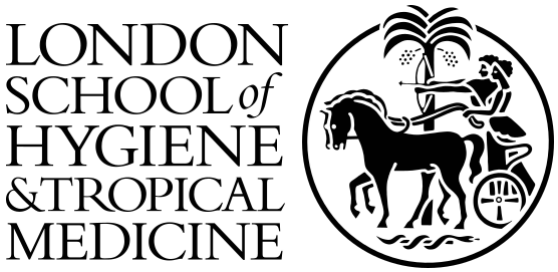

Antenatal Risk Reduction:

Effectiveness of a Community Based Public Health Initiative in Syracuse, New York

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Thesis submitted to the Faculty of Medicine of the University of London for the degree of Doctor of Philosophy

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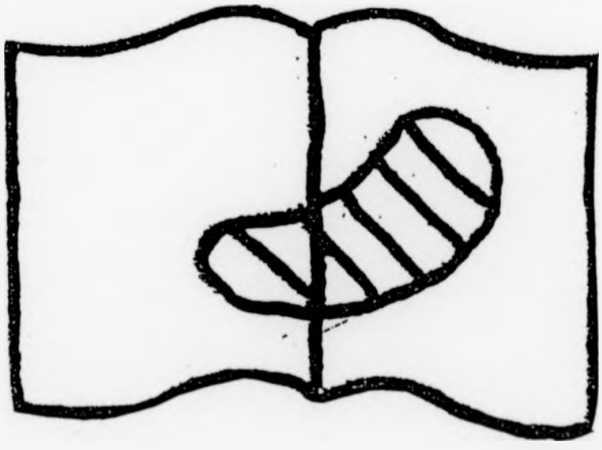

April 2006

Abstract

This thesis undertakes the evaluation of a multifaceted community intervention, the Syracuse Healthy Start Initiative, which aimed to reduce rates of infant mortality, particularly among African American women in Syracuse, New York. Analysis of the research literature confirms that preterm delivery and low birth weight are major causes of infant mortality. The project targeted interventions to causes of preterm/low birth weight, in four areas of risk: nutrition, smoking cessation, maternal stress and bacterial vaginosis infection.

Utilizing a conceptual framework of cumulative risk and a case-control study design, a retrospective chart review was undertaken which reviewed all the preterm/low birth weight deliveries during 2000-2001 in the project area. Each project intervention was analyzed. Interviews with fifteen women who delivered singleton infants in the project area were also conducted. Using a semi-structured interview guide women were queried specifically about smoking habits, nutritional status, stress during pregnancy and infection history.

The quantitative data was subjected to a simple descriptive analysis and then to a logistic regression analysis controlling for any confounding. The effect of race was also analyzed. The interviews with postpartum women were transcribed and subjected to a thematic coding procedure described by Maykut and Morehouse (1994).

The results indicate a significant association between preterm/low birth weight delivery and women who were positive for bacterial vaginosis but not treated [OR 2.48 (95% CI 1.23-5.86)]. This was the only intervention that reached significance. Major themes in the qualitative analysis highlight the complexity of women's lives and the existence of cumulative risk in each case. The role of BV treatment was also apparent among the interviewees. The results of this evaluation support previous work which demonstrates the relationship of BV infection and preterm delivery. It is suggested that a targeted BV screening strategy which combines risk assessment with prevalence information should be considered.

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Abbreviations

BMI	Body Mass Index
BV	Bacterial Vaginosis
CDC	Centers for Disease Control
CRH	Corticotropin Releasing Hormone
DFMR	Decreased Fetal Movement Record
FOB	Father of the Baby
FPL	Federal Poverty Level
GBS	Group B Streptococcus
GED	General Education Diploma
HIPAA	Health Insurance Portability and Accountability Act
HIV	Human Immunodeficiency Virus
HMO	Health Maintenance Organization
HS	High School
HSV	Herpes Simplex Virus
IM	Infant Mortality
IMR	Infant Mortality Rate
IRB	Institutional Review Board
LBW	Low Birth Weight
LPN	Licensed Practical Nurse
LR	Likelihood Ratio
Mgt	Management
MIC	Maternal and Infant Care Project
MLBW	Moderately Low Birth Weight
NCC-WCH	National Collaborating Center for Women's and Children's Health
NICE	National Institute for Clinical Excellence

NICU	Neonatal Intensive Care Unit
NIH	National Institute of Health
NY	New York
OB	Obstetric
OR	Odd Ratio
P	P-value
PAR	Population Attributable Risk
PIH	Pregnancy Induced Hypertension
PNC	Perinatal Care Center
PT hx	Preterm history
RCT	Randomized Controlled Trial
RR	Relative Risk
SCHC	Syracuse Community Health Center
SES	Socio-economic status
SHS	Syracuse Healthy Start
SUNY	State University of New York
UID	Unique Identification
U.K.	United Kingdom
UHCC	University Health Care Center
U.S.	United States
USDA	U.S. Department of Agriculture
VLBW	Very Low Birth Weight
WIC	Women's Infant's and Children's (nutrition program)

Acknowledgements

The experience of working with Syracuse Healthy Start, the Centers for Disease Control and most especially the London School of Hygiene and Tropical Medicine has achieved a remarkable personal professional transformation and taught me more than I could ever have imagined. Through the patient mentorship of Sandra Lane, Veronique Filippi and Linda Morison I have discovered the potential for epidemiology to explore and enhance clinical health care practice. This academic venture has expanded my vision and provided the foundational principles which have enabled me to find a place within the public health care system. I have now fulfilled a lifetime goal of blending my clinical experience and research skills for the benefit of women in the greater community.

I would like to express my gratitude and deepest appreciation to my Ph.D. supervisor, Veronique Filippi whose thoughtful guidance, careful critique and patient counsel have taught me the art and science of epidemiology. Linda Morison has spent many hours reviewing my statistical analysis and deserves my undying gratitude as well. She has guided me through the complexities of deconstructing this evaluation in mathematical terms and has helped me to translate classroom learning into "real life" analysis. Both Veronique and Linda have offered friendship, understanding and support over these years of study and this has been a tremendous gift to me.

Sandra Lane has been a longstanding friend and mentor. It was Dr. Lane who first suggested that I apply to the London School of Hygiene and Tropical

Medicine. As Director of Syracuse Healthy Start, she ensured that I participated actively in every phase of project. Her keen interest in the progress of my studies and her faithful friendship has been a great source of support throughout these years.

Other academic colleagues have also contributed to my development as a researcher and to the completion of this project. Dominique Behague provided valuable comments and critique of the qualitative work in this thesis. Philippe Mayaud has also given thoughtful comments and advice on this document.

Dr. Emily Koumans has been an enthusiastic supporter of this work, providing public health expertise, CDC sponsorship and facilitating the processing of my data collection instruments through her office in Atlanta.

I am deeply thankful to all the women whose lives I shared during their pregnancies and childbirth experience in Syracuse, but most especially to Anna, whose courageous example will be with me forever. And to Ruth, my colleague and friend, thank you for modeling the best of midwifery care and for your inspiring devotion to "our girls."

I must also express my gratitude to my mother and to my brother Michael. Without their enduring love and belief in my possibilities this work would not have been completed.

And finally to John, the love of my life, who is my constant reminder that in the end there are three things that matter, love and faith and hope. And the greatest of these, is love.

CHAPTER 1

INTRODUCTION

1. INTRODUCTION

1.1 RATIONALE

1.1.1 Prenatal Care

Despite the dramatic reduction of infant mortality in the developed world during the twentieth century, the role of prenatal care as an effective public health intervention remains unproven (Fiscella,1995). Core maternity care has not changed substantially since it originated in the early twentieth century. It has been suggested that the content of prenatal care visits is guided by tradition rather than science (Villar et al., 2004). There remains a lack of clear evidence to support clinically effective service delivery and the issue of what constitutes the essential elements of prenatal care continues to be an important area for research worldwide.

In the U.K., antenatal care interventions were recently reviewed in depth by the National Collaborating Centre for Women's and Children's Health (NCC-WCH) for the National Institute for Health and Clinical Excellence (NICE). New evidence based national antenatal care guidelines were created. According to Jane Thomas, former Director of the NCC-WCH, "Whilst the pattern of antenatal care has evolved over the last 80 years it has been based on ritual and has not always had a scientific basis. This guideline outlines a more appropriate pattern of care for the 21st century – one that is evidence-based (Midirs, 2003)." The U.K. review also identified the evidence gaps and recommended new and

ongoing research into many areas of antenatal care (National Collaborating Centre for Women's and Children's Health, 2003).

The need for further review extends to obstetric practice in the developing world as well, where scarce resources and persistently high infant mortality rates challenge the researcher to identify the most effective elements of prenatal care. Recently the Cochrane Collaboration (Villar, 2004) reviewed patterns of routine antenatal care for low risk pregnancy in the developing world and concluded that fewer antenatal visits could be attempted without affecting low birth weight rates. Particularly, the work of Villar and colleagues, which was sponsored by the World Health Organization in Argentina, Cuba, Saudi Arabia and Thailand, suggested that the most important feature of antenatal care was the scientific quality of interventions rather than the number of visits. However, the impact of individual interventions and the relationship of these interventions to other aspects of a woman's life experience have yet to be adequately evaluated.

1.1.2 **Prenatal care in the U.S.**

In the United States (U.S.), despite increased utilization of prenatal care, expanded services and improved technology, recent studies have reported only limited improvements in birth weights. The U.S. continues to lag far behind other developed countries in overall infant mortality (IM), ranking 21st in 1995 at 7.6/1000 and slipping to 26th by 2000, with an IM of 6.9/1000 (Arias, et al., 2003). High rates of low birth weight, particularly very low birth weight relative to other developed countries underlie these statistics (Guyer, 1997).

Race and class-based disparities characterize infant mortality statistics worldwide. In the U.S., a profound racial disparity in perinatal outcomes exists, with African American women demonstrating rates of infant death and low birth weight that are over twice their White counterparts in most localities (Hoyert et al., 2001).

Moreover, in light of the fiscal constraints imposed in the U.S. by Medicaid Managed Care (the federal cost savings effort to provide essential medical services) and by the health insurance industry in America, there is a critical need to determine the effectiveness of specific prenatal interventions on birth outcomes.

In the U.S., about two thirds of infant death occurs in the neonatal period. Most recently, the majority of neonatal mortality has been the result of deaths occurring in neonates born at less than 26 weeks gestation (Wise et al., 1995; Overpeck et al., 1992). Examination of the clinical determinants of prematurity reveals its heterogeneous origins. Current evidence suggests that low-grade infectious processes may be implicated in preterm labor and premature birth (Andrews et al., 1995). Evidence from epidemiological studies has shown a strong association between bacterial vaginosis and preterm birth (Hay et al., 1994; Hillier et al., 1995; Meis et al. 1995). Certain social risk criteria such as maternal stress factors, including poverty, domestic violence, lack of partner support, low educational level and housing/transportation problems, coupled with inadequate nutrition and behavioral factors such as smoking and drug or alcohol use, have been found to be associated with poor pregnancy outcomes (Spencer, 2003). A healthy maternal environment is essential for optimal fetal

outcomes. Lifetime health requires favorable living conditions across the entire lifespan. Thus, an evaluation of the biological, social and behavioral variables associated with infant mortality may elucidate factors which are not only concurrent with but which predate the pregnancy. Overall, a reduction in preterm birth is likely to require a biopsychosocial approach, which integrates evidence-based medical with social and behavioral interventions within the context of individual women's lives (Spencer, 2003). If prenatal care does indeed confer health benefits to mother and baby, research is needed to evaluate the complexities of care and identify factors which have proven effect.

1.2 AIMS OF THE STUDY

This study examines a multifaceted set of prenatal care interventions implemented by the Onondaga County Health Department in Syracuse, New York through a federally funded program entitled the *Syracuse Healthy Start Initiative*.

Public health research seeks to provide robust scientific evidence to underpin interventions. Although potential efficacy may be demonstrated in ideal laboratory conditions, it is the effectiveness of an intervention under normal conditions in field settings which it is important to determine. The evaluation undertaken in this thesis describes a community based project which was not originally designed as a research study.

The *Syracuse Healthy Start Initiative* is a community based project designed to address issues of high infant mortality and racial disparity in the City of

Syracuse. There have been approximately 1,000 births per year to women enrolled in *Healthy Start* from 1998 onward. Since implementation of *Syracuse Healthy Start,* low birth weight, preterm delivery and infant death have all decreased among women in the project area. The 23.8% decrease in overall infant mortality and 32.6% decrease in Black infant mortality which occurred in the first three years of the Syracuse Healthy Start Initiative motivated this project evaluation.

This study provides a unique opportunity to assess the effects of an integrated program of biosocial and behavioral interventions on infant mortality and preterm low birth weight. The challenge however, is to "disentangle" the various interventions, in a retrospective analysis, in order to identify possible associations between *Healthy Start* interventions, and decreased infant mortality.

Investigation of such complex issues as the causes of preterm birth must of necessity evaluate multiple interacting mechanisms, taking into account the effects of cumulative risk on birth outcomes. Evaluation of antenatal programs is also complex. This study aims to assess the protective effect of project interventions in total, that is, full participation in the Syracuse Health Start project, as well as the effect of individual interventions, while controlling for multiple risk factors. The SHS interventions evaluated in this study include:

1. Women's, Infants' and Children's (WIC) nutritional support
2. Smoking cessation program
3. Social support measures, specifically case management

4. Universal screening and treatment if needed, of bacterial vaginosis

1.3 STRUCTURE OF THE THESIS

A survey of the literature on trends in infant mortality and the current content of prenatal care will be presented in Chapter 2. Risk factors for low birth weight will be reviewed and the literature relevant to the four risk factors addressed by *Syracuse Healthy Start* interventions will be discussed. Chapter 3 provides the background of the Syracuse Healthy Start project. The conceptual framework for this paper will be described in Chapter 4. The objectives and hypotheses of this thesis are outlined in Chapter 5. The methodology and data analysis of the quantitative study are presented in Chapters 6 -11. The qualitative work, consisting of participant interviews, is discussed in Chapter 12. The thesis conclusions are contained in Chapter 13.

CHAPTER 2

LITERATURE REVIEW

2. LITERATURE REVIEW

The literature review was undertaken to appraise issues in infant mortality and prenatal care specific to the United States, the country where this study was undertaken.

Ultimately, the effectiveness of any system of prenatal care should be evaluated by outcome measures such as infant mortality rates, that is, the rate of infant death within the first year. Preterm birth and low birth weight are widely recognized as important predictors of infant mortality and morbidity (Epidemiology of Infant Mortality, 2000) and were the outcome measures evaluated in this study. The review of the literature focuses on these three outcomes, infant mortality, low birth weight and preterm birth, and reviews demographic trends, risk factors and evidence for effective intervention.

2.1 INFANT MORTALITY AND PRETERM LOW BIRTH WEIGHT: DEMOGRAPHIC TRENDS

Infant mortality rates in the U.S. have declined significantly for the past two decades. In 1970 there were 20 deaths for every 1,000 live births. As previously mentioned, by 2000 the rate had dropped to 6.9 per 1,000 live births. Despite these apparent advances, in 2000 the U.S. only ranked 26th in the world for overall infant mortality.

According to Hack and Merkatz (1995), high rates of premature birth and associated low birth weight (LBW) are responsible for the poor performance of

the U.S. in the international ranking of infant mortality. The rates of both preterm birth (before 37 weeks gestation) and low birth weight (less than 2500 grams) have actually risen in the United States during recent years. The percentage of preterm births was 12.0% in 2002, a rise from 10.6% in 1990. In 2002, 7.8 % of all U.S. infants were born at low birth weight, the highest level in more than three decades. Of these, 1.45 % of the LBW infants were under 1,500 grams (very low birth weight), and 6.35% were in the 1500-2499 gram range (Arias, et al., 2003).

Birth outcomes vary dramatically by birth weight. In the year 2001, infant death in the U.S. was 6 times higher for infants who weighed 1500 to 2499 grams compared to those born over 2500 grams. Mortality was more than 100 times higher for infants with birth weights of less than 1500 grams (Arias, 2003). The "Annual Summary of Vital Statistics -2002" indicates that in the year 2001, 67% of all infant deaths occurred among LBW babies and 53% of these were among the very low birth weight (VLBW) group, infants who were unquestionably born too soon and too small (Arias et al., 2003).

2.2 RACIAL AND ETHICAL DISPARITIES IN INFANT MORTALITY

There also exists a significant disparity between Black and White infants in the U.S. Regardless of maternal age, education, income or marital status, children of Black mothers are twice as likely to die in the first year of life than their White counterparts. This disparity is linked to increased rates for preterm delivery, LBW and VLBW, the leading causes of infant mortality among African-American infants (New Jersey Department of Health, 1999). Although infant mortality

rates have declined in the U.S. over the past twenty years, the rate of decline has not been the same for Blacks and Whites. In fact, the ratio of Black to White infant mortality has increased since 1980 from 2:1 to 2.5:1 in 2001 (CDC, 2002).

As noted previously, the risk of infant mortality increases as birth weight decreases. The prevalence of LBW among African-Americans is more than double that of Whites, 13.1 % and 6.4 % respectively (NIH, 2000). Studies conducted in both the medical and social sciences have failed to clearly identify the causes of the discrepancies in infant mortality and low birth weight rates between the races. Demographic risk factors such as maternal age, education or income do not provide the sole explanations for racial disparities in birth outcomes. According to the CDC (2002) factors that might contribute to the disparity include, "... racial differences in maternal medical conditions, stress, lack of social support, bacterial vaginosis, previous preterm delivery and maternal health experiences..." A broader examination of the causes of racial disparities in birth outcomes is needed.

2.3 EFFECTIVE ELEMENTS OF PRENATAL CARE

This study adopts a broad view of prenatal care as, "... Any intervention during pregnancy which enhances the health and well-being of mothers and their off-spring" (Kotch, 1997, p.102). In the American context such interventions generally occur within a health care framework but may incorporate coordination with existing social service agencies.

According to Guillermo Carroli and colleagues (2001) of the World Health Organization, "The rationale for antenatal care is that it is essential to screen a predominately healthy population to detect early signs of, or risk factors for disease, followed by timely intervention." Organized prenatal care in the U.S. was introduced in the early 20th century by social reformers and nurses and focused upon the reduction of maternal mortality (Strong, 2000). It was postulated that antenatal health care and screening could reduce maternal mortality and morbidity and serve as a gateway to care during the intrapartum and postpartum periods and perhaps, into the future lives of women.

Currently in the U.S. the components of the initial prenatal care visit recommended by the American Academy of Pediatrics and the American College of Obstetricians and Gynecologists (1997) include:

1. Risk assessment to include genetic, medical, obstetrical and psychosocial factors
2. Estimated due date
3. General physical examination
4. Laboratory tests: hematocrit (hemoglobin), urinalysis, urine culture, blood grouping, Rhesus antibody screen, rubella status, syphilis screen, Pap smear, hepatitis B surface antigen and human immunodeficiency virus with consent. Optional labs include hemoglobin electrophoresis, mantoux testing for tuberculosis and screening for chlamydia and gonorrhea
5. Patient education, e.g. use of seatbelts, avoidance of alcohol and tobacco.

The currently recommended components of routine prenatal care after the first visit include:

Visit intervals	Every 4 weeks until 28 weeks; then every 2 weeks until 36 weeks and weekly until delivery.
Each visit	Assess blood pressure, weight, urine protein and glucose, uterine size, fetal heart rate, fetal movement, Contractions, bleeding, edema
15-20 weeks	Maternal serum alpha-fetoprotein screening
24-28 weeks	Screen for gestational diabetes
28 weeks	Give anti-d immune globulin if indicated
36 weeks	Screen for group B streptococcus.

(American Academy of Pediatrics and American College of Obstetricians and Gynecologists,1997).

As evidence-based approaches to health care assume increasing prominence in western medicine, the content and effectiveness of specific prenatal care interventions, particularly as they relate to infant outcomes, has come into question. According to David Sackett (Sackett et al.,1996), evidence-based medicine integrates the best available research evidence with clinical expertise in a systematic manner to inform patient care. Randomized controlled trials are considered to be the "gold standard" by which to evaluate screening techniques, diagnostic tests and health care interventions.

In 1972, Archie Cochrane noted that antenatal care had escaped the critical assessment to which most screening procedures were subjected and furthermore, he recommended that the emotional atmosphere surrounding antenatal care should be removed and the subject treated like any other medical activity and investigated by randomised controlled trials (Cochrane, 1989). However, this field of research continues to lack the robust evidence base which clearly supports the benefit of many current and proposed antenatal interventions (National Collaborating Center for Women's and Children's Health, 2003).

Evaluating prenatal care as a package is a complex undertaking. Antenatal care is not a single event. It consists of a series of assessments and multiple interventions. The number of visits and therefore the delivery of prenatal care may be influenced by many factors including the gestational age at entry to care, the recommended frequency of visits, pregnancy complications, hospitalization and gestational age at delivery. In the U.S., informal recommendations for care are published by the American College of Obstetricians and Gynecologists and by a national task force but compliance with these recommendations differs from practice to practice. Thus quantity and quality of prenatal care may vary greatly.

Study design in the field of antenatal care is challenging. Randomized controlled trials (RCT's) involving pregnant women are often difficult to implement for ethical reasons, specifically if there is a possibility of risk to mother or infant. Multiple maternal risk factors, such as past obstetric history or current medical complications, may confound the data in antenatal

observational studies. Selection bias can also affect the internal validity of observational studies. Women who choose to access antenatal care, and agree to participate in research studies, may differ in significant ways from women who do not attend for care. The results of such studies may not be generalisable. Furthermore, data collection has been hampered by new privacy regulations in the U.S. which restrict access to patients and their records. These restrictions limit research possibilities in the perinatal setting and in fact, greatly complicated the data collection process for this study.

Although some evaluation studies provide evidence that comprehensive prenatal care approaches are effective in improving birth outcomes, these studies reflect care settings in which multiple interventions have been implemented (Korenbrot,1989; Peoples and Siegel, 1983; Sokol, et al., 1980) and do not identify the effect of individual interventions on particular outcomes. In 1989 Korenbrot and colleagues evaluated a Teenage Pregnancy and Parenting Program which provided enhanced prenatal care for pregnant adolescents. Although this prospective study showed that participation in the prenatal program was associated with better birth weight outcomes for teens who had counseling and coordination of health, education, psychosocial and nutrition services, the effectiveness of the individual services was not analyzed.

Peoples and Siegel (1983) used vital statistics data to assess the effects of a comprehensive program of prenatal care, the North Carolina Maternal and Infant Care Project (MIC), on low birth weight. The project had an active outreach service, provided transportation and follow up of missed appointments. The MIC participants also received public health nursing, nutrition and social

services, health education and dental and medical care. The study compared a group of MIC care recipients with two groups of women from other counties with similar socioeconomic status, health resources and perinatal status. The groups were compared on adequacy of prenatal care and on low birth weight. Although total population data indicated only minor effects of the MIC project overall, subpopulation analysis showed that associations differed across categories of maternal risk, particularly in high-risk mothers. MIC comprehensive services appeared to contribute to a reduction in the incidence of low birth weight at least for high risk subpopulations. Exactly which interventions were effective was not evaluated.

In Cleveland, Ohio, Sokol et al. (1980) analyzed a federally funded MIC Project in which participants received more education, nutrition counseling, social service assessment and intervention, special services for adolescents and missed appointment follow up than non-participants. Pregnancy risks and perinatal outcomes were compared in participants and non participants after adjusting for potential bias. The two groups were found to be similar on 245 of 250 antepartum/intrapartum risk factors surveyed. A review of records for a two year period showed that project participants had 60% less perinatal mortality than non participants despite their similar risk assessments. The researchers concluded that the individual components of the package, which included patient education, home visitation, nutrition assessment and counseling, social service assessment and intervention and dental care were important elements of the antenatal care package. The vital statistics database did not allow independent analysis of each intervention.

Although comparison of participants and non participants in observational studies of enhanced prenatal programs have yielded some impressive results, randomized controlled trials of intensive prenatal care (more than the recommended number of prenatal visits) for high-risk women of low socioeconomic status have not supported these findings (Kramer et al., 2001).

Kevin Fiscella (1995) set out to evaluate the evidence that prenatal care improves birth outcomes, specifically LBW and preterm delivery. A review of published observational and experimental studies of prenatal care was carried out, and studies were graded according to the three point scale of good, fair, poor used by the United States Preventive Services Task Force. Well designed randomized controlled trials were graded the highest, followed by well-designed controlled trials without randomization, well-designed cohort and case-control studies and multiple time series. The selected studies assessed adequate prenatal care compared to inadequate care; enhanced prenatal care for high risk women compared to standard care; and, the effect of increased availability of prenatal care on birth outcome statistics. Once again, the difficulties inherent in the analysis of prenatal care became evident. A preterm delivery bias was identified based upon the temporal relationship between prenatal care and birth outcomes. Deliveries that are the most preterm involve the least opportunity for prenatal care. Failure to adjust for critical confounders, particularly smoking and substance abuse was also noted. Direct randomized controlled trials of adequate prenatal care compared to no prenatal care were not possible. Therefore, an indirect approach was used to evaluate interventions. Eleven RCTs of enhanced care were reviewed, none of which showed a significant effect for the outcomes of preterm low birth weight. Five trials of home

visitation involving 4000 at-risk women showed no overall reduction of rates of low birth weight infants or preterm delivery. Two trials of comprehensive care involving 1700 women also showed no improvements in overall birth weight or low birth weight rates. Four preterm delivery prevention programs supported the observation that very few preterm births are potentially preventable through the identification of preterm labor. The review concludes that current evidence does not establish that prenatal care definitely improves birth outcomes. (Fiscella, 1995).

Fiscella's conclusions have been supported by further research. The March of Dimes Research Report (1998) likewise concluded that most interventions designed to prevent preterm birth do not work and noted that preterm birth rates are slowly increasing in the U.S. In a recent review of the evidence of the effectiveness of prenatal care for prevention of low birth weight, Lu and colleagues (2003) concluded that neither clinical risk assessment nor health promotion activities have been shown to be effective in preventing preterm birth. Although there are some promising biomedical interventions available, their effectiveness has yet to be demonstrated. Overall, few potentially modifiable risk factors for LBW and preterm labor have been identified for analysis.

Carroli and colleagues reviewed the effectiveness of prenatal care in relation to maternal mortality and serious morbidity for the World Health Organization in 2001. Studies from both developed and developing countries reflected the need for good-quality evidence and rigorous evaluation of many routine antenatal practices. The lack of reliable information is critical in nations where

staff and resources are scarce and levels of mortality and morbidity remain high (Carroli, et al., 2001).

In the spirit of Archie Cochrane, the National Institute for Health and Clinical Excellence (NICE) commissioned the formulation of new evidence based antenatal care guidelines for the care of healthy pregnant women living in England and Wales. A systematic review of the literature relative to specific clinical questions and cost effectiveness was undertaken and analyzed by a Guideline Development Group and by external reviewers. On October 22, 2003 the final document was launched. A number of traditional prenatal activities, which were not supported in the literature, are no longer recommended in England and Wales as essential components of the antenatal care package. Among these are:

1. The classic visit pattern of monthly until 28 weeks and then fortnightly to 36 weeks and then weekly until delivery. The new recommendation for a nulliparous woman with an uncomplicated pregnancy, is ten visits. For parous women with uncomplicated pregnancies, seven visits are recommended.
2. Measurement of weight at each visit. The new recommendation is to calculate BMI at the first prenatal visit. Thereafter, weight is not measured.
3. Urine glucose check at each visit and 24 week glucose tolerance test. Screening for gestational diabetes is not recommended.
4. General physical exam, breast exam and internal vaginal exam at the initial OB visit, including Pap smear and optional cultures for Gonorrhea

and Chlamydia. The exam and accompanying screenings are not recommended.

5. Routine iron supplementation and vitamin D supplementation. These were not recommended.

6. Repeat syphilis screening at 32-36 weeks. This screening is not recommended.

7. Screening for Group B Streptococcus (GBS) at the 36 week exam. GBS screening is not recommended.

8. Fetal heart check at each visit. Routine auscultation of fetal heart sounds is not recommended.

9. Daily fetal movement record (DFMR) or routine fetal movement checks. These records are not recommended.

Additionally,

10. Routine screening for domestic violence. As there is insufficient evidence for the effectiveness of interventions such as counseling for the woman and/or her partner or referral to women's shelters on pregnancy outcomes, routine screening was not recommended.

11. Antenatal screening for depression using the Edinburgh Postnatal Depression Scale. This was not found to be predictive of postnatal depression.

At this time, the evidence also does not support the addition of screening for cytomegalovirus, hepatitis C, toxoplasmosis or bacterial vaginosis in routine prenatal care. Screening for preterm birth by assessment of cervical length or using fetal fibronectin is not supported by current research; nor is antenatal electronic cardiotocography, ultrasound

scanning after 24 weeks or umbilical or uterine artery Doppler ultrasound.

The key NICE recommendations for antenatal care in England and Wales include:

1. Pregnant women should be offered evidence-based information and support to enable them to make informed decisions regarding their care. Information should include details of where they will be seen and who will undertake their care. Addressing women's choices should be recognized as being integral to the decision-making process (Based on observational studies).

2. A schedule of antenatal appointments should be determined by the function of the appointments. For a woman who is nulliparous with an uncomplicated pregnancy, a schedule of ten appointments should be adequate. For a woman who is parous with an uncomplicated pregnancy, a schedule of seven appointments should be adequate.

3. Pregnant women should be offered an early ultrasound scan to determine gestational age and to detect multiple pregnancies.

4. Pregnant women should be offered screening for Down's syndrome with a test which provides the current standard of a detection rate above 60% and a false-positive rate of less than 5%. (The specific test will depend upon gestational age.)

(National Collaborating Centre for Women's and Children's Health, 2003).

Clearly, there remains significant variation in national recommendations for antenatal care in the developed world. Risk factors and disease prevalence

unique to individual communities are important considerations. Cultural patterns are reflected in guideline development. Political systems which dictate the style of health care delivery and which control health care spending and research priorities also play an important role. But the challenge of identifying universal elements of care which actually improve pregnancy outcomes, whether at individual or population levels, remains.

