortages. Barriers to use of existing services that are more characteristic of rural than urban populations include poverty (13% vs. 11%),[12, p. 2] lack of health insurance (23% vs. 18%),[11, p. 28] and unpaid sick leave for doctor visits (57% vs. 50%).[11, pp. 35-36] While a smaller proportion of rural than urban residents have no motor vehicle (4% vs. 11%),[13, p. 57] those without a vehicle are very unlikely to have access to public transportation: 88% of small communities (< 2,500 population) lack a public transportation system.[11, p. 26] Rural sociocultural characteristics, such as reduced anonymity, pride in self-reliance, distrust of outsiders, also contribute to underuse of services.[14, p. 131] The need to address rural health issues is substantiated by the recent initiation of the Rural Healthy People 2010 project at the Southwest Rural Health Research Center at Texas A & M University. The Center recognized "that rural areas frequently pose different and, in some instances, greater challenges than urban areas in addressing a number of Healthy People 2010 objectives."[15]

Problems in health care accessibility and availability are exacerbated for rural African Americans. According to Probst et al.,[16, pp. 24-26] who analyzed data from USA Counties 1998 and the February 2000 Area Resource File, in rural communities, African Americans are more likely than white Americans to experience poverty (34% vs. 14%) and live in a county:

- That is entirely or partly a Health Professional Shortage Area (71% vs. 64%)
- In the bottom quartile for the physician/population ratio (15% vs. 12%)
- Without a hospital (12% vs. 10%)

Availability of maternal-infant preventive services is compromised in rural communities. Availability of prenatal care has declined: Rural obstetricians decreased by 20% between 1984 and 1989,[17] and rural family physicians providing obstetric care decreased from 43% to 37% between1988 and 1992.[18] According to Colwill and Cultice,[19, p. 32] the maldistribution of

practitioners by specialty in counties of less than 50,000 population has not changed since 1980. Consequently, the proportion of physician visits to obstetricians and gynecologists in rural areas is less than in urban areas (3% versus 9% in 1996).[11, p. 33] The rural pediatrician-to-child population ratio in 1996 was one third the urban ratio: 12 versus 39/100,000 children <18 years.[20, p. 2] These disparities in availability of maternal-infant care may partially explain the independent association between nonmetropolitan residence and greater risk of late prenatal care and postneonatal mortality found in by Larson, Hart, and Rosenblatt.[6]

Hargraves[21] summarized the unique conditions faced by rural white women and rural women of color. He suggested these conditions contribute health disparities among women in rural, minority communities and called for further research on the health conditions related to the cumulative effects of these conditions and services designed to overcome them.[p.215]

> ...geographic and informational isolation, fragmentation of services, limitations regarding transportation, gender biases and inequalities, educational limitations, and disproportionate poverty. Women of color experience all of the above conditions in addition to the following: cultural differences; differences regarding health beliefs; racism; political, economic, and access inequalities; language barriers; migratory patterns that further fragment services and health care; and abject poverty.[p. 214]

3. Health Services for Rural, Minority Populations Inadequately Understood

Rural minority populations, including pregnant women and infants, have received inadequate attention from health-services and health-outcomes researchers. In a comprehensive review of research literature from 1970 to 1993, Mueller et al.[10] found only 158 peer reviewed investigations of health problems and health care access among rural minorities. Of these, 71 related to African Americans, 7 related to pregnant women or infants, and 3 related to African American pregnant women or infants.[pp. 241-244] Although most (86%) of the African American population is urban, nearly 5 million African Americans live in rural counties, most (69%) in the Southern belt of Louisiana, Mississippi, Alabama, Georgia, and South Carolina.[16, p. 19] The impact of maternal-infant health services among this sizeable population warrants focused study.

4. Home Visitation Using Lay Health Workers

The concept. Case management is a community-focused approach to augmenting prenatal and well child care which incorporates health education and social support. Case management is an integral part of the Healthy Start Program within the Health Resources and Services Administration, which currently funds 96 sites. Lay health care workers from the clients' community are thought to be influential in modifying behavioral and environmental determinants because of their common social, cultural, and environmental milieu. Shared communication patterns, health beliefs and values, understanding of barriers to care, and personal experiences (e.g., teen parenting) foster a provider-client relationship characterized by mutual trust, caring, and respect. Potential cost savings and a shortage of health professionals in rural areas provide further rationale for use of lay health workers.[22, p. 362, 23]

Previous studies of effectiveness. A review of studies evaluating the effectiveness of case management programs using lay health workers among low-income, largely urban African American women suggest that such programs increase use of prenatal care and pregnancy-related services and may decrease poor pregnancy and birth outcomes and cost of infant medical care.[24-34] However, this body of research suffers these limitations:

- Insufficient inclusion of rural populations
- Short-term measurement of outcomes
- Inconsistent pregnancy and birth outcomes
- Narrowly defined infant outcomes
- Scant study of cost effectiveness

5. Focus of This Report

This report presents the results of a small pilot study evaluating the effectiveness of a home visitation program using lay health workers. This program, unlike most of those represented in the

literature, is located in a rural area. We obtained data during its initial year of implementation. The purpose of our research was two-fold: To demonstrate a rigorous method for assessing program effectiveness and, within the limitations of a short time frame, to assess the effectiveness of the home visitation approach in reducing of maternal and infant health disparities in a rural area.

Chapter Two will provide a description of the home visitation program, Low Country Healthy Start Resource Mothers Program. The evaluation research design will be described, including rationale for restriction of the sample.

Chapter Three will present an analysis of the adequacy of maternal-infant preventive services, including the results of the impact of the Resource Mothers Program on prenatal care, postpartum check-up, and well child care. Second, the analysis of health outcomes will be presented, including the results of the impact of the Resource Mothers Program on pregnancy and birth outcomes, preventable short pregnancy interval among mothers, and preventable illness and injury among infants.

Chapter Four discusses conclusions and makes recommendations for further research and rural health policy. The Appendixes provide detailed methods and tables.

CHAPTER TWO

THE RESOURCE MOTHERS PROGRAM: PROGRAM CHARACTERISTICS AND EVALUATION

1. Description of the Resource Mothers Program

Healthy Start projects across the nation take different approaches to case management which is one of seven core interventions of the federally funded Healthy Start Initiative. The use of community based health workers varies from project to project. The Low Country Healthy Start Resource Mothers Program, which used lay health workers, was designed as a care coordination program primarily for low-income, African American pregnant women and their infants. The Program aimed to reduce racial disparities in pregnancy and birth outcomes and improve infant health in two rural, medically underserved counties in southwestern South Carolina.

Clients were referred to the Resource Mothers Program by physicians, nurse-midwives, nurses, social workers, and school personnel in the service area. When a referral was received, a master's prepared social worker visited the potential client in her home to determine eligibility, assess social service needs, and enroll the client, if eligible. Pregnant women receiving Medicaid with one or more of the following characteristics were eligible: age less than 20 or more than 35; previous low-weight birth, still birth, or fetal death; gave birth, or had a pregnancy that ended, less than 24 months ago; or history of high risk pregnancy.[35] Program services augmented customary prenatal care through home visits by lay health workers, who provided culturally-congruent social support and practical assistance with the nonmedical aspects of pregnancy and child care.

The Resource Mothers Program was initiated September 1, 1999, by Low Country Healthy Start under the auspices of the South Carolina Office of Rural Health. At the end of its first year of operation, the Resource Mothers Program included a staff of four lay health workers, also known

as *resource mothers,* and two master's prepared social workers. It was expected that each of the four resource mothers would carry a case load of no more than 35 pregnant women or mother-infant pairs. This goal was realized except in rare instances when a case load reached 40 clients (V. White, personal communication, February 19, 2004).

2. Evaluation Approach

Retrospective, population-based comparisons. Evaluation of service programs presents methodological challenges in the measurement of program effects. Participants in service programs may be different from others who are eligible but do not participate. Using an experimental design to control for threats to the validity of the findings is not feasible because clients cannot be randomly assigned to intervention and control groups. In this study, validity was strengthened by use of multiple comparison groups and statistical methods to control variables known to be associated with dependent variables during data analysis. Table 1 displays the criteria for inclusion and exclusion of subjects into the three comparison groups.

Table 1
Criteria for Inclusion/Exclusion of Subjects in the Study

Pregnant Medicaid women and their resulting infants, excluding multiple births:	
Study Group A_2	(a) in Allendale and Hampton Counties; (b) participated in the Low Country Healthy Start Resource Mothers Program; (c) delivery/birth occurred Nov 1999–May 2000
Same Counties Comparison Group A_1	(a) in Allendale and Hampton Counties; (b) delivery/birth occurred during the 2 years prior to initiation of Resource Mothers Program: Nov 1997–Oct 1999
Similar Counties Comparison Group B_1	(a) in Clarendon, Edgefield, Fairfield, and Lee Counties, where no similar case management program is offered; (b) delivery/birth occurred Nov 1999–May 2000

Selection of similar counties. In order to evaluate the impact of the Resource Mothers Program, similar comparison counties were selected in which there was no Healthy Start Program nor other home visitation program using lay health workers but whose social, pregnancy/birth status, and health resource characteristics were most similar to the Low Country Healthy Start service area counties. See Table 2.

