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Public reporting burden for this collection of information reviewing the collection of information. Send comments Information Operations and Reports, 1215 Jefferson Devi	is estimated to average 1 hour per response, including the to regarding this burden estimate or any other aspect of this or shighway, Suite 1204, Arington, VA 22024302, and to the shighway, Suite 1204, Arington, VA 22024302, and to the shighway of the	ime for reviewing instructions, searching existing du collection of information, including suggestions for the Office of Management and Budget, Pagework Ra	ta sources, gathering and maintaining the data needed, and completing and educing this burden, to Washington Needquarters Services, Directorate for duction Project (7716-0188) Washington, Dr 201503.
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4. TITLE AND SUBTITLE	1.5411.77		5. FUNDING NUMBERS
LOW BIRTH WEIGHT: A	DESCRIPTIVE STUDY OF RI	ISK FACTORS	
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9. SPONSORING/MONITORING AGENCY	NAME(S) AND ADDRESS(ES)		10. SPONSORING/MONITORING
THE DEPARTMENT OF T	HE AIR FORCE		AGENCY REPORT NUMBER
AFIT/CIA, BLDG 125			EV00.20
2950 P STREET			F 199-39
WPAFB OH 45433			
11. SUPPLEMENTARY NOTES			
12. DISTRIBUTION AVAILABILITY STATULIMITED distribution	TEMENT		126. DISTRIBUTION CODE
In Accordance With AFI 35-2	205/AFIT Sup 1		
13. ABSTRACT (Maximum 200 words)			L
		1999	0120 006
14. SUBJECT TERMS			15. NUMBER OF PAGES
			77 16. PRICE CODE
17. SECURITY CLASSIFICATION OF REPORT	18. SECURITY CLASSIFICATION OF THIS PAGE	19. SECURITY CLASSIFICATION OF ABSTRACT	20. LIMITATION OF ABSTRACT
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Standard Form 298 (Rev. 2-89) (EG) Prescribed by ANSI Std. 239.18 Designed using Perform Pro, WHS/DIOR, Oct 94

LOW BIRTH WEIGHT:

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A DESCRIPTIVE STUDY OF RISK FACTORS

Florence Ann Valley Maj, USAF, NC

The University of Arizona, 1998

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Maternal risk factors of multiple gestation (OR = 5.00), race being black (OR = 2.59), and history of asthma (3.39) were found to be significant risk factors for the DoD population. Variables identifying the intensity of care were also analyzed and non-stress tests, fetal ultrasounds, and antepartum visits were significant variables related to the LBW outcome.

LOW BIRTH WEIGHT:

A DESCRIPTIVE STUDY OF RISK FACTORS

by

Florence Ann Valley

A Thesis Submitted to the Faculty of the

COLLEGE OF NURSING

In Partial Fulfillment of the Requirements For the Degree of

MASTER OF SCIENCE

In the Graduate College

THE UNIVERSITY OF ARIZONA

1998

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Date

ACKNOWLEDGMENTS

I wish to express my appreciation to the following individuals for their assistance and support.

To the members of my thesis committee: Dr. Paula Meek, as chairperson, provided me with tireless encouragement enabling me to expand my perceptions of nursing beyond the bedside to tackle new and exciting frontiers; Dr. Joyce Verran, whose exuberance for systems research inspired me to gain a broader understanding of outcome research; and Dr Judy Effken who opened up a window of opportunity by helping me appreciate and work with large data bases.

To Colonel William Strampel, Director, Quality Management, Department of Defense – Health Affairs, who made it possible to use an outstanding government database enabling me to study low birth weight in the Department of Defense population.

To Lorna Cook who gave me the report of the 1997 Birth Product Line Review published by the Department of Defense because she thought I would like to see it. Inside the pages was information that led me to Colonel Strampel.

To my husband Ray, for his endearing love, support, and knowledge of computers.

Finally to my daughter Olivia, who gave me joy and comfort through my struggles and accomplishments.

DEDICATION

This thesis is dedicated to the patriotic men and women and their families that make up the United States Department of Defense. My dream of an advanced degree was only realized through the support received from my fellow comrades who covered the mission during my absence. Because of their total commitment to advanced education, I was allowed to be a full time student while on active duty. My sincere goal is to improve the medical care received by those military members and their families that have, and continue to defend the United States of America.

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ABSTRACT

To define maternal risk factors for the birth of a low birth weight infant specific to Department of Defense (DoD) beneficiaries, a secondary data analysis was conducted on DoD data. Verran's (1997) theory-driven framework for outcome research was used to guide the selection of process and structural variables. The study controlled for structure by limiting subjects to those delivering in a facility with a neonatal intensive care unit. Using maternal risk factors for LBW identified by literature review, a group of subjects with LBW (220) were compared to a group without LBW (223) using logistic regression.

Maternal risk factors of multiple gestation (OR = 5.00), race being black (OR = 2.59), and history of asthma (3.39) were found to be significant risk factors for the DoD population. Variables identifying the intensity of care were also analyzed and non-stress tests, fetal ultrasounds, and antepartum visits were significant variables related to the LBW outcome.

CHAPTER I

INTRODUCTION

Outcome research is no longer simply used to make market decisions. Today outcome research is used as evidence necessary for accreditation purposes and for increasing the scientific knowledge base needed to improve health care. As urgent as these needs for information are, the necessary outcome research will take time, considerable effort, and funding.