2.4 PRETERM LOW BIRTH WEIGHT: RISK FACTORS

Extensive research has identified numerous associations between maternal characteristics and birth outcomes. The perspective of risk differs among the experts however. Using a cross sectional approach, the Institute of Medicine report *Preventing Low Birthweight* (1985) identified six categories of risk for low birth weight: demographic, medical risks predating pregnancy, medical risk during current pregnancy, behavioral and environmental risks, health care risks, and finally, evolving concepts of risk. See Table 1 below:

Table 1 Principal Risk Factors for Low Birth Weight

CATEGORIES	SUB-CATEGORIES
1 Demographic Risks	A Age (less than 17; over 34) B Race (Black) C Low socioeconomic status D Unmarried E Low level of education
2 Medical Risks Predating Pregnancy	A Parity (0 or more than 4) B Low weight for height C Genitourinary anomalies/surgery D Selected diseases such as diabetes, chronic hypertension E Nonimmune status for selected infections such as rubella F Poor obstetric history, including previous low birth weight infant, multiple spontaneous abortions G Maternal genetic factors (such as low maternal weight at own birth)
3 Medical Risks in Current Pregnancy	A Multiple pregnancy B Poor weight gain C Short interpregnancy interval D Hypotension E Hypertension/pre-eclampsia/toxemia F Selected infections such as symptomatic bacteruria, rubella and cytomegalovirus G First or second trimester bleeding H Placental problems such as placenta previa, abruption placentae I Hyperemesis J Oligohydraminios/polyhydraminios K Anemia/abnormal hemoglobin L Isoimmunization M Fetal anomalies N Incompetent cervix O Spontaneous premature rupture of membranes
4 Behavioral and Environmental Risks	A Smoking B Poor nutritional Status C Alcohol and other substance abuse D Exposure and other toxic exposures, including occupational hazards E High altitude
5 Health Care Risks	A Absent or inadequate prenatal care B Iatrogenic prematurity
6 Evolving Concepts of Risk	A Stress, physical and psychosocial B Uterine irritability C Events triggering uterine contractions D Cervical changes detected before onset of labor E Selected infections such as Mycoplasma and Chlamydia trachomatis F Inadequate plasma volume expansion G Progesterone deficiency

(Institute of Medicine, 1985)

In 1993, Berkowitz and Papiernik evaluated current research and classified risk factors for preterm birth according to the certainty of association: established risk factors, probable risk factors, factors weakly associated or not associated with preterm birth, inconclusive risk factors, factors for which there are

insufficient data. This approach to risk, which reflects the evidence based medicine movement, isolates factors associated with preterm birth and fails to integrate the effects of cumulative risk. See Table 2 below:

Table 2 Risk Factors for Preterm Birth

Established Risk Factors	Black race Single marital status Low socioeconomic status Previous low birth weight or preterm delivery Multiple second trimester spontaneous abortions In vitro fertilization pregnancy Placental abnormalities Gestational bleeding Cervical and uterine anomalies In utero diethylstilbestrol exposure Multiple gestations Cigarette smoking
Probable Risk Factors	Urogenital infections Cocaine use No prenatal care or inadequate prenatal care Seasonality
Factors weakly associated or not associated with preterm birth	Maternal age Infant sex Maternal weight gain Dietary intake Parity Short interpregnancy interval Prior first trimester induced abortion Alcohol consumption Caffeine intake Sexual activity during late pregnancy
Inconclusive risk factors	Psychosocial stress Short stature Low prepregnancy weight/low BMI Anemia Employment-related physical activity
Factors for which there are insufficient data	Familial and intergenerational factors History of infertility Use of marijuana and other illicit drugs Leisure-time physical activity Occupational and environmental toxicants

(Berkowitz & Papiernik, 1993)

Finally, Nick Spencer has reviewed the literature on the determinants of birth weight and identified biomedical, social and environmental studies on both birth weight and prematurity. The main birth weight determinants to be included in his biopsychosocial model of pathways to birth weight were elicited from the review. Spencer observed that most risk originates well before pregnancy and that none of these variables can be treated as independent factors but should be seen in the broader context of overall maternal socioeconomic status and maternal health (Table 3).

Table 3 Variables with a Major Impact on Birth Weight

Maternal height
Pre-pregnancy weight
Body mass index (BMI)
Maternal birth weight
'Race'/ethnicity
Parity
Malaria (less-developed countries only)
Genital infection
Pregnancy induced hypertension (PIH) , <20 weeks
PIH with proteinuria
Socio-economic status (SES), including social class, income, education, maternal age, marital status
Gestational weight gain/work
Micronutrient deficiencies including anemia
Smoking
Stress and psychological factors

(Spencer, 2003)

The causal links between many of these risk factors and LBW/prematurity remain unclear. Stress for example, appears as a risk factor in each listing, but with reservation. The Institute of Medicine (1985) calls it an "evolving concept of risk." Berkowitz and Papiernik refer to psychosocial stress as an "inconclusive risk factor." Spencer writes that the association of stress with low birth weight is "unresolved." Research in this area is confounded by the heterogeneity of factors, inaccurate and incomplete data collection techniques and research bias.

Even when factors associated with low birth weight or preterm delivery can be clearly identified, many are not directly modifiable. Demographic characteristics such as socioeconomic status, age, race, maternal birth weight and height cannot be altered by prenatal care programs. Furthermore, few studies focus on the risks associated with the most severely affected infants, those born at very low birth weights.

Four risk factors were the primary focus of Syracuse Healthy Start interventions: infection, nutrition, smoking and maternal stress. These were conditions identified in a review of the literature undertaken in the planning stages of the SHS Initiative and in an analysis of infant death and local maternal demographics. They were also conditions which were amenable to public health intervention. The following sections will review the literature upon which Syracuse Healthy Start based its public health interventions. More recent supporting research is also reviewed.

2.4.1 Genitourinary Infection and Bacterial Vaginosis

Clinical research has demonstrated that nearly 80 percent of early preterm births (delivery prior to 30 weeks gestation) are associated with an intrauterine infection that precedes the rupture of membranes (Andrews, et al., 1995). Several randomized trials have shown that both symptomatic and asymptomatic urinary tract infections are associated with an increased risk of preterm delivery and that treating asymptomatic bacteruria may reduce the risk of preterm birth (Romero, et al., 1989). While somewhat equivocal evidence suggests that incident chlamydial infection, gonorrhea, syphilis and primary HSV infection may be associated with preterm delivery, a growing body of evidence has associated bacterial vaginosis (BV) with preterm delivery (Wasserheit & MacKay, 1997). Although BV may be associated with other outcomes of pregnancy, including endometritis and infant lung infection, none have as large and costly effects on infant morbidity and mortality as does preterm delivery (Oleen-Burkey & Hillier, 1995).

Cohort studies that have examined the relationship between bacterial vaginosis and premature birth and/or low birth weight have calculated relative risks for preterm delivery ranging from 1.4 (95% CI 1.1-1.8) (Hillier et al., 1995) to 6.9 (95% CI 2.5-18.8) (Kurki et al., 1992). In other cohort studies in which BV diagnosis took place before 24 weeks of gestation, the relative risk for preterm birth was 2.0 or greater: 5.5 (95% CI 2.3-13.3) (Hay et al., 1994); 3.1 (95% CI 1.8-5.4) (Gratacos et al., 1998); 3.3 (95% CI 1.2-9.1) (McGregor et al., 1994); and 2.0 (95% CI 1.0-3.9) (Riduan et al., 1993).

BV is a condition characterized by a decrease in the normally predominate vaginal levels of lactobacillus, in favor of high concentrations of vaginal anaerobes, including Gardnerella vaginalis and a number of potentially pathogenic micro-organisms including Prevotella (Bacteroides), Peptostreptococcus, Mobiluncus, Mycoplasma hominis and Ureaplasma urealyticum (Jones et al., 2000).

Research demonstrates that BV is more prevalent among African American, Afro-Caribbean and African women than other ethnic groups. A 2.0 to 2.5-fold increased risk of BV has been confirmed by numerous studies, for example Schmid (1999) and Goldenberg et al. (1996). Thus far, this difference has not been explained by measures of socioeconomic status (Meis et al., 2000). Treating and preventing bacterial vaginosis may, in fact, help to reduce at least part of the racial disparity in preterm delivery (Fiscella, 1996).

Romero et al. (2001) have proposed a four-stage process leading to intrauterine infection. In the case of BV, there is an initial overgrowth of gram negative and anaerobic bacteria. In this ascending infection, micro-organisms gain access to the intrauterine cavity and reside in the decidua. Deciduitis and then chorionitis develops. The micro-organisms may cross the fetal membranes resulting in amnionitis and/or inflammation of the fetal vessels. Ultimately the bacteria may gain access to the fetus. Congenital pneumonia, otitis, conjunctivitis, bacteremia and/or sepsis can result.

Preterm birth resulting from genital tract infection is believed to occur as a result of the secretion of proinflammatory cytokines by the mother and/or fetus

in response to microbial invasion. These cytokines have been shown to promote spontaneous labor and rupture of membranes through synthesis of prostaglandins and by stimulating the synthesis and release of fetal cortisol and placental corticotropin releasing hormone (CRH) (Culhane et al., 2001). Placental CRH exerts actions on the uterus and cervix to augment changes caused by estrogen. In addition to stimulating the release of prostaglandins from the placenta, CRH potentiates oxytocin, which stimulates myometrial (uterine) contractility (Culhane, et al., 2001). Research indicates that CRH levels are elevated in women experiencing preterm labor when compared with gestational age matched controls ($p < .0001$) (Hobel et al.,1998).

The first published trials of treatment for BV among high-risk women had a small sample sizes and the nature of symptoms was not stated (Morales et al., 1994), but therapy with metronidazole was associated with a large reduction in the risk of premature delivery (See Table 4). Another trial demonstrating reduction in preterm birth was based on a subgroup analysis of women with a positive BV diagnosis (Hauth et al., 1995). Although this study presents some problems of interpretation due to lack of randomization, the similarity of treatment (at least one week of oral metronidazole) between the two trials and the significant preterm reduction led to recommendations by the CDC and the American College of Obstetricians and Gynecologists that high risk pregnant women, that is, women with a history of prior preterm birth or women who are symptomatic with BV, should be screened and treated if BV is present. A trial completed after the recommendations were made, and which demonstrated reductions in prematurity among high risk women, further supported these recommendations (McDonald et al., 1997).

Two randomized trials have been conducted among low risk or asymptomatic women neither of which demonstrated a reduction in adverse outcomes (McDonald, 1997; Carey et al., 2000). However, both studies treated women in mid-pregnancy rather than early pregnancy and neither used the CDC recommended dosages. Treatment early in pregnancy (less than 22 weeks gestation) with the currently recommended CDC regimen in asymptomatic BV positive women has not yet been evaluated.

Table 4 BV Treatment Trials

Outcome	RR/OR (95% CI)	Treatment	Reference
Preterm Birth	RR 0.4(0.2-0.85)	Metronidazole 500 mg, twice daily x 7 days	Morales et al., 1994
Preterm Birth	RR 0.6 (0.48-0.9)	Metroniadazole 500 mg, twice daily x 7 days	Hauth et al., 1995
Preterm Birth, high risk women	OR 0.14 (0.01-0.84)	Metroniadazole 400 mg, twice daily x 2 days	McDonald et al., 1997
Preterm Birth, all enrolled	RR 0.7 (0.3-1.7)	Metroniadazole 400 mg, twice daily x 2 days	McDonald et al., 1997
Preterm birth	RR 1.0 (0.8-1.2)	Metronidazole 2 gm x 2; repeated once	Carey et al., 1999

The Centers for Disease Control (CDC) currently recommends BV screening of symptomatic pregnant women and screening for asymptomatic women with a history of preterm delivery (CDC, 1998). However, the work of Hay (1994), Ralph (1999) and Oakeshott, et al. (2002) all demonstrated an independent association between BV and miscarriage from 13-16 weeks gestation. This finding supports the position that BV screening and treatment needs to occur early in pregnancy, to impact this ascending infection before subclinical chorioamnionitis and an inflammatory response occurs.

Two studies published in March, 2003 evaluated the pregnancy outcomes of asymptomatic women who were treated before 20 weeks gestation for bacterial vaginosis. Ronald Lamont et al. (2003) found that treatment of women with 2% clindamycin vaginal cream reduced the incidence of preterm birth by 60% when compared to placebo. Austin Ugwumadu and colleagues (2003) studied the effect of early oral clindamycin treatment on late miscarriage and preterm delivery and found significant reductions in the rates of second trimester miscarriage and spontaneous preterm birth. A third study was conducted by Herbert Kiss and colleagues in Vienna (Kiss et al., 2003). This preterm prevention program featured simple screening and treatment for vaginal infection during late first trimester/early second trimester. Over 4,000 pregnant women were screened and treated with clindamycin vaginal cream if positive for bacterial vaginosis. Treatment for trichomonas was local metronidazole, 500mg daily, and candidiasis was treated with topical antifungals. A 50% reduction in preterm birth was noted, especially in LBW infants from 1500-2500 grams.

The Centers for Disease Control in the U.S. continues to recommend metronidazole 250mg three times a day for seven days as the optimal BV treatment for high risk and/or symptomatic BV positive pregnant women. This recommendation is based upon evidence that other recommended regimens have lower efficacy and a reduced spectrum of activity (Koumans et al., 2002). Two large meta-analyses analyzing 150,000 and 200,000 patients, respectively, failed to find any evidence of teratogenicity with early pregnancy exposure to metronidazole (Caro-Paton, et al., 1997; Burtin, et al., 1995).

2.4.2 Smoking

2.4.2.1 Effects of smoking on birth weight

Smoking by pregnant women, and their passive exposure to second-hand smoke, is a well documented risk factor for low birth weight, shorter gestational age, smaller head circumference, shorter crown-heel length, and more perinatal complications (Eliopoulos et al., 1996; Mongoven et al., 1996; Bardy et al., 1993; Haddow et al., 1987; Eskenazi et al., 1993). Women who smoke during pregnancy deliver infants who are 188-441 grams lighter than the infants of women who are not exposed to tobacco smoke (Bardy et al., 1993; Haddow et al., 1987). Women who are exposed to second-hand smoke give birth to infants between 45 and 107 grams lighter than non-exposed women (Haddow et al., 1988; Eskenzai et al., 1995). Birth weight decreased by one gram for every nanogram per milliliter of cotinine in the mother's blood (Eskenazi et al., 1995).

Two large cohort studies observed that women who quit smoking during pregnancy give birth to infants who are heavier than those of smokers (Ahlsten et al., 1993; Lieberman et al., 1994). Women who are unable to quit entirely, but reduce smoking have been found to give birth to infants weighing on average 92 gm more than women who do not quit or reduce cigarette consumption (Li et al., 1993). The timing of quitting (and relapse) is also important. Women who quit smoking before the third trimester were found by Lieberman and her colleagues (1994) not to be at increased risk for small-for-

gestational-age infants, whereas intrauterine growth retardation increased in proportion with the number of cigarettes smoked during the third trimester.

2.4.2.2 SHS evidence base for smoking cessation programs

Smoking in pregnancy is one of the few known potentially modifiable factors associated with low birth weight, very preterm birth and infant mortality. In response to the well documented adverse health and related economic effects of maternal smoking during the prenatal period, modification of tobacco use is now integral to a wide variety of clinical and public health strategies for reducing infant mortality and morbidity (Kleinman et al.,1988).

Two meta-analyses of smoking cessation in clinical practice and during prenatal care published in the mid-1990's indicated that while even brief advice by physicians during office visits was modestly successful in raising quit rates, more intensive counseling showed greater effect (Dolan-Mullen et al.,1994; Silagy & Ketteridge, 1996). This information formed the basis of guidelines for primary care providers, published by U.S. Department of Health and Human Services (Fiore et al., 1997).

The *Healthy Start* appraisal of various models of smoking cessation was initiated in 1997, four years before the 2003 Cochrane review of smoking cessation programs in pregnancy was published. The papers assessed by SHS staff included reviews of self-help smoking cessation (Kendrick et al., 1995; Petersen et al., 1992), integration of brief advice into routine prenatal care (Petersen, et al., 1992), smoking relapse prevention among pregnant

women (Lowe et al., 1997), use of nurses to impart the smoking cessation information (Byrd & Meade, 1993), theoretical models of behavior change, including self-efficacy (DeVries & Backbier, 1994), and the stages of behavior change (Prochaska, 1996; Prochaska & DiClemente, 1993; Ruggiero et al., 1997).

Of the models cited above, Healthy Start identified several which were found to be at least modestly successful in reducing smoking among pregnant women. Besides brief advice from physicians and intensive counseling, home visiting by nurses was also found to be effective in reducing smoking among pregnant women (Byrd et al., 1993; Olds et al., 1986). In a randomized trial of home visiting by public health nurses, Olds and colleagues (1986) found that smoking reduction was the only significant measurable effect of home visiting. The home visited pregnant women had lower cotinine levels, and there was a 75% reduction in the incidence of preterm delivery when compared to controls.

A randomized evaluation of smoking cessation interventions for pregnant women conducted by J.P. Mayer and colleagues (1990) at a WIC clinic addressed the entire spectrum of psychosocial, behavioral and pharmacological aspects of smoking. In this study the highest percentage of women who quit smoking received multiple interventions which included counseling about risk, behavior change and self-help materials.

Another approach, the transtheoretical model of health behavior change, was developed by the Prochaska/DiClemente group (Prochaska & Velicer, 1997).

This model integrates stages and process of change from different theories of intervention. A study of smokers in professional treatment revealed that participants used different processes of behavior change at different stages of change. The five stages of change identified in the transtheoretical model are precontemplation, contemplation, preparation, action and maintenance. Matching an individual's stage along a readiness-to-quit continuum with an appropriate behavioral change process formed the basis of a large smoking cessation study conducted by this group. In a large nonrandomized intervention study, 5100 smokers were recruited proactively rather than in the traditional reactive fashion of waiting for individual smokers to seek help. The stage of readiness to quit was assessed and interventions were targeted to the appropriate stage. Abstinence rates at 18 and 24 months for the transtheoretical system were 21.7% and 25.6% respectively versus 16.6% and 19.7% for those who did not receive the stage based interventions. The study was replicated in a population of 4653 smokers and the differences were also highly statistically significant (p-values not provided) (Prochaska & Velicer, 1997). In 1997 Ruggiero and Prochaska also published a stage-matched smoking cessation program for pregnant smokers (Ruggiero et al., 1997).

2.4.2.3 Recent research on smoking cessation programs

Research published subsequent to the initiation of the SHS smoking strategy provided additional data to support the metholology adopted by Healthy Start. Haslam and Draper (2000) conducted research in the U.K. and also proposed assessing a woman's readiness to change smoking behaviors at the start of antenatal care. Following this assessment, they suggested that appropriate

multimodal interventions, including relevant behavioral counseling, could then be implemented.

The 2003 Cochrane review of "Interventions for Promoting Smoking Cessation During Pregnancy" was published. This review was based on 34 trials and concluded that smoking cessation programs appeared to reduce smoking in pregnancy as well as low birth weight and preterm birth (OR=0.53, 95%CI 0.47-0.60) (Lumley et al.,2003). There was no effect detected for very low birth weight or perinatal mortality. However the small number of trials in which these more extreme variables were assessed had inadequate power to detect a significant effect.

As in the Dolan-Mullen analysis where risk ratios for smoking cessation ranged from 0.9-7.6 for eleven different programs, there was substantial variation in the type and intensity of intervention assessed in the Cochrane review. Types of interventions included:

1. Information about the harmful effects of smoking on the fetus and infant, the mother herself or other family members (verbal, written or both).
2. Advice by a health professional to 'stop smoking.'
3. Supplementation of advice by reinforcement at subsequent antenatal visits
4. Supplementation of advice by group counseling
5. Supplementation of advice by the provision of peer support
6. Supplementation of advice by recording smoking status, or measuring by-products of smoking at other antenatal visits

7. Supplementation of advice by feedback of the effects of smoking on the fetus (fetal movements, fetal breathing, fetal heart rate).
8. Supplementation of advice by positive information about the fetus and fetal development (e.g. describing the ultrasound in detail).
9. Individualized advice and support for smoking cessation based on 'stages of change.'
10. Provision of pregnancy-specific self help manual on strategies for quitting
11. Provision of the following as an adjunct to information and advice: nicotine replacement therapy; telephone follow-up with reinforcement of advice and strategies for quitting; rewards and incentives
12. Strategies to change the attitudes, knowledge and behavior of health care providers with respect to smoking cessation.

(Lumley et al., 2003)

Trials with either high intensity intervention or a high quality score (rated on there being an explicit theoretical basis) or both, had pooled odds ratios for smoking cessation of 0.54 (95% CI 0.46-0.63), 0.52 (95% CI 0.44-0.60) and 0.53 (95% CI 0.44-0.63) respectively (Lumley et al., 2003

A recent randomized trial conducted in Denmark concluded that a multimodal intervention which included individual counseling supplemented by a smoking cessation program with nicotine replacement therapy as a voluntary option

had a significantly higher cessation rate among pregnant women than the usual care control group (Hegaard et al., 2003).

Recent epidemiological data and qualitative survey studies of gender issues related to smoking cessation, suggest that women may require behavioral counseling tailored specifically to their issues, including a high caring burden, socio-economic problems, bodyweight gain, social support to foster abstinence and environmental cues which may trigger smoking (Perkins, 2001; Tod, 2003).

2.4.3 Nutrition

Nutritional research examining the effect of diet in pregnancy on infant birth weight incorporates many contextual issues. Maternal diet, maternal pre-pregnancy weight, dietary composition and socio-economic and cultural factors have all been examined but direct links to infant birth weight are difficult to demonstrate.

A well known cohort study, the Aberdeen *Children of the 1950s*, recorded the food intake of primagravid women in the 7th month of pregnancy and found only slight differences in birth weights based upon maternal diet. Women who consumed less than 1800 calories per day had infants who weighed just 240 grams (0.5 lb) less than women who ate 3000 or more calories per day (Batty et al., 2004).

Studies of famine during World War II in the Netherlands, Germany and Russia (USSR) showed a fall in mean birth weight of 327 grams, only when infants were exposed to famine during the second half of gestation. In Leningrad where the famine was most severe and caloric intake dropped to 300 calories per day, term infants whose mothers had decreased intake in the second half of their pregnancies, weighed less than 2500 grams (Barker, 1998).

It has been postulated that this second trimester effect may be related to maternal nutritional status at conception. A number of studies have documented that mean birth weights in underweight mothers are lower than in women with a normal body mass, even when weight gain during pregnancy is normal (Rosso & Salas, 1994). In a retrospective chart review Ehrenberg et al. (2003) analyzed a large perinatal data base in Cleveland, Ohio from January 1997 to June 2001 and found that low maternal weight and BMI at conception or delivery, or poor weight gain during pregnancy were associated with low birth weight, prematurity and maternal delivery complications.

A review by Merialdi et al. (2003) searched the Cochrane library and RCTs in an attempt to study the effect of nutrition interventions on fetal growth. The reviewers concluded that only balanced protein energy supplements reduced the risk of small for gestational age infants, especially in populations with a high prevalence of under nutrition. There is insufficient evidence of association to support a recommendation of single or multiple micronutrient supplementations to prevent LBW. The new U.K. antenatal care guideline launched in October, 2003 does not recommend routine vitamin or iron

supplementation in normal pregnancy (National Collaborating Centre for Women's and Children's Health, 2003).

A recent study by the U.S. Bureau of Census measured food insecurity and hunger in the U.S. for a twelve-month period ending April, 1995. The study attempted to measure poverty- linked access to food and found that about 11.9 million households experienced food insecurity at some level during the study year. Affected households had higher rates of poverty, were predominately female-headed, included young children, were Black or Hispanic, and were located in central city areas (USDA, 1997).

The Pregnancy, Infection, and Nutrition Study (n=2247) conducted in North Carolina looked at nutrient and food group differences by race. A second trimester dietary review revealed that although the average caloric intake of Black women was higher, White women had healthier diets, consuming greater amounts of protein, iron, folate and fiber (Siega-Riz et al., 2002). Nutritional racial disparities may have implications for birth weight differences in the short term and adult health in the long term (Roseboom et al., 2001; Rich-Edwards et al., 1999).

The United States Department of Agriculture (USDA) sponsors the Special Supplemental Nutrition Program for Women, Infants and Children (WIC). WIC provides healthy foods, nutrition education and referrals to health care and social service agencies. The program is targeted to women who are pregnant, breastfeeding, postpartum and children under five years old. WIC supplements diets in specific nutrients by providing milk or cheese, iron

fortified cereal, Vitamin C juice, eggs, peanut butter or dry beans and iron fortified formula for bottle-fed infants. The studies of the effect of WIC upon birth weight have varied. In the Massachusetts WIC Statewide Evaluation Project, Kennedy and Kotelchuck (1984) documented an increase in mean birth weight among participants compared to non-participants and a concomitant decrease in incidence of low birth weight, i.e. 6.9 % versus 8.7 %.

More recently, evidence from 90,117 women who took part in New Jersey's comprehensive prenatal care program, Health-Start, from 1988-1997 was analyzed. This model which controlled for social and demographic, psychosocial and behavioral factors as well as medical risk factors and prenatal services showed that receipt of WIC services was associated with an increase in mean birth weight of 22 grams (compared with no WIC services) and with a reduction in risk of low birth weight, OR 0.87 ($p<0.001$) (Reichman, & Teitler, 2003).

A cost effectiveness analysis published by Gregory and deJesus (2003) concluded that prenatal WIC participation was associated with lower cost to Medicaid and better birth outcomes, particularly for Black women. Buescher et al., did a similar review linking Medicaid and WIC data files to birth certificates in North Carolina in 1988. They also concluded that prenatal WIC participation reduced low birth weight and newborn medical care costs among poor women.

However, a national evaluation of WIC by Besharov and Gemanis (2000) questioned WIC's possible impacts on infant mortality, prematurity and birth

weight. Weaknesses in previous research, including selection bias, simultaneity bias and lack of generalizability were identified. They concluded that additional research was required.

2.4.4 Psychosocial Stress Factors

Psychosocial stress is listed by the Committee to Study the Prevention of Low Birthweight as, "...an evolving concept of risk" (Institute of Medicine, 1985). However, since biblical times acute maternal stress in response to severe life events has been associated with the onset of labor:

> *And his daughter-in-law, the wife of Phinehas, was pregnant near to giving birth, and got to hear the report that the ark of the true God was captured and that her father-in-law and her husband had died. At that she bowed herself and began giving birth, because her pangs came unexpectedly upon her.* *1 Samuel 4:19*

2.4.4.1 Physiological evidence

Physiologically, it appears that maternal stress may act via a neuroendocrine pathway through the hypothalmic-pituitary-adrenal axis, stimulating the "fight or flight" response. This results in the release of cortiotropin releasing hormone which, as previously noted, is implicated in the initiation of preterm labor. Stress may also be expressed biologically through an immune/inflammatory pathway. In the presence of elevated levels of cortisol

due to acute or chronic stress, the consequent immunosuppressive effect may result in increased susceptibility to infection.

Wadhwa et al. (2001) postulated that because neuroendocrine and immune processes cross-regulate one another, interactive and multiplicative effects can occur when pregnant women are exposed to both high levels of chronic stress and infectious pathogens resulting in preterm birth. Research was proposed to explore the linkages between stress and infection in pregnancy.

In 2001 Culhane et al. published a paper showing an association between high levels of chronic stress and BV. Stress was assessed using a standard self report stress scale and BV was diagnosed by Gram-stain. BV positive women had a significantly higher mean chronic stress score than BV negative women ($p<0.01$).

2.4.4.2 Research evidence

Observational studies reveal associations between various psychosocial phenomenon and LBW. In a study by Lobel et al. (1992) one hundred thirty women of low socioeconomic status were interviewed throughout pregnancy. Early deliveries, and consequently low birth weight, were predicted by medical risk and prenatal stress. Wadhwa et al. (1993) designed a prospective study to test the influence of maternal antenatal psychosocial stress on birth outcomes, controlling for biomedical risk. Biomedical risk was defined as one or more antepartum medical complications during pregnancy. A measure of life event stress was used to assess disruptive changes during pregnancy such as a

separation or divorce, job loss, or other major personal disruption. They found that for every increase of prenatal "life event" stress, there was a 55.03 gram decrease in infant birth weight and a significant increase in the likelihood of low birth weight ($p<0.05$; OR 1.32, CI not provided).

Hobel et al., (1998), demonstrated that elevations in CHR between 18 to 20 weeks gestation, associated with maternal age and stress level, appear to be linked to preterm delivery. Dawn Misra et al. (2001) showed that stress during pregnancy and poor perceptions of locus of control were strongly associated with preterm delivery and consequent LBW, with odds ratios close to 2 for both variables, even with the addition of biomedical factors to the model

Maternal stress has also been associated with other risk factors for preterm birth and LBW. In addition to the previously mentioned link between infection and stress, a study by Nelson et al. (2003) demonstrated that women with high stress were more likely to use cigarettes and marijuana during pregnancy.

Hogue et al. (2001) theorized that a fetus exposed to stress hormones in utero may have impaired neural development which predisposes him/her to increased sensitivity to stress in later life. They postulated that such individuals have a decreased ability to modulate their physiological reactions to stress. They also suggested that a chronically stressful environment may effectively "condition" an individual. Learned physiological responses may trigger higher reactivity when exposed to similar circumstances. This theory leads potentially, to the hypothesis that stress responses may be intergenerational and have a cumulative effect in populations such as African

American women, whose histories are significant for generations of chronic stress.

The evaluation of preterm low birth weight risk factors should include factors associated with social stress: poverty, maternal age, maternal educational level, involvement of the father of the baby (FOB), and intendedness of pregnancy. Consideration should also be given to the effects of racism and discrimination on the stress levels of African American women whose rates of infant mortality do not improve even when socioeconomic levels are high.

2.4.4.3 Stress and social support

Home visitation and case management have long been advocated as strategies for social support among disadvantaged women during pregnancy. It is presumed that such programs will ameliorate some of the chronic stress in the lives of these women which appears to be associated with preterm delivery and low birth weight. Social support programs for women at risk of low birth weight have been systematically reviewed by Hodnett and Fredericks (2003) for the Cochrane Library. Despite good quality trials, with comprehensive interventions and a well founded theoretical basis for linking stress, social support and pregnancy outcome, their meta-analysis did not demonstrate significant reductions in LBW (13 trials, n=10235, RR=0.98, 95%CI 0.89 to 1.08) or preterm delivery (11 trials, n=10237, RR=0.98, 95% CI 0.86 to 1.07). They did not recommend any further trials and the reviewers concluded:

Pregnant women need and deserve to have the help and support of caring family members, friends and health professionals. However, such support is unlikely to be powerful enough to overcome the effects of a lifetime of poverty and disadvantage...and thereby influence the remaining course of a pregnancy. (Hodnett & Fredericks, 2003, p. 6)

There is however some work around informal support during pregnancy. U.K. researchers who followed pregnant women prospectively and found that prenatal social support including support from family, support from the baby's father and general functional support was associated with infant birth weight (Feldman et al., 2000). A recent study from Germany correlates poor partner relationship and poor female networks to preterm labor and early delivery (Rauchfu, & Gauger, 2003). There may be some advantage to enhancing and supporting family systems through outreach as well as the provision of tangible assistance as required.

2.4.5 Summary of literature review

This chapter contains a summary of the literature upon which SHS interventions were based. Current research on infant mortality and effective elements of prenatal care was reviewed. New relevant evidence regarding antenatal care as well as infection, nutrition, smoking cessation and social support was also presented.

The contribution of prenatal care to positive pregnancy outcomes remains unclear. Using a population attributable risk analysis, review of infant death

and the current medical evidence base, Syracuse Healthy Start initiated measures to address the unacceptably high infant mortality rates which had persisted in the City for over ten years time.