Table 2
Selected Social, Perinatal Status, & Health Resource Indicators, by Location

Indicator	Location of Comparison Group	
	Study/Same Counties[a]	Similar Counties[b]
% Deliveries paid by Medicaid, 1998	78	66
% Low-weight births, 1998	10	12
% Less than adequate prenatal care, 1998	49	34
% Population living in urban areas, 1990	25	19
% Population nonwhite, 1998	60	57
Per capita income in dollars, 1998	17,597	16,986

Data compiled by the South Carolina Office of Research and Statistics in March 2001.
[a]Allendale and Hampton Counties. [b]Clarendon, Edgefield, Fairfield, and Lee Counties.

The Similar Counties were not contiguous to the program service area because they were selected using social, perinatal status, and health resource indicators rather than location as criteria. Figure 2 displays the location of study and comparison counties.

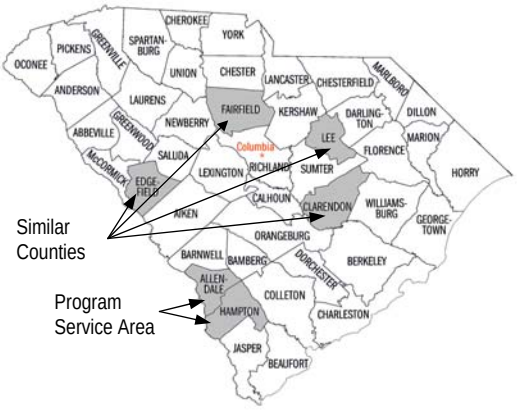


Figure 2. Resource Mothers Program Area & Similar Counties

Participants. All participants in the study were pregnant Medicaid women and their infants, excluding multiple births. Initially, the Study Group included 78 mother-infant pairs; the Similar Counties Comparison Group, 384; and the Same Counties Comparison Group, 455.

During its first year, the Resource Mothers Program served 123 pregnant women. Of these, only 78 were Medicaid recipients who had participated in the Program for at least 3 months before delivery (A home visitation intervention of less than 3 months would lack the strength to make an impact on its recipient.). Medicaid recipient numbers could not be matched for 12 mother-infant pairs, limiting the Study Group to 66 mother-infant pairs.

The Similar Counties Comparison Group was 384 pregnant Medicaid women and their infants, excluding multiple births, from Clarendon, Edgefield, Fairfield, and Lee Counties, whose delivery/birth occurred November 1999–May 2000. The Same Counties Comparison Group was

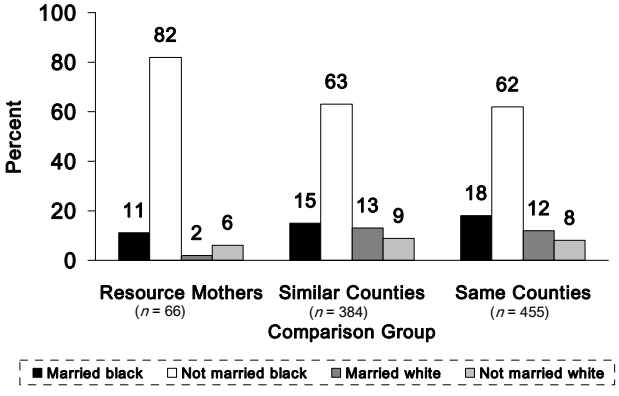
comprised of 455 pregnant Medicaid women and their infants, excluding multiple births, from Allendale and Hampton Counties, whose delivery/birth occurred during the 2 years prior to the initiation of the Program, November 1997–October 1999.

Data sources. Data for the study were obtained from the South Carolina Office of Research and Statistics (ORS), which manages the most complete set of state health and social services databases in the United States. ORS stores data electronically in a configuration that allows the linking of selected data to answer specific research questions. Through this South Carolina Data Warehouse, the Low Country Healthy Start Data File was linked to Vital Records Birth and Medicaid Data Files. All factors which could identify individual mothers and infants were deleted from the data set prior to release to the investigator.

3. Preliminary Analysis, Results, and Restriction of Sample

Data on adequacy of prenatal care was available for 866 mothers in the three study groups. Forty-six percent of women obtained adequate prenatal care. Marital status and race were associated with adequacy of prenatal care. Unmarried mothers were more likely than married mothers to obtain less than adequate care [Wald χ^2 (1, 866) = 6.57, p = .01, OR = 1.53]. Black mothers were more likely than white mothers to obtain less than adequate prenatal care, [Wald χ^2 (1, 866) = 1.76, p < .01, OR = 1.53]. The high-risk mothers who participated in the Resource Mothers Program were more likely than same county or similar county mothers to be unmarried and African American (p < .05). See Figure 3.

Figure 3. Percent Mother-Infant Pairs, by Marital Status, Race, & Group (N=905)



Given that participants in the Study Group were disproportionately high risk unmarried and black women, and that there were too few observations in other categories for statistical controls to be effective, the studied sample was restricted to single black mothers and their infants. This reduced the total number of mother-infant pairs from 905 to 565. The final sample for which mother and infant data could be matched included 39 mother-infant pairs in the Study Group, 243 mother-infant pairs in the Similar Counties Comparison Group, and 283 mother-infant pairs in the Same Counties Comparison Group. The low number of program mother-infant pairs constitutes a limitation to the study, but was imposed by the time frame during which the program was observed and lag times before data were available.

Secondary analysis design and assumptions about the sample. This study analyzed data on rural, African American mother-infant pairs who were Medicaid recipients. Data were collected by the (a) South Carolina Department of Health and Environmental Control Public Health Statistics and Information Services (birth certificate data), (b) South Carolina Department of Health and Human Services (Medicaid data), and (c) Low Country Healthy Start (participant list). Thus, for the purposes of this research, the investigators assumed that the sample shared the sociocultural characteristics and encountered the disparities in resources and barriers to use of existing services in rural minority communities discussed earlier (see pages 10 - 12). These include:

- Availability of care limited by distance and health professional shortages
- Use of existing services limited by poverty and Medicaid coverage
- No public transportation system for those without a personal vehicle
- Knowledge deficits related to maternal and infant health promotion and illness prevention
- Culture-specific health beliefs and patterns of care patterns (i.e., rural, Southern, African American)

CHAPTER THREE

ANALYSIS AND INTERPRETATION OF RESULTS

1. Characteristics of Studied Mothers

The average age at time of delivery was 22 among the 565 low-income, unmarried, African American mothers. Of these, 15% were less than 18 years old. Nearly one third (30%) had not completed high school. Nearly half (46%) were first-time mothers. Among the 85 teenagers, 15% had previously given birth. Prenatal care began, on average, in the fourth month of pregnancy; only 56% obtained early prenatal care. While the majority (59%) of mothers were diagnosed with conditions placing them at medical risk for this pregnancy, such as anemia, chlamydia, diabetes, eclampsia, or hypertension, only 20% were medically supervised for a high risk pregnancy. Characteristics of the Study Group and the Similar and Same County Comparison Groups were similar. (Table B-1, p. 38)

2. Adequacy of Maternal-Infant Preventive Services

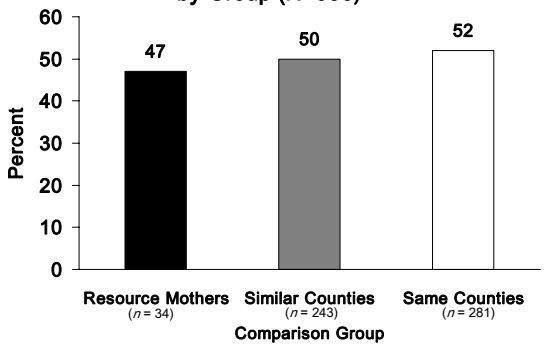
A. Prenatal Care

Adequate prenatal care was defined as prenatal care initiated in the first 3 months of pregnancy *and* the mother obtaining the number of medical visits for length of pregnancy recommended by the Institute of Medicine. For example, for a pregnancy of 36 weeks duration at birth, a minimum of nine visits is recommended.[36, p. 1008] Less than half (46%) of the sample obtained adequate prenatal care, defined as meeting both criteria. Resource mothers (42% with adequate care) did not differ statistically from the Same Counties (43%) and Similar Counties (50%) comparison groups. (Table B-2, p.39)