In an effort to prioritize health outcome research, the Center for Disease Control (CDC) developed the "Healthy People 2000" program to target health outcomes that were in most need of improvement. One of these targeted health outcomes was reducing the number of low birth weight infants. Low birth weight (LBW), defined as a live infant weighing 2,500 grams or less at birth, accounts for the majority of infant deaths, from birth to one year, in the United States (US)(Center for Disease Control, 1997). Although the "Healthy People 2000" objective aimed to reduce the percentage of LBW infants to 5 percent, the actual percentage of LBW infants increased to 7.2 percent in 1996, the highest level since 1975. Internationally, based on 1996 data, the US still ranks 21st in infant mortality even though the infant mortality rate reached an all time low level of 7.4 deaths per 1000 births. The US falls well behind countries such as Japan, which has a level of 4.2 deaths per 1000 births (United Nations Statistical Office, 1997).

Research on the outcome of LBW infants has begun to narrow its focus to specific populations rather than attempting to find one solution that fits every population. The present outcome study is a secondary data analysis using a theoretical framework that

provides a description of risk factors which can become the groundwork for future intervention strategies targeted at reducing the incidence of LBW infants in the Department of Defense (DoD) population. The data set used in this study was originally collected by the DoD at the national level and contains data on DoD beneficiaries who obtained obstetric and neonatal care in 1996.

Background

"As flexibility and change become the only constants in health care delivery, providers are seeking improved methods for delivering quality, cost-effective services" (Fleschler & King, 1995, p.21). Perinatal outcome management programs, like those described by Flescher and King (1995), are being designed with the goal of improving the care delivered to obstetric and neonatal patients. The priority for these programs is to focus on costly negative outcomes, such as LBW, and find interventions that decrease the incidence of the outcome. However, to accurately measure the effectiveness of intervention strategies requires researchers to find ways to "account for" or "adjust for" patient differences prior to treatment.

Low Birth Weight

Birth weight is the most powerful and proximate determinant of an infant's survival chances. The National Center for Health Statistics (NCHS), in 1995, reported that 285,152 infants born in the US were LBW, accounting for 10 percent of all health care costs for children (Lewit, Baker, Corman, & Shiono, 1995). Babies born too small or too early often require increased resources, including care in a neonatal intensive care unit (NICU) at a cost ranging from \$1,000 to \$2,500 per day (Krebs, 1993). A severely

ill newborn may spend several weeks or months in a NICU, depending on the complexity of the health problem. The lifetime medical costs for one premature baby are conservatively estimated at \$500,000 (Walker, 1991). The possibility of NICU care is not the only expense. Health care, education, and child care for the 3.5 to 4 million LBW infants from birth to 15 years cost between \$5.5 and \$6 billion per year (based on 1988 dollars) more than they would have if those children had been born at a normal birth weight (Lewit, Baker, Corman, & Shiono, 1995).

For perinatal health care to be effective and efficient in reducing LBW, programs must target known causes. Currently, most perinatal programs are concerned with detecting major complications of pregnancy, not with preventing LBW (Shiono & Behrman, 1995). Shiono and Behrman also contend that

"While there is an urgent need to know more about the physiological mechanisms that trigger preterm birth, produce growth retardation, and heighten the risk of infant mortality, there is no need to wait for major breakthroughs...Several proven means exist to prevent these tragic birth outcomes." (1995, p 14)

For example, nutritional counseling and asthma management have been shown to reduce a mother's risk of giving birth to a LBW infant (Taren & Gaven, 1991; Schatz, et al. 1995). Prioritization of interventions in a perinatal health care program requires assessment of contributing factors specific to the target population.

Outcome Research

Measuring health care outcomes has long been a part of programs designed for evaluating and continuously improving quality care. The processes involved in achieving these outcomes have also held center stage in total quality management efforts. Current attempts to assess care processes in terms of costs, both human and fiscal, as they relate directly to a specific outcome are a more recent development.

The decrease in profit margins created by the recession of the 1970's and exploding cost of health insurance made the leading payers of health care, large corporations and the US government, take a critical look at cost benefit ratios. Costs for care vary considerably within the health industry. The purchaser decides whether to pay more for what is reported to be a superior product or settle for a lessor product. Unlike most large industries, health care has little evidence to prove that the more money spent on health care, the better the "product" or in this case the outcome.

Payers demanded reform that resulted in the exponential growth of managed care, with its industrial accountability and productivity models. Health maintenance organizations (HMO) became a catalyst for change in the way the industry was managed and reimbursed. Variation in practice was no longer rewarded and a move toward consistency was generated through the proliferation of practice guidelines. During the creation of these guidelines it became evident that the health care industry did not have an abundance of empirically verified information about the processes of care or the outcomes of that care (Kane, 1997). Health care practice guidelines are focused on the process of health care delivery, with the thought that, if the processes were perfected, then the outcomes would be positively influenced.

Poor health outcomes do not always indicate the need for process change. Process is but one element in the total picture of an outcome. For example, Kane (1997) argues that clinical outcomes are the result of risk factors as well as treatment characteristics. Verran (1997) agrees, stating that theories that support practice changes need to incorporate elements associated with both the structure and process of care delivered as well as the outcomes expected.

Verran (1997) published a theory-driven framework for evaluating practice change. In contrast to others that assume process follows structure, in Verran's framework (Figure 1) structure follows process. The way Verran defines the framework makes it useful in developing outcome research. Verran terms the process portion of the template, technology. Technology is broken down into two components. Material technology, which includes factors such as patient demographics and severity of illness, and knowledge technology, which includes those care strategies proven to influence outcomes. Technology is then followed by structure, which Verran splits into internal context, which involves human, material, and fiscal resources, and external context, which involves the use of multidisciplinary resources. Verran states that the "incorporation of a research template into nursing practice resolves some of the problems associated with the speed required for assessment of health care systems change" (Verran, 1997, p. 172). Verran's template is well matched to the ever-changing outcome management of perinatal health care.