The link between preterm birth and infection as well as the association between bacterial vaginosis and African American ethnicity led to the formation of the BV protocol adopted by the project. Metronidazole was identified as the drug of choice for treatment based on CDC recommendations and a review of meta-analyses which demonstrated no evidence of teratogenicity. Evidence has since shown that early treatment of BV may be effective in reducing late miscarriage and spontaneous preterm birth.

Health Start's smoking intervention was based upon a review of studies which appeared to have some degree of efficacy in the prenatal period. The project utilized the "stages of change" theoretical model and offered women a variety of clinical options including individual counseling and nicotine replacement A meta analysis published recently has shown that smoking cessation programs appear to be effective in reducing LBW and preterm birth.

Early studies linking reduction in low birth weight with nutritional supplementation through WIC formed the evidence upon which SHS based its intervention in this area. More recent evaluations raise questions about WIC's impact on infant mortality. Cost effectiveness analyses are positive however and suggest that WIC reduces medical costs.

The literature linking psychosocial stress and preterm labor led to the initiation of case management as a means of social support for the pregnant women in this program. There was some research evidence to indicate that support of family systems may enhance pregnancy outcomes. A more recent Cochrane review did not find significant reductions in LBW when social support was offered (Hodnett & Fredericks, 2003).

CHAPTER 3

Background

Syracuse Healthy Start Initiative

3.0 BACKGROUND OF SYRACUSE HEALTHY START INITIATIVE

The influence of social context on health and illness, discussed in preceding chapters, forms the overarching theme in the conceptual framework of this thesis (described in detail in Chapter 4) . This chapter aims to describe the city of Syracuse, New York and the social milieu in which the Syracuse Healthy Start Initiative was developed.

3.1 CITY OF SYRACUSE

Syracuse is a small city located in Onondaga County, in central New York State.

Figure 1 Map of New York State

When the project began, Syracuse had 163,860 inhabitants (1990 Census) and--excluding New York City--was the fourth largest city in the State, after Buffalo, Rochester and Yonkers. Syracuse is located in Onondaga County (1990 population: 468,973). The City of Syracuse differs significantly from the balance of Onondaga County in that it has more poverty, a greater proportion of racial and ethnic minorities and a younger population than the surrounding suburban and rural areas.

3.2 POPULATION OF SYRACUSE

The City of Syracuse has a racially and ethnically diverse population which at the beginning of the project was 75% White, 20% Black and 5% Asian/Native American. Approximately 2.4% of Syracuse residents are of Hispanic origin. Three-quarters of all non-White and Hispanic residents of Onondaga County live in Syracuse (Syracuse Healthy Start: Onondaga County Health Department, 2001).

The African American community in Syracuse bears a disproportionate burden of poverty (Table 5). The federal poverty level (FPL) in the U.S. is the amount of income determined by the Department of Health and Human Services needed to provide a bare minimum for food, clothing, transportation, shelter and other necessities. In the year 2000 the FPL was $13,880 for a family of three, equivalent to approximately £8675 in 2000 (www.hivma.org). Nearly 40% of African Americans in Syracuse live below the federal poverty level, four times greater than the countywide average. The poverty rate for African American children is 64%, more than double that for white children, 25%.

Medicaid-paid deliveries, a proxy for low income status, account for 54% of all births to White women in Syracuse but Medicaid was the primary source of payment for 71% of African American births. (Syracuse Healthy Start: Onondaga County Health Department, 2001).

Insufficient education is correlated with poverty as well as with increased risk of poor birth outcomes and increased risk of developmental delay. The percentage of high school graduates in Syracuse varies considerably by race and ethnicity; 74% of White Syracusans age 25 or older are high school graduates, compared with 59% of African Americans. (Syracuse Healthy Start: Onondaga County Health Department, 2001).

The city environment in which African American women live is characterized by violence. Measures of community violence are related to a variety of social conditions that can have adverse effects on pregnancy outcomes and child health. The local homicide rate for African Americans (26.2 per 100,000) is 7.5 times greater than the rate for Whites (3.5 per 100,000). (The homicide rate for England and Wales in 1997 was 1.4/100,000 and in London it was 2.4/100,000 [Barclay et al., 2001]). Rates of hospitalization for assaults follow similar patterns. There is a six-fold difference between the African American rate, 223 per 100,000 and the White rate of 36 per 100,000. (Syracuse Healthy Start: Onondaga County Health Department, 2001).

Table 5 African American and White Populations in Syracuse

	African American	White
Percent of total population below federal poverty level	40%	12%
Percent of children in poverty	64%	25%
Percent of total population with Medicaid funded deliveries	71%	54%
Percent of total population completing high school	59%	74%
Homicide rate	26.2/100,000	3.5/100,000
Assault rate	223/100,000	36/100,000

(Syracuse Healthy Start: Onondaga County Health Department, 2001).

3.3 BIRTH STATISTICS IN SYRACUSE, NEW YORK

3.3.1 Fertility: high in some groups

On average 2,350 infants are born each year (1996-1998) to Syracuse residents; 1,385 (59%) are White, 848 (36%) are African American and 130 (5.5%) are of other races (Syracuse Healthy Start: Onondaga County Health Department, 2001). More than 150 (6.4%) of the children born in Syracuse are Hispanic. The corresponding fertility rates for African Americans and Hispanics, 96.4 and 142.6 births per 1,000 females aged 15-44 years, far exceeds the U.S. averages of 62.4/1000 for African American women and 65.6/1000 for Hispanic women (Syracuse Healthy Start: Onondaga County Health Department, 2001).

In contrast, the fertility rate for White Syracusans is 43.1/1000 more than three times lower than the African American rate and also substantially lower than

the U.S. average of 60.0/1000 (Syracuse Healthy Start: Onondaga County Health Department, 2001).

3.3.2 Infant mortality: declining but has reached a plateau

In 1985-1987, infant mortality in Syracuse averaged 15/1000, making it the fourth worst of 56 small United States cities surveyed by the Children's Defense Fund (Syracuse Healthy Start: Onondaga County Health Department, 2001). The infant mortality rate (IMR) for African-American Syracuse reached 30.8/1000 during 1985-1987, the highest of any of 47 U.S. cities reporting comparable data. Rising national awareness of racial disparities in health care focused local attention on these dire statistics. Many intervention programs began or expanded in response to this crisis and rates improved moderately during the early 1990s. By 1996 however, the African American infant mortality remained at a standstill, fluctuating around 21/1000 from 1993 to 1998. This value was 2.75 times the 1996-1998 White IMR of 7.8/1000 (Table 6) (Syracuse Healthy Start: Onondaga County Health Department, 2001).

3.3.3 Fetal death and perinatal mortality

The fetal death rates, neonatal death and postneonatal mortality patterns closely reflect the ethnic disparities evident in infant mortality in Syracuse. During 1996-1998, rates of fetal deaths at 20 or more weeks gestation for African Americans in Syracuse were 12.8/1000 which was two times greater than that for White infants, 6.0/1000. More than 3% of all African Americans in

Syracuse who gave birth during 1996-1998 had a history of at least one prior fetal death at 20 or more weeks gestation, compared with 1.8% for White women. Marked racial disparities in deaths extend into the perinatal period (fetal deaths at 28 or more weeks gestation and infant deaths under one week of age) for Syracusans. The perinatal death rate for African Americans 18.1/1000 during the period 1996-1998 was three times greater than that of White babies, 6.0/1000 (Syracuse Healthy Start: Onondaga County Health Department, 2001).

3.3.4 Low birth weight and prematurity

LBW and prematurity are leading causes infant death, and again, during the period 1996-1998, the racial disparity in Syracuse statistics was evident. Of 230 deliveries annually in which the birth weight was less than 2,500 grams about half were African Americans and the corresponding rate, 13.6%, was 50% higher than the rate for Whites, 9.1%. Multiple births affect LBW statistics, but racial disparities actually increased after adjustment for multiples; 11.5% of African American singleton births were LBW, compared with 5.8% of singleton White births. Racial disparities also existed in the VLBW category (less than 1,500 grams at birth) for Syracuse residents: African American, 3.1% of births vs. White, 1.4% of births (Syracuse Healthy Start: Onondaga County Health Department, 2001).

Prematurity is closely correlated with LBW, and the rates in Syracuse follow a corresponding pattern. About 11% of births to Syracusans between 1996-1998 were under 37 weeks gestation, which was similar to New York State

and national rates. However, the prematurity rate for African Americans was 13.3%, which was considerably higher than that of Whites, 9.5%. Late pre-term infants (born 32-36 weeks gestation) are at lower risk for complications than those of shorter gestations; 73% of premature African American babies were late pre-term, compared with 82% late pre-term for Whites (Syracuse Healthy Start: Onondaga County Health Department, 2001).

Table 6 Birth Statistics in Syracuse New York 1996-1998

	African American	White
Infant mortality rate	21/1000	7.8/1000
Fetal death rate	12.8/1000	6/1000
Percent with history of fetal death	3%	1.8%
Perinatal mortality rate	18.1/1000	6.0/1000
Percent of low birth weight	13.6%	9.1%
Percent of very low birth weight	3.1%	1.4%
Percent of premature birth	13.3%	9.5%
Percent of late preterm	73%	82%

(Syracuse Healthy Start: Onondaga County Health Department, 2001)

3.3.5 Risk factors for low birth weight in Syracuse population

Many of the risks for LBW and preterm delivery described by the Institute of Medicine (1985) and by Berkowitz and Papernick (1993) (see Chapter 2) were evident among pregnant Syracusans during the years 1994-1996. Demographic risk factors of young age, low socioeconomic status, single

parenthood and low education were evident in local statistics. Short pregnancy intervals, high parity and inadequate prenatal care were medical/health care risks noted in the population in Syracuse. Evolving concepts of risk including genital infection and stress engendered by structural, environmental and social conditions were also observed among pregnant women in Syracuse. The risk for African American women was universally higher than for White women. Table 7 illustrates some of these risk factors.

Table 7 Risk Factors for Low Birth Weight in Syracuse New York: 1994-1996

Risk Factor	Syracuse: White	Syracuse: African American	Syracuse: All
Age <18	6.2%	13%	8.5%
Less than high school education in women over 19 years	23.2%	28.7%	
Prenatal care First trimester Entry to care	73%	57%	66%
Parity ≥3 in women over 24	10%	18%	12%
Social support/stress No father on birth certificate	19%	42%	
Infection (Gonorrhea)	81.3/100,000	1333/100,000	476/100,000

(Lane, 1998)

The teen pregnancy rates in Syracuse during the mid 1990's were over twice the rate for New York State. Sub-optimal interpartum spacing is also a likely consequence of repeated childbearing during the teenage years. More than half (53%) of births to Syracuse teenagers occur within 24 months of a previous birth (Syracuse Healthy Start: Onondaga County Health Department, 2001).

Infant mortality was higher for mothers in Syracuse who did not graduate from high school (odds ratio=1.5; 95% confidence interval: 1.1 - 2.2). As Table 7 illustrates more than a quarter of Syracuse mothers over age 19 who delivered LBW infants had less than a high school education.

Delayed entry to prenatal care and under-utilization of prenatal programs and services are proxies for both behavioral risk factors and access to care issues. The Kotelchuck Index of adequacy of prenatal care codifies prenatal care utilization into four categories:

1. Adequate Plus: Prenatal care begun by the 4th month and 110% or more of recommended visits received
2. Adequate: Prenatal care begun by the 4th month and 80%-109% of recommended visits received
3. Intermediate: Prenatal care begun by the 4th month and 50%-79% of recommended visits received
4. Inadequate: Prenatal care begun after the 4th month or less than 50% of recommended visits received. (Kotelchuck, 1994).

In Syracuse, only two-thirds of pregnant women received adequate or adequate plus prenatal care by the Kotelchuck criteria.

In about 12% of Syracuse births to females age 24 or older, the mother had previously delivered three or more living newborns. High fecundity, implicated as a co-associate of poor birth outcomes, is frequently linked with early sexual initiation combined with unprotected sexual activity. Contraception use is closely tied to access and use of the health care system.

Female- headed households in Onondaga County have 12 times the poverty rate of two parent households (Syracuse Healthy Start: Onondaga County Health Department, 2001). Single mothers not only lack financial support but are less likely to have social support from the fathers of their babies to assist with parenting. Informal interviews indicate that if the father is not listed on the Birth Certificate it usually indicates that he is not assuming paternal responsibilities (Lane, 1998). The father not being named on the Birth Certificate was significantly associated with very low birth weight in Syracuse, with an odds ratio 2.64 (95% CI 1.41-2.64).

Gonorrhea, syphilis and HIV infection are other indicators of unprotected sexual activity. The rate of genital infection for African American women in Syracuse was 16 times higher than the rate for White women. Congenital syphilis bridges both maternal and child health and is a marker for behavioral and access issues. The Syracuse 1998 rate was 10.7 per 100,000 births, compared with a rate of 3.9 in New York State overall (Syracuse Healthy Start: Onondaga County Health Department, 2001).

3.4 SYRACUSE HEALTHY START INITIATIVE

Many intervention programs began or expanded in response to the infant mortality crisis in Syracuse. The City of Syracuse Commission on Women was the first to publicly address the alarming rates and to call on health and human service leaders to work with them on this critical issue. The Onondaga

County Departments of Health and of Social Services responded by conducting an Infant Mortality Review (1990-1993). In 1991, both a perinatal network, Family Ties Network, Inc., and a number of case management agencies, including the ACCESS Center, the Comprehensive Medicaid Case Management program, the Community Health Worker Program, and the Salvation Army Teen Support and Advocacy program were established. Infant mortality came down somewhat in the first half of the 1990s. As noted previously, between 1993-1996, the African-American rate for Syracuse fluctuated around 21 per 1000 live births, but in 1995-1997 an increased rate of 22.7 per 1000 engendered concern in both the political and medical communities that infant mortality was beginning to rise again.

The federal Healthy Start Initiative, established in 1991, was a funding program whose aim was the reduction of infant mortality and the improvement of perinatal outcomes. In response to the elevated infant mortality rates, the Onondaga County Health Department received a $5 million four year award (1997-2001) from the federal Health Resources and Services Administration for the Syracuse Healthy Start Initiative (SHS).

3.4.1 Population Attributable Risk (PAR)

To ensure that the SHS project reached those with the greatest risk of poor pregnancy outcome, a prenatal public health risk analysis, using 1996-1997 data on all births in the City of Syracuse was carried out. PARs were calculated for a wide range of potential medical, social and behavioral risk factors. The PARs for LBW for each risk factor assessed were as follows:

1. Age <19 (PAR%: 7.1)
2. Age <22 (11.8)
3. Education: high school (HS) (12 years) or less (29.3)
4. Smoking (15.8)
5. Medicaid (29.7)
6. Prior child death (3.0)
7. Prior LBW (7.4)
8. First pregnancy (4.9)
9. Unintended pregnancy (14)

The model did not include inadequate prenatal care because all pregnant participants of SHS received a prenatal care appointment and were followed up to ensure that they received ongoing prenatal care. The risk associated with Medicaid enrollment involved potential difficulties with access and reflected low socioeconomic status. Clinical risks that may be grave for an individual woman (i.e. placenta previa or abruption, gestational diabetes, hypertensive disorder of pregnancy) occur sufficiently rarely that they represent much less than 10% PAR.

Five risk factors were noted to have a PAR greater than or equal to 10 % for low birth weight or infant death:

1. Age less than 21 years
2. Education less than high school completion
3. Medicaid enrollee
4. Smoker
5. Unintended or mistimed pregnancy (Lane, 1998).

These five risk factors were widespread, together accounting for 75% of the City of Syracuse population of women giving birth during 1996-7. A woman was considered as being at risk if she had one or more of these risk factors.

A stepwise model examined the contribution of each of the five risk factors to a cumulative PAR for the outcomes of low birth weight:

1. Medicaid alone (PAR%; 29.7)
2. Medicaid or education (37.9)
3. Medicaid, education or smoking (38.9)
4. Medicaid, education, smoking or age (40.3)
5. Medicaid, education, smoking, age or unintended pregnancy (48.4).

As noted in #5 above the total cumulative PAR for the model was 48.4% for LBW. For the outcome of infant death the cumulative PAR was 61%. This risk system identified that 409 out of 470 women with LBW infants and 47 out of 52 mothers whose infants died had at least one of the five risk factors cited above. If the excess risk associated with the presence of these variables were reduced, up to 50% of LBW could be avoided.

Risk factors addressed by the SHS project were those social, behavioral or environmental phenomena for which a public health intervention could be designed. Therefore, race was not defined as a risk factor. To make sure that bias was not introduced in not using race as a risk factor, the five variables in the risk assessment model were assessed with and without the inclusion of race. These two models differed only slightly. The largest difference was with

infant mortality as an outcome in which case the difference in sensitivity with and without African American race in the model was 3.8%. The sensitivity was 90.4% without African American race and increased to 94.2% with African American race.

3.4.2 SHS Enrollment

Women in Syracuse were enrolled in the new SHS program based upon residence within the ten ZIP (postal) codes that overlap the project area, which effectively encompassed the entire City of Syracuse. In some city medical practice sites all eligible women were enrolled. In other practices women were offered the option of enrollment through an office social worker or nurse. Some women self referred to Healthy Start by contacting the advertised number at the Onondaga County Health Department. During 1999, 2000 and 2001 nearly 50% of deliveries in the City of Syracuse were to SHS participants (Lane, 2000).

In 1999, 1255 women were enrolled in SHS. There were 720 deliveries among project participants. The ethnicity of women registered in Healthy Start in the year 1999 was 52% African American, 33% White, 10% Hispanic, 4% Asian and 2% Native American. Nineteen percent of the Healthy Start deliveries were to women less than or equal to19 years of age. Among women greater than or equal to 20 years of age, 40% had not completed high school. Eight three percent of the women in the program received some form of public assistance. Sixty six percent of the pregnancies were unintended

(Lane, 2000). Clearly the enrolled women typified the risk factors identified in the prenatal public health risk assessment.

3.4.3 SHS Interventions

The interventions instituted by SHS attempted to target modifiable behavioral and medical risk factors elicited in the risk analysis previously described and supported in the literature review. Behavioral risks were addressed by a case management referral scheme and by a project–wide smoking cessation program. A case manager was assigned to each participant in Healthy Start. The case manager was able to assist with Medicaid insurance enrollment, access to prenatal care, WIC referrals and to provide social support and home visits as needed. Training in the SHS smoking cessation program, based on the transtheoretical model of behavior change described previously, was offered to all local providers. Specific training was also undertaken among case managers and community health nurses to promote this approach to smoking cessation.

Maternal health interventions for potential medical risk in the Syracuse population included the promotion of WIC attendance and a screening and treatment protocol for BV. As noted earlier in this paper, WIC attendance in Syracuse prior to the Healthy Start program was 46%. Pregnant women must be enrolled in prenatal care in order to qualify for WIC. Prenatal care providers were encouraged to provide WIC registration information and documentation of a positive pregnancy test for each new registrant as a

means of promoting good nutrition in pregnancy among women whose economic resources were limited.

A clinical intervention to reduce preterm low birth weight deliveries involved screening, treatment and appropriate follow-up of pregnant women for bacterial vaginosis. This intervention was based on a review of infant mortality records for the early 1990s. Sepsis was noted to be listed as a cause of death in 50% of cases. BV screening was introduced through in-service education to over forty obstetricians, nurse midwives and medical residents at prenatal care clinics and private offices in Syracuse and at obstetric Grand Rounds at Crouse Hospital. The policy was to screen women by vaginal swab at their first prenatal visit after consent was given. The swabs were sent for laboratory examination at Crouse Hospital Lab. Nugent's criteria were used to evaluate samples. Results were reported as positive, negative or indeterminate.

The clinical consultant for the Healthy Start project and director of the local high risk Perinatal Center, Dr. Richard Aubry provided education and encouragement to providers throughout the community to implement all interventions with their entire patient populations. Frequent updates on Healthy Start projects were given by Dr. Aubry at weekly Grand Rounds.

Overall project management of SHS was coordinated through the Onondaga County Health Department. Dr. Sandra Lane, a medical anthropologist, wrote the initial grant and served as the Healthy Start Director. She was supported by Dr. Aubry. A health services research fellow maintained statistical records.

Approximately 15 office practices and the major obstetrical hospital in the City of Syracuse were actively involved in the SHS initiative.

3.5 SHS Risk Screening

The Syracuse Healthy Start project developed a social risk assessment form that was used by a neighborhood health center's obstetrical providers and two home visiting/case management agencies. The additional staff time and effort required to administer the questionnaire resulted in only partial community uptake of this tool which aimed to provide guidance for social intervention. During 2000, 67% of all SHS participants (n=675) were administered the social risk interview. This assessment was conducted as early as possible in pregnancy, so that clients received intervention for their identified risks. The Table 8 below presents the percentages of risk identified among the pregnant participants of Syracuse Healthy Start in the year 2000, sorted by race and Hispanic ethnicity.

Table 8 Syracuse Healthy Start Participants, Social Risks by Race/Ethnicity, Year 2000

RISK (n=675 participants)	WHITE (n=186)	AFRICAN AMERICAN (n=335)	HISPANIC (n=67)	OTHER (n=86)
Smoking*	56%	32%	30%	45%
Any alcohol this pregnancy	7%	8%	5%	6%
Any drugs this pregnancy	9%	12%	5%	10%
Current domestic violence	4%	3%	3%	1%
Domestic violence in the past year	18%	8%	16%	6%
Did not want this pregnancy**	20%	16%	10%	15%
Wanted to be pregnant later**	41%	40%	43%	35%
Not sure about feelings about pregnancy**	16%	23%	15%	24%
Wanted to be pregnant sooner	4%	3%	5%	5%
Wanted this pregnancy	18%	18%	27%	22%

*This is the proportion of SHS participants identified as smokers at the first prenatal contact. SHS has a major smoking cessation focus, so that many women have either quit or significantly reduced their smoking by the time of the birth.

** These three variables together constitute "unintended pregnancy."

(Syracuse Healthy Start: Onondaga County Health Department, 2001)

As is clear from this table, women from all racial and ethnic backgrounds in the Healthy Start project area reported considerable use of drugs and alcohol and exposure to domestic violence. It is likely that given the social stigma attached to these behaviors, the figures are under-reported.

3.6 Birth Outcomes in the first three years of SHS

During the first three years of the Healthy Start project, infant mortality in Syracuse decreased overall and for both White and African American births. Infant mortality rates fell by 23.8%, from 12.2/1000 during 1994-1996 to 9.3/1000 during 1998-2000. In the African American population the rate decreased by 32.6%, from 21.5/1000 to 14.5/1000. In the White population, the decrease was 10.3%, from 7.8/1000 to 7/1000. The corresponding African American/White disparity in infant mortality dropped from over 4 times to 2.2 greater. These trends were not statistically significant in the overall population (p=0.11) or in White women (p=0.70). However in Black women the p-value approached significance, p=0.0582 (Syracuse Healthy Start: Onondaga County Health Department, 2001).

The Healthy Start Evaluation Report for the year 2000 provided an analysis, based on Health Department statistics, of the percent reduction in maternal and perinatal morbidity in the Healthy Start project area:

Table 9 Percent Reduction in Maternal and Perinatal Morbidity: 1997 to 2000, in Syracuse NY

	1997 n=2577 births/year	2000 n=2333 births/year	Percent reduction	P-value
Antepartum hospitalization	14.9%	9.1%	39%	0.21
Low birth weight	12.2%	10.2%	16%	0.45
Very low birth weight	2.6%	1.8%	31%	0.23
NICU admissions	9.0%	7.1%	21%	0.62

(Syracuse Healthy Start: Onondaga County Health Department, 2001)

Although the trends are downward, the numbers are small for each variable assessed and the difference in the proportions did not reach significance.

Risk factors which reflected disparities in health care were analyzed for mothers of very low birth weight babies. The analysis is presented in Table 10.

Table 10 Maternal Risk Factors: VLBW Deliveries In Syracuse, NY 1997 & 2000

Risk Factor	1997 n=67	2000 n=42	% Decrease	P-value
Non-private provider*	87%	62%	29%	0.003
<12 years education	55%	38%	31%	0.08
Medicaid**	70%	48%	31%	0.02
African American	75%	24%	68%	0.0001

*i.e., prenatal care clinics serving highest risk, poor women

** government funded health care for the poor

(Syracuse Healthy Start: Onondaga County Health Department, 2001)

The risk factor profile of women who delivered very low birth weight babies changed significantly over time. There were significantly fewer clinic patients, Medicaid recipients or African American women in this group in 2000 compared to 1997. The number of poorly educated women was also trending downward (Syracuse Healthy Start: Onondaga County Health Department, 2001).

The initial statistics in the Syracuse Healthy Start project were very encouraging. Downward trends were noted in infant mortality, low birth weight and very low birth weight. Admissions to the Neonatal Intensive Care Units (NICU) and the antepartum hospital units were decreased. Hospital admissions during pregnancy are often related to symptoms of preterm labour and NICU admissions occur most frequently in cases of preterm delivery. In the event of very low birth weight, which is the most common cause of infant mortality, the disparity between rich and poor and Black and White also appeared to be lessening. Such findings encouraged project leaders to begin a more in-depth analysis of the SHS Initiative to investigate the factors contributing to the observed trends. Further analysis of the Healthy Start data is the aim of this study.

CHAPTER 4

CONCEPTUAL FRAMEWORK

4.0 CONCEPTUAL FRAMEWORK

In 1994, at the International Conference on Population and Development in Cairo, the following definition was endorsed by 165 nations:

> *Reproductive health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity, in all matters relating to the reproductive system and to its functions and processes* (Center for Reproductive Rights, 2004).

The integration of biosocial behavioral processes in reproductive health is perhaps most apparent in the analysis of preterm/low birth weight outcomes in pregnancy. The interplay between social determinants which occur at a population level, behavioral factors which occur at the individual level and biological events which precipitate early delivery and low birth weight forms the basis of the conceptual framework in this research.

The literature reviewed in the previous chapter surveys work relating to preterm/low birth weight from the fields of infectious disease, nutrition, behavioral medicine, psychology and immunology. The particular risk factors included in this model are those identified as having a 10% or greater population attributable risk in the Syracuse Healthy Start analysis of infant mortality in the city of Syracuse. The complex interactions between and among these factors in any one individual creates a situation of cumulative risk

in which impaired aspects of physical, mental and social well-being, as described at Cairo, combine to produce the disaster of preterm/low birth weight delivery and high infant mortality.

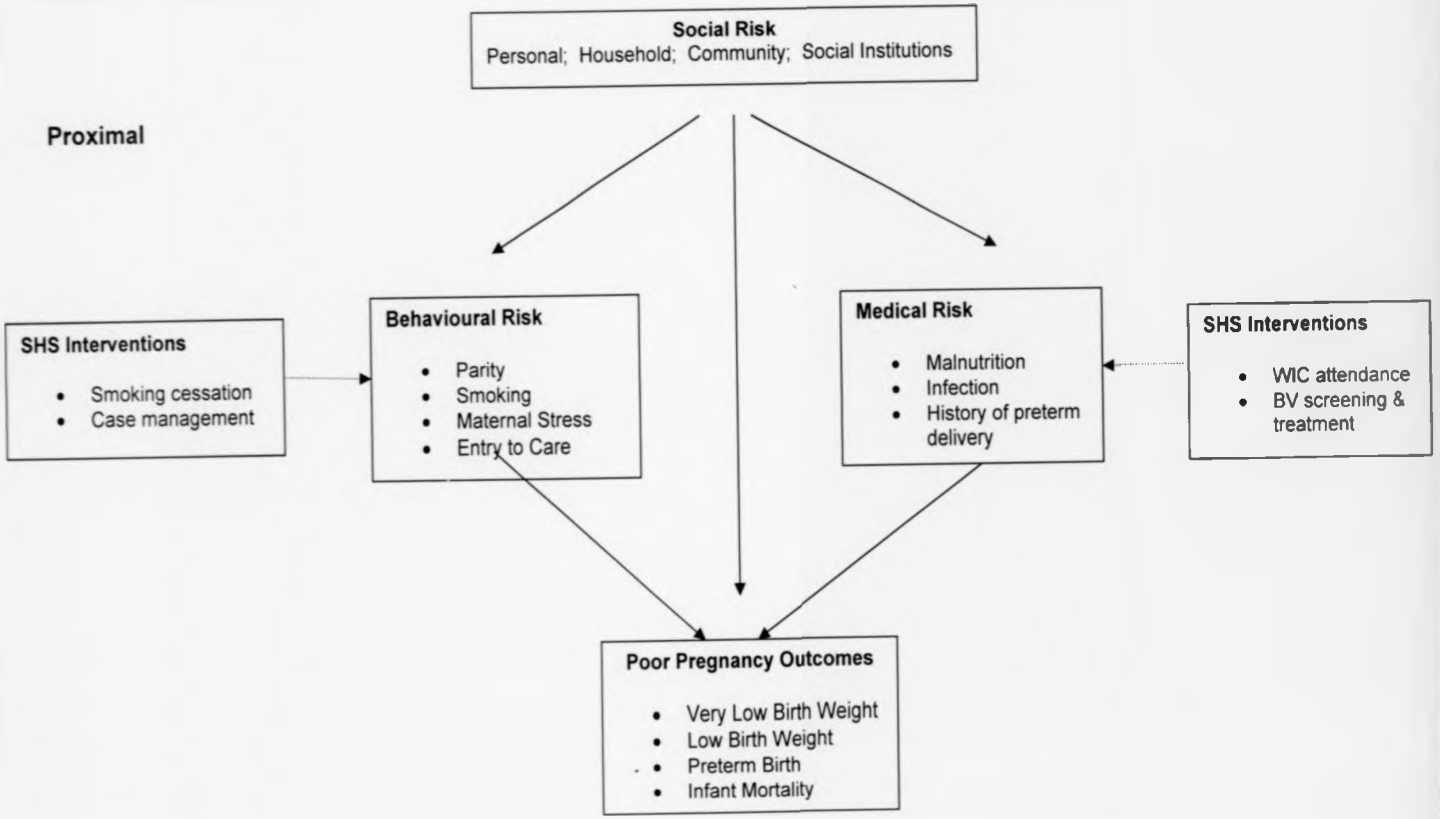
The design of the conceptual model for this study was influenced by the work of Mosley and Chen (1984), Zurayk et al. (1993) and Spencer (2003). Mosley and Chen (1984) conceived a hierarchical framework for child health which featured socioeconomic variables (the distal determinants) operating through biological variables (the proximal determinants) producing the disease state. Zurayk et al. (1993) expanded this framework specifically for reproductive health by subdividing proximate determinants into two categories, intermediate social risk factors and medical risk factors. Background (distal) risk factors included the structural determinants of health – personal, household, community and social institutions. The variables were linked in a cumulative and interactive manner.

Nick Spencer's recent work on modeling the biopsychosocial pathways to birth weight takes account of variables which have consistently been shown to affect birth weight and gestational age (Table 3). He adds the dimension of life course or longitudinal effects as well as cross-sectional clustering of risk exposures. Like Zurayk and colleagues he emphasizes the role of distal factors exerting their influence through proximal exposures and develops a model of birth weight determination (Spencer, 2003).