B. Postpartum Check-Up

Half (51%) of all mothers obtained a postpartum check-up between 4 to 8 weeks following delivery, with no difference among the three groups. (Figure 4 and Table B-2, p. 39)

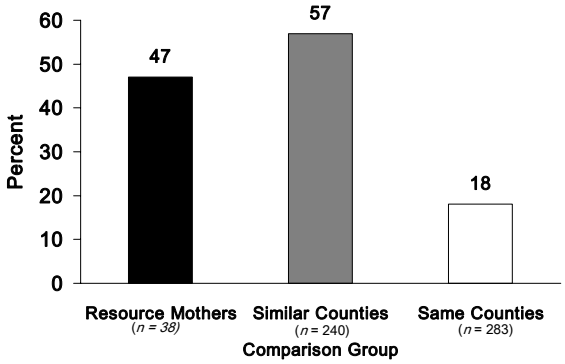
Figure 4. Percent Adequate Post Partum Care, by Group (*N*=558)



C. Well Child Care

Among all infants in the sample, just over one third (37%) obtained adequate preventive services, defined as at least four well child visits by age 1 year. Infants in the Study Group (47%) were nearly 3 times as likely as those in the Same Counties Comparison Group (18%) to obtain adequate preventive care ($p < .0001$). Adequacy of infant preventive services in the Study and Similar Counties Groups (55%) were equivalent. See Figure 5. (Table B-2, p. 39)

Figure 5. Percent Adequate Well Child Care, by Group (*N*=561)

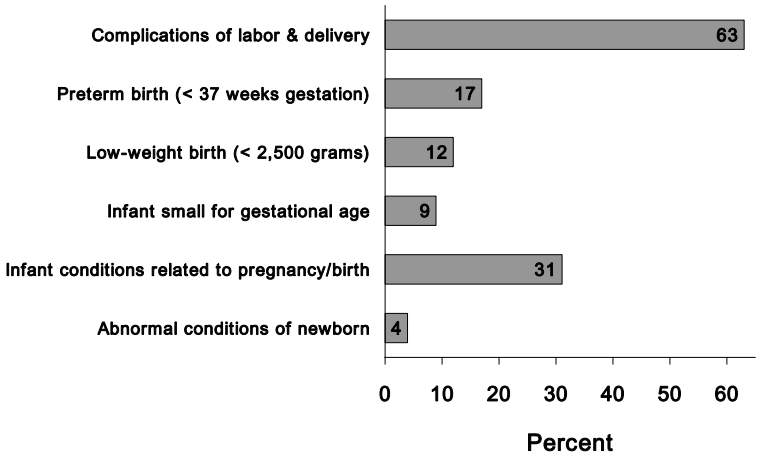


3. Health Outcomes

A. Pregnancy and Birth Outcomes

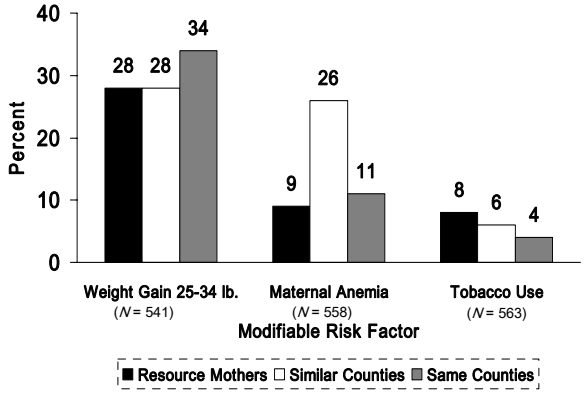
A favorable outcome of pregnancy and birth was defined as the uncomplicated labor and delivery of a healthy, full-term baby weighing at least 5½ pounds (2,500 grams). Pregnancy and birth outcomes were similar among the Study and Comparison Groups: Nearly two thirds of mothers and one third of infants experienced an unfavorable outcome. No infants in the sample died during their first year of life. See Figure 6. (Table B-3, p. 40)

Figure 6. Percent Pregnancy and Birth Outcomes
Among All Mother-Infant Pairs (*N* = 565)



Factors related to poor pregnancy and birth outcomes. Both inadequate and high weight gain during pregnancy are related to poor pregnancy outcomes, such as small or large babies and cesarean delivery.[37, 38] Optimal weight gain is 25 to 35 pounds for women whose prepregnancy body mass is within normal limits.[39, p. 10] There was no difference in the patterns of weight gain during pregnancy between groups. However, mothers in the Similar Counties Comparison Group were more likely to have been diagnosed with anemia during pregnancy than those from the Study and Same Counties Comparison Groups. See Figure 7. (Table B-4, p. 41)

Figure 7. Percent Mothers, by Modifiable Risk Factor and Group

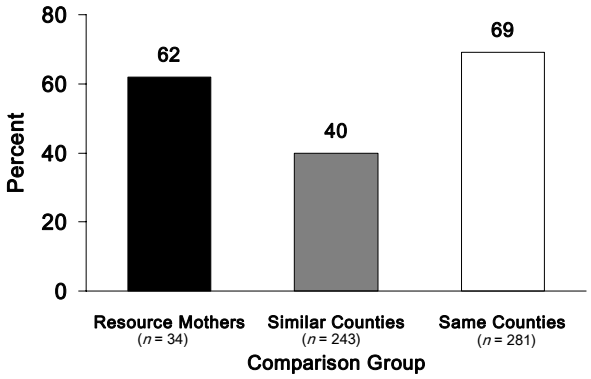


Maternal smoking and alcohol use also adversely affect birth weight and infant growth and development.[40-43] Five percent of the sample used tobacco and 1% drank alcohol during pregnancy, with no difference between groups. (Table B-5, p. 42)

B. Prevention of Short Pregnancy Interval

Infants born to women who space their pregnancies 2 years apart are more likely to be full-term and of normal birth weight compared to those born to women with shorter or longer pregnancy intervals.[44, 45] More than half of the mothers in the sample (56%) became pregnant within 12 months of delivery. Mothers in the Similar Counties Comparison Group were least likely to experience a short pregnancy interval following this birth ($p <$ .0001). See Figure 8. (Table B-5, p. 42)

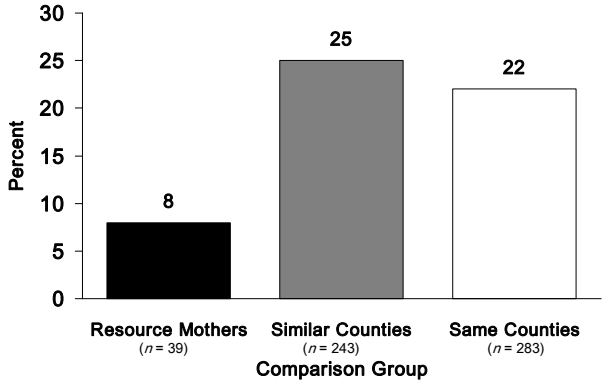
Figure 8. Percent Mothers Pregnant Within 12 Months After This Birth, by Group



C. Preventable Illnesses and Injuries Among Infants

Health education for mothers related to parenting, breast feeding, infant sleeping position, infant safety, and hygiene can reduce the frequency of diarrhea, respiratory infections, ear infections, child abuse and neglect, and unintended injuries.[46, pp. 9_14, 15_3-5, 16_8-9] Most (78%) infants in the sample were not treated for a preventable medical condition during their first 60 days of life, and only 9 infants were hospitalized for a preventable condition (Similar Counties, 2; Same Counties, 7). Infants in the Study Group were one third as likely as those in the Similar and Same Counties Comparison Groups to experience medical treatment for preventable illness and injury (p =.0589). See Figure 9. Given the small size of the Study Group and the relatively large effect

Figure 9. Percent Infants With 1 or More Visits for Preventable Medical Conditions, by Group (N = 565)

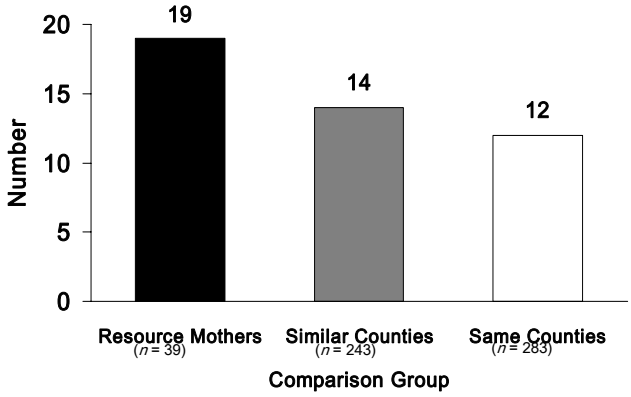


size, this tendency could possibly have been statistically significant with a larger subsample. (Table B-6, p. 42)