Figure 1. Modified from "An Evolving Framework for Research" (Verran, 1997, p. 171).

Risk Adjustment

Research has identified many factors associated with LBW. The result has been numerous published studies identifying demographic, medical, and obstetric characteristics that place a woman at increased risk for giving birth to a LBW infant. These studies have provided the foundation for risk screening instruments as well as for national data collection and analysis. These risk factors also play a part in a specific type of outcome research called risk adjustment.

Kane (1997) equates risk adjustment to creating a level playing field. Clinicians with either superior or inferior patient outcomes may challenge an analysis based on the perceived complexity of the patients cared for. To "create a level playing field" as Kane suggests, researchers must find a way to correct for the differences in the composition of the patients who are being treated (Kane, 1997, p. 7). This leveling out is referred to as risk adjustment. In the case of LBW, risk factors linked to LBW are weighted as to their individual impact on the outcome. With this leveling information, researchers can attempt to determine the effectiveness of treatment modalities. It is also important that the risk adjustment incorporates the weight of the risk factors as they apply to a specific population. For example, the risk factor of "race = black" may be weighted differently

in a low income population as opposed to a population where income is higher and access to medical care is not an issue.

The ability to identify and prioritize factors for LBW in specific populations may require patient data that is derived directly from that particular population as opposed to aggregated national data. Differences in comorbid disease between groups may generate differences in the outcomes, thus confounding treatment effects (Kane, 1997). National LBW data analysis continues to provide useful information to guide national policy decisions. However, national data is an aggregate of millions of individuals and may not be sensitive to issues in a specific population, such as Department of Defense (DoD) beneficiaries, where access to health care is not an issue and some level of risk management is already in place.

Department of Defense Health Care System

The hierarchical structure of the DoD medical care system enables it to aggregate subject data from a diverse population. The DoD beneficiary population consists of a wide range of demographic characteristics including such factors as income, age, ethnicity, race, assignment location, and marital status. The present study uses a database collected by the DoD for quality review of obstetric care provided to DoD beneficiaries.

TRICARE is the health management organization responsible for the health care of DoD beneficiaries. The National Quality Management Program (NQMP) is the quality improvement and utilization management oversight program of TRICARE. The NQMP has six components (a) readiness, (b) accreditation, (c) credentialing and privileging, (d) licensure, (e) National Practitioner Data Bank, and (f) external peer review. The external review component contains tools that allow TRICARE to oversee the utilization management and quality management decisions being made. The findings from these functions are used to provide and update existing TRICARE policy. Special studies are a part of the quality management function. The 1997 Birth Product Line Review (BPLR) is the third quality management study in an on-going annual assessment of maternity care, following two previous reviews analyzing fiscal year (FY) 1993 and FY 1995 data. This study is a secondary analysis of the data collected for the 1997 review.

Statement of the Problem

Related to the \$5.5 to \$6 billion per year spent on the special needs of the current 3.5 to 4 million LBW infants, continuous quality improvement is a prudent tool for obstetric management with groups such as the DoD. To test intervention strategies aimed at reducing the incidence of LBW, an understanding of risk factors is necessary. An indepth description of the risk factors specific to the DoD population that contribute to the current rate of LBW is needed before problems can be prioritized and intervention strategies tested. Verran's framework can assist in describing and prioritizing these risk factors.

Statement of Purpose

The purpose of this research is to describe the relationship of material technology and knowledge technology variables (process) as they relate to the outcome of giving birth to a LBW infant in the population of DoD beneficiaries when the structural variables are controlled.

Research Questions

- What are the most significant material technology variables (e.g. comorbidities) contributing to LBW in the population of DoD beneficiaries when important structural variables are controlled?
- 2. What are the most significant knowledge technology (e.g. intensity of care) variables contributing to LBW in the population of DoD beneficiaries when important structural variables are controlled?

Significance to Nursing

Nurses have taken an active role in preventing LBW infants. Nurse case managers have become important team members in interdisciplinary efforts to improve poor perinatal outcomes such as LBW while decreasing resource expenditures (Foust, 1997). Nurse outcome managers accountable for managing obstetric populations have focused utilization management techniques on costly negative outcomes such as LBW (Fleschler & King, 1995). In the examples mentioned, each nurse was intervening with the goal of reducing the incidence of poor perinatal outcomes like LBW. To develop these intervention programs, a thorough assessment of the patient or population was made and problems identified. The same nursing process is needed when establishing programs for other populations such as DoD beneficiaries. Creating strategies to reduce the incidence of LBW infants before completing a thorough assessment of the target population would be akin to giving a patient an antibiotic with the hope that it cures what ever the patient came to the clinic for. The present study is part of the assessment phase and will be useful for subsequent problem identification and nursing intervention strategies focused on reducing the incidence of LBW infants born to DoD beneficiaries.

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CHAPTER II

CONCEPTUAL FRAMEWORK AND LITERATURE REVIEW

Chapter Two includes a description of the conceptual framework, literature review, and a definition of terms including the Department of Defense (DoD) health care system. Verran's "research framework for theory-driven evaluation" (1997, p. 171) provides the conceptual framework for the study. The review of the literature includes information that was part of an analysis done by the Institute of Medicine (IM) on the prevention of low birth weight (LBW) and associated research findings on the topic of LBW (1985).