This study draws upon the models described above for its conceptual, ethnographic and epidemiologic approaches. The three models are

incorporated in an attempt to understand and analyze the medical, demographic, social and behavioral risk factors which result in preterm/ low birth weight. The model also provides a framework for the evaluation of Syracuse Healthy Start interventions, which were targeted for intermediate and proximal levels of risk, adjusted for the social risk factors. (See conceptual framework model below).

Figure 2 CONCEPTUAL MODEL: Cumulative Risk for Poor Pregnancy Outcomes and Intervention Strategies



Social variables represent the ecological context of LBW. Personal variables include race/ethnicity, maternal age and education. Household variables involve financial resources (poverty) and housing conditions. Community variables encompass access to care, transportation facilities, public assistance programs (including the welfare to work programs), security in neighborhoods, availability of adequate grocery stores in neighborhoods. Social institutions include Department of Social Services policies and availability of supportive church/community organizations.

It is in the realm of the behavioral and medical variables that health-related interventions may have immediate effect. Maternal stress exacerbated by social factors in the environment, may respond to outreach by case managers and health care workers. Family planning and smoking cessation, also supported through community outreach, may impact other behavioral variables. Amelioration of intermediate variables may affect the biological causes of preterm delivery and stimulate social change as well. Biomedical interventions implemented by the Healthy Start program to address two of the proximal risk factors for preterm/low birth weight included enhanced nutrition during pregnancy and universal screening for bacterial vaginosis.

This study aims to identify elements of risk in the Syracuse population which may be predictive of poor outcomes and to evaluate Healthy Start treatment strategies. As both the quantitative and qualitative data analysis will show, many of the

women in the study have a history of multiple risk. Identification of individual or cumulative risk factors which critically affect birth outcomes is a central issue in perinatal public health program development. Designing, implementing and evaluating effective interventions are the next steps. The evaluation of the Syracuse Healthy Start efforts will be presented in the following chapters.

CHAPTER 5
OBJECTIVES AND HYPOTHESES

5.0 OBJECTIVES AND HYPOTHESES

5.1 OBJECTIVES

The overall aim of this study is to determine whether the recent improvements in infant mortality, low birth weight and very low birth weight deliveries in Syracuse, NY may be associated with the implementation of the Syracuse Healthy Start enhanced prenatal care project. The study also aims to elicit participants' views of their pregnancy experience. It is hoped that the findings of this study may influence the design or content of antenatal care programmes in other populations suffering inequalities in the United States of America and elsewhere.

The specific objectives are:

1. To conduct a case-control study of infants born at less than 2500 grams and less than 37 weeks gestation and a comparison group of infants born at greater than or equal to 2500 grams and greater than or equal to 37 weeks gestation, living in the Syracuse Healthy Start Project area and delivered at Crouse Hospital from 2000-2001.
2. To assess level of exposure to Syracuse Healthy Start project participation and treatment of bacterial vaginosis, WIC attendance, case management and smoking cessation between cases and controls.

3. To conduct a qualitative study of women who recently delivered women babies at Crouse Hospital and who live in the project area, regarding:
    a. Perception of good prenatal care.
    b. Factors facilitating:
        i. Early attendance at prenatal care
        ii. Behavioural change motivation
        iii. Chronic and acute stressors and women's responses to stress
        iv. Perceptions of BV risk factors
    c. Factors which motivate behavior change including prenatal decisions regarding smoking cessation (for smokers) and nutritional choices.
    d. Chronic and acute stressors and women's responses to stress in their lives.
    e. Factors which women believe might increase risk of BV infection.

5.2 HYPOTHESES

The hypotheses are as follows:

1. Women who deliver premature low birth weight infants are less likely to have participated in Syracuse Healthy Start.
2. Women who are screened for bacterial vaginosis early in pregnancy and treated if appropriate, are less likely to deliver a premature low birth weight infant.
3. Women who receive enhanced prenatal care including nutritional supplementation, smoking cessation, and social support interventions, specifically case management, may have a small but measurable decrease in preterm low birth weight delivery.
4. No hypothesis is proposed for the qualitative work as this analysis is exploratory and will be interpreted based upon the responses of the participants.

CHAPTER 6
METHODOLOGY

6.0 METHODOLOGY

6.1 STUDY DESIGN

This research utilized a case-control design supplemented by a qualitative investigation which consisted of semi-structured interviews among a purposive sample of postpartum women.

The case-control design was employed to study the effect of participation in the Syracuse Healthy Start Initiative by comparing women who delivered infants born at less than 2500 grams and less than 37 weeks gestation with women who delivered full term normal birth weight babies. The cases were all women living in the project area, who delivered LBW infants of less than 2500 grams and, at less than 37 weeks gestation at Crouse Hospital in the years 2000 and 2001. Controls were chosen from a random sample of live born singleton infants with birth weights greater than or equal to 2500 grams and with a gestational age greater than or equal to 37 weeks gestation. All controls were born at Crouse Hospital and their mothers lived within the designated SHS project area. Computer generated random numbers and the patients' unique ID numbers were utilized to identify controls from the Electronic Birth Certificate database. Cases and controls were compared with respect to participation in the Healthy Start program overall. They were then compared with regard to participation in each individual project

intervention, including bacterial vaginosis screening and treatment, WIC attendance, case management, and smoking cessation.

This study was concurrent with a Centers for Disease Control (CDC) retrospective analysis of medical records of all women and their infants who were enrolled into the Healthy Start program from 1999-2001. The CDC evaluation was undertaken to study the effect of early, universal BV screening using Nugent criteria, and early BV treatment when indicated, on birth outcomes in the SHS population. By contrast, the purpose of this case-control study was to assess the effect of the entire package of enhanced prenatal care services offered by Healthy Start, comparing preterm low birth weight infants, to a control group of full term infants normal birth weight, drawn from a target population including both Healthy Start and non-Healthy Start participants.

A qualitative study was designed to complement the quantitative analysis of each Healthy Start intervention, by seeking information from individual women who received services in the project area.

A case study was presented in order to provide a rich narrative description of the lifestyle of women in the project area. Semi-structured interviews of 15 newly postpartum women from the project area were also conducted, using an open-ended interview guide.

This descriptive-interpretive research focused on five areas, including those investigated in the quantitative study. Women were asked about their perceptions of their own pregnancy outcomes, and about nutrition, smoking cessation, stress and infection in pregnancy. In the context of a semi-structured interview, women responded to open-ended questions, which I recorded by hand and transcribed into narrative form within 24 hours of the encounter. An emergent case study approach was utilized, in which the interview guide was altered as new topics arose (Maykut & Morehouse, 1994). Specifically, questions about coping strategies for stress and support networks including extended family and church communities were added to the interviews.

6.1.1 Justification for choice of study design

Syracuse Healthy Start is a complex community level health program with multiple components and target populations which include both health care providers and pregnant women in the project area. Although empirical methods of evaluation provide mathematical measures of effectiveness, the results of complex analysis can be mixed or conflicting, failing to provide robust evidence which is generalizable beyond the research setting. Programs such as SHS are inextricably linked to local contextual factors. These factors are critical in the assessment of programmatic interventions. Statistical analysis is designed to control for contextual differences between cases and controls and presents results in mathematical

terms at the population level. Traditional qualitative research is done in the vernacular and explores individual experience which is unique and may not have the external validity sought by programme evaluators.

Current health evaluation literature describes several alternative approaches to using purely empirical methods or quantitative research on its own in order to capture the effects of biological, psychological and social factors outcome. Pawson and Tilley (1997) identify several perspectives which employ both quantitative and qualitative methods for evaluation. In particular the pluralist perspective takes the position that all view points add important insights to knowledge of events. This approach helps to explain potential causal pathways. The realist approach is built around explicit theories of how interventions work in specific contexts and is used to test theories of context, providing health care professionals with a deep, rich understanding of complex social interventions which is useful in planning and implementing community programs.

Recognizing the multi-dimensional aspects of the SHS Initiative, and the difficulty of designing a single methodological approach which would link interventions to the outcomes of interest, this research employed a multi-method approach to analysis.

6.1.1.1 Quantitative Analysis

The case-control design permits an analysis of a rare outcome. Preterm low birth weight was chosen as the outcome of interest. Both preterm delivery and LBW are independent risk factors for infant mortality (see Chapter 2; Epidemiology of Infant Mortality, 2000). There is also a causal relationship between these two factors and thus 'preterm low birth weight' was chosen as the outcome measure for this study.

The case-control design also allowed for exploration of several exposures within the population of interest. The design can be useful in the context of an evaluation study because it can be initiated relatively early in relation to program interventions, thus providing results and feedback to researchers more rapidly. The method is cost effective, time effective and easy to carry out (Friis & Sellers, 1999).

An unmatched sample was chosen for the following reasons:

1. Precision gained in matched samples is generally small and requires a significantly more complex analysis (i.e. conditional logistic regression) (London School of Hygiene & Tropical Medicine, 2004).
2. Examination of the risk associated with the matching factor cannot be done in a matched sample. In this study race was the logical candidate for matching because of the association of higher BV infection rates with

African American and Afro Caribbean women and the association of Black women and poverty variables. As it was important to be able to examine the effect of race in the analysis both as a confounder and as an effect modifier, the sample was not matched.

3. The possibility of overmatching on a variable associated with the exposure may result in a loss of power (London School of Hygiene & Tropical Medicine, 2004). In this study, it is possible that matching on race could effectively match on other risk factors of interest, for example, father of the baby on the birth certificate (a marker for social support) or payor source which was a marker for socioeconomic status.

6.1.1.2 Qualitative analysis

Patient interviews were conducted using open-ended interview questions to explore the behavioral factors which were not measured in the quantitative component of the study. Findings from such interviews contribute to the interpretation of the quantitative results particularly in regard to utilization of antenatal services and risk factors for preterm LBW. The quantitative data collected from medical records is limited by the controlled format and structure of the records. Structured interviews and questionnaires also lack the flexibility to explore issues beyond the format of a closed question. And in some areas, such as social support, there is a lack of accepted assessment scales which comprehensively measure this concept with acceptable levels of reliability and

validity (Bowling, 1997). Therefore a semi-structured interview design, which provided topical guidance but allowed freedom of expression among interviewees, was utilized.

6.1.2 Case and Control Definitions

6.1.2.1 Cases

Cases were all live born infants with birth weights of less than 2500 grams and born at less than 37 weeks gestation, whose mothers were residents of Zip codes 13202 through 13208, 13210 and 13224 in the City of Syracuse, New York during the years 2000 and 2001.

Although there is a close interrelationship between LBW and preterm delivery, the correlation is not necessarily universal (Spencer, 2003). Intrauterine growth retardation can occur in full term infants and macrosomia can be present in preterm infants of diabetic women. Therefore, both birth weight and gestational age have been listed as inclusion criteria. Only babies who fit both criteria were included as cases.

Mode of delivery was considered in defining the inclusion and exclusion criteria for cases and controls. This study aims to evaluate the effect of SHS participation on

the outcome of preterm LBW. It is presumed that these births are precipitated by spontaneous preterm labor or spontaneous rupture of membranes and not by planned caesarean section or voluntary termination of pregnancy. However, some physicians in Syracuse consider preterm labor as an indication for caesarean section, regardless of the precipitating event. Therefore, birth by caesarean was not excluded from the study. Terminations, however, were excluded from this study.

The risk of preterm delivery is increased in multiple gestation. These pregnancies were excluded from cases and controls. As syphilis in pregnancy is known to lead to preterm delivery, women with a positive syphilis serology were excluded from the study.

Human immunodeficiency virus (HIV) positive women may have increased rates of infection in pregnancy secondary to immune suppression and should therefore have been excluded from the study. However due to privacy regulations in the U.S., HIV positive serology results could not be abstracted so it is not listed as an exclusion criteria for cases or controls.

Additionally, major congenital anomalies both chromosomal and non-chromosomal, are known to cause stillbirth and preterm labor (Neasham et al., 2001). Therefore, infants with major congenital anomalies have been excluded from the study (Table 11):

Table 11 Congenital Anomalies Excluded from the Study

Chromosomal

a. Down's Syndrome

3. Non-chromosomal

a. Neural tube defects

1. Anencephaly
2. Spina bifida
3. Encephalocele

b. Other central nervous system anomalies

1. Microcephaly
2. Reduction deformities of brain
3. Hydrocephaly

c. Cardiac anomalies

1. Bulbus cordis
2. Septal closure
3. Great arteries and veins

d. Renal and urinary

e. Musculoskeletal

1. Limb reduction
2. Diaphragm and abdominal wall

f. Multiple anomalies

(Neasham et al., 2001)

6.1.2.2 Controls

Controls were live born infants with birth weights of 2,500 grams or higher and born at greater than or equal to 37 week gestation, whose mothers were residents of Zip codes 13202 through13208, 13210 and 13224 in the City of Syracuse, New York during the years 2000 and 2001. Controls were randomly selected using the Electronic Birth Certificate database, a data file of all births entered by date of birth. Two controls for each case were selected. Mothers were identified by a unique identification number (UID) which ensured anonymity in the selection process.

Following the exclusion criteria used for cases, multiple gestation, positive syphilis serology and major congenital anomalies also were excluded in the control group.

6.1.2.3 Qualitative Sample

Participants in the qualitative interviews were recruited among postpartum women who lived in the Healthy Start project area and received care in a clinic setting in the project area. They were recruited at their six week postpartum visit by the office nurse and asked if they wished to be interviewed for this research. Patients who responded positively were then contacted and meeting times and places were arranged. I conducted all interviews.

6.1.3 Study Enrollment

Women in this sample were enrolled in the Healthy Start program in several ways. One large clinic offered enrollment to every pregnant woman. Another clinic referred all socially high risk women to an in-house outreach worker who enrolled interested participants. Some women self referred by phoning the well advertised Healthy Start program directly. Fifteen clinics/offices participated in the program, although not all providers offered all Healthy Start services. There is no data available on exactly how many women received each of the services offered. The number of Healthy Start services offered at each prenatal site also changed over time as providers phased in various interventions over time.

6.1.4 Exposure Variables and Data sources

The primary exposure variable in this study was participation in SHS. The secondary exposure variables were within the total package of care developed by Syracuse Healthy Start and included BV screening and treatment, case management, smoking cessation and enhanced nutrition. Sources for data collection included three electronic databases and the CDC chart abstraction forms. The electronic databases consisted of the New York State Electronic Birth Certificate, the Onondaga County Perinatal Data System and Syracuse Healthy Start Registry and were merged by statisticians at the Onondaga County Health

Department using a common unique identification (UID) number. The CDC chart abstraction forms for both of inpatient and outpatient charts which utilized this UID number for patient identification. All exposure variables, research definitions and data sources are described in the Table 12:

Table 12 Definitions and Data Sources for Exposure Variables

Exposure	Definition	Data Source
Healthy Start participation	Registered as Healthy Start Participant	Merged database*
BV screening and treatment • Unscreened • Screened and negative • Screened, positive and treated • Screened, positive and not treated	Screened for BV using Nugent's criteria Received metronidazole for non trichomonas infection during pregnancy	Inpatient and outpatient chart abstraction
Home visitation/case management	One home visit/contact during pregnancy	Merged database
Smoking cessation	Documentation in chart of advice to stop smoking at first prenatal visit	Outpatient chart abstraction
Enhanced nutrition	Participation in WIC during pregnancy	Merged database

*Merged database: New York State Electronic Birth Certificate, the Onondaga County Perinatal Data System, Syracuse Healthy Start Registry

6.1.5 Risk Factors and Data Sources

Numerous socioeconomic and biomedical risk factors may confound or interact with the exposure variables of interest to influence the strength of the relationship with preterm LBW. Table 13 below lists risk factors which were considered in the statistical analysis of this study. Since all cases and controls lived in the project area, which is the most economically depressed area of Syracuse, there were expected similarities in socioeconomic status within the study population. However, additional markers for socioeconomic status, particularly payor source (i.e. Medicaid status) and antenatal care provider (clinic or private provider) were included for analysis. Traditional demographic factors such as race, maternal education, marital status and maternal age were abstracted. "No father on the birth certificate" which may be a marker of social and economic support, was included in the data collection. Prior preterm delivery is a widely accepted risk factor for LBW and was included in the analysis. In reality, this event may simply be a sign of underlying problems, such as untreated infection, poor access to care or chronic stress. Information on parity was also collected.

Table 13 Definitions and Data Sources for Other Risk Factors

Risk Factor	Definition	Data Source
Race	Maternal race, self described	Merged dataset
Education	1=≤12 yrs (Basic high school or less) 2=>12 yrs (Some college)	Merged dataset
Maternal age	1= <20 (teen) 2=≥20	Merged dataset
Marital Status	0=married 1=married	Merged dataset
No father of baby listed on Electronic Birth Certificate	Father not named	Merged dataset
Prenatal care provider	1=private 2=UHCC 3=SCHC 4=PNC 5=Other	Merged dataset Inpatient chart abstraction
Medicaid, as proxy for poverty	Medicaid or Medicaid HMO insurance	Merged dataset
Parity	1=primiparous 2=multiparous* without history of preterm delivery 3=multiparous with history of preterm delivery	Merged dataset Inpatient chart abstraction
Previous preterm delivery	0=No 1=Yes	Merged dataset

*Multiparous A woman who has had two or more pregnancies resulting in potentially viable offspring (MedTerms com, 2002).

6.1.6 Sample Size

6.1.6.1 Case-control Study

Multiple studies demonstrate that the relationship between the risk factors targeted by Healthy Start interventions, particularly stress, smoking and bacterial vaginosis, had relative risks for low birth weight of 2.0 or greater (see Section 2.4). In this study, as the positive effects of the intervention were being examined, an OR of 0.5 was assumed. Over the three year period of this study it was expected that data on 390 cases would be collected. It was planned to obtain two controls for every case. Power calculations to determine the sample size required to detect an OR of 0.5 were based upon the following information, representing the prevalence of exposure in the general population:

1. Penetration of Healthy Start in the project area (50%).
2. BV screening among Healthy Start participants (50% screened).
3. Case management rate among Healthy Start participants (50%).
4. WIC attendance in the community (50%).
5. Estimated compliance with smoking cessation guidelines based on chart audits at the largest community health center in the project area (20% in Healthy Start sites).

It was expected that the cases would have less than average penetration of the exposures and that the controls would have a slightly higher penetration of exposures than the average population. Therefore in order to obtain an OR of 0.5 it

was assumed that there was a 60% penetration of SHS, case management, BV screening and WIC among controls and 43% among cases. For smoking cessation it was assumed that the penetration was 30% in controls and 17% in cases. Power calculations were performed in Epi Info, for unmatched case-control studies. This sample size was adequate to provide 99.98% power. It was expected that adjustment for known risk factors would further enhance the protective association of Healthy Start and preterm low birth weight.

6.1.6.2 Qualitative Study

The original proposal was to conduct interviews with 50 newly delivered women in the postpartum unit of Crouse Hospital. The proposal was not approved by the hospital Institutional Review Board, due to "insufficient benefit to the patient." The study was approved however by the State University of New York (SUNY) Institutional Review Board for implementation at the six-week postpartum visit at University Health Care Center (UHCC). Access to eligible patients was much more limited in this ambulatory setting as the recruitment process was allocated to the nursing staff. Slow recruitment of women into the study and research time constraints necessitated revision of the study protocol. In determining sample size for the qualitative study the guidelines suggested by Arksey and Knight in their book Interviewing for Social Scientists (1999) were followed.

Women were recruited for this study at their postpartum visit to UHCC if willing to participate, were then contacted to arrange an interview date. Patient charts were

not reviewed and names were not retained, due to new patient privacy regulations in the U.S. (HIPAA regulations) which were strictly enforced by the local Institutional Review Board. The interviews were conducted by me, either at the women's homes or at the clinical site.

Interviews were conducted with 15 postpartum women. Only one mother of a preterm infant was recruited, as high-risk women in the UHCC setting are routinely transferred to the regional Perinatal Center for management and postpartum follow up. The sample included at least two women in each of the categories identified in the protocol and listed below (note extensive overlap between categories):

1. African American women
2. Caucasian women
3. Hispanic women
4. Asian women
5. Teenagers less than 18 years old (young teenagers)
6. Women older than 18 years (old teenagers and beyond)
7. Women with less than 12 years of education
8. Women with more than 12 years of education
9. Primiparous women
10. Multiparous women
11. Healthy Start participants
12. Non-Healthy Start participants

6.2 DATA COLLECTION METHODS AND PROCEDURES

6.2.1 Quantitative data collection: methods and instruments

The data was collected through chart abstraction of inpatient and outpatient charts using the CDC data abstraction guide for their concurrent cohort study of bacterial vaginosis. Data was recorded on a standard "bubble form". The information was then sent to the CDC in Atlanta, Georgia and scanned into an electronic database. A separate file was created for data relating particularly to this study. In conjunction with CDC researchers and SHS personnel, I participated in the design of the abstraction form and conducted training of hospital and office nurses in data abstraction methods. I also performed data abstraction of both inpatient and outpatient charts at 15 office sites and organized all quality assurance reviews. The first 10 chart abstractions for all new data collectors were reviewed either by myself or by a nurse whom I trained. Copies of both the in-patient and outpatient chart abstraction forms are attached in Appendix A.

6.2.2 Qualitative data collection

An interview guide was created for collection of the qualitative data (see p. 253) SHS Project Director, Dr. Sandra Lane, a medical anthropologist, consulted on the development of this instrument and provided training and guidance for me in the techniques of semi-structured interviewing. The interviews were conducted either in the clinic office or at the new mother's home. Early postpartum interviews were

done to minimize recall bias and to provide easy accessibility to the patient population of interest. Data was collected using open-ended questions in the context of semi-structured individual interviews. I recorded responses on the interview guide form and fully transcribed them within 24 hours. A copy of the Interview Guide is available in Appendix B.

The interview guide was modified slightly after using it with the first five patients in order to pursue women's perceptions about prenatal care and coping mechanisms for stress in more depth.

6.3 DATA ANALYSIS METHODS

6.3.1 Quantitative Analysis

The data analysis was carried out with consideration for the conceptual framework of this study. Risk factors (explanatory variables) addressed in the study which correspond to the conceptual framework are illustrated in Table 14.

Table 14 Conceptual Framework and Risk Factors (Explanatory Variables) for Preterm Low Birth Weight in the Syracuse Population

Social (Distal)	Behavioral (Proximal)	Medical (Proximal)	Outcome
Personal • Race • Education • Age Household • Poverty(Medicaid) Community • Care Provider (access to care) Social Institutions • Marriage (stable partnership, financial support and cooperative parenting)	Parity Smoking Stress/social support Entry to care	Malnutrition Infection History of preterm delivery	Preterm low birth weight

In this framework, background variables are likely to act through a number of inter-related intermediate factors to affect the outcome in either a direct or cumulative manner. Although each of the factors may individually affect the risk of LBW or

prematurity and its severity, the effect of multiple risk appears to be cumulative and to increase the possibility of an adverse outcome. Each risk factor may act as a potential confounder, mediating variable or effect modifier. A multivariable model was therefore utilized which included all measurable risk factors.

Enrolment in the Healthy Start programme was compared between cases and controls and then the four individual interventions that make up the SHS Initiative were compared.

Case management and smoking cessation constituted the behavioral interventions. Case management was coordinated through the County Health Department and each case manager carried a patient load of about 20 women at any one time (Lane, 1998).

Every woman enrolled in Syracuse Healthy Start received case management. Thus in the dataset, these two interventions, Syracuse Healthy Start participation and case management, are denoted by the same variable code.

Smoking status was assessed in every clinic and office site at the first prenatal visit. Uptake of the transtheoretical model of smoking cessation was limited however. The largest obstetric clinic implemented it and public health nurses and case managers also utilised it. Other offices used a variety of approaches, primarily advice from the health care provider to stop smoking (Lane, 2001).

The medical interventions offered by Healthy Start included WIC enrolment and BV screening. Women were advised of the WIC registration procedure early in pregnancy either through the case manager or through the office staff. Brochures about WIC services were provided, which included the contact information for the local WIC office. Confirmation of pregnancy was provided at prenatal care sites to facilitate WIC registration.

Routine BV screening occurred in the prenatal office setting. Women who were seen in the hospital setting for obstetric emergencies were also screened by the house staff there. Thus BV variables in this study include prenatal office screening, hospital screening and a combined variable of hospital and office screening. Some women were not screened at all during their pregnancies; some women were screened and found to be negative; other women were screened, found to be positive and treated; and, there were some women who were screened and found to be positive but not treated for a variety of reasons which may have included oversight of results by office staff, missed appointments by the patient or a decision not to treat by the provider. There is no data available on precise reasons for non-treatment. The variable describing screening and treatment of BV therefore had four levels: unscreened; screened and negative; screened positive and treated; screened positive and not treated.

Stata version 8.0 (Statacorp, Texas) was the statistical package used for analysis. First, a crude analysis, including frequencies and odds ratios for exposures and

explanatory variables and the outcome of interest, preterm low birth weight delivery, was performed.

A univariate analysis of exposure variables and potential confounders for the control group only was carried out to identify potential risk factors characteristic of the general population of pregnant women in the project area.

The effect of each exposure variable on the outcome of premature LBW for cases and controls was adjusted for all the demographic, behavioral and medical explanatory variables within the theoretical framework. The adjusted models were fitted with and without the variable for history of preterm birth which is known to be associated with subsequent preterm delivery, in order to avoid over adjusting. Effect modification of race on the bivariate and multivariate models was assessed by Likelihood Ratio testing. A final model for each exposure variable was fitted, controlling for confounding and effect modification as appropriate.

Descriptive data was generated about women in the sample with relation to BV screening and treatment. The demographic characteristics of the screened and unscreened, treated and untreated patients were compared with particular emphasis on race because of the higher prevalence of BV among Black women. Implementation of screening and treatment by provider group was also compared.

The analysis described above examined the main objectives of the study but a series of additional analyses were undertaken to examine several other aspects of the project.

In the clinical setting in Syracuse, women with an indeterminate BV test were treated as positive and offered metronidazole. Thus the indeterminate patients were included as positive in the initial analysis. A second analysis which excluded women with an indeterminate test was carried out.

The demographic characteristics of the women who delivered very low birth weight babies were analysed. Although underpowered, it was considered worthwhile to perform this analysis as very low birth weight is strongly associated with infant mortality. It was also hypothesized that treating for BV early in pregnancy may have a significant effect upon very early delivery. A crude analysis of SHS interventions among women who delivered babies less than 1500 grams was performed and a multivariable analysis of BV screening in the prenatal office site was also done.

A similar analysis of BV screening and treatment at the prenatal site at less than 22 weeks gestation was carried out. The literature supports the hypothesis that treatment of BV positive women is not effective after mid second trimester in preventing early delivery (Carey et al., 2000; Ugwumadu et al., 2003). The effect of early screening and treatment was therefore of great interest.

6.3.2 Qualitative Analysis

The qualitative analysis was indexed manually. Interpretation of the data was undertaken utilizing Maykut and Morehouse's (1994) "interpretive-descriptive" approach. A template was created for analysis of each of the five conceptual areas explored in the interviews. These areas included nutrition, smoking, stress, infection and general reflections about good health in pregnancy. The interview transcripts were carefully reviewed, line by line. Key phrases, topics, patterns and themes were recorded for each concept. Themes were then compared across conceptual areas and a provisional category list of prominent ideas and themes was created. An initial propositional statement based upon the data collected, was written for each category. These statements effectively summarized the research findings. The propositional statements were then re-examined. Those that stood alone and those that formed relationships and patterns across categories became the final outcome propositions.

6.4 LIMITATIONS AND BIAS

Bias was considered in development of the study design as follows:

1. Selection bias was minimized in the case control study by choosing all possible cases of preterm low birth weight in the project area so that all adverse outcomes would be included in the analysis.

2. Selection bias among controls was avoided by randomly choosing women from the project area who delivered at the same hospital. This process ensured that cases and controls would have similar socioeconomic backgrounds and be comparable samples. Since all the women were pregnant, all had potential for preterm low birth weight deliveries.
3. Information bias was possible due to either incomplete or inaccurate records and is considered in the analysis. There was no reason to believe however that the accuracy of records differed between cases and controls. Quality control measures were put in place to screen for observer bias and errors in chart abstraction.
4. A limitation that could introduce confounding and may not be controlled for involves the interaction of multiple social risk factors, many of which are rooted in poverty and race. Known and measured risk factors do not account for all of the variability in health outcomes.
5. The sample of women interviewed as part of the qualitative study received care at University Health Care Center where the high risk Perinatal Center is co-located. Women with preterm delivery or problems in pregnancy were referred to the specialist clinic and were seen there for the postpartum visit. Therefore, they were not recruited for the qualitative study. Otherwise, the demographic profile of the sample contains the cross-section of women planned and is representative of the study population.

6. All interviewees were from UHCC which may have introduced bias based upon site of care.
7. The interviewees were a self-selected population and this may have introduced selection bias into this aspect of the study.
8. One woman was interviewed in the presence of her teenage daughter which may have affected her responses to the interview questions.
9. The qualitative study was conducted at 6 weeks postpartum due to Ethics Committee constraints. This time delay may have introduced recall bias.
10. My own experience as lead midwife in the Healthy Start project and my close involvement with the women of the target community clearly enhanced my ability to effectively identify key issues within the qualitative intervention but also challenged me to maintain objectivity during the interview, data collection and analysis processes. Also, I may have been identified by the interviewees as a health care practitioner working for Syracuse Healthy Start. This had the potential to bias their responses.

6.5 ETHICAL ISSUES

Ethical approval was required by each institution involved in this study.

Every woman in the *Healthy Start* program completed and signed a registry form and social risk questionnaire, which enrolled her in the program. *Healthy Start* program data are analyzed routinely within the Onondaga County Health Department and used to target new interventions to populations at risk. All data collected as part of this evaluation was handled similarly to other program data. Confidentiality was maintained through de-identification of data. Unique ID numbers were assigned to each woman and all identifying demographic information was removed from the record. Only population level data analysis was carried out. Training of chart abstractors emphasized the maintenance of confidentiality.

The Crouse Hospital Institutional Review Board (IRB) determined that the *Healthy Start* program was not a formal research project but a retrospective review of charts, and therefore, did not require a formal IRB review. Nonetheless, a formal IRB application was completed and submitted. A letter of exemption was received. This study was carried out in accordance with the Declaration of Helsinki to the extent appropriate for a retrospective case review.

IRB approval was sought and obtained from the State University of New York (SUNY) Upstate Medical Center for the qualitative interviews conducted for this study. These interviews were also determined to be compliant with the new Health Insurance Portability and Accountability Act (HIPAA) regulations regarding patient privacy (http://www.hhs.gov/ocr/hipaa/). No chart review was undertaken. Patient

names were not revealed prior to recruitment into the study. No information was collected other than patient responses to interview questions.

The Ethics Committee of the London School of Hygiene and Tropical Medicine approved this study.