D. Encounters for Nonpreventable Conditions

Our analysis indicates that infants in the Study Group were in poorer health than those in the Similar and Same Counties Comparison Groups. The average number of medical visits for nonpreventable conditions during the first 60 days of life among infants in the Study Group was greater than that among infants in the Similar and Same Counties Comparison Groups ($p < .0001$). See Figure 10. (Table B-7, p. 42)

Figure 10. Mean Number Medical Encounters for Nonpreventable Conditions, by Group ($N = 565$)



For hospitalized infants, the average length of stay for nonpreventable conditions was between 4 and 5 days. There was no difference between groups ($p > .05$). (Table B-8, p. 42)

CHAPTER FOUR

CONCLUSIONS AND POLICY IMPLICATIONS

Given the purpose of the pilot study (to test feasibility of the design and procedures), the small Study Group sample size (39 mother-infant pairs), and generation of data during first year of operation of the home visitation program, statistical results must be interpreted with caution. Our findings may also be biased by the poorer health of infants in the Study Group versus those in either Comparison Group. However, we believe that we have demonstrated that a retrospective, population-based, comparative design is a feasible method for evaluating the effect of a maternal-infant home visitation program on adequacy of preventive services and health outcomes. Preliminary findings indicate that lay health workers may contribute to improved rates of well child care and preventable conditions, warranting further study.

1. Discussion of Results

A. The Evaluation Process

One purpose of the project was to ascertain that it was feasible to conduct an evaluation of a maternal-infant intervention, linking programmatic Healthy Start data to other data bases, including Vital Records and Statistics (birth certificate) and payer (Medicaid). We found that this process was feasible, but more time consuming and challenging than originally anticipated. Changes that we would suggest for future researchers include:

- Sample from a period when the program is fully operational. Our project used data from the first year of operation of Low County Healthy Start Resource Mothers Program. Delays in staffing, and therefore outreach activities, reduced the number of mother-infant pairs available for study, thus reducing study power. Differences between study infants and others—study infants appear to have been, by chance, in

poorer health—further weakened the ability of the study to demonstrate the effectiveness of lay worker intervention. In addition, the first few months of program operation may not have been representative of the program at full strength

- Extend the period of observation of the infant. Our study, paralleling others, found few differences between study and comparison mothers with regard to prenatal and post-partum care. It did, however, find an improved rate of well child visits among study infants and a tendency for them to have fewer visits for preventable conditions. If education of the mother regarding effective child care results in fewer preventable illnesses, the effects of the intervention may stretch across the first few years of life. At minimum, future researchers should assess program outcomes and cost-effectiveness through the first year of life, with assessment across the first 2 years being preferable.

B. Adequacy of Maternal-Infant Preventive Services

Late prenatal care. In order to obtain adequate prenatal care, which is associated with healthy pregnancy and birth outcomes, a woman must begin prenatal care within the first 3 months of pregnancy. Among our sample of 565 impoverished rural, black mothers, 44% began prenatal care in their 4th month of pregnancy or later. This proportion was higher than that of black women in the United States (26%) and South Carolina (30%) in 2001.[49, p. 67] Late initiation of care was not unexpected given that the intervention was aimed at locating and serving persons at high risk for not seeking or obtaining prenatal care. A question for future study is whether or not rural residence and economic circumstance contribute to inadequate care among black women.

Post partum check-up. Results from our small pilot study found that participation in a home visitation program made no difference in the rate of adequate post partum care, which was 51% across the three comparison groups. This finding is consistent with a 1995-96 survey of 15 largely urban Healthy Start care coordination projects, which found no difference in adequacy of

post partum care between participants and nonparticipants. In the 1995-96 survey, nearly 65% of mothers obtained a postpartum check-up. However, in the 1995-96 survey, post partum care was measured at 6 months following delivery rather than 8 weeks, as in our study.[26, p. 56]

Well child care. Studies of home visitation programs have reported mixed results in increasing adequacy of well child clinic visits among low-income infants, whether the case manager was a public health nurse[50-52] or a lay health worker.[25, 53, 54] We found that infants in the Study Group were 3 times more likely to obtain adequate well child visits than infants in the Same Counties Comparison Group. Given the small size of our Study Group (n = 39), this is an important finding that warrants further investigation.

It is noteworthy that our rural sample had a substantially lower rate of adequate well child visits (55%) than a similar, but urban population. Schuster et al.[54, p. 1001] used a population-based, randomized control design (N = 365) to study the impact of case management on adequacy of well child care among low-income African American infants in South Central Los Angeles. Eighty-one percent of infants who had received at least four home visits during their first year of life obtained adequate (4 or more) well child clinic visits by age 1 year, as opposed to 70% of infants in the control group (p = .012). The adequacy of well child visits in the South Central Los Angeles sample was comparable to the national rate among children aged 3 to 17 years (77%)[55], while our sample was not. No national surveillance data for adequacy of well child care for infants was available for comparisons.

C. Health Outcomes and Care Patterns

Birth weight. Rates of premature and low-weight births were similar among our three groups (p > .05) and comparable to those across the nation in 2001.[49, p. 56] Seventeen percent of infants in our sample were born early,[1] comparable to 18% of black infants but higher than 11% of

[1]Less than 37 weeks from conception to birth.

white infants nationwide.[49, p. 80] Low birth weight infants comprised 12% of the sample, similar to 13% of black infants but higher than the 7% of white infants across the nation.[49, p. 82]

Maternal-infant morbidity. Both mothers and infants in our three groups experienced higher rates of morbidity related to pregnancy than the general population of mothers and newborns. In our sample of 565 rural, black, low-income mothers, 63% experienced complications of labor and delivery. An analysis of National Hospital Discharge Survey data for women who gave birth between 1993 and 1997 found that 43% of mothers had complications of labor and delivery.[56] Prevalence rates varied from state to state. A study of conditions reported on Oregon birth certificates in 2000 found that 22% of first-time mothers of single infants experienced complications at labor and delivery[57, p. 2] while the New Jersey Department of Health and Senior Service reported a 43% prevalence rate among non-Hispanic black mothers in 1999.[58]

Infants in our pilot study experienced an unusually high rate of conditions related to pregnancy and/or labor and delivery (e.g., disorders related to short pregnancy and low birth weight, respiratory distress, drug withdrawal, etc.). The 31% prevalence rate for infants in the sample is 8 times the 4% prevalence rate among of nonwhite Medicaid infants in South Carolina in 2001.[59] Given the exploratory nature of our pilot work, this finding is not definitive and warrants further investigation.

Modifiable risk factors for poor pregnancy and birth outcomes. Less than one third (30%) of our sample achieved optimal weight gain during pregnancy, which is 25 to 34 pounds. Nearly half (45%) gained less than 25 pounds, while one fourth (25%) gained over 34 pounds. While this pattern is of concern, it is comparable to that among African American mothers nationwide.[49, p. 54]

Five percent of the sample in our pilot study used tobacco during pregnancy, slightly lower than the 8% reported for unmarried black women giving birth in South Carolina in 2001.[60] One percent of the sample reported alcohol use, no higher than the national average[49, p. 14] but

considerably lower than the 10% reported for unmarried black mothers in South Carolina in 2001.[60] Both smoking and alcohol use are underreported on the birth certificate.[49, pp. 13-14] However, our pilot data are consistent with the national data.

Prevention of short pregnancy interval. Over half (55%) of mothers in the pilot study became pregnant within 12 months of delivery. Mothers in the Study Group (62%) and Same Counties Comparison Group (69%) were more likely than those in the Similar Counties Comparison Group (40%) to experience a short pregnancy interval following this birth ($p <$ .0001). These rates are considerably higher than national baseline data: In 1995, 14% of black mothers aged 15 to 44 years gave birth within 24 months of a previous birth.[46, p. 9_13]

Illness and injury among infants. Our finding that infants in the Study Group were one third as likely as those in the Similar and Same Counties Comparison Groups to experience treatment for preventable illnesses and injuries fell short of statistical significance (p =.0589). Given the small size of the Study Group (n = 39) and relatively large size of the Same (n = 283) and Similar (n = 243) Counties Comparison Groups, this result suggests one potential area in which community health worker programs may contribute to improved health outcomes.