Conceptual Framework

Theory-Driven Framework

The need for theory-based investigations is important for the generalizability of results and development of health care policy. But in reality, the time, effort, and interest required to establish a theory base to support practice changes or evaluate their outcomes are rarely available. To overcome these problems, Verran (1997) developed a framework that fits most systems research investigations (Figure 1). Verran states "The fit for these templates is at the construct or concept level; the theory is then individualized at the variable or operational level" (Verran, 1997, p. 171). The framework not only attempts to solve the problems associated with the speed required for the initial assessment of health care systems, but also introduces a means for routine data collection that can be incorporated into a decision-support framework readily available for future decisions.

Keeping system evaluations current will enable organizations to stay competitive and at the cutting edge of the health care industry (Verran, 1997).

The framework defines the interrelationships among structure, process, and outcomes. Verran argues that when assessing practice effectiveness, it is important to determine what type of structure results in the best outcome for reasonable cost. Along with structure comes process. Further, the outcome process, or technology provides information about how nursing practice achieves its results. Verran views both process and structure to be equally necessary to create fully developed and useful theories.

Technology is subdivided into two distinct areas, knowledge and material technology. Knowledge technology is the information required to perform the work and the materials used to accomplish the task. One index useful for measuring knowledge technology is "intensity of medical care." Examples of actual variables might be whether the provider was a primary care physician or a specialist, like a cardiologist, or how often the patient received a given treatment. On the other hand, materials technology does not refer to specialized instruments but rather is defined as being "the nature of the client with whom the nurse deals" (Verran, 1997, p. 171). Verran describes client problems and variability of clients as useful indices for measuring materials technology. Comorbid conditions and defining characteristics, such as age and sex, are useful variables at the operational level. Verran sees both knowledge technology and material technology as having causal influence on structure.

The framework identifies structure as containing two contextual elements, internal and external. Internal context refers to human resources required to do the work.

Variables could be the nurse to technician ratio, or nurse to patient ratio. In rural areas, the low physician to patient ratio could become a factor in health care outcomes. Although internal context has a large impact on health outcomes, so can the external context. Within the framework, external context is defined as those variables external to the actual organization. External context variables might include factors known to influence outcomes, such as area of the country.

It is Verran's (1997) contention that a middle-range theory, such as this, can guide evaluation of fast-paced practice changes. If organizations routinely collected data on process and structure elements based on theory, necessary elements would be readily available for analysis and could become the catalyst for practice changes, rather than the current process where problems become the reason for change. Lynn and Lyman's (1996) published review of nursing administration research supports this, concluding that current research can best be characterized as fire stomping. When theory guides research rather than specific organizational problems, comparison across sites is facilitated. Verran's framework becomes a proactive management tool that can be extremely useful for both urgent and long-range decision making.

Application of the Conceptual Framework

Changes in practice patterns within the perinatal episode of care, starting with preconception counseling and ending with postpartum and neonatal care, are occurring at a rapid pace. Influences from sources such as established HMOs have drastically changed inpatient care processes and focused attention on antepartum care (before delivery). Health maintenance organizations analyze data and can promote the use of

certain processes and procedures that they determined to produce the best maternal and neonatal outcomes for the least cost. It is difficult to determine if any theory guides the collection of this data. If analysis is based primarily on the limitations of billing records, perhaps the ability to compare across sites and generalize across populations is impossible.

Verran's framework could provide a solid foundation for both data collection procedures and data analysis on LBW research, that will enable the results to be compared across sites and populations. The ability to compare in this way is important to populations such as DoD beneficiaries because the DoD has recently created a managed care structure called TRICARE that spans across the United States (US) and overseas. The framework can be used from the initial descriptive stages of research, such as the present study, through the development and evaluation of intervention strategies and preexisting practice patterns.

Literature Review

The literature review contains information on the topic of LBW obtained from current research literature and from a published report commissioned by the IM. The IM convened a planning group in 1982 to explore how the nation might best invest its resources to promote child health and development. The planning group recommended examination of the literature to determine the potential for prevention of LBW in the US. Experts were selected to form a committee to perform the examination. The committee's report, Preventing Low Birthweight, was published in 1985 and contained a compilation of research on the topic of LBW current at the time. A report of this nature has not been replicated since, due in part to current efforts being focused locally versus nationally.

State level perinatal outcome research efforts have replaced national level efforts. Bird and Bauman (1995) concluded that a substantial portion of the variance in statelevel infant mortality (5.8 – 11.8 per 1,000 live births) is accounted for by states' structural (social, economic, and political) characteristics, which are partially mediated by health services. Population differences in areas such as access to health care and ethnicity of the general population have persuaded national policy makers to allow individual states to decide what intervention strategies would be most efficient in their particular state.

Low Birth Weight

The practice of weighing infants at birth has been around for a long time. Measurement techniques were somewhat crude in the beginning and the means to determine what was a normal birth weight took time to establish. In 1948, the World Health Organization (WHO) assembly defined those infants at risk for adverse neonatal outcomes as being an immature live-born infant with a birth weight of 2,500 grams or less, or specified as immature. Subsequent research findings suggested a need for further classification of this risk group. The WHO expert committee on maternal and child health in 1961 concurred and subdivided the group into those infants who were "premature," defined as being less than 37 weeks gestation, and those infants that were "stunted," defined as infants who were at least 37 weeks gestation but who were still less than 2,500 grams in weight at birth. This second group would eventually be described as

"intrauterine growth retarded" (IUGR) based on an accepted standard curve for fetal growth (Institute of Medicine, 1985).

The IM's 1985 report cites four reasons to continue to use the single standard of 2,500 grams as a risk marker even though more sophisticated means of classification are available. First, although birth weight and gestational age used together provide useful information, they require accurate assessments of gestation age based on date of conception, which is considerably more difficult to measure than birth weight. Second, birth weight appears to be more useful in determining prognosis than gestational age. Third, the use of standard birth weight limits allows comparisons across time and populations. Finally, a substantial amount of literature exists to support the use of low birth weight as a useful "marker" or "risk factor" for mortality and morbidity. These factors have proven to be just as relevant today in the examination of risk factors.