6.6 Funding

Funding for my position as lead midwife for Syracuse Healthy Start at Syracuse Community Health Centre was provided through the SHS grant. The Centers for Disease Control provided funds for the chart abstraction carried out in conjunction with this study. An addition $2500 was received from the American Nurses Foundation to supplement CDC funding. There was no external funding for the qualitative study or for the data analysis procedures.

CHAPTER 7
INTRODUCTION TO DATA ANALYSIS

7.0 INTRODUCTION TO DATA ANALYSIS

This chapter provides an overview of the sample selected for this study in relation to the conceptual framework. Data collection for this study took place between October 2001 and October 2003. Charts were abstracted from one hospital site and 15 outpatient sites.

7.1 SAMPLE OBTAINED

All eligible preterm LBW delivered in the years 2000 and 2001 who met the inclusion criteria for this study were defined as cases. One hundred and thirty cases were anticipated per year. Originally a three-year evaluation (1999 to 2001) was planned. Initially, a total sample size of 390 cases and 780 controls was expected over a three year recruitment period, representing a 1:2 case to control ratio. However, due to funding constraints, data collection was carried out for deliveries in 2000 and 2001 only. A final total sample size of 169 cases was identified. A randomly selected control sample of full term normal birth weight deliveries was chosen. A 1:3 case to control ratio was used to enhance the power of the study. Power calculations for this sample are presented in Table 15. Power calculations are also presented for two sub-group analyses: cases of very low birth weight and cases of low birth weight with early BV screening and treatment.

Overall, 33.7% of the original cases (n=57) were VLBW deliveries.

The VLBW sample was too small to be adequately powered for an odds ratio of 0.50. However, the issue of very low birth weight was deemed to be important enough to merit examination of the odds ratios even if the confidence intervals were wide

Recent studies suggest that women who are diagnosed with BV early in pregnancy and treated during late first trimester/early second trimester have a significant reduction in preterm low birth weight deliveries (see Section 2.4.1; Ugwumadu et al, 2003; Kiss, 2004). Fifty three percent of women in the total sample were screened for BV at <22 weeks gestation (n=54 cases and 126 controls). Although this sub-sample was also inadequately powered for the expected odds ratio, an examination of odds ratios was considered valuable, as timing of BV treatment remains an important research issue (Ugwumadu et al., 2003).

Table 15 Power to detect a significant association (p=.05) if OR=0.5

Exposure & Estimated Prevalence	Original Sample 390 cases/ 780 controls **Power**	Actual Sample 169 cases/ 507 controls **Power**	Very low birth weight sample 57 cases/ 507 controls **Power**	<22 gestation sample 54 cases/ 126 controls **Power**
Healthy Start Case Management BV screening WIC 43% in cases vs 60% in controls	99 98%	96 1%	64%	49%
Smoking Cessation 17% in cases vs 30% in controls	99 86%	92%	47%	36%

The data sets for cases and controls were complete for the variables of interest

Overall the sample was 48% Black and 40% White. More than one third of the sample had less than a high school education and 19% were teenagers. Medicaid was the payor source for over 50% of the women. A wide range of providers served this population with 35% of women receiving antenatal care from private physicians and 31% from the large community health centre in Syracuse. The University clinic served another 18% of women. Thirty six percent of the sample was primiparous and only 3% had experienced a previous preterm birth. Most of this sample was unmarried (70%) and a third of women did not record the father of the baby's name on the birth certificate. Twenty one percent of the women smoked during pregnancy. A detailed description of the sample characteristics will follow.

7.2 REALISATION OF CONCEPTUAL FRAMEWORK

The data analysis was undertaken in light of the conceptual framework discussed in Chapter 4. Syracuse Healthy Start programs were targeted to the intermediate and proximal levels of risk where it was hypothesized that effective intervention could be implemented. Data was collected on risk factors within each level of risk. The indicators for risk factors included:

Distal/ social risk

Risk Factors:	Indicators/Explanatory variables
Personal	Age, education, race/ethnicity of the mother
Household	Payor source as proxy for income level
Community	Care provider, representing access to care in the community
Social Institutions	Marriage (representing stable partnership, financial support and cooperative parenting).

Proximal/ behavioral risk

Risk Factors:	Indicators/Explanatory variables
Parity	Number of living children
Smoking	Smoking at first prenatal visit
Maternal Stress	Father of the baby on the birth certificate as an indicator of social support
Entry to Care	All participants were enrolled in care

Proximal/medical risk

Risk Factors:	Indicators/Explanatory variables
Malnutrition	Not measured
Infection	BV positive
History of preterm delivery	Preterm delivery noted in obstetrical history

The indicators of the explanatory variables above were entered into the statistical

model which evaluated the efficacy of SHS interventions among women with varying levels of risk.

CHAPTER 8
DESCRIPTIVE STATISTICS

8.0 DESCRIPTIVE STATISTICS

This chapter examines the characteristics of the study population. First, the demographic features of cases and controls are described. After describing the Healthy Start intervention variables, an analysis of the control group of women is presented. This analysis examined how the receipt of the interventions varied by women's demographic characteristics. This was done for control women only as they were assumed to reflect the general population of the project area.

8.1 SOCIO-DEMOGRAPHIC CHARACTERISTICS AND HEALTH BEHAVIORS OF CASES AND CONTROLS

The demographic data which describes the study population is summarized in Table 16 below:

Table 16 Demographic characteristics in study population overall and cases and controls separately

Demographic characteristics	Sample N=676	Sample %	Cases N=169	Cases %	Controls N=507	Controls %	OR	95% CI	P-value (LR test)
Age									
<20	129	19.1	34	20.1	95	18.7	1.00		0.694
≥20	547	80.9	135	79.9	412	81.3	0.92	0.59-1.14	
Race/Ethnicity									
White	268	39.6	64	37.9	204	40.2	1.00		
Black	327	48.4	92	54.4	235	46.4	1.25	0.86-1.81	0.059
All other	81	12.0	13	7.7	68	13.4	0.61	0.32-1.17	
Education									
<12 years	258	38.2	63	37.3	195	38.5	1.00		
≥12 years	418	61.8	106	62.7	311	61.5	1.05	0.73-1.51	0.784
Payor Source									
Medicaid	352	52.1	82	48.5	270	53.3	1.00		
HMO	106	15.7	25	14.8	81	16.0	1.02	0.61-1.70	0.081
Private	190	28.1	49	29.0	141	27.8	1.14	0.76-1.72	
Self pay	28	4.1	13	7.7	15	3.0	2.80	1.30-6.24	
Provider									
Private	235	34.8	42	24.9	193	38.1	1.00		
UHCC*	118	17.5	19	11.2	99	19.5	0.88	0.49-1.60	0.000
SCHC*	209	30.9	44	26.0	165	32.5	1.23	0.77-1.96	
PNC*	97	14.3	56	33.1	41	8.1	6.28	3.72-10.59	
Other/None	17	2.5	8	4.7	9	1.8	4.08	1.49-11.21	
Parity									
Primiparous	241	35.7	67	39.6	174	34.3	1.00		
Para 2-4	399	59.0	91	53.9	308	60.8	0.77	0.53-1.11	0.273
Para ≥ 5	36	5.3	11	6.5	25	4.9	1.14	0.53-2.45	
Previous preterm birth									
No	654	96.7	158	93.5	495	97.6	1.00		0.013
Yes	22	3.3	11	6.5	12	2.2	3.14	1.34-7.38	
Father of baby									
Name on birth certificate: N	240	35.5	60	35.5	180	35.5	1.00		1.00
Name on birth certificate: Y	436	64.5	109	64.5	327	64.5	1.00	0.70-1.44	
Married									
Yes	205	30.3	48	28.4	157	31.0	1.00		0.528
No	471	69.7	121	71.6	350	69.0	1.13	0.77-1.66	
Prenatal smoker									
Yes	143	21.2	40	23.7	103	20.3	1.00		0.360
No	533	78.8	129	76.3	404	79.7	0.82	0.54-1.25	
BV positive									
No	467	69	112	66.3	355	70.0	1.00		0.362
Yes	209	31	56	33.7	152	30.0	1.19	0.82-1.72	

*UHCC: University Health Care Center; SCHC: Syracuse Community Health Center; PNC Perinatal Center

The social, behavioral and medical risk factors identified in the conceptual framework were compared between cases and controls to assess their potential to bias the results of the analysis if not controlled for in the final model. Cases and controls were found to be quite similar for most characteristics. Only four significant differences between the groups were found among risk characteristics. Women who were self pay patients (i.e., no insurance), those who attended the high risk Perinatal Center, women who had a history of a previous preterm birth or those who had no prenatal care all had higher odds of being a case.

There were no significant differences between cases and controls in the area of behavioral characteristics. However, one medical risk factor, a history of preterm birth, was significantly higher in cases than controls.

8.2 CHARACTERISTICS OF (CONTROL) WOMEN IN SYRACUSE HEALTHY START PROJECT AREA

Women who had premature LBW deliveries represent a relatively rare group within the obstetric population. In order to assess how receipt of the intervention varied by the characteristics of women living in the Healthy Start project area an analysis was done in the control group only. Onondaga County Health Department data shows that 60% of all pregnant women living in the Healthy Start project area deliver at Crouse Hospital. The control women, all of whom delivered at Crouse, were likely to be representative of a large proportion of the population of pregnant

women living in the project area. The results of this analysis are presented in Table 17 and 18 below:

Table 17 Variation in receipt of intervention by characteristics of control women (n=507): SHS/Case Management; WIC; & Smoking Cessation

Variable: SHS/Case Mgt WIC Smoking Cessation	SHS/Case Management received/ total	%	OR (95% CI)	P-value P>|z|	WIC received/ total	%	OR (95% CI)	P-value P>|z|	Smoking Cessation received/ total	%	OR (95% CI)	P-value P>|z|
Age												
<20	86/95	90.5	1		77/95	81.1	1		4/95	4.0	1	
≥ 20	160/412	38.8	0.07 (.03-.14)	0.000	220/412	53.4	0.27 (.15-.46)	0.000	21/412	5.0	.82 (.27-2.44)	0.719
Race												
White	72/204	35.3	1		88/204	43.1	1		13/204	6.4	1	
Black	142/235	60.4	2.80 (1.90-4.13)	0.000	164/235	69.8	1.56 (.82-3.0)	0.179	9/235	3.8	1.7 (.72-4.09)	0.228
Other	32/68	47.1	1.63 (0.94-2.84)	0.085	45/68	66.2	2.25 (.63-8.06)	0.213	3/68	4.4	1.5 (.41-5.34)	0.554
Education												
<12 years	144/195	73.9	1		158/195	81.0	1		15/195	7.7	1	
≥12 years	102/312	32.7	0.17 (.12-.26)	0.000	139/312	44.6	0.30 (.15-.60)	0.001	10/312	3.2	2.5 (1.1-5.72)	0.028
Married												
Yes	28/157	17.8	1		38/157	24.2	1		1/157	.64	1	
No	218/350	62.3	7.61 (4.8-12.1)	0.000	259/359	74.0	0.11 (.07-.17)	0.000	24/350	6.9	11.5 (1.5-85.67)	0.017
Father on Birth Certificate												
No	118/180	65.6	1		137/180	76.1	1		8/180	4.4	1	
Yes	128/327	39.1	0.34 (.23-.49)	0.000	160/327	48.9	0.30 (.20-.45)	0.000	17/327	5.2	0.85 (.36-2.0)	0.710
Parity												
Primiparous	96/174	55.2	1		99/174	56.9	1		6/174	3.5	1	
1-4	135/308	43.8	0.63 (.44-.92)	0.017	178/308	57.8	1.0 (.71-1.5)	0.849	19/308	6.2	0.54 (.21-1.39)	0.202
≥ 5	15/25	60.0	1.22 (.52-2.86)	0.650	20/25	80.0	3.0 (1.1-8.4)	0.034	0/25	0.0	NA	NA

Previous preterm Birth												
No	238/496	48.0	1		289/496	58.3	1	0.343	24/496	4.8	1	
Yes	8/11	72.7	2.89 (76-11.02)	0.120	8/11	72.7	1.9 (50-7.3)		1/11	9.1	.54 (06-4.14)	0.527
Payor Source												
Medicaid	183/270	67.8	1		214/270	79.3	1		19/270	7.0	1	
HMO	29/81	35.8	0.27 (16- 45)	0.000	36/81	44.4	0.21 (.12- 35)	0.000	3/81	3.7	1.97 (.57-6.82)	0.286
Private	26/141	18.4	0.11 (.07- 18)	0.000	36/141	25.5	0.09 (.06- 14)	0.000	2/141	1.4	5.26 (1.21-22.92)	0.027
Other/self	8/15	53.3	0.54 (19-1.55)	0.253	11/15	73.3	0.72 (.22-2.35)	0.585	1/15	6.7	1.06 (.13-8.5)	0.956
Provider												
Private	45/193	23.3	1		51/193	26.4	1		4/193	2.1	1	
UHCC	65/99	65.7	6.29 (37-10.71)	0.000	73/99	73.7	7.81 (4.5-13.6)	0.000	12/99	12.1	0.15 (.05- 49)	0.002
SCHC	114/165	69.1	7.30 (4.60-11.76)	0.000	141/165	85.5	16.36 (9.5-28.0)	0.000	8/165	4.9	0.41 (12-1.4)	0.158
PNC	18/41	43.9	2.57 (1.28-5.19)	0.008	27/41	65.9	5.37 (2.6-11.0)	0.000	1/41	2.4	0.85 (.09-7.78)	0.883
Other	4/9	44.4	2.63 (68-10.26)	0.162	5/9	55.6	3.48 (.9-13.5)	0.071	0/9	0.0	NA	NA

Table 18 Variation in receipt of BV related components of SHS (hospital and prenatal office) by characteristics of control women (n=507)

Variable: BV Screening & Treatment	Unscreened N	%	Screened N	%	OR (95% CI)	P value P>|z|	Variable	Treated N	%	Untreated N	%	OR (95% CI)	P value P>|z|
Age							Age						
<20	20	21.5	75	80.0	1		<20	20	21.1	75	79.0		
≥ 20	177	43.0	235	57.0	0.35 (.21- 60)	0.000	≥ 20	30	7.3	382	92.7	0.30(16- 55)	0.000
Race							Race						
White	93	45.6	111	54.4	1		White	15	7.4	189	92.7		
Black	77	32.7	158	67.2	1.72 (1.17-2.53)	0.006	Black	28	11.9	207	88.1	1.70(88-3.29)	0.112
Other	27	39.7	41	60.3	1.27 (.73-2.22)	0.398	Other	7	10.3	61	89.7	1.45(56-3.71)	0.443
Education							Education						
<12 years	50	25.6	147	47.1	1		<12 years	29	14.9	166	85.1		
≥12 years	145	74.4	165	52.9	0.39 (.26- 57)	0.000	≥12 years	21	6.7	291	93.3	0.41(23- 75)	0.003
Married							Married						
Yes	82	52.2	75	47.8	1		Yes	6	3.8	151	96.2		
No	115	32.9	235	67.1	2.23 (1.52-3.28)	0.000	No	44	12.6	306	87.4	3.62(1.51-8.68	0.004
Father on Birth Certificate							Father on Birth Certificate						
No	60	33.3	120	66.7	1		No	25	13.9	155	86.1		
Yes	137	41.9	190	58.1	0.69 (.47-1.01)	0.058	Yes	25	7.7	302	92.4	0.51(29- 92)	0.026
Parity							Parity						
Primiparous	73	42.0	101	58.1	1		Primiparous	15	8.6	159	91.4		
1-4	115	37.3	193	62.7	1.21(83-1.77)	0.319	1-4	33	10.7	275	89.3	1.27(67-2.41)	0.462
≥ 5	9	36.0	16	64.0	1.28(54-3.07)	0.572	≥ 5	2	8.0	23	92.0	0.92(20-4.30)	0.917

Variable: BV Screening & Treatment	Unscreened N	%	Screened N	%	OR (95% CI)	P value P>|z|	Variable	Treated N	%	Untreated N	%	OR (95% CI)	P value P>|z|
Previous preterm Birth							Previous preterm Birth						
No	193	38.9	303	61.1	1		No	50	10.1	446	89.9		
Yes	4	36.4	7	63.6	1.11(.32-3.86)	0.864	Yes	0	00.0	11	100.0	NA	NA
Payor Source							Payor Source						
Medicaid	85	31.5	185	68.5	1		Medicaid	35	13.0	235	87.0	1	
HMO	31	38.3	50	61.7	0.74(.44-1.24)	0.255	HMO	9	11.1	72	88.9	0.84(.39-1.83)	0.659
Private	77	54.6	64	45.4	0.38(.25-.58)	0.000	Private	5	3.6	136	96.5	0.25(.09-.65)	0.004
Other/self	4	26.7	11	73.3	1.26(.39-4.08)	0.696	Other/self	1	6.7	14	93.3	0.48(.06-3.76)	0.484
Provider							Provider						
Private	110	57.0	83	43.0	1		Private	6	3.1	187	96.9	1	
UHCC	29	29.3	70	70.7	3.20(1.90-5.37)	0.000	UHCC	9	9.1	90	90.9	3.12(1.08-9.02)	0.036
SCHC	33	20.0	132	80.0	5.30(3.29-8.53)	0.000	SCHC	29	17.6	136	82.4	6.65(2.68-16.45)	0.000
PNC	20	48.8	21	51.2	1.39(0.71-2.73)	0.338	PNC	4	9.8	37	90.2	3.37(.91-12.53)	0.070
Other	5	55.6	4	44.4	1.06(0.28-4.07)	0.932	Other	2	22.2	7	77.8	8.90(1.52-52.24)	0.015

There appeared to be an association between many of the patient characteristics and receipt of the Syracuse Healthy Start interventions. Fifteen out of twenty characteristics were associated with SHS/case management and WIC, with $p<0.05$. A significantly higher percentage of young women, Black women, poorly educated women, single women, women receiving Medicaid and attending the two clinics in Syracuse participated in SHS. High levels of association were also seen between BV screening and treatment and patient characteristics. Once again women who were young, Black, poorly educated, single and attending the clinics were more likely to be screened. Women in private practices were less likely to have BV screening. Smoking cessation however, showed little relationship with patient demographic features. High education level, unmarried status, private payor source and attendance at UHCC appeared to be the only significant associations for smoking cessation.

Because of the high level of association of risk factors with Healthy Start interventions all risk factors were included in the analysis.

CHAPTER 9

ASSOCIATION OF INTERVENTIONS WITH PRETERM LOW BIRTH WEIGHT

9.0 ASSOCIATION OF INTERVENTIONS WITH PRETERM LOW BIRTH WEIGHT

9.1 CRUDE ANALYSIS

A crude analysis was performed to assess the association of each Healthy Start intervention with the outcome of premature low birth weight. Enrollment in the Healthy Start package is the main exposure variable (SHS) presented in Table 19. Individual exposure variables which were components of the SHS package are then presented.

Table 19 Comparison of intervention components (exposures) between cases and controls

Exposure Variable	Sample N=676	Cases N= 169 N	Cases %	Controls N=507 N	Controls %	OR	95% C.I.	P-value (LR test)
SHS/Case management								0.790
No	350	89	52.7	261	51.5	1.00	0.67-1.35	
Yes	326	80	47.3	246	48.5	0.95		
WIC								0.787
No	282	72	42.6	210	41.4	1.00	0.70-1.36	
Yes	394	97	57.4	297	58.6	0.95		
Decrease smoke								0.18
No	644	162	95.86	482	95.07	1.00		
Yes	32	7	4.14	25	4.93	0.83	.35-1.96	
BV screen/treat: all sites								
Unscreened	260	63	37.2	197	38.9	1.00	0.63-1.49	0.396
Negative	207	49	29.0	158	31.2	0.97	0.60-1.60	
Positive/treated	134	32	18.9	102	20.1	0.98	0.90-2.73	
Positive/untreated	75	25	14.8	50	9.9	1.56		
BVscreen/treat: hospital								
Unscreened	516	128	75.7	388	76.5	1.00	0.72-1.96	0.859
Negative	89	25	14.8	64	12.6	1.18	0.48-1.76	
Positive/treated	56	13	7.7	43	8.5	0.92	0.21-2.73	
Positive/untreated	15	3	1.8	12	2.4	0.76		
BV screen/treat: office								0.218
Unscreened	334	80	47.3	254	50.1	1.00		
Negative	181	43	25.4	138	27.2	0.99	0.65-1.51	
Positive/treated	101	24	14.2	77	15.2	0.99	0.59-1.67	
Positive/untreated	60	22	13.0	38	7.5	1.84	1.03-3.29	

Although no significant overall effect of enrolment in the program as a whole or any of the individual components of the program was found, it appears that in the prenatal office setting, the odds ratio for cases who were BV positive and not treated, compared to the baseline of unscreened women was significant, OR1.84 (95% CI 1.03-3.29) .

9.2 ASSOCIATION OF SHS INTERVENTIONS AND OUTCOMES ADJUSTED FOR CONFOUNDING

Tables 16, 17 and 18 show some associations between the variables in the conceptual framework with both the exposure (intervention components of SHS) and the outcome (preterm low birth weight). Therefore the model was adjusted for potential confounding by all variables included in the conceptual framework.

9.2.1 Results of logistic regression for Syracuse Healthy Start and interventions

Separate models were fitted for each intervention component. Each intervention variable and all other variables included in the conceptual framework were entered into the model. Likelihood ratio tests were used to assess the contribution of the main (intervention component) exposures. Adjusted odds ratios were obtained.

A history of preterm birth is a well known predictor for subsequent preterm delivery. In order to avoid the possible danger of over adjusting the analysis was done with and without this risk factor.

The results are recorded in Table 20 below. As in the crude analysis, no significant overall effect of enrolment in the program as a whole or any of the components was found but there was some indication that the odds ratio comparing positive untreated women to those unscreened was significant. The intervention variable was significant among women screened in the prenatal office site. Women who were BV positive and not treated had a crude odds ratio of 1.84 compared to those not screened. After adjusting for all potential confounders, the odds for preterm low birth weight increased to 2.48. When a history of preterm birth was eliminated from the model the OR for BV positive and not treated decreased slightly to 2.40. The p value for the likelihood ratio test for the two adjusted models with and without history of preterm birth was $p<0.022$.

Table 20 Interventions Adjusted for Confounding

Intervention	Crude OR	95% CI	P value LR test	Adjusted OR	95% CI	P value LR test	Adjusted OR Without PT hx	95% CI	P value LR test
SHS/case mgt	0.954	.67-1.35	0.790	0.970	.61-1.54	0.900	0.978	.62-1.55	0.925
WIC	0.953	.67-1.35	0.787	0.932	.58-1.49	0.770	0.936	.59-1.49	0.781
Decrease smoke	0.833	.35-1.96	0.180	0.905	.35-2.36	0.838	0.961	.37-2.47	0.934
BV – all sites			0.396			0.277			0.310
Screened-negative	0.970	.63-1.49		1.03	.64-1.68		1.08	.67-1.75	
Screened-pos/treated	0.981	.60-1.60		1.29	.74-2.25		1.31	.75-2.29	
Screened-pos/not treated	1.56	.90-2.73		1.84	.96-3.52		1.82	.95-3.47	
BV – hospital			0.859			0.916			0.873
Screened-negative	1.18	.72-1.96		0.982	.55-1.74		1.08	.62-1.89	
Screened-pos/treated	0.916	.48-1.76		1.03	.50-2.14		1.06	.51-2.18	
Screened-pos/not treated	0.758	.21-2.73		0.609	.15-2.52		0.59	.14-2.44	
BV – office			0.218			0.075			0.089
Screened-negative	0.989	.65-1.51		1.23	.76-1.98		1.24	.77-2.00	
Screened-pos/treated	0.990	.59-1.67		1.46	.81-2.63		1.43	.79-2.58	
Screened-pos/not treated	1.84	1.03-3.29		2.48	1.25-4.93	0.022*	2.40	1.21-4.76	0.022*
						*P value in logistic regression analysis for this variable			*P value in logistic regression analysis for this variable

9.2.2 Interaction with race

Interaction between Black race and BV screening and treatment in the prenatal office was examined. This was done because there is an a priori association between Black race and BV infection and Black race and low birth weight. Therefore, a differential effect of BV treatment and screening is possible between races (Fiscella 1996).

Table 21 Interaction with race

Intervention	P-value (LR test) With PT birth	P-value (LR test) Without PT birth
BV office screening	0.9219	0.9457
SHS/Case management	0.8924	0.8871
WIC	0.4474	0.3988
Smoking cessation program	0.3598	0.2868

There does not appear to be any interaction effect. Thus the benefits of the intervention are not exclusive to Black women.

9.2.3 Summary of Results

In summary none of the intervention components showed any significant association with preterm low birth weight apart from BV screening and treatment. There was an increased odds of preterm low birth weight delivery in those who were positive and not treated relative to those unscreened.

9.3 FURTHER DESCRIPTIVE STATISTICS: BV SCREENING AND TREATMENT

9.3.1 Prenatal office screening for BV and risk

As BV screening and treatment in the office setting appeared to be the most promising intervention component further descriptive analysis was carried out. Demographic characteristics of the study sample by prenatal office screening status and all identified risk factors are described in Table 22 below:

Table 22 Risk Factors and BV Screening & Treatment – Prenatal Office Setting

BV Screening & Treatment – Office	Unscreened *Frequency* *Row %* *Column %*	Negative *Frequency* *Row %* *Column %*	Positive/ treated *Frequency* *Row %* *Column %*	Positive/ Not treated *Frequency* *Row %* *Column %*	OR 95% CI	P value	Total
Age							
<20	43 33.33 12.87	43 33.33 23.76	23 17.83 22.77	20 15.50 33.33	1		129 100.00 19.08
≥20	291 53.20 87.13	138 25.23 76.24	78 14.26 77.23	40 7.31 66.67	0.47 (.30-.76)	0.002	547 100.00 80.92
Race							
White	148 55.22 44.31	77 28.73 42.54	23 8.58 22.77	20 7.46 33.33	1		268 100.00 39.64
Black	149 45.57 44.61	79 24.16 43.65	67 20.49 66.34	32 9.79 53.33	1.02 (.69-1.50)	0.924	327 100.00 48.37
Other	37 45.68 11.08	25 30.86 13.81	11 13.58 10.89	8 9.88 13.33	1.30 (.73-2.31)	0.375	81 100.00 11.98
Education							
<12 years	90 34.88 26.95	83 32.17 45.86	46 17.83 45.54	39 15.12 65.00	1		258 100.00 38.17
≥12 years	244 58.37 73.05	98 23.44 54.14	55 13.16 54.46	21 5.02 35.00	0.44 (.30-.64)	0.000	418 100.00 61.83
Payor Source							
Medicaid	150 42.61 44.91	93 26.42 51.38	71 20.17 70.30	38 10.80 63.33	1		352 100.00 52.07
HMO	55 51.89 16.47	28 26.42 15.47	12 11.32 11.88	11 10.38 18.33	0.82 (.49-1.39)	0.460	106 100.00 15.68
Private	116 61.05 34.78	52 27.37 28.73	15 7.89 14.85	7 3.68 11.67	0.72 (.48-1.10)	0.127	190 100.00 28.11

BV Screening & Treatment – Office	Unscreened *Frequency* *Row %* *Column %*	Negative *Frequency* *Row %* *Column %*	Positive/ treated *Frequency* *Row %* *Column %*	Positive/ Not treated *Frequency* *Row %* *Column %*	OR 95% CI	P value	Total
Payor Source							
Other/self pay	13 46.43 3.89	8 28.57 4.42	3 10.71 2.97	4 14.29 6.67	0.99 (.40-2.49)	0.987	28 100.00 4.14
Provider							
Private	156 66.38 46.71	55 23.40 30.39	21 8.94 20.79	3 1.28 5.00	1		235 100.00 34.76
UHCC	50 42.37 14.97	33 27.97 18.23	25 21.19 24.75	10 8.47 16.67	1.87 (1.09-3.20)	0.022	118 100.00 17.46
SCHC	57 27.27 17.07	68 32.54 37.57	47 22.49 46.53	37 17.70 61.67	3.38 (2.12-5.40)	0.000	209 100.00 30.92
PNC	58 59.79 17.37	24 24.74 13.26	7 7.22 6.93	8 8.25 13.33	1.17 (.67-2.10)	0.579	97 100.00 14
Other	13 76.47 3.89	1 5.88 0.55	1 5.88 0.99	2 11.76 3.33	0.22 (.03-1.71)	0.147	17 100.00 2.51
Married							
No	211 44.80 63.17	119 25.27 65.75	88 18.68 87.13	53 11.25 88.33	1		471 100.00 69.67
Yes	123 60.00 36.83	62 30.24 34.25	13 6.34 12.87	7 3.41 11.67	0.561 (.77-1.63)	0.561	205 100.00 30.33
Father on birth Certificate					1		
No	106 44.17 31.74	59 24.58 32.60	46 19.17 45.54	29 12.08 48.33			240 100.00 35.50
Yes	228 52.29 68.26	122 27.98 67.40	55 12.61 54.46	31 7.11 51.67	0.96 (.65-1.42)	0.842	436 100.00 64.50
Parity							
Primip	122 50.62 36.53	66 27.39 36.46	34 14.11 33.66	19 7.88 31.67	1		241 100.00 35.56
1-4	191 47.87 57.19	108 27.07 59.67	64 16.04 63.37	36 9.02 60.00	1.05 (.71-1.53)	0.820	399 100.00 59.02
≥5	21 58.33 6.29	7 19.44 3.87	3 8.33 2.97	5 13.89 8.33	0.62 (.25-1.53)	0.295	36 100.00 5.33
Preterm history							
No	323 49.39 96.71	174 26.61 96.13	99 15.14 98.02	58 8.87 96.67	1		654 100.00 96.75
Yes	11 50.00 3.29	7 31.82 3.87	2 9.09 1.98	2 9.09 3.33	1.18 (.45-3.10)	0.735	22 100.00 3.25

It appears that women who were older or those who had more education had less screening. Those who attended the two clinic sites for prenatal care had

significantly more office screening. There was no difference in office screening by payor source, race, or other demographic characteristics.

Provider groups in Syracuse may have implemented the BV screening protocol differently in their individual practices. It is possible that birth outcomes may differ between practices due to differential screening schedules. Table 22 shows that women attending private practices were less likely to be screened than women attending other types of health facilities. Syracuse Community Health Center (SCHC), a large inner city clinic where the Healthy Start program was very active, screened the most. However, SCHC had most untreated positives and private practices had the least. Outcomes for premature LBW in the private practices versus Syracuse Community Health Center did not vary significantly, (O.R. 1.23, C.I.[.77-1.96], p=0.398).

9.3.2 Racial disparity

Bacterial vaginosis may have an association with the racial disparity in birth outcomes observed in Syracuse due to the higher prevalence of BV in Black women (Fiscella, 1996). According to Table 21, the prevalence of BV infection in women screened in the prenatal office setting was 16% in White women and 30% in Black women. The prevalence of BV in unscreened women is not known. Nearly half of the White women with BV (46.5%) were not treated while only a third of Black women (32.2%) did not receive treatment. The odds ratio for preterm LBW among Black women compared to White women was higher but not significantly different: (O.R. 1.25, C.I. [.86-1.8], p=0.241).