It is unlikely that Study Group infants were less likely to seek medical care for preventable conditions since they were more likely to obtain medical care for nonpreventable conditions than infants in both Comparison Groups ($p <$ .0001). Furthermore, they were 3 times more likely to obtain adequate well child visits than infants in the Same Counties Comparison Group ($p <$ .0001). Both patterns of care are indicative of preventive care behaviors which might be attributed to culturally appropriate health promotion activities of lay community health workers.[61, pp. 199-202, 62, p.123]

2. Recommendations for Further Research

In order to address the racial disparities in the health of African American pregnant women and their infants in low-income rural communities in light of scarce financial resources, cost effective interventions must be identified. It is critical to dispel the ambiguity surrounding the cost effectiveness of home visitation programs using lay health workers to improve infant health and decrease the cost of medical care. In FY 2001 the Health Resources and Services Administration[63] allocated $82.6 million to 106 Healthy Start projects to provide care coordination services to impoverished at-risk populations. This figure was expected to increase to $91.6 million in FY2003. Is the program cost to achieve adequate maternal-infant preventive services for mothers and their infants a wise investment?

The care coordination program evaluation reported here focused on rural mothers and their infants, measured patterns of preventive care, pregnancy and birth outcomes, and infant health in the first 60 days of life. It tested analytical methods for cost of medical care in the first 60 days of life and measuring the dollar cost of an effective intervention for program participants. However, the number of mother-infant pairs in the Study Group was small (39) and had participated in the intervention during its first year of implementation, when the home visitation protocol and procedures for data reporting were being established. Thus we recommend:

- Further investigation of the effectiveness and cost effectiveness of maternal-infant home visitation programs among rural, minority populations in underserved areas. The Cost Effectiveness Ratio for assessing adequacy of preventive services appears, based on preliminary testing, to be a feasible analytic approach.
- Particular attention to systematic measurement of the impact of a lay home visitation program on health-related behaviors. Our preliminary findings indicated the possible positive impact of lay health workers on increasing adequacy of well child visits and

decreasing encounters for preventable illness and injury among infants.

- Research efforts extend the monitoring of effects of care coordination on children past the perinatal period, as the greatest effects of the intervention is likely to be on infant care and health. We recommend evaluation through the first 2 years of life.
- Process evaluation should be incorporated into the research design to monitor the quality of program implementation and data reporting.
- Data included in formal program evaluation should be drawn from the period when the program is at full strength, with all staff and systems operational.

3. Programmatic Recommendations

As a preliminary evaluation effort primarily designed to assess the feasibility of rigorous study of the Resource Moms program, our research does not yield broad programmatic recommendations regarding provision of services. However, as evaluators, we note that an effective community-focused maternal-infant health promotion program will produce changes in client knowledge, beliefs, behavior, and/or environmental conditions, which in turn facilitate achievement of improved infant health and decreased medical costs. Such changes will fail to be detected unless effective data capture procedures are in effect. We recommend that all Healthy Start programs apply continuous quality improvement techniques to primary data collection. Without consistent, reliable and timely data collection, program evaluation results are jeopardized and the ability to make future policy recommendations threatened.

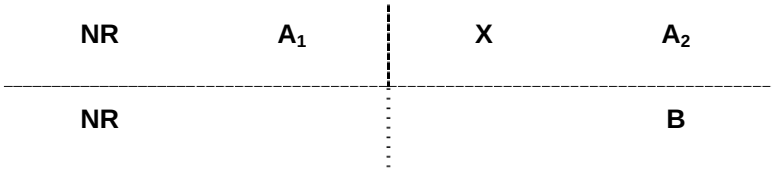
APPENDIX A

METHODS

1. Design of the Study

Overview. A retrospective, population-based, posttest-only design using an independent pretest sample measured the impact of a home visitation program using indigenous paraprofessionals to provide health education, referral, and social support to rural, African American pregnant Medicaid recipients and their infants. Secondary analysis of selected data elements from the Vital Records Birth, Medicaid Data, and Low Country Healthy Start Data files examined adequacy of maternal-infant preventive services, maternal behaviors which adversely affect pregnancy outcomes and infant health, health outcomes, and cost effectiveness. Hypotheses were tested at the $\alpha = .05$ level using nonparametric statistics. See Figure A-1.

Figure A-1. Population-Based, Posttest-Only Design Using an Independent Pretest Sample (*N* = 565)



NR = nonrandom. A_1 = Same Counties Control Group (*n* = 283). A_2 = Study Group (*n* = 39). B = Similar Counties Control Group (*n* = 243).

2. Setting and Sample

The intervention to be measured and rationale for its selection. The intervention measured was the Low Country Healthy Start (LCHS) Resource Mothers Program, a care coordination program primarily for African American at-risk pregnant women and their infants who lived in Allendale and Hampton Counties, SC. This program was selected because its aim was to reduce racial disparities in perinatal outcomes and improve infant health in a rural,

medically underserved area through enhanced coordination of care across settings and providers. While other women who met eligibility criteria were not excluded,[35] the target population was rural, low-income, pregnant African American women and their infants.

The Resource Mothers Program was initiated September 1, 1999, in Allendale and Hampton Counties by Low Country Healthy Start under the auspices of the South Carolina State Office of Rural Health, funded through the Healthy Start Initiative of the Maternal and Child Health Bureau. The program was administered by the director of Low Country Healthy Start. By the end of the first year of operation, the core staff included four indigenous paraprofessionals, known as "resource mothers," and two master's prepared social workers. Space and secretarial support for the Resource Mothers Program staff was provided in the Low Country Healthy Start office in Denmark, SC.

Pregnant women with one or more of the following characteristics were eligible for services: age < 20 or > 35; previous birth was low-weight (< 2,500 grams), still birth, or fetal death; interpregnancy interval < 2 years; and history of high risk pregnancy or psychosocial risk factors.[35] Potential clients were referred to the program for case management services by physicians, nurse-midwives, nurses, social workers, and school personnel in the service area.

The Resource Mothers Program augmented customary prenatal care by providing culturally-congruent social support and practical assistance with the nonmedical aspects of pregnancy and child care. Case management services provided during home visits, hospital visits, and telephone calls included:

a. Facilitation – making it easy for mothers to access community services to support their needs;
b. Education – instructing mothers about pregnancy, childbirth, child development, parenting, and decision making for future education and employment;

c. Role modeling – providing an example for effective parent/child relationships;

d. Reinforcement – praising the mother for positive behaviors as well as attempts at change;

e. Support – listening, helping the mother explore alternatives, coaching during labor and delivery[64]

The resource mothers made home visits to pregnant women in their case loads weekly or biweekly, depending on need. After delivery, weekly visits were followed by gradually decreasing visits over 1 year. Each visit was structured by specific goals and instructional guidelines provided by the "Partners for a Healthy Baby" prenatal and infancy curricula.[65] Through culturally-congruent health education, referral, and social support, resource mothers supplemented and reinforced the prenatal and child health care obtained by clients from their health care providers.

Criteria for selection of case managers included personal warmth, successful parenting, knowledge of community resources, acceptance of responsibility, natural leadership, residence in and shared culture with the community. Upon hiring, each case manager underwent 1 week of intensive training in the "Partners for a Healthy Baby" prenatal and infancy curricula. "Wrap Around Training" (2-4 hours of continuing education) occurred every 2 weeks thereafter.[35]

Close supervision of the perinatal resource coordinators was provided by the master's prepared social workers. The social worker modeled the home visiting process weekly during the first month the resource mother was employed and monitored the process monthly through joint home visits. The resource mother and social worker discussed complex and difficult client problems in a weekly Case Review Conference. Newly enrolled, discharged, and problem cases were discussed in a weekly Staffing Conference.[35]

Description of the Low Country Healthy Start service area. Allendale and Hampton Counties are located in southwestern South Carolina. In 2000 the population[66] of the service area

totaled 32,456. The area is very rural, with only 4,018 residents in the largest town. A relatively high proportion of residents were poor (26%) and African American (61%) compared to the nation as a whole (12% poor; 12% African American). The 1998-2000 mean IMR in the service area (11.2 per 1000 births) is higher than the national rate (7.0), with the death rate among black infants (12.1) over 5 times that of white infants (2.3).[3, p. 8, 7, p. 33] In 2000, a higher proportion of low birth weight infants were born in the service area (10%) than the nation (6%), with the rate more than twice as high among black than white infants (12% vs. 5%).[3, pp. 49-51, 67, p. 16] In 2000, the teen pregnancy rate (pregnancies per 1,000 women 15-17 years old) in Allendale County (87.5) was 359% higher than that of the nation (24.4), while the rate among the Allendale County black population (95.2) was 381% higher than the rate among the white population (25.0).[3, pp. 69-71, 67, p. 47] Sixty-eight percent (322/476) of live births in the two counties in 2000 were African American,[60] and approximately 84% of births occurred out of county (ranging from 56% in Allendale County to 99.5% in Hampton County.[68]

Comparison counties. Counties for the Similar Counties Comparison Group were selected from South Carolina counties in which there was neither Healthy Start Program nor other case management program using indigenous paraprofessionals but whose social, perinatal status, and health resource characteristics were most similar to the Low Country Healthy Start service area counties by the South Carolina Office of Research and Statistics. The public health nurse supervisor in potential comparison counties was called to verify that no ongoing programs similar to the Low Country Healthy Start Resource Mothers Program were operating in that county. See Table A-1.