The term LBW can be connected to three outcomes of pregnancy: (a) preterm delivery, (b) IUGR, and (c) a combination of the two. Although there is more to uncover in the search for theoretical models to explain LBW, research has uncovered a large amount of information regarding risk factors and causal relationships within these outcomes.

Preterm Labor

Thet physiologic and biochemical events which are the mechanism for normal labor are still unclear, much less preterm labor, defined as labor prior to 37 weeks gestation. It would appear from the literature that a single etiology for premature birth will not be found, but rather a list of conditions that have been associated with

prematurity either as directly causal or just as risk factors. This listing consists of conditions in which: (a) the uterus is unable to retain the fetus, (b) there is interference with the course of the pregnancy, (c) placental separation occurs prior to delivery, or (d) some form of stimulation is present causing effective uterine contractions before term. However, an association with a known causal condition or risk factor is not always identifiable (Institute of Medicine, 1985).

Preterm delivery is more common in the US than in many other industrialized nations, and is the factor most responsible for the relatively high infant mortality rate in the US. Paneth (1995) concluded that the mechanism(s) of labor, both term and preterm, have not received as much scientific scrutiny as have many other biological processes of lesser public health significance. Paneth suggests investigating sub-clinical infection, placental abnormalities, lead pollution, and conditions at work as possible factors for preterm delivery. Paneth believes that each of these mechanisms could plausibly explain part or the entire social class gradient in risk of preterm birth. Paneth in this instance referred to statistics that indicate that women of black race have twice the chance of delivering a LBW infant as do non-black women.

Intrauterine Growth Retardation

A statistically formulated growth curve shows the correlation of age (starting at conception) and weight and can be used to determine whether an infant is IUGR (Hamill, et al., 1979). The mean or average weight at any given age has been determined along with corresponding standard deviations. Those fetuses falling outside two standard

deviations from the mean, or approximately 5 percent, would fit the description of IUGR (Institute of Medicine, 1985).

The variety of factors associated with IUGR can be grouped into four categories: (a) problems with the placenta, (b) problems with the pregnant woman herself, (c) problems with the fetus itself, or (d) any combination of the three. Similar to prematurity, there may be no single identifiable factor contributing to IUGR. Prematurity and IUGR occur together in about 30 percent of low birth weight cases (Institute of Medicine, 1985). Beyond these cases there are those cases where no known causal factor can be identified.

Risk Factors

The IM's interdisciplinary committee's original goal was to rank order risk factors, according to their weight in contributing to the outcome of LBW, so that intervention efforts could be prioritized. During its investigation the committee found many methodological and conceptual problems that made the formation of a rank order listing impossible. Although some of these problems could have been solved, others could not. Even without the hierarchical ranking of risk factors, it was found that the known risk factors could be grouped in a way that helped to structure preventive interventions. Table 1 matches each risk factor to a subheading defined in Verran's framework.

The IM's committee also compiled an expanded table of risk factors (1985, pp. 241–248). For example, "selected infections" had only three types listed in the first table

 Table 1

 Categorization of Risk Factors for Low Birth Weight within the Verran Framework

I. Demographic Risks

- (MT) A. Age (less than 17; over 34)
- (MT) B. Race (Black)
- (MT) C. Low socioeconomic status
- (MT) D. Unmarried
- (MT) E. Low level of education
- II. Medical Risks Predating Pregnancy
- (MT) A. Parity (0 or more than 4)
- (MT) B. Low weight for height
- (MT) C. Genitourinary anomalies
- (MT) D. Selected chronic disease
- (MT) E. Nonimmune status for selected infections such as rubella
- (MT) F. Poor obstetric history (previous LBW infant, multiple spontaneous abortions)
- (MT) G. Maternal genetic factors (low maternal weight at own birth)

III. Medical Risks in Current Pregnancy

- (MT) A. Multiple pregnancy
- (MT) B. Poor weight gain
- (MT) C. Short interpregnancy interval
- (MT) D. Hypotension
- (MT) E. Hypertension/ preeclampsia/toxemia
- (MT) F. Selected infections
- (MT) G. First or second trimester bleeding
- (MT) H. Placental problems
- (MT) I. Hyperemesis
- (MT) J. Oligo/polyhydramnious
- (MT) K. Anemia

- (MT) L. Isoimmunization
- (MT) M. Fetal Anomalies
- (MT) N. Incompetent cervix
- (MT) O. Spontaneous premature rupture of membranes
- IV. IV.Behavioral or Environmental Risks
- (MT) A. Smoking
- (MT) B. Poor nutritional status
- (MT) C. Alcohol and substance abuse
- (EC) D. DES (diethylstilbestrol) exposure and other toxic exposures, including occupational hazards
- (EC) E. High Altitude
- V. Health Care Risks
- (IC) Absent or inadequate prenatal care
- (KT) Iatrogenic prematurity
- VI. Evolving Concepts of Risk
- (MT) A. Stress, physical and psychosocial
- (MT) B. Uterine irritability
- (EC) C. Events triggering uterine contractions
- (MT) D. Cervical changes detected before onset of labor
- (MT) E. Selected infections such as mycoplasma and Chlamydia trachomatis
- (MT) F. Inadequate plasma volume expansion
- (MT) G. Progesterone deficiency

<u>Note.</u> Table 1 modified from Table 2.1 Institute of Medicine (1985, p. 51.) Verran's Technology and Structural elements (1997); NT = Knowledge Technology, MT = Materials Technology, IC =Internal Context, EC =External Context but nine in the expanded table. The second table also listed limited research results uncovered on each risk under the outcome headings of preterm labor, IUGR, and LBW (unspecified). Those risk factors shown to have a link with all three outcomes were chosen for the present study. These risk factors were chosen because the risk factors had significant findings in each of the three outcomes and because the study is focused on the outcome of LBW in general not specifically on the underlying etiologies. More complete information on how these variables have been operationalized will be provided in Chapter III. The following section discusses the risk factors in general, following Verran's framework, and is not limited to the variables chosen.