9.3.3 Treatment strategy regarding indeterminate BV testing

In the office setting there was some variability within the fifteen participating medical practices regarding the treatment of women with an indeterminate BV screening result. Most clinicians (physicians, midwives, nurse practitioners) elected to treat these women rather than risk progression of infection. For this reason, the initial analysis was carried out with all BV positive and BV indeterminate women grouped together as positive. There were 60 women in the sample who were either BV positive or BV indeterminate by office screening and not treated. Among the cases (n=22) 1 was indeterminate and 21 were positive and among controls (n= 38) 2 were indeterminate and 36 were positive.

9.3.4 Sensitivity of analysis to treatment excluding indeterminate BV

An analysis of BV screening and treatment in the office was carried out eliminating all indeterminate screenings, including only

#those women who were BV positive. This analysis was conducted adjusting for all potential confounders and then eliminating history of preterm birth as a confounder. The results are presented in Table 23 below:

Table 23 BV screening in prenatal office: analysis of BV positive women only for outcome of preterm low birth weight, adjusted for confounding

Intervention BV screening in Prenatal office setting	Unadjusted OR	95% CI	Adjusted OR	95% CI	P-value (LR test)	Adjusted OR without History of PT birth	95% CI	P-value (LR test)
Unscreened	1.00		1.00		0.318	1.00		0.349
Screened-negative	0.97	.63-1.49	1.04	.64-1.69		1.09	.68-1.76	
Screened-pos/treated	0.96	.59-1.57	1.25	.71-2.20		1.28	.73-2.24	
Screened-pos/not treated	1.56	.89-2.75	1.82	.94-3.52		2.80	.94-3.47	

The pattern of the relationship between BV positive and not treated and preterm low birth weight was essentially unchanged in this analysis, although the results no longer reach statistical significance.

CHAPTER 10
ASSOCIATION OF INTERVENTIONS WITH VERY LOW BIRTH WEIGHT AND EARLY TREATMENT

10.0 ASSOCIATION OF INTERVENTIONS WITH VERY LOW BIRTH WEIGHT AND EARLY TREATMENT

10.1 EARLY TREATMENT ANALYSIS

The literature review suggests that treatment for BV early in pregnancy is important due to the inflammatory effect of this ascending infection and its potential to cause preterm labor early in pregnancy (Romero et al., 2001). Therefore an analysis was carried out to evaluate the association between early treatment and preterm low birth weight delivery. Women who were screened BV positive at less than 22 weeks were analyzed for odds of preterm low birth weight delivery by treatment status. There were 182 women in this sample. The demographic characteristics of this sample are presented in Table 24:

Table 24 Demographic characteristics of women screened in prenatal office settings at less than 22 weeks gestation

Early screening	Sample N=182	Sample %	Cases N=38	Cases %	Controls N=144	Controls %	OR	95% C.I.	P-value (LR test)
Age									0.1445
<20	54	29.7	15	39.5	39	27.1	1.00		
>20	128	70.3	23	60.5	105	72.9	0.57	27-1.20	
Race/Ethnicity									0.8939
White	56	30.8	12	31.6	44	30.6	1.00		
Black	101	55.5	20	52.6	81	56.3	0.91	.41-2.02	
All other	25	13.7	6	15.8	19	13.2	1.16	.37-3.54	
Education									0.2521
<12 years	105	57.7	25	65.8	80	55.6	1.00		
>12 years	77	42.3	13	34.2	64	44.4	0.65	.31-1.37	
Payor Source									0.9129
Medicaid	115	63.2	24	63.2	91	63.2	1.00		
HMO	27	14.8	6	15.8	21	14.6	1.08	.39-2.98	
Private	29	15.9	5	13.2	24	16.7	0.79	.27-2.29	
Self pay	11	6.0	3	7.9	8	5.6	1.42	.35-5.77	
Provider									0.0182
Private	28	15.4	4	10.5	24	16.7	1.00		
UHCC	42	23.1	7	18.4	35	24.3	1.20	.32- 4.55	
SCHC	96	52.8	18	47.4	78	54.2	1.38	.43- 4.49	
PNC	13	7.1	8	21.1	5	3.5	9.60	2.06-44.74	
Other/None	3	1.7	1	2.6	2	2.6	3.00	.22-41.35	

Early screening	Sample N=182	Sample %	Cases N=38	Cases %	Controls N=144	Controls %	OR	95% C.I.	P-value (LR test)
Parity									0.7429
Primiparous	65	35.7	14	36.8	51	35.4	1.00		
Para 2-4	111	61.0	22	57.9	89	61.8	0.90	.42-1.91	
Para ≥ 5	6	3.3	2	5.3	4	2.8	1.82	.30-11.0	
Previous preterm birth									0.0187
No	178	97.8	35	92.1	143	99.3	1.00		
Yes	4	2.2	3	7.9	1	0.7	12.26	1.24-121.4	
Father of baby									0.6991
Name on birth certificate N	72	39.6	14	36.8	58	40.3	1.00		
Name on birth certificate Y	110	60.4	24	63.2	86	59.7	1.16	.55-2.42	
Married									0.4237
Yes	37	20.3	6	15.8	31	21.5	1.00		
No	145	79.7	32	84.2	113	78.5	0.68	.26-1.78	
Prenatal smoker									0.5343
Yes	64	35.2	15	39.5	49	34.0	1.00		
No	118	64.8	23	60.5	95	66.0	0.79	.39-1.65	
BV Positive									0.9520
No	87	47.8	18	47.4	69	47.9	1.00		
Yes	95	52.2	20	52.6	75	52.1	1.02	.50-2.09	

The data contained in Table 24 was compared with Table 16, the demographic (risk) characteristics of the overall sample, and shows that the early screening was more frequently performed among younger women, women with less education and Black women. More of the recipients of early screening were on Medicaid and more attended the inner city clinics at UHCC and SCHC than attended private physicians' offices. There were fewer married women in the early screening group and more women who had no father of the baby listed on the birth certificate. The BV positive rate was higher than the original sample with 52.2% positive or indeterminate among women screened early in pregnancy compared to 31% rate of BV positivity overall.

The data in Table 24 was also compared with Table 22, demographic (risk) factors of women screened in the prenatal office setting. In Table 22 there were three significant associations. Women who were 20 years of age or older, and had at least 12 years of education were less likely to be screened for BV in the office.

Women who attended SCHC and UHCC were more likely to be screened prenatally in the office. These associations were not noted in the early screening analysis. Only attendance at the high risk perinatal center was associated with early screening.

Although the power calculations for this sample showed only 49% power to detect an OR of 0.5 (or 2) for screening at <22 gestation, the evaluation was considered worthwhile as the timing of BV treatment remains an important research topic. The crude and adjusted ORs are shown in Table 25 below. The adjusted analyses were done with and without history of preterm delivery.

Table 25 BV screening and treatment in prenatal settings at less than 22 weeks gestation

Intervention: BV screening and Treatment In prenatal Office site	OR Unadjusted	P value LR test	95% CI	OR Adjusted	95% CI	P value LR test	Adjusted OR without history of PT birth	95% CI	P value LR test
		0.2149				0.1953			0.2789
Screened-negative	1.00			1.00			1.00		
Screened-pos/treated	0.69		28-1.66	0.82	31-2.17		0.75	29-2.00	
Screened-pos/untreat	1.69		70-4.06	1.29	45-3.66		1.33	48-3.69	

No significant associations were demonstrated in this analysis. However, although there was insufficient power to detect an OR of 0.5 the results do reflect the trends seen in the larger study with a protective effect of treatment and an increased odds of preterm low birth weight when positive BV tests were not treated. It appears that adjusting for population characteristics had little effect on this model.

10.2 VERY LOW BIRTH WEIGHT ANALYSIS

The analysis was repeated to assess the effect of the interventions on very low birth weight births, that is, infants weighing less than 1500 grams. These are the babies most likely to die. They also represent the pregnancies most likely to be maintained if treatment for BV infection occurs early in pregnancy (Ugwumadu et al., 2003). The demographic characteristics of the very low birth weight sample are presented in Table 26 below:

Table 26 Demographic Characteristics of Very Low Birth Weight Cases and Controls

Very Low Birth Weight N=564 Cases = 57 Controls = 507	Sample N=564	Sample %	Cases N=57	Cases %	Controls N=507	Controls %	OR	95% C.I.	P-value (LR test)
Age									0.5797
<20	104	18.4	9	15.8	95	18.7	1.00		
>20	460	81.6	48	84.2	412	81.3	1.23	0.58-2.60	
Race/Ethnicity									0.0482
White	230	40.8	26	45.6	204	40.2	1.00		
Black	264	46.8	29	50.9	235	46.4	0.97	.55-1.70	
All other	70	12.4	2	3.5	68	13.4	0.23	.05-1.00	
Education									0.0420
<12 years	209	37.1	14	24.6	195	38.5	1.00		
≥12 years	355	62.9	43	75.4	312	61.5	1.92	01.02-3.60	
Payor Source									0.2702
Medicaid	298	52.8	28	49.1	270	53.3	1.00		
HMO	89	15.8	8	14.0	81	16.0	0.95	0.42-2.17	
Private	157	27.8	16	28.1	141	27.8	1.09	0.57-2.09	
Self pay	20	3.6	5	8.8	15	3.0	3.21	1.09-9.51	
Provider									0.000
Private	201	35.6	8	14.0	193	38.1	1.00		
UHCC	103	18.3	4	7.0	99	19.5	0.97	0.29-3.32	
SCHC	174	30.9	9	15.8	165	14.0	1.32	0.50-3.49	
PNC	76	13.5	35	61.4	41	7.0	20.59	8.90-47.65	
Other/None	10	1.8	1	1.8	9	1.8	2.68	0.30-23.80	
Parity									0.2393
Primiparous	199	35.3	25	43.9	174	34.3	1.00		
Para 2-4	336	59.6	28	49.1	308	60.8	0.63	0.36-1.12	
Para ≥ 5	29	7.0	4	7.0	25	4.9	1.11	0.36-3.47	
Previous preterm birth									0.0177
No	548	97.2	52	91.2	496	97.8	1.00		
Yes	16	2.8	5	8.8	11	2.2	4.34	1.45-12.96	
Father of baby									0.3298
Name on birth certificate:N	204	36.2	24	42.1	180	35.5	1.00		
Name on birth certificate:Y	360	63.8	33	57.9	327	64.5	0.76	0.43-1.32	
Married									0.1924
Yes	170	30.1	13	22.8	157	31.0	1.00		
No	394	69.9	44	77.2	350	69.0	1.52	0.80-2.90	
Prenatal smoker									0.3032
Yes	118	20.9	15	26.3	103	20.3	1.00		
No	446	79.1	42	73.7	404	79.7	0.71	0.38-1.34	

When the characteristics of the very low birth weight cases were compared to the previous analysis of low birth weight cases in Table 16, women who delivered very low birth weight infants were not found to be younger or less educated than the previous sample. The racial mix of preterm mothers showed a slightly higher percentage of White women (by 7.7%) and slightly lower percentage of Black women (by 3.5%) than in the Table 16 analysis. The percentage of primiparous women in the very low birth weight sample was slightly increased, by 4.3%. There were marginally more single women, 5.6% and fewer fathers named on birth certificates in the very low birth weight group, 6.6%. Smoking rates were increased among very low birth weight mothers by only 2.6%. Four characteristics were significant in this analysis: history of previous preterm birth, a well known risk factor; provider source; payor source; and education level. The high risk Perinatal Center is included in the provider group and obviously biased this result. Higher levels of education appeared to be a significant risk for VLBW delivery. Women who were self pay or had no health insurance were also at increased risk.

A crude analysis of the very low birth weight sample was undertaken and the results are noted in Table 27 below:

Table 27 Comparison of intervention components (exposures) between very low birth weight cases and controls

Very Low Birth Weight N=564 Cases = 57 Controls = 507	Sample N=564	Cases N=57	Cases %	Controls N=507	Controls %	OR	95% C.I.	P-value (LR test
SHS								0.8689
No	291	30	52.6	261	51.5	1.00		
Yes	273	27	47.4	246	48.5	0.96	0.55-1.65	
WIC								0.2666
No	238	28	49.1	210	41.4	1.00		
Yes	326	29	50.9	297	58.6	0.73	0.42-1.27	
Decrease smoke								0.2226
No	538	56	98.3	482	95.1	1.00		
Yes	26	1	1.8	25	4.9	0.34	0.05-2.59	
BV screen/treat all								0.6579
Unscreened	221	24	42.1	197	38.9	1.00		
Negative	174	16	28.1	158	31.2	0.83	0.43-1.62	
Positive/treated	111	9	15.8	102	20.1	0.72	0.32-1.62	
Positive/untreated	58	8	14.0	50	9.9	1.31	0.56-3.10	
BV screen/treat hospital								0.1205
Unscreened	432	44	77.2	388	76.5	1.00		
Negative	75	11	19.3	64	12.6	1.52	0.72-1.96	
Positive/treated	44	1	1.8	43	8.5	0.21	0.48-1.76	
Positive/untreated	13	1	1.8	12	2.4	0.74	0.09-5.79	
BV screen/treat Prenatal office								0.5547
Unscreened	283	29	50.9	254	50.1	1.00		
Negative	150	12	21.1	138	27.2	0.76	0.38-1.54	
Positive/treated	86	9	15.8	77	15.2	1.02	0.46-2.26	
Positive/untreated	45	7	12.3	38	7.5	1.61	0.66-3.94	

There were only marginal differences between the percentages of cases receiving Healthy Start Interventions in the very low birth weight group and the original sample. There were no significant findings in the crude analysis of very low birth weight cases and controls.

As the power calculations showed only 64% power to detect an OR of 0.5 (or 2) in this sample, it was decided to limit further analysis to the one intervention which showed a significant effect in the main study, prenatal office screening and

treatment for BV, adjusted for confounding, with and without history of preterm delivery. The results of this analysis are presented in Table 28.

Table 28 VLBW and BV Screening and Treatment in the Prenatal Office, Adjusted for Confounding

BV screening in office	Unadjusted OR	95% CI	P value LR test	Adjusted OR	95% CI	P value LR test	Adjusted OR without Hx of PT birth	P value LR test	95% CI
Unscreened	1.00		0.555	1.00		0.242	1.00	0.289	
Screened-negative	0.76	0.38-1.5		1.21	.52-2.86		1.24		.53-2.89
Screened-pos/treated	1.02	0.46-2.2		2.41	.88-6.63		2.36		.86-6.52
Screened-pos/not treat	1.61	0.66-3.9		2.55	.77-8.46		2.33		.72-7.58

There are no significant associations in this analysis and confidence intervals are wide.

CHAPTER 11
QUANTITATIVE DISCUSSION

11.0 Quantitative Discussion

11.1 MAJOR FINDINGS

11.1.1 Introduction

The qualitative analysis of the SHS Initiative has aimed to assess both the overall effect and the effect of individual elements of SHS in relation to premature low birth weight deliveries in the project area. The analysis has confirmed some previous findings and has also raised some issues about current practice.

11.1.2 Syracuse Healthy Start Overall

Current evidence has not yet established that prenatal care definitely improves birth outcomes (Fiscella,1995; Carroli, 2001). In both the crude and adjusted analyses enrolment in the Syracuse Healthy Start project overall did not have a statistically significant effect on birth outcomes in this sample. Careful scrutiny of each element of the programme was undertaken and a subanalysis of parity, payor sources, provider sites and BV screening was also carried out. Without these sub-analyses several potentially important finding would have remained hidden, obscured by an apparent lack of Healthy Start influence on preterm low birth weight and also by lack of overall effect of BV screening.

The analysis of Syracuse Healthy Start and each intervention showed remarkable consistency with findings of previously published work. Despite all the confounding influences present in this public health evaluation, the results of this study agree with current literature and research. Such consistency strengthens the validity of the findings in this study.

11.1.3 Bacterial Vaginosis Screening and Treatment Intervention

Previous studies have associated preterm birth with BV (Hillier, 1995; McGregor, 1994). In populations where universal BV screening occurred early in pregnancy and positive screens were treated, rates of preterm birth and second trimester miscarriage decreased (Ugwamadu, 2003; Kiss, 2004).

In this analysis, absence of treatment after a positive screening test in the prenatal care site increased the odds of delivering a preterm LBW baby. Failure to treat women who screened positive for BV in the prenatal office setting had a crude odds ratio of 1.84 (95%C.I.1.03-3.29) for premature low birth weight babies. When adjusted for risk the odds ratio was 2.48 (95% CI 1.25-4.93). The study demonstrates the importance of assiduous follow up of antenatal test results and treatment of positive BV tests. This study implies indirectly but does not prove that early screening and treatment in antenatal care office may have played a role in the decline or control of infant mortality in the Syracuse area. It also implies that wider screening would result in the discovery of more asymptomatic infection which, if treated would decrease preterm LBW deliveries. The study also implies that women with an indeterminate BV

screening should be treated as positive as the odds of preterm low birth weight increased when these women were not treated.

Hospital screening and treatment, often for women with symptoms of preterm labour, did not appear to have an effect on outcomes but only women past 20 weeks gestation were admitted to the labour ward and thus this intervention was only carried out on women in later pregnancy. The lack of effect in hospital screening diluted the effect of screening overall. Previously reviewed studies which showed no effect of BV treatment in late pregnancy were supported in this analysis (Carey, 2000).

Key questions to unravel in the evaluation of this program are, "Who are the unscreened women?" and, "Who are the women who received a diagnosis but not treatment?" A descriptive analysis of patients who had screening and treatment in the office setting was carried out. This analysis looked at the frequency of positive BV screening in the treated and untreated groups by Black and White race, and at educational level, provider group, payor source, marital status and father of the baby on the birth certificate. The literature describes a higher prevalence of BV in African, Afro-Caribbean and African American women than in White women. The frequency of BV positivity in Black women in this sample was 30% compared to 16% in White women. Among women in the sample who were BV positive and treated 23% were White and 66% were Black. Nearly half of the BV positive White women (46.5%) were not treated while only a third of Black women (32.2%) did not receive treatment. The odds ratio for preterm low birth weight among Black women compared to White

women was higher but not significantly different: OR 1.25, p=0.241, (CI .86-1.8). It is possible that the racial disparity disappeared because although the prevalence of BV was higher in Black women they had a higher rate of screening and treatment.

Screened and unscreened women were also examined by provider group. This analysis sheds light upon the two key questions mentioned above: "Who are the unscreened women?" and, "Who are the women who received a diagnosis but not treatment?" As noted previously, the timing of screening and treatment as well as the frequency of screening varied among provider groups. Table 22 shows that providers in private practices screened the least (46.7% unscreened) but treated 95% of the women who tested positive (5% not treated). Syracuse Community Health Center (SCHC) screened most women (17.1% unscreened) but 61.7% of positive women were untreated. Outcomes for premature low birth weight did not vary significantly (OR 1.23, 95% CI .77-1.96) between the private providers and SCHC. It is quite likely that the poor treatment rate at SCHC may have been because women did not return for their test results or because in a large, busy clinic, results were overlooked. The importance of following up screening with treatment is highlighted by these findings. Failure to follow up screening results undermined the role of the Healthy Start program in reduction of infant mortality. Screening is not meaningful unless subsequent treatment is undertaken if indicated. Responsible screening programs which identify women at risk and intervene appropriately are supported by this data.

In this sample 23.8% of 676 women were positive or indeterminate for BV. Social risk factors including low educational level (<12 years), poverty (Medicaid payor source proxy), social support (marital status and father of the baby on birth certificate) were elevated in every case for BV positive women (see Table 22). Overall, 37% of BV positive women did not receive treatment. There were no increased odds of preterm low birth weight delivery in BV positive women who were treated. Once again, BV treatment appears to have equalized the outcome among high risk women.

In the very low birth weight analysis the demographic characteristics were similar to the original sample. There were no significant findings in this analysis. The sample size was small and co-morbidities were not considered in the analysis.

Likewise, the analysis of BV screening and treatment at $\leq$ 22 weeks did not yield significant results, perhaps due to small sample size. It is interesting to look at the trend in the crude odds ratios, however. The OR for positive/treated BV trends downward relative to the OR for negative BV screening and the OR for preterm low birth weight babies among women with untreated BV trends upward.

11.1.4 Case Management Intervention

According to a recent Cochrane review, the value of social support programs in pregnancy has not been demonstrated (Hodnett & Fredericks, 2003). Healthy

Start data was consistent with this conclusion. Case management activities initiated for all participants in Syracuse Healthy Start did not have a statistically significant effect on birth outcomes in this sample.

11.1.5 WIC Nutrition Intervention

The work of Besharov et al. (2000), has called into question the positive impact of WIC on birth weight. Nutritional supplementation in western society remains difficult to justify. The recently published NICE Guideline for Antenatal Care found no evidence to support vitamin supplementation for pregnant women in the U.K. (National Collaborating Centre for Women and Children, 2002).

Participation in WIC had no significant effect on preterm-low-birth-weight delivery in this study population.

11.1.6 Smoking Cessation Intervention

The implementation of successful smoking cessation programmes in health care remains an area of active research. Behavioral theory and the physiology of addiction both contribute to the understanding and development of interventions to assist individuals to stop smoking (Lumley et al., 2003).

In this study a stage-matched smoking cessation program for pregnant smokers was promoted which matched a woman's readiness to quit smoking with appropriate counseling and/or medical intervention. The program was not fully

implemented across the entire project as some practices declined the opportunity for staff training in this methodology. The effect of the program on preterm low birth weight was non significant.

11.1.7 The Syracuse Healthy Start Population

Tables 17 and 18 illustrate significant associations between project interventions and patient characteristics. The target population which Syracuse Healthy Start aimed to reach appears to have received the interventions. There was a significant difference between cases and controls in four areas.

In this sample, women with a history of preterm delivery had an OR of 3.14 (95% CI 1.34-7.38) for another preterm low birth weight baby.

The Perinatal Center (PNC) is Syracuse's high-risk obstetric center. It is logical that women who were patients there would have a higher risk of preterm birth. In fact, these women had an OR of 6.6 (95% CI 3.72-10.59) for premature low birth weight delivery compared to the general population of pregnant women. Interestingly, women whose prenatal care provider could not be identified (other) or who received no prenatal care were also at risk for premature low birth weight delivery with an OR of 4.1 (95% CI 1.49-11.22). This may indicate a very high level of social risk among these women (for example, drug use) relative to pregnant women overall or it may indicate some advantage of prenatal care.

There was a significant difference between cases and controls if they were self pay patients with an OR for preterm birth of 2.9 (95% CI 1.30-6.42). These were likely to be women without any insurance, who may therefore have under utilized the health care system. Frequently uninsured women are the "working poor," employed at minimum wage jobs, without the resources to pay for health care or prescription medications (Syracuse Healthy Start: Onondaga County Health Department, 2001).

An analysis of the association between risk factors and the interventions (explanatory variables) in the control group of full term normal birth weight deliveries, demonstrated that all of the risk factors with the exception of parity <5 were associated with at least one of the interventions. Therefore, all of the risk factors were included in the analysis.

11.2 LIMITATIONS

11.2.1 Evaluation of Complex Interventions

According to the Oxford Handbook of Public Health Practice (Pencheon et al., 2003) the quality of a public health intervention can usually be determined by assessing the structure of the health care delivery system involved, the process of care delivery and the outcomes of care. In laboratory conditions the experimental environment and the application of the intervention can be carefully controlled and outcome measures accurately calculated; this is

efficacy. In real world settings these activities are more challenging, particularly when working outside a research environment. The effectiveness of an intervention, that is the extent to which an intervention does what it intends to do in a defined population, is more difficult to evaluate. Most of current day epidemiology has left behind the clear cut and dramatic questions pursued by early researchers and now struggles to unravel confusing and inter-related factors which are not easy are to disentangle. It is often impossibly difficult to test public health hypotheses experimentally as there are too many factors to distill. For instance, the links between health and diet are extremely complex and, as this thesis demonstrates, so are the associations between antenatal variables and birth outcomes.

11.2.1.1 Structure

The structure of care refers to people who deliver care, facilities where care is given and funding of care. In community-based settings these factors can vary greatly. Antepartum interventions may involve physicians, midwives, nurses, dieticians and social workers in a myriad of practice sites and styles. Individual practitioners may chose the degree to which they implement any public health intervention. Their freedom to act in the perceived best interest of the patient, their skill in delivering the interventions and their adherence to professional standards may all vary. Facilities in the U.S. may also vary in the level of technology available, the support services offered to patients, and payment methods accepted.

11.2.1.2 Process

A public health evaluation must assess what care was actually delivered. Were all potential participants able to access care? Did health care providers actually participate fully in the implementation of the program? If medication was required, were all of the patients able to purchase the medicine and did they take it? When a program involves more than one intervention, the uptake of individual components must also be assessed. This is often extremely difficult to accomplish. Recent statistical methods which permit researchers to adjust for confounding and effect modification still may not capture the subtleties of lifestyle or varying degrees of uptake of numerous interventions which exist within the study population.

11.1.2.3 Outcomes

Consistency and accuracy in the assessment of outcome measures can be problematic in the realm of perinatal health. In the U.S. in general and in Syracuse, N.Y. where the study described herein took place, there has been great concern about the racial and ethnic disparity in infant mortality (Lane et al., 2001). But the classification of race is not straightforward. Since 1980 the description of race for all live births in Syracuse has been based on the race/ethnicity of the mother. However, the infant death's classification of race is based on the child's race, as categorized on the birth certificate. In a city such

as Syracuse, where there are only 2,350 births per year, small numbers of misclassified births can make a large difference in the statistics.

The classification of infant death is also not clear-cut. In Syracuse, N.Y. the largest maternity hospital opened a new maternity center in September 1999. Prior to that time pregnant women with a pre-viable fetus underwent spontaneous abortions on the gynecology floor. In the new center labor and delivery nurses attended these miscarriages. These nurses are highly trained in detecting any signs of life and calculating Apgar scores. A slightly pulsating umbilical cord in a pre-viable preterm age baby, who otherwise had no muscle tone or attempts at respiration, would be deemed an infant birth and consequently be issued both a birth and death certificate. The way in which outcomes are counted makes a tremendous difference in statistical analysis of rare events.

11.2.2 Study site limitations

The Syracuse Healthy Start Initiative was not designed as a research project but as a community intervention. Consequently this complex intervention had both structural and process limitations. SHS was spread across 15 different antenatal care sites, all of which implemented the Healthy Start interventions to varying degrees. Not only was there site variability but there were also individual provider differences in uptake of the interventions and of course, patient differences in compliance as described by the women interviewed for

this study. Undoubtedly some of the lack of significance in study results is related to the lack of consistency in the application of interventions.

11.2.3 Methodological limitations

Researchers continue to grapple with the challenge of measuring the effects of multiple social risk factors and their effects upon health outcomes. This study of high risk women may have been confounded by multifactorial risk which has not been adequately measured. All of the possible permutations and combinations of project implementations together with an analysis of risk in women whose lives are quite complex poses great difficulties in the evaluation of a program such as Syracuse Healthy Start. Ideally, a study of effective interventions would be carried out in controlled conditions, testing each aspect of the program independently with an adequate sample size.

Retrospective data collection from 1352 hospital and office records can pose problems in terms of missing data, although through persistent efforts, the data necessary for analysis of this sample was fundamentally complete and the accuracy of records, based on quality control during data abstraction was comparable between cases and controls.

The greatest limitation of case-control studies is their susceptibility to bias (London School of Hygiene & Tropical Medicine, 2004). Observation bias in the extraction of information from medical records was possible despite efforts to standardize data collection. Bias introduced by researchers who were

personally involved with the program may also have been a limiting factor in this study.

Although the data collection tool was the product of "expert opinion" and was field tested by CDC researchers, the questions could have been further simplified for clarity and efficiency of abstraction.

Misclassification of the "not treated" group may have biased the results of this study toward the null. Although prescriptions for metronidazole were given, that is patients were "treated," there is no way to know if they were filled, particularly among women whose insurance did not cover the cost of the medicine. Nor is there any way to know if the medication was actually taken or for how long it was taken. Metronidazole can be unpleasant, causing nausea. This is particularly difficult for women in early pregnancy who may be nauseated anyway due to the pregnancy. The effect of non treatment may well be larger than it was possible to demonstrate here.

"Preterm bias" may affect the analysis of any prenatal program. Mothers of babies born early necessarily received fewer program interventions because their pregnancies are shorter. Within the preterm group the role of interventions may be more difficult to demonstrate.

11.3 PROGRAMATIC IMPLICATIONS

Assuring treatment after screening is an important implication of this work. In the experience of this researcher as lead midwife in the project, busy clinic staff were challenged to keep abreast of large volumes of incoming lab reports. Non attendance rates tended to be high in clinic settings and telephone contact was not always possible as poor women often do not have telephones. There may be an opportunity in such instances to utilize community outreach staff effectively to visit and advise women who require treatment.

Another important question for practice remains whether to recommend universal screening for bacterial vaginosis at the first prenatal visit. The results of this evaluation of Syracuse Healthy Start would indicate that there is a group of women with demographic characteristics including Black race, low educational level, poverty and poor social support who are more likely to be BV positive and would benefit from screening and treatment. A selective screening policy based upon risk criteria seems a reasonable approach.

Bodnar et al. (2002) suggest the use of prevalence information in combination with a set of selective screening criteria to guide clinical decision making for screening programs. It may be worthwhile to implement the Healthy Start strategy of identifying population attributable risk in high BV prevalence settings to determine a policy for prenatal screening. It may also be that the current CDC recommendation for screening of women with previous preterm delivery

and those who are symptomatic is too restrictive. Test of cure after treatment for women with a positive BV test could also be valuable.

Case management and WIC did not appear to affect the outcome of preterm low birth weight delivery. These interventions may well have positive outcomes in other important areas. A systematic review of home visiting studies by Ciliska et al. (2001) showed a positive impact of nursing visits on maternal physical health, mental health and development, social health, health habits and knowledge and service utilization of mothers and babies. The WIC program may have salubrious effects on infant health which were not assessed in this study. The benefits of these programs should be further evaluated.

As smoking is known to be associated with low birth weight it is important to continue to pilot various methods to assist pregnant smokers to eliminate or control their smoking behaviors.

11.4 RESEARCH IMPLICATIONS

The case-control design utilized in this study was advantageous in that it permitted an analysis of a rare outcome, i.e. preterm low birth weight deliveries. It also allowed for the study of several exposures within the sample and provided a method for disentangling the multiple interventions of Syracuse Healthy Start. However, this observational research is not as robust as the "gold-standard" randomized controlled trial (RCT). A future study in the form of a large multi-ethnic randomised controlled trial in the U.S. using the Syracuse

Healthy Start protocol is recommended. That protocol would include a control group receiving standard care and a treatment arm receiving:

1. Universal BV screening at the first prenatal visit
2. Early treatment, in the first trimester if possible, of all BV positive women
3. Prescription of an appropriate dose of metronidazole, that is 250 mg three times a day for one week
4. Test of cure within one month of treatment.