Table A-1
Selected Social, Perinatal Status, & Health Resource Indicators, by Location

Indicator	Location	
	Service Area[a]	Similar Counties[b]
% Deliveries paid by Medicaid, 1998	78	66
% Low-weight births, 1998	10	12
% Less than adequate prenatal care, 1998	49	34
% Population living in urban areas, 1990	25	19
% Population nonwhite, 1998	60	57
Per capita income in dollars, 1998	17,597	16,986

Data compiled by the South Carolina Office of Research and Statistics in March 2001.
[a]Allendale and Hampton Counties. [b]Clarendon, Edgefield, Fairfield, and Lee Counties.

The study assumed that subjects in the comparison groups obtained customary maternal-infant preventive services. Customary prenatal care includes prenatal check-ups and health education delivered by health professionals in health departments, community health centers, rural health clinics, and physician offices. Customary infant care includes well-child check-ups and immunizations. High risk mother-infant pairs may have received home visits as needed by county health department medical social workers or public health nurses through Family Support Services, if resources are available. All counties in the Service Area and Similar Counties Comparison Group were entirely or partially designated as Health Professional Shortage Areas for primary care, dental, and mental health professionals.[69]

Criteria for inclusion/exclusion of subjects in the study. See Table A-2.

Table A-2. Criteria for Inclusion/Exclusion of Subjects in the Study

Pregnant Medicaid women and their resulting infants, excluding multiple births (which tend to be low weight[70, p. 275]):	
Study Group A_2	(a) in Allendale and Hampton Counties; (b) participated in the Low Country Healthy Start Resource Mothers Program; (c) delivery/birth occurred November 1999–May 2000
Same Counties Comparison Group A_1	(a) Allendale and Hampton Counties; (b) delivery/birth occurred during the 2 years prior to initiation of Resource Mothers Program: November 1997–October 1999
Similar Counties Comparison Group B	(a) in Clarendon, Edgefield, Fairfield, and Lee Counties, where no similar home visitation program was offered; (b) delivery/birth occurred November 1999–May 2000

Sample size. Study Group = 39 mother-infant pairs. Same Counties Comparison Group = 283 mother-infant pairs. Similar Counties Comparison Group = 243 mother-infant pairs. The small number of observations in the Study Group is recognized as a principal limitation of this study.

Sampling method. This study used a nonprobability, population-based sample of convenience with nonrandom assignment to groups. All (100%) mother-infant pairs meeting selection criteria during the time frame for inclusion were included in the sample. This sampling method is appropriate in evaluation research where interventions can only be implemented in intact service areas.

3. Variables and Their Measurement

Measures of dependent/outcome variables and demographic characteristics of subjects were obtained by linking three state electronic data sets: Low Country Healthy Start Data File, Vital Records Birth File, and Medicaid Data File. Selected data elements from the three data sets were obtained through the South Carolina Office of Research and Statistics. Applications for release of data stored by the Office of Research and Statistics were made and approved following approval of the study by the Medical University of South Carolina Institutional Review Board. Table A-3 displays the independent and dependent/outcome variables and their measurement by hypothesis/research question

Table A-3
Variables, Their Measurement, and Data Source, by Hypothesis / Research Question

H_1	Rural, low-income pregnant women who had prenatal care augmented by a home visitation program using indigenous paraprofessionals, relative to those who obtain customary prenatal care, are more likely to obtain adequate prenatal care
Independent variable:	Prenatal care augmented by a home visitation program using indigenous paraprofessionals *versus* customary prenatal care
How determined:	Participation *versus* nonparticipation in the Resource Mothers Program
Dependent variable:	Adequate prenatal care
How determined:	An adequate *versus* less than adequate Kessner Index, where 1 = Adequate; 2 = Intermediate; 3 = Inadequate[36]
Data source:	Vital Records Birth File

Note: The Kessner Index defines adequate prenatal care as care initiated in the first trimester of pregnancy and the number of medical visits for gestation at birth recommended by the Institute of Medicine (e.g., a minimum of nine visits for a birth of 36 weeks gestation or longer)[36, p. 1008]

H_2	Rural, low-income pregnant women who experience prenatal care augmented by a home visitation program using indigenous paraprofessionals, relative to those who obtain customary prenatal care, are less likely to demonstrate behavioral risk for poor birth outcomes
Independent variable:	Prenatal care augmented by a home visitation program using indigenous paraprofessionals *versus* customary prenatal care
How determined:	Participation *versus* nonparticipation in the Resource Mothers Program
Dependent variable:	Behavioral risk for poor birth outcomes
How determined:	Presence of one or more of the following: (a) tobacco use, (b) alcohol use, (c) inadequate weight gain during pregnancy *versus* absence of all three[46]
Data source:	Vital Records Birth File
H_3	Rural, low-income pregnant women who experience prenatal care augmented by a home visitation program using indigenous paraprofessionals, relative to those who obtain customary prenatal care, are more likely to have a favorable perinatal outcome
Independent variable:	Prenatal care augmented by a home visitation program using indigenous paraprofessionals *versus* customary prenatal care
How determined:	Participation *versus* nonparticipation in the Healthy Start Case Management Program
Dependent variable:	Favorable perinatal outcome
How determined:	Absence of all of the following: (a) preterm birth (gestational age < 37 weeks), (b) low birth weight (< 2,500g), (c) small for gestational age (< 2,500g + ≥ 37 weeks), (d) complication of labor and delivery, (e) abnormal condition of newborn, (f) infant hospitalization for condition related to perinatal period, (g) maternal hospitalization for post partum complication *versus* presence of one or more[70, p. 476, 71, 72, p. 461, 73]
Data source:	(a) to (c) Vital Records Birth File; (d) to (g) Medicaid Data File
H_4	Infants of rural, low-income families who experience a home visitation program using indigenous paraprofessionals, relative to those who do not, are more likely to obtain adequate preventive child health care
Independent variable:	Child health care augmented by a home visitation program using indigenous paraprofessionals *versus* customary child health care
How determined:	Participation *versus* nonparticipation in the Resource Mothers Program
Dependent variable:	Adequate preventive child health care
How determined:	Presence of both of the following: four well child visits by age 1 year
Data source:	Medicaid Data File
H_5	Infants of rural, low-income families who experience a home visitation program using indigenous paraprofessionals, relative to those who do not, are less likely to experience preventable illnesses and injuries related to modifiable risk factors
Independent variable:	Child health care augmented by a home visitation program using indigenous paraprofessionals *versus* customary child health care
How determined:	Participation *versus* nonparticipation in the Resource Mothers Program
Dependent variable:	Preventable illnesses and injuries related to modifiable risk factors
How determined:	Number outpatient, emergency room, and hospital encounters for diarrhea; respiratory infection; ear infection; injury, poisoning, and preventable accidents; child maltreatment; and sudden infant death syndrome[46, 74-77]
Data source:	Medicaid Data File

Control variables. Five demographic characteristics of the mother were selected and dichotomized for use as control variables in the analysis of maternal data because of their association with adequacy of prenatal care and pregnancy outcomes.[4] These five variables are: age (< 18/18+), race (black/white), marital status (unmarried/married), education (< 12 years/12 years+), and previous pregnancy (0/≥1). In the analysis of infant data, race of infant will be

dichotomized (black/white) for use as a control variable because of its association with adequacy of vaccination coverage[46, p. 14_36] and preventable health outcomes.[78-80]

4. Procedure

a. The South Carolina Office of Research and Statistics identified Study Group mother-infant pairs by selecting first-year participants in the Resource Mothers Program from the Low Country Healthy Start Data File. The Office of Research and Statistics used a personal identifier to link Study Group mother-infant pairs and their Low Country Healthy Start data elements to requested data elements from the Vital Records Birth and Medicaid Data Files.

b. The Office of Research and Statistics used a personal identifier to link the requested data elements from the Vital Records Birth and Medicaid Data Files for mother-infant pairs in the Similar Counties and Same Counties Comparison Groups.

c. The Office of Research and Statistics created a master electronic data file which contained linked data elements for mother-infant pairs in the Study and Comparison Groups. The Office of Research and Statistics de-identified all subjects in the master file by substituting codes for personal identifiers. All personal identifiers that could link subjects to data were destroyed by the Office of Research and Statistics prior to release to the principal investigator in a Microsoft Excel electronic file. See Figure A-2.