Materials Technology

The risk factors compiled by the IM committee are grouped into categories of demographic risks, medical risks predating pregnancy, medical risks in the current pregnancy, behavioral and environmental risks, health care risks, and evolving concepts of risk. Most of these risk factors, as demonstrated in Table 1, fall within Verran's framework under the heading of "material technology" as comorbid conditions and variability of patient characteristics. "Fetal anomalies" is a risk factor that in the case of LBW could be defined as a comorbid condition present in the current pregnancy.

Subject "variability" is another factor defined by Verran (1997) under material technology. The range of subject variability has to do with what limits, either natural or unnatural, that are in place during the selection of subjects. In the research on LBW, the range of variability might include any female of childbearing age who has given birth to a live infant, as it is for the present study. A study could be limited further to females of

childbearing age under the age of 17, those of a certain ethnicity, or those with a particular comorbidity.

The IM committee listed "absent or inadequate prenatal care" as a risk factor linked to LBW. This risk factor could be directly related to decisions made by the mother. In this case it would fall under material technology. The variable would fall under internal context if the reason for the substandard care were thought to be caused by the health care organization's limitations regarding access to care. In the present study, because all beneficiaries have access to care, the variable of "adequate prenatal care" is deemed to be the mother's decision and designated as a material technology variable. Knowledge of the system under investigation is necessary to properly identify where variables should fall in the framework. Very few risks identified by the IM committee fall outside materials technology in Verran's framework. This finding is not surprising given that the IM committee had only past research on which to base its conclusions on and that examination of systems including structural variables is a rather recent development.

Knowledge Technology

Knowledge technology encompasses those care strategies proven to influence patient outcomes. Iatrogenic prematurity, listed under "health care risk" in the IM committee's table, refers to medical interference with the longevity of the pregnancy either by induction or by cesarean section when the fetus is not mature. The difficulties in correctly predicting gestation have resulted in the unintentional delivery of premature

infants. This variable fits under the heading of knowledge technology because it has to do with the provider's ability to make an accurate diagnosis.

Intensity of medical care is another index identified by Verran (1997) for knowledge technology. The IM committee identified that available research performed on large populations was often limited by the information contained on birth certificates. Information regarding the intensity of medical care provided is currently more available via automated billing records containing identifiable codes for specific procedures and also additions to the birth certificate such as the total number of prenatal visits. Billing records or other data sets, such as the one used in the present study, can provide the total number of specific diagnostic tests such as amniocentesis, ultrasounds, antepartum nonstress tests, and biophysical fetal profiles. The combined total number of these four diagnostic tests, per entire episode of care, has been selected by this researcher to be used as a proxy for the intensity of care. The modified biophysical profile is an excellent means of fetal surveillance and identifies a group of patients at increased risk for adverse perinatal outcome and small-for-gestational-age infants (Nageotte, Towers, Asrat, & Freeman, 1994). What contributions these four fetal surveillance measures make to the outcome of LBW would require further research. However, these antepartum tests are recognized as part of routine and high risk screening techniques by the American College of Obstetrician and Gynecologists and the American Academy of Pediatrics (Guidelines for Perinatal Care, 1992).

<u>Structure</u>

The IM's expert committee on the prevention of LBW listed several risk factors that would fall under Verran's framework (1997) heading of "structure." Verran describes internal context as being comprised of human, material, and fiscal resources. Nurse staffing patterns could be an internal contextual factor. Another factor might be the lack of staff at military hospitals related to war contingencies. The committee also identified several "external context" factors. External context of structure includes the environment outside a particular work group. The expert committee listed two factors that would fit under "external context," exposure to toxic chemicals in a mother's home or work environment, and mothers who live at high altitude. Both are at greater risk for giving birth to a LBW infant. Anther factor might be a state's policies regarding their Medicaid program.

Another factor that is considered by Verran (1997) to be "external context" is the availability of intensive care services. Phibbs, Bronstein, Buxton, and Phibbs (1996) reported differences in outcomes based on level of neonatal care available within the facility. They used the outcome of death within the first 28 days of life, or within the first year of life if continuously hospitalized. They found that patient volume and level of NICU care at the hospital of birth both had significant effects on mortality. Compared with hospitals without a NICU, infants born in a hospital with a level III NICU with an average NICU census of at least 15 patients per day had significantly lower risk-adjusted neonatal mortality (odds ratio, 0.62; 95% confidence interval, 0.47-0.82; p=.002). Risk-adjusted neonatal mortality for infants born in smaller level III NICUs, and in level II+

and level II NICUs, regardless of size, was not significantly different from hospitals without an NICU, and was significantly higher than hospitals with large level III NICUs. Because the structural variables available for this research were limited in the preexisting data set used, a decision to control the structural variables by limiting the data used to facilities having a level III nursery.