In summary the analysis of Syracuse Healthy Start suggests that treatment of BV positive women may reduce preterm low birth weight and consequently decrease infant mortality. This treatment may be particularly important among African American women who have a higher incidence of bacterial vaginosis than other groups of women and also of preterm low birth weight and infant mortality. However the study was subject to numerous potential confounding influences and should be repeated using an RCT design. Targeted screening of high risk women or, in high risk areas where infant mortality is endemic, may impact the racial disparities in infant mortality which currently exist worldwide. BV screening and treatment, as a feature of antenatal care, is still an open question and requires further research.

CHAPTER 12
PARTICIPANT INTERVIEWS

12.0 PARTICIPANT INTERVIEWS

"They don't know what goes on everyday."

(Syracuse teen mother [Interviewee #4] speaking about health care providers' perceptions of inner city life.)

The qualitative study described herein was designed to inform the quantitative analysis which examined interventions to decrease rates of preterm low birth weight and to address the racial disparities in birth weight and infant mortality occurring in Syracuse, New York. I was interested in speaking with women from the project area about their own pregnancy experiences, in order to shed some light on, "...what goes on everyday," and to better understand the antenatal care experience from the perspective of women in the project area.

The methods used for sample selection, data collection and analysis have been discussed in Chapter 6 of this document.

A case study is presented initially in order to provide a rich description of the life experience of one woman in the project area. It is important to appreciate the reality of life in inner city America if the context in which the SHS project was conducted is to be accurately evaluated.

12.1 INTERVIEW RESULTS

Demographic data about the interview sample is presented in Table 29, Section 12.1.1. An in-depth case study is then described, followed by a thematic analysis illustrated by quotations and comments from the women who were interviewed.

12.1.1 Demographics

Fifteen postpartum women from the Healthy Start project area were interviewed for this study. The demographic data relative to the sample is presented in Table 29:

Table 29 Demographic Characteristics: Interviewees

Background Characteristics	*N=15*
Race/ethnicity	
White	4
Black	7
Asian	2
Hispanic	2
Maternal age	
<18	2
18-35	11
>35	2
Parity	
Primiparous	8
Multiparous	7
Birth weight	
<2500	1
>2500	14
Education	
<12 years	6
12 years	3
>12 years	6
Healthy Start	
Yes	4
No	11
Bacterial vaginosis this pregnancy	
Yes	9
No	6

Although the demographic profile of the interviewees differed from that of the case-control sample, it did achieve the aim of interviewing at least two women in every category. Only low birth weight was under-represented for reasons already explained.

12.1.2 Case Study

One in-depth case study is presented to illustrate the complexity of the lives of women who reside within the project area community. The rich narrative description of "Maria's (pseudonym)" life history and pregnancy provides a framework for understanding and interpreting the responses of other interviewees.

Maria is a 39 year old woman of mixed heritage. Her mother is Puerto Rican and her father, who is deceased, was West Indian. She has two sisters and two brothers. None of the siblings share the same father. In fact, Maria's youngest brother is one of 22 children by his father. One of Maria's brothers is incarcerated and the other is, in her words, "...on the streets," using drugs. Maria's mother is also an active drug user.

Maria disclosed that she was the victim of sexual abuse as a child. Her first baby was born when she was 14 years old. That child was always , "...out of control," and at age 19 he shot and killed a man. He is now in prison for 25 years to life. Maria states that, "All the men in my life have been in jail...my father, my brother, my first husband and my son." Maria's son "Devon" is

married. He and his wife had one child together, a son, who was born shortly after Devon went to prison. A second little boy, by a different father was born about two years later to Devon's wife. Maria's daughter-in-law recently had a psychotic episode, exacerbated by drug use. She made a suicide attempt, turning on the cooking gas while the children were in the apartment sleeping. Fortunately, neighbors smelled the gas and the family was rescued. The boys were placed with Maria while their mother was hospitalized in a psychiatric facility. They remain with their grandmother who is providing a stable household. She has enrolled them in school and daycare and has worked to obtain social service benefits for them. There have been many recent interactions with Child Protective Services and the foster care program. The boys' mother wants the children back and actually attacked Maria physically , in an attempt to get the children.

Last year Maria married a man who was incarcerated at the time of the wedding. They dated for two years before he was imprisoned and although she waited patiently for his release, she did see someone else while he was gone. "I don't actually know to this day why he married me. He knew about my 'indiscretion' and yet he still married me." Within two weeks of his release she became pregnant. Maria was shocked. She had not conceived since her son's birth and presumed that she was infertile. She had a history of gonorrhea as a young woman and was told by her doctor that her fallopian tubes were likely to be scarred. Her first marriage however, was to a man with diabetes and Maria speculated that this may have been a factor in the couple's infertility as she

conceived quickly when she changed partners. Just days after announcing to her new husband that she was pregnant, he left her.

As an adult, Maria completed a General Education Degree (GED) to obtain her high school diploma and then finished a nine month licensed practical nurse (LPN) program. She is employed at a local health center and has worked hard to support herself. She drives an old car on a restricted license because she has had three traffic infractions within a year. She lives in a neighborhood noted for violence and relates that she is careful not to go out at night or to let the children play outside alone.

Maria continued to work throughout her pregnancy, as she could not afford to loose her income. Her health insurance through her job only covered 50% of the cost of Maria's care. Her provider "wrote off" the balance, in order to keep Maria's expenses down. Maria was enrolled in Healthy Start during her pregnancy. She received the Women's, Infants and Children's (WIC) nutritional supplement while pregnant but her grandsons or other family members ate most of the foods she received. Although Maria identified, "...exercise, a good diet and 'non stressors'" as elements of a healthy pregnancy, she admittedly consumed large amounts of "junk food," snacking on cookies and candy while at work. She took her iron supplements inconsistently, despite severe anaemia. She did not exercise at all during pregnancy and weighed 220 pounds at delivery.

Maria also had unprotected sex with her husband once when he came to visit after their separation. She was concerned enough to ask her midwife to screen her for STDs after this encounter. She was also treated for bacterial vaginosis during the pregnancy. Despite her training as a licensed practical nurse, she had no insight into the causes of this infection.

Maria had very inconsistent emotional support during the pregnancy. Her husband was gone. Her mother was a great worry, as she would, "...disappear to do drugs" after her monthly welfare check arrived, only to reappear needing money, food and a place to stay for the rest of the month. Maria's brothers and a sister who lives locally are not close to her. Maria's best support during the pregnancy came from a sister who lives in Maryland and an aunt in New York City.

Day to day Maria exercised great self reliance. "I have learned to 'deal' just by getting fresh air or by keeping busy so that I don't concentrate on my problems. I think 'mental damage' would have occurred if I allowed the stress to get to me and it would have affected the pregnancy." Throughout her entire pregnancy, despite loosing her husband, the crises with her grandchildren, problems with extended family and financial difficulties, she maintained a positive attitude and only once, did she become tearful.

Maria's story exemplifies all of the themes elicited in the analysis of the interview data, which seem to typify the life experience of women in the Healthy Start project area. Although Maria knew the standard public health messages

concerning "safe sex" and diet and exercise, she did not operationalize these principles during her own pregnancy.

Multiple stressors may have played a role in the prioritizing of Maria's health promoting activities in pregnancy. Lifestyle choices are influenced by the demands of family, social and economic pressures. Maria faced endless requests from family members seeking money, housing, help with legal services and child care.

Structural factors also impacted Maria's daily life. She lived with the ongoing threat of neighborhood violence, and with stress invoked by the social service system and the legal system. Her limited education negatively affected her earning potential.

Chronic stress is a way of life for this woman. The stress is multifactorial, compounding the effect. In Maria's case an unexpected conception, difficulties with the father of the baby, financial worries, violent episodes, work stress and family problems all threatened her well-being during this pregnancy. But Maria's inner strength and upbeat attitude remained unshaken. In February 2003 Maria delivered a healthy 8 pound baby boy by cesarean section at 41 weeks gestation.

12.1.3 Themes

Five themes were identified through analysis of fifteen postpartum interviews. The following discussion will focus on each individual theme, illustrated by comments from the interviewees.

Translating knowledge into practice

Interviewees were generally able to verbalize knowledge of standard public health messages. Exercise, good diet and 'non-stressors' were one woman's description of a healthy pregnancy (Interviewee #13). The women overwhelmingly sited good nutrition, including more fruits and vegetables, as important for a healthy pregnancy. "Taking care of yourself" (Interviewee #6, #12) as well as attending prenatal visits (Interviewee #12) were mentioned. Almost half of the women spoke of exercise and several advised decreasing stress. "No drugs, no alcohol, no smoking" was another message conveyed by several women (Interviewee #5, #8, #11).

Although thirteen of the women identified good nutrition as a factor in healthy outcomes of pregnancy, when speaking of their own food choices, women reported such things as, "I ate whatever was there. If it was strawberries I ate those, if it was chips I ate those (Interviewee # 1)." This woman's WIC foods were usually consumed by other household members. Another woman said, "I didn't have a chance to change my diet," meaning that she did not have enough money to buy nutritious food (Interviewee # 9). A third interviewee responded,

"I don't even know what a healthy diet is! I guess it is whatever you want, just not too greasy (Interviewee # 8)." Five of the women interviewed had significant nausea in pregnancy which necessarily limited their food intake at least temporarily. "I ate whatever I could tolerate," one woman reported (Interviewee # 2). Another woman with significant nausea in early pregnancy stated that once she felt better she, "...ate everything! I know that I didn't eat healthy. I just ate everything (Interviewee #15)."

Six of the women identified exercise as important to good health in pregnancy. Two of these women were Asian and both of them advised "...walking more" which they did (Interviewee # 7, #9). No other interviewees reported exercising during pregnancy.

Similarly, women were well aware of the health risks of smoking during pregnancy. Seven women in the sample were smokers at the beginning of their pregnancies. Only two actually stopped smoking completely and one of those was in the third trimester.

Although some of the women interviewed managed to incorporate the healthy practices they sited into their lives while pregnant, there were also gaps between knowledge and practice. Eating behaviors in particular exemplify the social, emotional, cultural and physical considerations which may affect "compliance" with public health messages.

Several women reported, "I ate all the time (Interviewee # 4, #5, #15)!" For these women pregnancy seemed to be an excuse to eat more than usual, to be unrestrained in their eating choices. Social control of food consumption in the household was an issue for some of the women interviewed. One woman who lived with her boyfriend's parents could only eat what was available(Interviewee # 1) . This young woman had little control over the purchase and allotment of food in the household. Another woman was frequently prevailed upon for food by drug abusing relatives (Interview #13). Because the sample was multi-ethnic, the effect of cultural factors in nutrition are apparent. For example, an Asian interviewee believed that an 8 pound weight gain in pregnancy (less than half the average weight gain of 25-35 pounds per the American College of Obstetrics and Gynecology (2002) was acceptable (Interview # 7). Economic factors also resulted in food shortages or poor choices based upon cost rather than nutritive value. A recent immigrant whose young husband was only employed part-time relied on infrequent visits from her mother-in-law to supplement an inadequate food supply (Interviewee #9). Other women complained that "food stamps" received through Social Services were insufficient.

Women's perceptions of "compliance" with health care messages may also be at odds with the "professional view." One woman, who was unemployed, at only what she could glean from her boyfriend's family and only stopped smoking only at the end of her pregnancy, attributed her perceived healthy pregnancy outcome to "...eating, resting and stopping smoking(Interviewee #1)" She resumed smoking immediately after delivery. Another woman stated that

although exercise was important, she did not feel that she needed to do it. "I am active and in good shape already." A third interviewee believed that good health in pregnancy depended upon, "...taking care of yourself, " including "exercising and eating right." She however, smoked throughout the pregnancy and on the day of the interview, was suffering with a dental abscess which had been ongoing for a month without treatment because , "I hate dentists!"

Clearly, hearing health-related messages and operationalizing them are entirely different concepts. The responses of women in this sample bring into question the possibility of basic knowledge gaps in relation to nutrition as well as the possibility of true food shortages which may affect intake.

It appears that WIC may be missing opportunities to promote good nutrition as well. One woman recounted that WIC, "...mixed up my checks" and gave her coupons for skimmed milk. "But no one in the house likes skimmed milk," she complained, implying that neither she nor any one else in the household would benefit from the milk supplement. WIC supplements include milk, cereal, fruit juice, eggs, cheese, tuna fish, carrots, peanut butter or dried beans. Other than milk, none of these supplemental foods were mentioned by the interviewees as a part of a "healthy diet" in pregnancy or alluded to when discussing their own dietary regimes. Although women reported reviewing their diets with WIC counselors and sometimes receiving advice about adding such things as vegetables or iron supplements to their intake, none of them reported receiving the formal nutrition education regarding preparation of healthy meals which the WIC program purports to provide (www.commcgi.cc.stonybrook.edu,2004)

"Eating well" for some women may simply mean eating enough food rather than eating a well balanced diet.

Although women who attend an Ob-Gyn clinic routinely receive a "safe sex" message, none of the interviewees mentioned infection as a perceived risk factor for early delivery or low birth weight. One of the women in the sample had Chlamydia during pregnancy and another, requested screening due to an unsafe sexual encounter. Nine of the women were treated for bacterial vaginosis.

Multifactorial aspects of risk and high levels of chronic stress

High levels of chronic ongoing stress, compounded by acute stress from multiple sources, is common in this population. When asked about stress, women in this study focused upon acute stressors, usually difficult relationships in their lives. Three of the women were stressed by the pregnancy itself, either because of concerns about the health of the baby, caring for a newborn or the problem of an unwanted pregnancy. The chronic stressors in their lives such as poor or dangerous housing, finances, unemployment, racism were often unacknowledged. Only one woman identified money as her biggest stress factor. Many of the interviewees spoke of specific life events, describing them as stressful and several of the women recognized stress as a risk factor for adverse pregnancy outcomes. However, in their discussion of life events during pregnancy, women often simply told the story of violence or trauma without describing their own emotional reaction. When asked about neighborhood

violence, one woman responded, "Since they put the gang around the corner in jail it is better." Another woman described the shooting of a friend but said, "I didn't let it bother me."

The co-occurrence or "clustering of risk factors" referred to in recent studies of pregnant women was very apparent within this sample (Spencer, 2003). Ten of the interviewees admitted that their recent pregnancies were unintended and that this proved to be a very stressful event for many. One interviewee attributed her early delivery to stress related to the pregnancy. The teenage daughter of one postpartum mother, who was present during the interview, described her mom's pregnancy as, "Very stressful for the whole family!" A 17 year old mother admitted, "I wanted a baby some day but just not now," and another interviewee, "...cried for two days" when her pregnancy test was positive. Eleven of the women admitted to stress related to the fathers of their babies, and twelve of them were, "...just getting by" or in financial difficulty. Neighborhood violence, including fear of physical harm on the streets around their homes, was a concern for seven women. Four of the women had co-existing health problems and exacerbation of symptoms, such as back pain, incontinence, and severe anemia during the pregnancy was a source of stress for all four of them. Another four women noted stress due to the demands of work or school during pregnancy. The five women who continued to smoke throughout pregnancy in this sample all attributed their smoking behaviors to stress. "They (referring to her health care providers) just don't know what goes on everyday," was the comment of a 19 year old primiparous woman who emphatically stated, "I hated being pregnant! I hated everything about it. I was

tired. I was fat. I had gas and heartburn. The delivery was hard. The contractions hurt until I got the epidural. I never even wanted a baby!"

As described in Chapter 2 of this paper, it has been postulated that women who experience chronic stress may, as a result, experience increased corticotrophin releasing hormone release and consequently impaired genital tract immunity, making them more susceptible to infections such as bacterial vaginosis (BV). As noted in Table 29, nine of the fifteen participants in this study had BV during pregnancy and one more woman had a postpartum infection. All reported being treated.

The multifactorial nature of risk in pregnancy is clearly evidenced by this study population and is a theme which recurred in each interview. Table 30 below illustrates this finding:

Table 30 Multifactorial Risk Among Interviewees

	Stress	Nutrition	Smoking	BV
Woman #1	X	X	X	X
Woman #2	X	X	X	
Woman #3	X		X	X
Woman #4	X		X	X
Woman #5	X			
Woman #6	X		X	X
Woman #7	X	X	X	
Woman #8	X	X		X
Woman #9	X	X		X
Woman #10	X			X

	Stress	Nutrition	Smoking	BV
Woman #11	X		X	
Woman #12	X	X		X
Woman #13	X			X
Woman #14	X	X		
Woman #15	X	X		X

Intergenerational and structural aspects of many risk factors, which have been well described by Spencer in Weighing the Evidence (2003), are evident in this interview sample.

Functional coping styles

Each person handles stress differently. Endler (1996) developed the Coping Inventory of Stressful Situations which categorizes individual coping styles into three types: task-oriented, emotion-oriented, and avoidance-oriented. Those who are task oriented take an active, problem focused approach to stressful life events. Emotion focused individuals become immersed in the feelings generated by stressful events. Passive coping is the third style and this may involve avoidance, distraction behaviors, or cognitive coping through intellectual activities such as rationalization. Emotion focused and passive strategies have been shown to increase risk of ill health, for example stroke (Anders et al., 2001). Constructive or active coping styles might include problem solving activities and positive self instruction such as exercise self care, prioritizing issues and balancing work and play have been associated with decreased stroke risk.

A third of women in this sample appear to exercise passive coping strategies when faced with difficulties. Five of fifteen women either "shut down" or ignored their problems. "I don't think about it. I put it in the back of my head." Two women described retreating, by going to a quiet room or by "...leaving and getting some fresh air." Other avoidance activities included eating and shopping. In terms of active coping, only two women mentioned coping with stress by working. Three women found talking to others helpful. Two of the women mentioned exercise.

Despite the high levels acute stress and the ongoing pressures of chronically stressful situations, none of the women complained of being overwhelmed or unable to cope. The women did not express sadness or lack of motivation. No one complained of depression. Likewise, no one described an overtly aggressive reaction to stress such as angry outbursts or violent episodes.

Although a passive coping style as defined by Anders was apparent in this sample, the strength and resilience exhibited by women in the face of overwhelming life circumstances was impressive. "I have to do this. I am a mother. I don't have time to bullshit around," said one interviewee (#12). Another woman reflected, "I just take it slow and put my head up and do the best I can (Interviewee # 14)." It would seem that an apparently passive acceptance of their difficult life circumstances, in no way indicated weakness or an inability to cope. Life's challenges, including unintended pregnancies, were

dealt with and the interviewees appeared to be moving ahead with plans for school and work and motherhood.

Emotional support, as differentiated from instrumental social support, provided by female social networks.

A prospective cohort study of small for gestational age infants done in Sweden by Elisabeth Dejin-Karlsson et al. (2000) suggested that, "There is also reason to believe that the effect of an inadequate social network and weak social support on intrauterine growth may be greater among women who are already subjected to some sort of social deprivation (i.e. immigrant women and women with little education)." Their analysis made a distinction between instrumental social support such as access to social services, transportation, child care, information and advice and general emotional support, that is the caring and support of relatives and friends which engenders feelings of confidence and trust.

Even when instrumental social needs were met, that is when women in the study had safe and secure housing, enough to eat and access to medical care, the need for love and emotional support, particularly from the father of the baby, was often unmet. Eleven of the women interviewed complained of difficulties with the fathers of their babies. "He (the father of the baby) can bring on stress in ways that you don't even realize. It affects everything, including how you feel about the pregnancy (Interviewee #15)." Another woman stated, "He bugs me but he helps with money and chores. That's why I keep him around(Interview

#4)." An Asian woman, who recently emigrated from China complained that her husband offered no emotional support and did not like the baby because it was a girl (Interview #9). Two of the women had partners who were in prison. One woman was abandoned during the pregnancy by her husband. Two of the women had partners who were not involved with them at all and another stated that the father of her baby was occasionally , "...helpful when his mother gives him money (Interview #10)."

Nine interviewees in this sample spoke of supportive female relatives and/or friends who served as confidants, provided respite care and in some cases, material support. These women appeared to serve as important sources of both emotional and instrumental support. "My last baby came 3 months early. I think support from my mother and my sister helped me to carry this new baby almost to term (Interview # 15)." Five of the women in the study lived with their mothers. Only two of the women spoke of their relationship with their mothers as a source of stress.

Structural factors limit choice

Structural or systemic factors which perpetuate societal inequalities may require political initiatives to promote changes which will eventually filter into local societies. In the meantime, such factors may influence women's ability to experience optimum health in pregnancy.

Although not explicitly identified by the interviewees, it is apparent that there are a number of structural factors operating in their lives which may affect overall health in pregnancy. Financial resources were a problem for twelve of these women. Syracuse, NY is an economically depressed region (Lane, 1998). The unskilled or manual labor jobs have been phased out as large manufacturing companies have relocated operations out of New York State and out of the country. It is difficult for individuals with little education to find work which will adequately support their families. Young inner city men, the fathers of the babies in this study, have few employment prospects. They are unable to contribute substantially to the well being of their pregnant partners or the new babies. The effect is to perpetuate the cycle of poverty, single motherhood and poor health.

Assistance through social services is becoming increasingly difficult. The "welfare-to-work" program called "Jobs Plus" in Syracuse imposes a five year lifetime limit on social service benefits. Many women are forced into the job market, working for minimum wage in menial service industry jobs, often without health insurance. Several of the interviewees had difficulty accessing insurance and this delayed their entry into prenatal care.

Additionally, ten of the women had unintended pregnancies which raises the question of access to contraceptive services. One Russian graduate student who was interviewed commented that it was only because of her education and resources through the university that she was able to access assistance. She was incredulous that young, uneducated women could ever make their way

through the American social services system. She described the self-confidence and persistence required to cope with the voluminous and reasonably complex paperwork, as well as the need for ongoing contact with social service agents to facilitate the welfare process.

The same student also complained about the paucity of food stores in the city and a lack of transportation to sources of fresh fruits and vegetables at either the local Farmer's Market or at large grocery stores. The public transportation system is quite limited in Syracuse and is difficult to maneuver with a baby, a stroller (pushchair) and shopping bags. Distances are too far to walk. (Interviewee # 11).

Outright food shortages may also be a problem as women complained that WIC coupons or Food Stamps did not adequately cover the grocery budget each month.

Many of the women interviewed mentioned neighbourhood violence or plans to move to better housing. These women all lived within a small inner city radius, noted for poor housing and high crime rates. The housing in Syracuse is functionally segregated with Black and Hispanic residents living predominatly in the center city. High unemployment rates, incarceration rates, low educational achievement, and health inequities are most prevalent among Black and Hispanic residents (Syracuse Healthy Start: Onondaga County Health Department, 2001).

12.2 INTERVIEW DISCUSSION

The interviews completed for this study demonstrate the relationships modeled in the conceptual framework in Chapter 4. The background characteristics which create the context of social risk, or disadvantage within society, for these women included personal variables of race and ethnicity, educational achievement, age, and household variables such as financial resources and housing conditions. Community level variables mentioned by interviewees included transportation facilities, public assistance programs, violent crime in neighborhoods, availability of grocery stores in city neighborhoods. Lack of jobs and access to health care were implied concerns. Social policy regarding housing, education, and the social service system are structural factors affecting the women in this study. It is clear that the background variables relevant to the lives of study participants influenced to some degree the individual behaviors which might place them at higher risk during pregnancy. Parity, birth interval and entry to care are all related to access, insurance schemes, social services benefits for the poor as well as to unemployment and educational status. Smoking and substance use are coping strategies used by some women in response to high levels of day to day stress. Chronic maternal stress as a reaction to difficult life circumstances is a situation which then increases medical risk possibly through elevated corticotrophin releasing hormone levels which predisposes pregnant women to infection and preterm labor. Malnutrition, whether it is manifest as overeating, under eating or a poorly balanced diet is also related to background and intermediate factors

Despite multifactorial risk, the women in this study had favorable pregnancy outcomes. Local and national statistics however, bear out the fact that overall, women with the type of social risk demonstrated by the interviewees in this study do not generally fair as well as middle and upper class White women (see Chapters 2 & 3). Designing effective interventions for social risk and measuring the impact of these interventions in statistical terms remains a challenging endeavor.

The study also highlights the need for health care providers to fill in the knowledge gaps in patient information and to verify health related behaviors frequently, understanding that the factors related to "non-compliance" may be complicated and may have their basis in distal structural factors as well as immediate social, economic and biological causes.

Overall the responses of women who were interviewed mirrored the findings of the quantitative study. Among the Syracuse Healthy Start interventions studied in this analysis, only failure to treat BV positive women proved to be a statistically significant risk for preterm birth. As noted in the interviews, nine of the women were treated for BV. Attempts to support good nutrition and smoking cessation were only marginally accepted by the interviewees. Social support generally came from family and friends. Case managers, visiting nurses or other health system support was not mentioned by anyone interviewed.

A limitation of the qualitative component of this study was that the health care providers involved in the program were not interviewed. Such interviews could add valuable information about perceptions of risk and motives for implementing the Healthy Start interventions and opinions about BV screening and treatment.

Future research to explore the impact of socioeconomic status, gender, race and ethnicity on health and health behaviors is needed if the U.S. goal of eliminating health disparities in racial and ethnic populations by the year 2010 is to become a reality (Whitfield et al.,2002). This will not only require examination of conventionally accepted risk and protective factors on the population level in mathematical terms, but further examination of psychosocial factors on the individual level in linguistic terms, which will provide a richer understanding of the health behaviours which affect outcomes.

CHAPTER 13
CONCLUSION

13.0 CONCLUSION

This thesis evaluated a community based "real world" intervention, *Syracuse Healthy Start*, which aimed to reduce infant mortality in a high risk community in central New York. The Healthy Start Initiative interventions were particularly designed to reduce the racial disparity in pregnancy outcomes which characterized inner city Syracuse in the late 1980s and early 1990s. During the first three years of project implementation decreased numbers of low birth weight, preterm deliveries and infant deaths in the project area were observed. Infants mortality decreased by 23.8%. The purpose of the study was to investigate the role of full participation in the Healthy Start project in decreasing infant mortality and to evaluate the effect of the four SHS interventions individually.

Demographic trends in infant mortality, preterm birth and low birth weight were reviewed for this study. Rising rates of prematurity and low birth weights in the U.S. were noted and racial disparities in these phenomena were discussed. Controversies about risk factors for preterm low birth weight delivery and about the efficacy of prenatal care were reviewed. The need to formulate an evidence base for antenatal care was discussed.

The risk factor analysis clearly shows the multifaceted nature of poor birth outcomes, ranging from biological, social, psychological factors to structural and behavioral causes. The four risk factors which were the primary focus of Syracuse Healthy Start interventions were presented along with the literature

reviewed prior to project implementation. The literature review included research on BV infection in pregnancy, smoking cessation, nutrition and the WIC program and stress and social support.

The evidence linking bacterial vaginosis to preterm birth is compelling and the fact that BV is more prevalent among women of African descent seems quite clear from published studies. The issue of how and when to screen and treat is still controversial in the literature.

A review of studies on smoking cessation revealed heterogeneity of approaches and lack of rigorous evidence to support any particular model. The transtheoretical approach to behavior change which was implemented by Syracuse Healthy Start was seen to be moderately successful in early studies.

Literature on the effects of nutrition in pregnancy was reviewed. The WIC program which provides food assistance to pregnant or lactating women in the U.S. has been an accepted social service support to pregnant women but recently the effect of participation in this program in relation to the incidence of low birth weight has been questioned.

The issue of stress as it relates to preterm birth is an area of current interest in the field of perinatal epidemiology. Theories of stress and neuroendocrine and immune processes were reviewed. Literature on interventions for stress, specifically social support, was also examined.

All areas of the literature review indicate that further research is required. The research presented in this paper utilizes the findings of a "real-life" community intervention to assess the effectiveness of an enhanced package of antenatal care which attempted to address high priority risk factors including infection, nutrition, smoking and stress.

A conceptual framework was developed which included various levels of risk for preterm low birth weight deliveries and infant mortality. The framework contained structural, behavioral and medical factors believed to be related to poor birth outcomes.

In order to address the research questions and to relate risk factors in the conceptual framework to pregnancy outcomes, a retrospective review of hospital and prenatal care charts was undertaken for women in the Healthy Start project area who delivered at the major obstetric facility in the City of Syracuse. A case-control study was designed to study women who delivered preterm low birth weight infants during the years 2000 and 2001 (cases) compared with women who delivered full term normal birth weight infants during the same period (controls). The cases and controls were compared on the entire Healthy Start package and on each intervention individually. The crude analysis was then adjusted for confounding by any of the identified risk factors in the conceptual framework. Effect modification by race was then analyzed.

A qualitative study was also undertaken. This involved interviewing fifteen postpartum women in the project area and asking open-ended questions about

health in pregnancy. The qualitative study provided additional insight into the lives of women involved in this project. The interview results supported the quantitative study results.

In the data analysis of the quantitative results, only one of the interventions operationalised by Syracuse Healthy Start appeared to be significant. Women who were BV positive and not treated had an adjusted OR of 2.48 for preterm low birth weight babies. These findings concur with studies in the literature review which show increased risk of preterm delivery in women with untreated bacterial vaginosis. There was no significant difference in pregnancy outcomes between Black and White women in this sample despite a higher prevalence of BV among Black women. It appears that treating BV in Black women may have had an effect on the racial disparity in birth outcomes and lowered the infant mortality rates in Syracuse overall.

This study illustrates the principle of efficacy versus effectiveness as it contextualizes a public health intervention within a community setting. The study highlights the difficulty of evaluating an ongoing public health program. The multitudes of variables which have the potential to influence program implementation complicate the analysis immensely.

Overall, the evaluation of the effectiveness of the Syracuse Healthy Start program supports the screening and treatment of BV infection in areas of high prevalence and high social risk. Medical science has the potential to impact the racial disparities in infant mortality rates. This is a very significant potential

finding of the SHS research and has implications for the care and treatment of African American women as well as for African and Afro Caribbean mothers and babies, as there is a high prevalence of BV in all of these populations. A program of BV screening and treatment is not costly or complex. Currently the CDC recommends screening women with a previous preterm delivery and women who are symptomatic with BV. The SHS experience would support expansion of this recommendation as a key public health strategy with potential to impact the racial disparity in infant mortality in the US.

Development of a valid and reliable risk assessment tool based upon a population attributable risk analysis and qualitative enquiry is also recommended. Such a tool would help to target interventions such as BV screening to the highest risk women.

The translation of research into practice in a system where there is no over-arching national health care service is problematic. Within the US healthcare system, screening recommendations are best disseminated through the Centers for Disease Control. This research was sponsored, in part, by the CDC and may engender further investigation. It is imperative that further research is undertaken to evaluate BV treatment and the effect on preterm low birth weight deliveries. International guidance should be encouraged through the WHO, particularly for women in the developing world.

Clearly there is a need for staff education regarding risk assessment and BV screening and treatment. Community health care providers should be

encouraged to evaluate new obstetric patients for BV, recognizing the high prevalence of asymptomatic infection. Local health care systems must then be in place to provide responsible follow up and treatment.

Women also need to understand the etiology of BV and the importance of compliance with treatment. Qualitative study methods will assist health care providers in developing methods to enhance patient understanding and participation in prenatal health interventions.