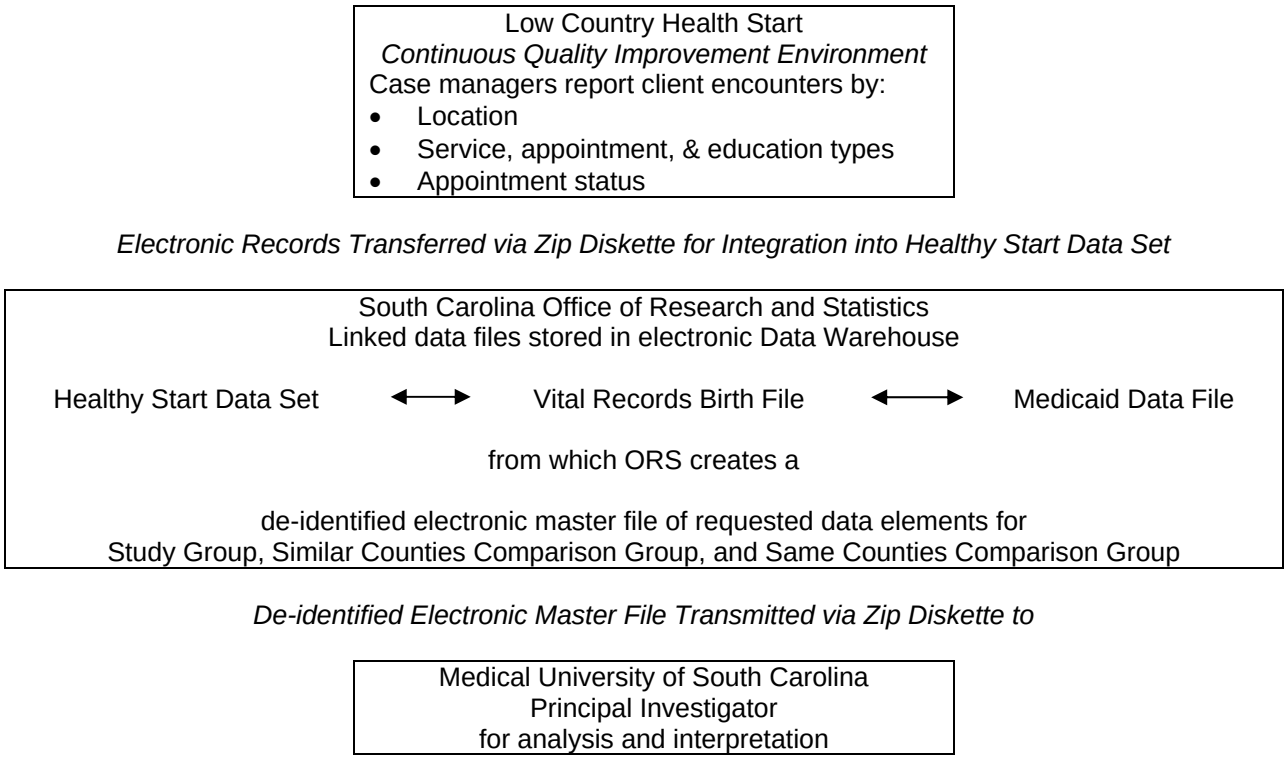


Figure A-2. Procedure.

5. Plans for Data Analysis

Simple descriptive statistics were calculated for the respondents, summarizing characteristics of the sample. Responses were compared by group (number and percent). Two-way contingency table analyses were conducted using the Fisher Exact Test for equivalent proportions to evaluate whether: (a) demographic characteristics (control variables) of the Study Group differed from those of the Comparison Groups; (b) participation/nonparticipation in the intervention was related to adequacy of maternal-infant preventive services, behavioral risk for birth outcomes, and perinatal outcomes. The Kruskal-Wallis one-way analysis by ranks test assessed whether participation/nonparticipation in the intervention was related to: (a) encounters for preventable illness and injury among infants, (b) encounters for nonpreventable conditions among infants, and (c) cost of medical care for the first 60 days of life.

6. Limitations of Methods

One limitation of the proposed study is the scope of the cost analysis. Ideally, we would conduct a comprehensive cost-effectiveness study that assesses the full array of costs (both direct and indirect) and converts outcomes to standard measures of effectiveness (e.g., Quality Adjusted Life Years or Disability Adjusted Life Years). Such a cost effectiveness analysis is beyond the scope of this study.

The most serious threat to the internal validity of the proposed study is that groups of subjects are compared that may differ on confounding variables due to nonrandom assignment. Internal validity was strengthened by use of multiple comparison groups and statistical methods to control variables known to be associated with dependent variables during data analysis. A second threat, present in the comparison of the Study Group to the Same Counties Comparison Group, is that unidentified, differing events in the subjects' environment may influence the dependent variables. The inclusion of the Similar Counties Comparison Group addresses this limitation.

A third threat to internal validity is that the quality of the data is dependent on the accuracy of records. This study performs secondary analysis of relevant data elements from live birth certificate and Medicaid claims data sets. Research[81-83] conducted to validate birth certificate data has matched birth certificates to data abstracted from medical records. Findings from these studies suggest a high degree of agreement for gravidity, parity, birth weight, Apgar score, and method of delivery. Other items were underreported, such as alcohol and tobacco use, medical history, complications of labor and delivery, and obstetrical procedures. Medicaid claims for billed visits showed a very high degree of correspondence with medical records.[84] These studies suggest that if data elements are selected with care from birth certificate and Medicaid data files, aggregate analyses will be valid for maternal-child research and evaluation.

It is recognized that study results may not be generalized to the larger population due to nonrandom selection of subjects. External validity was enhanced by comparing study results to results of previous studies.

Alternative designs. A pretest-posttest control group design would eliminate historical threats introduced by using nonidentical time frames for the Same Counties Comparison Group and Study Group. However, this design was not possible with an intervention directed to the outcomes of pregnant women. Random assignment to experimental conditions was also not possible in that the Healthy Start Resource Mothers Program was a service program without research purposes and resources.

APPENDIX B

DETAILED TABLES

Table		*Page*
B-1.	Number and Percent Subjects, by Demographic Characteristics and Group (*N* = 565)	38
B-2.	Number and Percent Subjects, by Adequacy of Preventive Services and Group (*N* = 565)	39
B-3.	Number and Percent Subjects, by Perinatal Outcomes and Group (*N* = 565)	40
B-4.	Number and Percent Mothers, by Modifiable Risk Factors for Poor Birth Outcomes and Group (*N* = 565)	41
B-5.	Number and Percent Mothers, by Pregnancy Status Within 12 Months of Delivery and Group (*N* = 558)	42
B-6.	Number and Percent Infants, by Number Encounters for Preventable Illness and Injury and Group (*N* = 561)	42
B-7.	Descriptive Statistics for Number Encounters for Nonpreventable Conditions in First 60 Days of Life, by Group (*N* = 561)	42
B-8.	Wilcoxon Scores (Rank Sums) for Number Encounters for Nonpreventable Conditions in First 60 Days of Life, By Group (*N* = 561)	42
B-9.	Descriptive Statistics for Length of Stay for Nonpreventable Conditions in First 60 Days of Life, by Group (*N* = 561)	43
B-10.	Wilcoxon Scores (Rank Sums) for Length of Stay for Nonpreventable Conditions in First 60 Days of Life, by Group (*N* = 561)	43

Table B-1. Number and Percent Subjects, by Demographic Characteristics and Group (N = 565)

Characteristic	Total (*N* = 565)		Comparison Group: Study (*n* = 39)		Comparison Group: Similar Co. (*n* =243)		Comparison Group: Same Co. (*n* = 283)		p[a]
	No.	%	No.	%	No.	%	No.	%	
Maternal age at delivery									
Less than 18 years	85	15	6	15	36	15	43	15	0.47
18 to 34 years	463	82	32	82	196	81	235	83	
35 years or more	17	3	1	3	11	5	5	2	
Maternal education at delivery									
0-11 years	170	30	12	31	76	32	82	29	0.85
12 years or more	391	70	27	69	164	68	200	71	
Missing	4		0		3		1		
Previous live births/parity									
None	258	46	15	38	107	44	136	48	0.59
1 to 4	297	53	24	62	130	53	143	51	
5 or more	10	2	0	0	6	2	4	1	
Teenager pregnant for the first time									
Yes	72	85	6	100	30	83	36	84	0.80
No	13	15	0	0	6	17	7	16	
Short interpregnancy interval[b] (multiparas only)									
Yes	136	48	9	41	65	50	62	47	0.66
No	148	52	13	59	64	50	71	53	
Missing	23		2		7		14		
Previous loss[c]									
Yes	107	19	7	18	55	23	45	16	0.15
No	458	81	32	82	188	77	238	84	
Early initiation of prenatal care (1-3 mo)									
Yes	303	56	18	51	138	58	147	55	0.63
No	239	44	17	49	100	42	122	45	
Missing	23		4		5		14		
Medical risk factors for this pregnancy									
Yes	332	59	21	62	147	60	164	58	0.87
No	226	41	13	38	96	40	117	42	
Missing	7		5		0		2		
Encounter for high risk pregnancy									
Yes	111	20	3	9	44	18	64	23	0.11
No	447	80	31	91	199	82	217	77	
Missing	7		5		0		2		
Gender of infant									
Boy	300	53	22	56	122	50	156	55	0.49
Girl	265	47	17	44	121	50	127	45	

The actual number of observations used in specific computations varied due to missing values.