The area of the country or even the area of a particular state can also be an external context variable. Hysterectomy is the most frequently performed major operation in the US and one of the most controversial. Easterday, Grimes, & Riggs (1983) reported large regional differences in hysterectomy rates. Research similar to this one, began to investigate the question of which processes produced the best outcome for the least cost. Detmer & Tyson (1978) reported regional differences in surgical care based on uniform physician and hospital discharge abstract data. They found that the surgical procedures when compared to the supply of physicians showed a significant variation in the rates of common procedures even within rather large planning districts. In general, the volume of surgery correlated with the supply of surgeons. Table 2 outlines the material and knowledge technology conceptual and operational definitions that will be used in this investigation.

Table 2

Conceptual and Operational Definitions of the Terms Used in the Research Questions

Materials Technology

Conceptual – nature of the patient with whom the nurse deals

Operational - demographic, medical, obstetric, and behavioral risks

Knowledge Technology

Conceptual - intensity of care

Operational – total number of antepartum visits, total number of ultrasounds, total number of biophysical profiles, total number of non-stress tests

Internal Context

Conceptual - human resources available to do the work

Operational - level III nursery, war contingencies

External Context

- Conceptual includes the environment outside the particular group
- Operational medical center, area of the country, state policies, environmental factors such as toxic chemical exposure,

Outcome

Conceptual – clinical outcome

Operational – birth weight less 2,501 gram

<u>Note:</u> Verran's Framework (1997) used for conceptual variable definition; operational variables derived from factors linked to LBW.
Summary

Verran's framework (1997) provides a tool that incorporates process and structural variables useful in the assessment of the outcome of LBW at the population level. The IM's (1985) compiled risk factors for LBW have been superimposed onto Verran's framework and discussed. Many of these risk factors fall within the framework under the heading of materials technology. Few structural elements were identified by the IM's expert committee, possibly related to the lack of systems research focused on specific health outcomes.

CHAPTER III

METHOD

Chapter Three addresses the methods used in the original study and the present study. The design, sample, setting, protection of human subjects, data collection procedure, and plan for secondary data analysis are included.

The Original Study Design

The original study was the third study commissioned by the Department of Defense (DoD) to assess the overall quality of obstetric care received by DoD beneficiaries. Secondary objectives of the 1997 Birth Product Line Review (BPLR) were to: (a) develop hospital-specific clinical practice profiles to determine practice patterns that lead to best clinical practice, (b) expand upon areas of clinical study in the form of outcome-based pathways, and (c) report results of civilian hospitals that provide care to military beneficiaries. Secondary goals of all three special studies were to assist military treatment facilities (MTF) reduce clinical risks and cost, and improve outcomes for mothers and neonates by identifying clinical practice protocols associated with superior clinical outcomes and resource use performance. A DoD subcontractor examined the association of maternal risk factors with outcome severity scores and resource utilization through ordered logistic regression (LR).

First, actual (observed) outcome severity scores and resource cost units were calculated. Then patient risk factors were identified. Third, outcomes and resource use were risk adjusted to obtain the expected, or predicted, values. The difference between the actual and expected values revealed the clinical practice profiles for each service branch, region, MTF, and civilian hospital. Then the processes of care leading to the best clinical practice were identified. Finally, decision support tools were developed for specific processes of care.

Low Birth Weight; Department of Defense versus Civilian Populations

Because of the similarities in services between civilian and MTFs and the diversity of the DoD patient population, it is assumed that the rate of low birth weight (LBW) is not significantly different in the DoD population than in a similar civilian population. The actual rate of LBW was not available to this researcher from DoD sources and could not be estimated using the data set related to sampling issues (these issues will be discussed in more detail later in this chapter). The diversity of the population stems from diverse demographic characteristics and the fact that DoD beneficiaries are located throughout the United States and around the world. Beneficiaries requiring obstetric care may receive their care at civilian facilities, when MTFs are not available in the area or can't offer the intensity of treatment required, or MTFs (staffed and operated by military personnel).

Services at MTFs are comparable to civilian counterparts and range from general medicine to high-risk specialty care. The MTFs operate under standards similar to civilian facilities. For example, MTFs have to be accredited by the Joint Commission for Accreditation of Healthcare Organizations (JCAHO). Practice guidelines published by national associations such as the American College of Obstetricians and Gynecologists are used as the basis for treatment and procedural policies. In addition, the newly formed TRICARE managed care organization follows accreditation standards set by the National

Commission of Quality Assurance (NCQA). Military treatment facilities range from 30 bed facilities to 1000 bed medical centers.

Original Study Sample and Setting

Data were collected from a random sample of births that occurred between September 1, 1995 and October 31, 1996 from MTFs worldwide and civilian hospitals that provided care to DoD maternity patients. Civilian hospitals were selected based on their providing a minimum of 36 births to DoD beneficiaries. Proportional sampling was used to select approximately 10 percent of births at each MTF, with 30 births as a minimum. The random sample from each MTF was generated by computer from the Standard Inpatient Data Record file and the random sample for civilian hospitals was selected by computer from the Defense Medical Information System database.

Protection of Human Subjects

The researcher received approval for secondary analysis of the data from the University of Arizona Human Subjects Committee (Appendix A). Department of Defense approval for the use of the data was received from Colonel William Strampel, Director of Quality Management, Department of Defense, Health Affairs (Appendix B). All subjects' identifying information was deleted prior to receipt of the data set.

Data Collection Procedure

The 1997 total included 5,687 cases from MTFs in and outside the United States and 2,017 cases from the civilian hospitals. Data were abstracted pertaining to the care received at the first prenatal visit through discharge following delivery into an electronic database structured around a comprehensive clinical data dictionary. The data included (a) symptoms, (b) physical findings, (c) the results of laboratory, radiological, and other prenatal tests such as amniocentesis and chorionic villus sampling, pelvic examinations, and fetal monitoring, and (d) data from operative reports, and progress and discharge notes. Detailed data concerning the processes of care were also collected, including pharmacological management such as epidural analgesia.