This research was carried out, in part, while I was also employed as lead midwife for the SHS Initiative. I have considered in Chapter 6, the potential for bias in my dual role as researcher and health care provider. Every researcher must influence the course of research and is ultimately a participant in the research. This was particularly true in my case as I not only took part in all phases of the research but also took part in delivering the interventions and was in effect, a participant observer. As a result, I have had the benefit of integrating theory and practice while observing the outcomes in context. The evaluation carried out in this thesis reflects a synergy between practice and research. Using multiple methods to explore the complexities of program effectiveness, I have sought the evidence to support practice and to contribute to the public health agenda which seeks to impact disparities in health outcomes.

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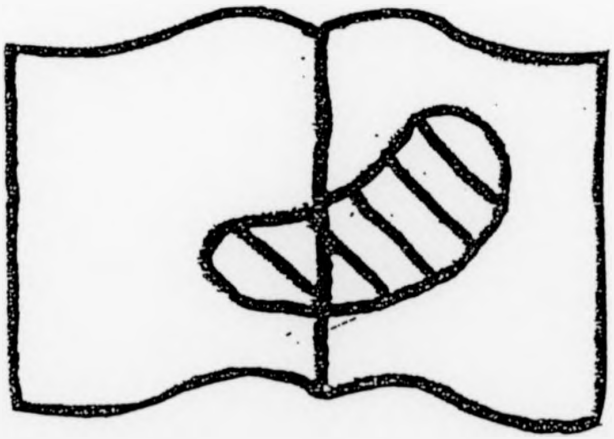
Appendix A

Best Copy Available

Variable Print Quality



Syracuse Healthy Start

Mother's Hospitalization

1. **Healthy Start Unique ID**

2. **Medical Record #**

3. **Mom's Date of Birth (mm/dd/yyyy)**

Shade Circles Like This--> ●
Not Like This--> ⊗ ✓

All questions with circle choices must have one answer.

4. **Hospital of delivery (in PDS)**

○ Crouse ○ St. Joseph's ○ Community General ○ Other

5. **Zip Code**

6. **Marital Status**

○ Single ○ Divorced ○ Widowed ○ Married ○ Other ○ Unknown

7. **Prenatal Summary Present in Hospital Chart**

○ Yes ○ No ○ Unknown

8. **Prenatal Care Provider #1**

○ Private
○ MC/UHCC/WHS
○ SCHC
○ PNC
○ MCHC (St. Joseph's)
○ Other
○ None
○ Unknown

9. **Prenatal Care Provider #2**

○ Private
○ MC/UHCC/WHS
○ SCHC
○ PNC
○ MCHC (St. Joseph's)
○ Other
○ None/Not Applicable
○ Unknown

1996B

10. **Prenatal Care Provider #3**

- O Private
- O MC/UHCC/WHS
- O SCHC
- O PNC
- O MCHC (St. Joseph's)
- O Other
- O None/Not Applicable
- O Unknown

11. **Prenatal Care Provider #4**

- O Private
- O MC/UHCC/WHS
- O SCHC
- O PNC
- O MCHC (St. Joseph's)
- O Other
- O None/Not Applicable
- O Unknown

12. **If care was transferred, gestational age at transfer (at 1st transfer or at transport)**

- O 0-20 Weeks
- O 20-28 Weeks
- O 28-36 Weeks
- O >36 Weeks
- O Not Applicable

13. **Hospital encounters during this pregnancy prior to delivery hospitalization?**

O Yes O No O Unknown

14a. **If yes, how many pre-delivery triage encounters (<12 hours)?**

14b. **If yes, how many pre-delivery short hospitalizations (>12 hours)?**

1. Healthy Start Unique ID (copy from page 1)

Hospital Encounter (During this Pregnancy Prior to Delivery Hospitalization)

2. Hospital Encounter Number

Answer Either Question 3 or Question 4 (one or the other)

3. Date of Triage (mm/dd/yyyy)

4. Date of Short Hospitalization (mm/dd/yyyy)

Admission Labs for this Triage/Short Hospitalization

	Test Done Positive	Test Done Negative	Test Done No Results	Not Documented
5. Gram stain for BV	O	O	O	O
6. Clue cells for BV	O	O	O	O
7. Group B Strep	O	O	O	O
8. Gonorrhea	O	O	O	O
9. Chlamydia	O	O	O	O
10. Herpes	O	O	O	O
11. HPV	O	O	O	O
12. RPR	O	O	O	O
13. Leukocyte Esterase	O	O	O	O
14. Urine Culture	O	O	O	O

15. If Urine Culture is Positive:

Urine Culture Results

- O E coli
- O Klebsiella or Proteus
- O Group B Strep
- O Mycoplasma
- O Not Applicable

Problem List/Diagnoses (Triage/Short Hospitalization)

	Test Done Yes/ Positive	Test Done No/ Negative	(No Pertinen Exam Done) Unknown
16. Term Labor	O	O	O
17. Preterm Labor	O	O	O
18. UTI	O	O	O
19. Pyelonephritis (temp documented positive urine culture)	O	O	O
20. Vaginal Bleeding	O	O	O
21. Supporting Evidence: Visible Blood from Exocervix (cervix/vagina)	O	O	O
22. Visible Blood from Intrauterine Cavity	O	O	O
23. Bacterial Vaginosis	O	O	O
24. Trichomonas (no=wet prep done, no mention of trich)	O	O	O
25. Yeast Vaginitis (no=wet prep done, no mention of trich)	O	O	O
26. Fever (>38°C from nursing notes)	O	O	O
27. Group B Strep-Prenatal	O	O	O
28. Group B Strep-Triage/Hosp.	O	O	O
29. Chorioamnionitis (no=no mention by MD or progress notes)	O	O	O
30. Supporting Evidence: Temperature >100°F or >38°C	O	O	O
31. Tender uterus	O	O	O
32. Abnormal discharge/odor	O	O	O
33. Suspected Chorio (from MD notes)	O	O	O
34. Sepsis	O	O	O
35. Eclampsia	O	O	O
36. Pre-eclampsia (diastolic blood pressure ≥ 90 mm Hg at least twice, + proteinuria)	O	O	O
37. Rupture of membranes (4-24 hrs pre-delivery)	O	O	O
38. Supporting Evidence: Ferning	O	O	O
39. Nitrozine	O	O	O
40. Pooling (meconium stained ok)	O	O	O
41. Rupture of membranes (> 24 hrs pre-delivery)	O	O	O
42. Supporting Evidence: Ferning	O	O	O
43. Nitrozine	O	O	O
44. Pooling	O	O	O
15. Multiple gestation	O	O	O
16. Other Problems	O	O	O

17. List Other Problems

Medications Given at this Pre-delivery Hospital Encount

Check nursing discharge notes, pink sheet

		Yes	No	Unk
48.	Ampicillin, Amoxicillin, Augmentin	O	O	O
49.	Antifungal Cream	O	O	O
50.	Azithromycin 1 gm (Zithromax)	O	O	O
51.	Azithromycin 2 gm (Zithromax)	O	O	O
52.	Betamotazone/beclomethazone/doxamethasone (pre-partum steroids)	O	O	O
53.	Cefazolin (Kefzol, Ancef)	O	O	O
54.	Cefotetan (Cefotan)	O	O	O
55.	Ceftazidine (Fortaz, Tazidim, Tazicef)	O	O	O
56.	Ceftizoxime (Cefizox)	O	O	O
57.	Ceftriaxone (Rocephin)	O	O	O
58.	Clindamycin (Cleocin)	O	O	O
59.	Doxycycline (Vibramycin)	O	O	O
60.	Erythromycin (E-mycin)	O	O	O
61.	Gentamycin	O	O	O
62.	Keflex	O	O	O
63.	Magnesium sulfate	O	O	O
64.	Metronidazole 2 g po (Flagyl)	O	O	O
65.	Metronidazole 500 bidx7d (Flagyl)	O	O	O
66.	Metronidazole 250 tidx7d (Flagyl)	O	O	O
67.	Metronidazole IV (Flagyl)	O	O	O
68.	Metronidazole vag gel (Metrogel)	O	O	O
69.	Nitrofurantoin (Macrodantin)	O	O	O
70.	Penicillin	O	O	O
71.	Terbutaline	O	O	O
72.	Other Medications	O	O	O
73.	List Other Medications/procedures (such as cerclage or Amniocentesis)			

Part 3

1. Healthy Start Unique ID (copy from page 1)

2. Admission Date of Hospitalization for Delivery (mm/dd/yyyy)

Delivery

3. Gestational Age at Admission (from physician notes)

Weeks Days

Definition of confirmed date of confinement: If the date by sono is within 2 weeks of the date by LNS and the pregnancy is <24 weeks, then the confirmed date of confinement is the date by LMP. If the date by sono is more than 2 weeks from the date by LMP, a second sono is done before 24 weeks gestation and the sono dates are averaged to get the confirmed date of confinement.

4. EDC, Confirmed by Sono <24 weeks (mm/dd/yyyy)

5. Delivery Date (mm/dd/yyyy)

6. Gestational age at Delivery (Confirmed)

Weeks Days

7. Birth Weight (Grams)

Delivery Hospitalization Antepartum Labs

	Test Done Positive	Test Done Negative	Test Done No results	Not Documented
8. Gram stain for BV	O	O	O	O
9. Clue cells for BV	O	O	O	O
10. Group B Strep	O	O	O	O
11. Gonorrhea	O	O	O	O
12. Chlamydia	O	O	O	O
13. Herpes	O	O	O	O
14. RPR (cord blood or Mom's blood)	O	O	O	O
15. Leukocyte Esterase	O	O	O	O
16. Urine Culture	O	O	O	O

17. If Urine Culture is Positive:

Urine Culture Results

- O E coli
- O Klebsiella or Proteus
- O Group B Strep
- O Mycoplasma
- O Not Applicable

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oblem List/Diagnoses

	Yes/ Positive	No/ Negative	(No Pertinent Exam Done) Unknown
8. Term Labor	O	O	O
9. Preterm Labor	O	O	O
0. UTI	O	O	O
1. Pyelonephritis (Temp documented positive urine culture)	O	O	O
2. Vaginal Bleeding	O	O	O
23. Supporting Evidence: Blood from Exocervix (cervix/vagina)	O	O	O
24. Visible blood from Intrauterine Cavity	O	O	O
5. Bacterial Vaginosis	O	O	O
6. Trichomonas (no=wet prep done, no mention of trich)	O	O	O
7. Yeast Vaginitis (no=wet prep done, no mention of trich)	O	O	O
8. Fever (>38°C) (from nursing notes)	O	O	O
9. Group B Strep-Prenatal	O	O	O
0. Group B Strep-Triage/Hosp.	O	O	O
. Chorioamnionitis (no=no mention by MD or progress notes)	O	O	O
32. Supporting Evidence: Temperature >100°F or >38°C	O	O	O
33. Tender uterus	O	O	O
34. Abnormal discharge/odor	O	O	O
. Suspected Chorio (from MD notes)	O	O	O
. Sepsis	O	O	O
. Eclampsia	O	O	O
. Pre-eclampsia (diastolic blood pressure ≥ 90 mm Hg at least twice, + proteinuria)	O	O	O
. Rupture of membranes (4-24 hrs pre-delivery)	O	O	O
40. Supporting Evidence: Ferning	O	O	O
41. Nitrozine	O	O	O
42. Pooling (meconium stained ok)	O	O	O
. Rupture of membranes (≥ 24 hrs pre-delivery)	O	O	O
44. Supporting Evidence: Ferning	O	O	O
45. Nitrozine	O	O	O
46. Pooling	O	O	O
. Multiple gestation	O	O	O
. Other Problems	O	O	O
. List Other Problems			

Medications Given (before delivery) at Delivery Hospital Encounter:

Check medication sheet, antimicrobial sheet, and anesthesia sheet, if present

	Yes	No	Unknown
50. Ampicillin, Amoxicillin, Augmentin	O	O	O
51. Antifungal Cream	O	O	O
52. Azithromycin 1 gm (Zithromax)	O	O	O
53. Azithromycin 2 gm (Zithromax)	O	O	O
54. Betametazone/beclomethazone/dexamethasone (pre-partum steroids)	O	O	O
55. Cefazolin (Kefzol, Ancef)	O	O	O
56. Cefotetan (Cefotan)	O	O	O
57. Ceftazidine (Fortaz, Tazidim, Taxicef)	O	O	O
58. Ceftizoxime (Cefizox)	O	O	O
59. Ceftriaxone (Rocephin)	O	O	O
60. Clindamycin (Cleocin)	O	O	O
61. Doxycycline (Vibramycin)	O	O	O
62. Erythromycin (E-mycin)	O	O	O
63. Gentamycin	O	O	O
64. Keflex	O	O	O
65. Magnesium sulfate	O	O	O
66. Metronidazole 2 g po (Flagyl)	O	O	O
67. Metronidazole 500 bidx7d (Flagyl)	O	O	O
68. Metronidazole 250 tidx7d (Flagyl)	O	O	O
69. Metronidazole IV (Flagyl)	O	O	O
70. Metronidazole vag gel (Metrogel)	O	O	O
71. Nitrofurantoin (Macrodantin/Macrobid)	O	O	O
72. Penicillin	O	O	O
73. Other Medications	O	O	O

74. List Other Medications/procedures

Complications During Labor and Delivery

	Yes	No	Unknow
75. Meconium (light or heavy)	O	O	O
76. Prolonged rupture of membranes (>24 hours before delivery)	O	O	O
77. Suspected chorio	O	O	O
78. Chorio/Amnionitis	O	O	O
79. Abruption	O	O	O

Mode of Labor and Delivery

	Yes	No	Unknown	N/A
80. Spontaneous Labor	O	O	O	O
81. Induced Labor	O	O	O	O
82. Augmented Labor	O	O	O	O
83. Vaginal - Spontaneous	O	O	O	O
84. Vaginal - Operative (forceps, vacuum, breech extraction)	O	O	O	O
85. VBAC (vaginal birth after caesarian)	O	O	O	O
86. Caesarian - Primary	O	O	O	O
87. Caesarian - Repeat	O	O	O	O
88. If this was a preterm delivery (gestational age <37 completed weeks), was there a medical indication for the preterm delivery?	O	O	O	O

89. If yes, what was medical indication?

Post-partum Diagnoses:

	Yes	No	Unknown
90. Endometritis (as documented by the clinician)	O	O	O
91. Supporting Evidence: Temperature >100°F or >38°C	O	O	O
92. Tender uterus	O	O	O
93. Positive Blood Culture	O	O	O
94. UTI	O	O	O
95. Pyelonephritis	O	O	O
96. Wound infection (as documented by the clinician)	O	O	O
97. Supporting Evidence: Temperature >100°F or >38°C	O	O	O
98. Wound red, inflamed, with pus	O	O	O
99. Mastitis	O	O	O
100. Other	O	O	O

20057

ntibiotics Given After Delivery

	Yes	No	Unknown
101. Ampicillin, Amoxicillin, Augmentin	O	O	O
102. Bactrim, Cotrimoxazole	O	O	O
103. Ceftazidine (Fortaz, Tazidim, Tazicef)	O	O	O
104. Ceftizoxime (Cefizox)	O	O	O
105. Clindamycin (Cleocin)	O	O	O
106. Keflex	O	O	O
107. Metronidazole (Flagyl)	O	O	O
108. Nitrofurantoin (Macrodantin, Macrobid)	O	O	O
109. Penicillin	O	O	O
110. Other	O	O	O

111. List Other Antibiotics

112. Results of Blood Culture

O Positive O Negative O Not Done O Unknown

113. Organism

114. Results of Wound Culture

O Positive O Negative O Not Done O Unknown

115. Organism

116. Results of Urine Culture

O Positive O Negative O Not Done O Unknown

117. Organism

118. Results of Other Culture (write source) (blank if none)

119. Organism (blank if none)

20057

	Positive	Negative	Not Done	Unknown
128. Evidence of Infarction	O	O	O	O
129. Acute Infarction	O	O	O	O
130. Chronic Infarction	O	O	O	O
131. Focal Infarction	O	O	O	O
132. Thrombus	O	O	O	O

133. Severity (If pathology not done, don't fill in)

O Mild O Moderate O Severe

134. Describe severity/Other Notes

120. Date of Discharge (mm/dd/yyyy)

[ ][ ] / [ ][ ] / [ ][ ][ ][ ]

121. Baby Home with Mother?

O Yes O No O Not Documented

Results of Placental Pathology Examination

	Positive	Negative	Not Done	Unknown
122. Pathology Present	O	O	O	O
123. Evidence of Infection	O	O	O	O
124. Acute Infection	O	O	O	O
125. Chronic Infection	O	O	O	O

126. Severity (If pathology not done, don't fill in)

O Mild O Moderate O Severe

127. Describe Severity/Other Notes

18. Date Abstracted (mm/dd/yyyy)

☐☐ / ☐☐ / ☐☐☐☐

19. Initials

☐☐

Maternal Discharge Diagnosis

	Yes	No	Unknown
135. Normal Spontaneous Vaginal Delivery	O	O	O
136. Caesarian Delivery, Uncomplicated	O	O	O
137. Caesarian Delivery, Complicated	O	O	O
138. Premature Delivery (<37 completed weeks)	O	O	O
139. Chorioamnionitis	O	O	O
140. Funisitis (Inflammation of cord from placental pathology report)	O	O	O
141. Eclampsia	O	O	O
142. Pre-eclampsia	O	O	O
143. Endometritis	O	O	O
144. Wound Infection	O	O	O
145. UTI	O	O	O

46. Other Discharge Diagnoses

47. Comments

Syracuse Healthy Start

Part 1

Mother's Pre-Natal Care

Healthy Start Unique ID

Abstraction is taken from:

○ Original outpatient record

○ Copy of outpatient record (e.g. hospital copy)

Mom's Date of Birth (mm/dd/yyyy)

Shade Circles Like This--> ●

Not Like This--> ⊗ ✓

Initial Agency for Prenatal Care

○ Private MD

○ PNC

○ MC/UHCC/WHS

○ SCHC

○ MCHC (St. Joseph's)

○ Other

○ None

○ Unknown

Transferred Prenatal Care (if no/not applicable, skip to #8)

○ Yes ○ No/Not Applicable ○ Unknown

Weeks of Gestation at Transfer (If not applicable, enter 00)

Weeks

Second Agency for Prenatal Care

○ Private MD

○ PNC

○ MC/UHCC/WHS

○ SCHC

○ MCHC (St. Joseph's)

○ Other

○ None/Not Applicable

○ Unknown

LMP (last menstrual period)date (mm/dd/yyyy). Indicate Not Applicable/Unknown certain by entering 00

Drop

9. EDC by Dates (LMP) (mm/dd/yyyy). Indicate Not Applicable/Unknown or Uncertain by entering 00

☐☐ / ☐☐ / ☐☐☐☐

10. EDC by Ultrasound <24 weeks (mm/dd/yyyy). If not done, enter 00

☐☐ / ☐☐ / ☐☐☐☐

11. If done, Second EDC by Ultrasound <24 weeks (mm/dd/yyyy). If not done, enter 00

☐☐ / ☐☐ / ☐☐☐☐

Gravity and Parity

12. a. Number of Prior Pregnancies and Deliveries (total gravidity)

☐☐

b. Number of Prior Preterm Pregnancies and Deliveries

☐☐

c. Number of Prior Spontaneous Abortions <24

☐☐

d. Number of Prior Induced Abortions <24

☐☐

e. Number of Living Children

☐☐

f. Date or Year of Last Delivery (mm/dd/yyyy) (00 if none) (from progress notes or from previous prenatal record. Alternatively, could use EDC from previous prenatal record if that previous gestation was 36-40 weeks)

☐☐ / ☐☐ / ☐☐☐☐

Current Pregnancy

13. Multiple Gestation

○ Yes ○ No ○ Unknown

14. Number of Fetuses (1 if singleton)

☐

15. First Prenatal Care Visit Date (mm/dd/yyyy)

☐☐ / ☐☐ / ☐☐☐☐

16. Number of Prenatal Visits Kept

[ ][ ]

17. Number of Prenatal Visits Missed (cancelled by patient, no show, etc.)

[ ][ ]

18. First BV Evaluation Date (mm/dd/yyyy) (Date test was done)

[ ][ ] / [ ][ ] / [ ][ ][ ][ ]

19. Initial RPR or VDRL Done?

○ Yes ○ No ○ Unknown

20. Titer 1: (write 00 if non-reactive or negative)

[ ][ ]

21. PAP Smear Results

○ Normal (if normal, skip to #23)
○ Ascus
○ LSIL
○ HSIL (if any of these, skip to #22)
○ Cancer-in-situ
○ Trichomonas
○ Coccobacillus
○ Other (if any of these, skip to #23)
○ Unknown

22. Treatment as a Result of PAP

○ Oral metronidazole 250 for 7 d
○ Oral metronidazole 500 for 7 d
○ Oral clindamycin for 7 d
○ Oral metronidazole 2g stat
○ Intravaginal Metronidazole
○ Intravaginal Clindamycin
○ Colposcopy
○ No Treatment
○ Treatment Status Unknown

23. Smoking at Time of First Prenatal Care Visit?

○ Yes ○ No ○ Unknown

Number of cigarettes a day (at registration)

☐☐

○ Not Applicable

○ Unknown

Number of cigarettes a day at last PNC Visit (enter 00 if none)

☐☐

○ Not Applicable

○ Unknown

Smoking Cessation Efforts Documented?

○ Not Applicable

○ Counseling

○ Nicotine Patch

○ Wellbutrin

○ Other

○ Unknown

reening/testing Visits

Healthy Start Unique ID (copy from page 1)

Screening/testing Visit Number

Date (mm/dd/yyyy)

__ / __ / ____

ptoms

	Yes	No	Unknown
Any Symptoms (If no, skip to # 13)	O	O	O
Discharge	O	O	O
Dysuria	O	O	O
Abdominal pain/contractions/cramping	O	O	O
Vaginal Itching	O	O	O
Vaginal Bleeding or spotting	O	O	O
Odor	O	O	O
Other	O	O	O

List Others

Bacterial Vaginosis (BV) Screen/test (if negative, not done, or unknown, skip 15.

Positive O Negative O Indeterminate O Not Done O Unknown

BV Treatment (answer required if previous answer was positive or indeterminate).

O Not Applicable
O Oral metronidazole 250 for 7 d
O Oral metronidazole 500 for 7 d
O Oral clindamycin for 7 d
O Oral metronidazole 2g stat
O Intravaginal Metronidazole
O Intravaginal Clindamycin
O Other
O Treated, drug not recorded
O Treatment Status Unknown

Chlamydia trachomatis (CT) Screen/test (if negative, not done, or unknown, skip 7.

O Positive O Negative O Indeterminate O Not Done O Unknown

Part 2

CT Treatment (answer required if previous answer was positive or indeterminate).

- ○ Azithromycin (Zithromax)
- ○ Amoxicillin
- ○ Erythromycin (E-mycin)
- ○ Other
- ○ Not Applicable
- ○ Treatment Status Unknown

Neisseria gonorrhoeae (NG) Screen/test (if negative, not done, or unknown, skip #19).

○ Positive ○ Negative ○ Indeterminate ○ Not Done ○ Unknown

NG Treatment (answer required if previous answer was positive or indeterminate).

- ○ Cefixime (Suprax)
- ○ Ceftriaxone (Rocephin)
- ○ Azithromycin (Zithromax)
- ○ Other
- ○ Not Applicable
- ○ Treatment Status Unknown

Trichomonas vaginalis (TV) Screen/test (if negative, not done, or unknown, skip to).

○ Positive ○ Negative ○ Indeterminate ○ Not Done ○ Unknown

TV Treatment (answer required if previous answer was positive or indeterminate).

- ○ Metronidazole 2g (Flagyl)
- ○ Metronidazole for 7 days
- ○ Other
- ○ Not Applicable
- ○ Treatment Status Unknown

UTI Screen/test (A positive leukocyte esterase or positive culture) (If negative, done, or unknown, skip to Part 3).

○ Positive ○ Negative ○ Indeterminate ○ Not Done ○ Unknown

UTI Treatment

- ○ Amoxicillin
- ○ A Cefalosporin
- ○ Other
- ○ Macrobid
- ○ Not Applicable
- ○ Treatment Status Unknown

UTI Organism (required if test positive)

- ○ E Coli
- ○ CNS
- ○ Proteus, Klebsiella
- ○ Other
- ○ Unknown

Healthy Start Unique ID (copy from page 1)

ther Prenatal Diagnoses During this Pregnancy

	Yes	No	Unknown
Abnormal MSAFP (Alpha Feto-protein)	O	O	O
Anemia	O	O	O
Asthma	O	O	O
Cerclage	O	O	O
Colposcopy During this Pregnancy	O	O	O
Diabetes, Pre-existing	O	O	O
Diabetes, Gestational	O	O	O
Domestic Violence	O	O	O
GBS Positive this Pregnancy	O	O	O
. Genetic Amniocentesis	O	O	O
. HPV this Pregnancy	O	O	O
. HPV - Warts	O	O	O
. HPV - Abnormal PAP	O	O	O
. Suspected Incompetent Cervix (>2.5 cm at <24 Weeks)	O	O	O
. Pre-Eclampsia (Diastolic BP >90 mm Hg at least twice, plus proteinuria) or eclampsia or HELLP Syndrome	O	O	O
. Preterm Labor	O	O	O
. Trauma	O	O	O
. Vaginal Bleeding or spotting	O	O	O
19. Visible Blood from Exocervix (cervix/vagina)	O	O	O
20. Visible Blood from Intrauterine	O	O	O
. Urine Drug Screen Positive	O	O	O

. Other

Drugs Taken During Pregnancy

	Yes	No	Un
23. Antihypertensive (hydralazine, propranald, nifedipine)	O	O	
24. Anti-Inflammatory (aspirin, ibuprofen)	O	O	
25. Antihistamine (allegra, claritin, zyrtec)	O	O	
26. Antidepressant (prozac, etc)	O	O	
27. Bronchodilators (albuterol, ventolin, etc)	O	O	
28. Insulin	O	O	
29. Terbutaline	O	O	

30. List Others

31. Date Abstracted (mm/dd/yyyy)

		/			/				

32. Initials

Appendix B

SUNY Upstate Medical University

Title of Study: Determinants of Low Birth Weight in Syracuse, NY: Protective and Risk Factors

Consent Form

Investigators: Sandra Lane, Ph.D., MPH
Mary Kathleen DeMott, MS, FNP, CNM
Maria Czerwinski, MD
Margaret Ostrander, MS, RN

BACKGROUND/PURPOSE:
You are being asked to participate in a research study because you have just had a baby. Many women in Syracuse have problems in their pregnancies which cause their babies to be born too soon or too small. Researchers in the Department of Obstetrics and Gynecology at Upstate Medical University are trying to understand how women stay healthy in pregnancy so that we can improve the care we give. We will ask 20 women to participate in this study.

PROCEDURES:
If you choose to participate in this study, a member of our study team will be interviewing you about your pregnancy experience. Your name will not be recorded or used in any reports. The interviews will take place at the Women's Health Center or at another mutually agreed upon site and will take approximately thirty minutes.

RISKS:
You may experience discomfort when asked to share information regarded as personal or private. The informed consent document and verbal information provided clearly states that you may refuse to answer any question(s) or stop the interview at any time.

BENEFITS:
Participation in this study will offer you the opportunity to contribute to our knowledge of factors which lead to healthy pregnancy outcomes.

VOLUNTARY PARTICIPATION:
Your participation in this study is entirely voluntary and you may refuse to participate or discontinue participation at any time without penalty or loss of benefits to which you would normally be entitled. Your decision about whether or not to participate in the study will not affect the care you receive at or your relationship with the SUNY Upstate Medical University.

ALTERNATIVES:
If you decide not to participate in this research study, you will not participate in the interview described above, which is being done for research purposes.

COSTS/PAYMENTS:
There are not costs to you and/or your insurance carrier for participating in this study. You will not be paid for your participation.

CONFIDENTIALITY:
Your research records will be kept confidential to the extent permitted by law. However, your records, (such as this consent document), may be reviewed by authorized staff at SUNY Upstate Medical University; and other government agencies carrying out their regulatory functions. You will not be identified in any publication or presentation resulting from this study.

QUESTIONS:
If you have any questions about the research, please contact Dr. Sandra Lane at (315) 445-2830. If you have any questions about your rights as a research subject, please contact the SUNY Upstate Medical University Institutional Review Board Office at (315) 464-4317.

CONSENT:

I hereby give my consent to participate in this research study. I will receive a copy of this consent form.

Subject_____ Date_____

Witness_____ Date_____

Person Obtaining Consent_____ Date_____

Case Studies of Postpartum Women
Interview Guide

Introduction. Many women in Syracuse have problems in their pregnancies which cause their babies to be born too soon or too small. We are trying to understand how women stay healthy in pregnancy so that we can improve the care we give. We would like to talk to you about your prenatal care and about some of the things which we believe may cause early labor or small babies. Your name will not be recorded or used in any reports. Your chart will not be read. The only data collected will be information you wish to share with us.

To the interviewer: Remember these are personal case studies. They should tell a story. Be aware of missed opportunities.

1. Demographic information

   Ethnicity/Race

   Age

   Education

   Gravity

   Birth weight

   Gestational Age

   Healthy Start

2. How did you find out you were pregnant?

3. Choice of care site:
   a. Factors which influenced site of care

   b. Factors which were barriers to obtaining care

   c. What do you know about the Healthy Start Program?

4. Quality of care
   a. How would you rate the quality of care you received?

5. Pregnancy outcomes:
   a. What do you think makes for good health in pregnancy?

   b. What do you think causes early delivery?

   c. Do you know anyone who had a premature birth? Did anyone have

any idea about why this occurred?

6 Assessment of risk factors of interest:

A. Nutrition

1. Describe your normal daily diet (diet diary)

2. How did your diet in pregnancy differ from your normal diet?

3. Do you think taking prenatal vitamin supplements or iron is important during pregnancy?

4. Describe your experience with the WIC program

5. If your younger sister was pregnant, what would you advise her about weight gain in pregnancy?

B. Smoking

1. Tell me about your smoking habits. Do you smoke cigarettes now?

2. How much did you smoke when you were pregnant?

3. Were you exposed to second-hand smoke during pregnancy?

4. What was your reaction to the smoking cessation message you heard while you were pregnant?

C. Chronic stress during pregnancy

1. Did you plan this pregnancy?

2. Partner stress – was he present, helpful with domestic chores and/or finances?

3. Relationship stress – extended family, other children. Was help available with domestic chores, child care, finances through other family members?

4. How many preschool children are in the home? What type of support is available to help with these children?

5. Adequacy of housing – was there crowding, lead exposure, pests, etc.?

6. Financial stress – was there enough money for food, heat, electricity?

7. Violence – domestic/neighbourhood

8. Job/school stress – is there unusual physical or mental stress at work or school?

9. Describe your experience with the welfare to work (JOBS) program

10. Describe any interactions you had with the legal system while you were pregnant

11. Describe any traumatic events which occurred during pregnancy

12. How do you cope with stress in your life? (church attendance?)