[a]Fisher exact probability test. [b]Less than 24 months; calculated from date of last live birth or other termination (birth certificate). [c]Calculated from other terminations.

Table B-2

Number and Percent Subjects, By Adequacy of Preventive Services and Group (*N* = 565)

			Comparison Group						
	Total (*N* = 565)		Study (*n* = 39)		Similar Co. (*n* =243)		Same Co. (*n* = 283)		
Preventive Service	No.	%	No.	%	No.	%	No.	%	*p*[a]
Kessner Index of prenatal care									
Adequate	247	46	15	42	112	50	120	43	0.25
Less than adequate	292	54	21	58	112	50	159	57	
Missing	26		3		19		4		
Post partum check-up within 4-8 weeks post delivery									
Yes	283	51	16	47	122	50	145	52	0.87
No	275	49	18	53	121	50	136	48	
Missing	7		5		0		2		
# encounters for routine infant health check by 1 year									
0 to 3	355	63	20	53	103	43	232	82	< 0.0001
4 or more	206	37	18	47	137	57	51	18	
Missing	4		1		3		0		

The actual number of observations used in specific computations varied due to missing values.

[a]Fisher exact probability test.

Table B-3

Number and Percent Subjects, By Perinatal Outcomes and Group (*N* = 565)

			Comparison Group						
	Total (*N* = 565)		Study (*n* = 39)		Similar Co. (*n* =243)		Same Co. (*n* = 283)		
Perinatal Outcome	No.	%	No.	%	No.	%	No.	%	*p*[b]
Complications of labor and delivery									
Yes	353	63	16	47	153	63	184	65	0.11
No	205	37	18	53	90	37	97	35	
Missing	7		5		0		2		
Gestational age									
< 37 weeks	92	17	8	22	43	20	41	15	0.10
37 to 42 weeks	428	80	27	75	167	77	234	84	
> 42 weeks	12	2	1	3	8	4	3	1	
Missing	33		3		25		5		
Birth weight									
< 1,500g	14	2	1	3	6	2	7	2	0.26
1,500 to 2,499g	57	10	9	23	24	10	25	9	
2,500 to 4,499g	494	87	30	77	213	88	251	89	
≥ 4,500g	0	0	0	0	0	0	0	0	
Small for gestational age[a]									
Yes	50	9	4	11	18	8	28	10	0.69
No	482	91	32	89	200	92	250	90	
Missing	33		3		25		5		
1-minute Apgar score									
< 7	70	12	6	15	26	11	38	13	0.51
≥ 7	495	88	33	85	217	89	245	87	
5-minute Apgar score									
< 8	30	5	5	13	11	5	14	5	0.10
≥ 8	535	95	34	87	232	95	269	95	
Abnormal conditions of newborn at birth									
Yes	24	4	3	8	10	4	11	4	0.45
No	537	96	35	92	230	96	272	96	
Missing	4		1		3		0		
Congenital anomalies of child at birth									
Yes	43	8	6	16	13	5	24	8	0.06
No	518	92	32	84	227	95	259	92	
Missing	4		1		3		0		
Conditions related to perinatal period									
Yes	173	31	16	42	79	33	78	28	0.12
No	388	69	22	58	161	67	205	72	
Missing	4		1		3		0		
Infant died within 28 days of birth									
Yes	0	0	0	0	0	0	0	0	--
No	561	100	38	100	240	100	283	100	
Missing	4		1		3		0		

The actual number of observations used in specific computations varied due to missing values.

[a]Small for gestational age = birth weight < 2,500g + gestational age ≤ 37 weeks. [b]Fisher exact probability test.

Table B-4

Number and Percent Mothers, by Modifiable Risk Factors for Poor Birth Outcomes and Group (*N* = 565)

			Comparison Group						
	Total (*N* = 565)		Study (*n* = 39)		Similar Co. (*n* =243)		Same Co. (*n* = 283)		
Modifiable Risk Factor	No.	%	No.	%	No.	%	No.	%	*p*[a]
Tobacco use during pregnancy									
Yes	27	5	3	8	14	6	10	4	0.2595
No	536	95	35	92	228	94	272	96	
Missing	2		1		1		0		
Average # cigarettes/day among smokers									
< 10	17	68	2	67	7	58	8	80	0.7071
10 or more	8	32	1	33	5	42	2	20	
Missing	2								
Alcohol use during pregnancy									
Yes	5	1	2	5	0	0	3	1	0.0118
No	558	99	36	95	242	100	280	99	
Missing	2		1		1				
Maternal anemia in pregnancy									
Yes	95	17	3	9	62	26	30	11	<0.0001
No	463	83	31	91	181	74	251	89	
Missing	7		5		0		2		
Weight gain during pregnancy									
< 25 pounds	254	47	22	61	102	44	130	47	0.056
25 to 34 pounds	168	31	10	28	65	28	93	34	
> 34 pounds	119	22	4	11	63	27	52	19	
Missing	24		3		13		8		
Kessner Index for prenatal care									
Adequate	253	46	21	41	112	50	120	43	2.81
Less than adequate	300	54	30	59	112	50	158	57	

The actual number of observations used in specific computations varied due to missing values.

[a]Fisher exact probability test.

Table B-5
Number and Percent Mothers, by Pregnancy Status Within 12 Months of Delivery and Group (*N* = 558)

	Total (*N* = 558)		Comparison Group: Study (*n* = 34)		Similar Co. (*n* =243)		Same Co. (*n* = 281)		
Pregnant Within 12 Months?	No.	%	No.	%	No.	%	No.	%	*p*[a]
Yes	311	56	21	62	96	40	194	69	<0.0001
No	247	44	13	38	147	60	87	31	
Missing	7		5		0		2		

[a]Fisher exact probability test.

Table B-6
Number and Percent Infants, by Number Encounters for Preventable Illness and Injury and Group (*N* = 561)

	Total (*N* = 561)		Comparison Group: Study (*n* = 38)		Similar Co. (*n* =240)		Same Co. (*n* = 283)		
Number Encounters	No.	%	No.	%	No.	%	No.	%	*p*[a]
None	436	78%	35	92%	181	75%	220	78%	0.0589
1 or more	125	22%	3	8%	59	25%	63	22%	

[a]Fisher exact probability test.

Table B-7
Descriptive Statistics for Number Encounters for Nonpreventable Conditions in First 60 Days of Life (*N* = 561)

Group	*N* obs	*N*	Mean	*SD*	Median	Minimum	Maximum
Study	39	38	19.40	36.41	12	2	198
Similar Co.	243	240	13.98	19.54	10	1	179
Same Co.	283	283	12.26	26.97	7	1	397
Total	565	561					

Table B-8
Wilcoxon Scores (Rank Sums) for Number Encounters for Nonpreventable Conditions in First 60 Days of Life, by Group (*N* = 561)

Group	*N*	Sum of Scores[a]	Expected Sum H_0	*SD* under H_0	Mean Score
Study	38	11,599.50	10,678.00	963.27	305.25
Similar Co.	240	74,831.50	67,440.00	1,896.55	311.80
Same Co.	283	71,210.00	79,523.00	1,916.56	251.63

[a]Average Scores were used for ties.

Kruskal-Wallis, $x^2(2, N = 561) = 18.87$, $p < .0001$.

Table B-9

Descriptive Statistics for Length of Stay for Encounters for Nonpreventable Conditions in First 60 Days of Life (*N* = 561)

Group	*N* obs	*N*	Mean	*SD*	Median	Minimum	Maximum
Study	39	38	4.71	7.98	2	0	44
Similar Co.	243	240	4.51	11.53	2	0	107
Same Co.	283	283	4.08	9.59	2	0	96
Total	565	561					

Table B-10

Wilcoxon Scores (Rank Sums) for Length of Stay for Encounters for Nonpreventable Conditions in First 60 Days of Life, by Group (*N* = 561)

Group	*N*	Sum of Scores[a]	Expected Sum H_0	*SD* under H_0	Mean Score
Study	38	11,396.00	10,678.00	963.74	299.89
Similar Co.	240	65,977.50	67,440.00	1,739.95	274.91
Same Co.	283	80,262.50	79,523.00	1,758.31	283.63

[a]Average Scores were used for ties.

Kruskal-Wallis, $x^2(2, N = 561) = 1.11$, $p > .05$.

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