Secondary Study Design

The secondary analysis used was an ex post facto retrospective design to investigate the relationship among material technology variables and knowledge technology variables in the outcome of LBW when structural variables are controlled. Structural variables were controlled by limiting subject selection to those giving birth at a medical center with a NICU. Two groups of subjects were chosen: (a) Group 1, those mother - infant pairs with the outcome of LBW delivered at a facility with a level III neonatal intensive care unit (NICU), and (b) Group 2, those mother - infant pairs without the outcome of LBW delivered at a facility with a level III NICU.

Secondary Study Subject Selection

A complete subject record contained a data mix of both mother and infant variables. Subjects for the present study were selected using the two major criteria of the birth facility having a level III NICU available and the birth weight less than or equal to 2,500 grams. Giving birth at a facility with a level III NICU was the first criteria for subject selection. The resulting subject pairs were examined to ensure that birth weight data was available. Those subject pairs without a birth weight were dropped from the selection process. The resulting subject pairs were evaluated to select those pairs with infant birth weight of less than or equal to 2,500 grams. Those pairs meeting this criteria for LBW constituted Group 1. The remaining subjects meeting the first criteria but not the second LBW criteria were put through a randomized selection process at a rate that resulted in an approximately equal number of subjects to Group 1. The subjects selected via randomized selection were labeled as Group 2.

The decision to limit subject selection to those subjects giving birth at a facility with a NICU was made for two reasons. The first reason was to limit the effect of the original subject selection criteria on the present study. Because of the criteria used in the original study, a portion of the actual LBW infants were not accounted for. The policy of many smaller MTFs is to attempt to transport mothers who are experiencing signs of labor prior to 35 - 36 weeks gestation to medical centers. The total number of preterm labor patients transferred to any one tertiary center may not reach the original study's sampling criteria of 36 births. Subsequently these preterm births were not a part of the original data collection and their absence, it was assumed, would skew the results. This assumption was based on the fact that an undetermined percentage of preterm births were not accounted for. The total LBW subject group obtained directly from the original database might have a larger percentage of inter-uterine growth retarded (IUGR) infants and a smaller percentage of preterm infants than what actually existed. Secondly, the decision to limit the subject selection to subjects giving birth in a facility with a NICU was made to control for the structural variable. By using the NICU criteria, internal contextual variables such as the component of maintaining an NICU, (e.g. specialists and

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sophisticated equipment) and the external contextual variable of a medical center were controlled.

Data Analysis

Munro (1997) explains that multiple regression is only useful when the outcome or dependent variable is continuous. When the dependent variable is categorical, either occurrence or nonoccurrence, it becomes a dichotomous variable and multiple regression is not useful. Two techniques have been used to research dichotomous dependent variables that have multiple independent variables, discriminant function analysis and LR. Munro defines discriminant analysis as a statistical technique that provides a prediction of group membership based on predictor variables. Discriminant analysis requires assumptions based on the multivariate normality of the independent variables and equal variance - covariance matrices in the two groups. Munro defines LR as a technique designed to determine which variables affect the probability of an event. Munro indicated that researchers preferred LR for dichotomous health outcomes, such as low birth weight, because it was better suited to the data and the results included odds ratios that lent interpretability to the data. Odds ratios are used to estimate relative risk. Munro defines odds ratio as the probability of occurrence over the probability of nonoccurrence. Logistic regression can also be used to weight risk factors associated with a specific outcome. By using LR to compare groups of otherwise similar subjects consisting of one group without the outcome and the other with the outcome being analyzed, determinations can be made as to which risk factors had the most impact on the outcome. Logistic regression was used for this study because the incidence of LBW is

relatively rare. By using this analysis method more subjects with LBW were analyzed than in other statistical methods.

The DoD subcontractor using the Stata Corporation's statistical computer program STATA TM compiled the original data. For the present study the selected risk factors from the IM committee's expanded table that are available in the data set (Table 3) were extracted from the STATA database and placed in a Microsoft ® EXCEL TM computer program. The data set was then imported into a SPSS ® Statistical Program for Social Sciences (SPSS) for analysis. Data were transformed to allow statistical analysis using SPSS. Using SPSS, the data were coded. All subject pairs meeting the criteria of LBW (Group 1) were coded as a (1) and all other subject records (Group 2) were coded as a (0). Variables were given a unique identifying number. SPSS was used to perform descriptive statistics and LR to answer both research questions. An analysis of differences was done on all the variables and those variables found to have significant differences when comparing Group 1 with Group 2 were placed into the LR equation based on the conceptual framework in three blocks. The blocks assisted in formulating a method for variable entry into the equation. The material variables that were considered non-modifiable variables (e.g. race) were entered in block 1, material variables considered modifiable (e.g. asthma) were entered in block 2, and knowledge technology variables were entered in block 3.

Selection and Availability of Chosen Variables

The entire list of risk factors assembled by the Institute of Medicine's (IM) committee was examined and risk factors for LBW were chosen based on links with both

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pre-term labor and IUGR as variables for the present study as explained in Chapter Two. In addition, evidence to support the inclusion of internal context variables related to intensity of care and the external context variable of area of the country was presented. Table 3 compiles the chosen variables and identifies whether the variable was available in the original data set.

Statistical Analysis

The statistical program SPSS was used to analyze the data for this study. The research questions and plan for data analysis to answer each question were as follows:

1. What are the most significant material technology variables (e.g. comorbidities) contributing to LBW in the population of DoD beneficiaries when structural variables are controlled?

Descriptive statistics were used to determine the variables that were entered into the LR equation. Logistic regression using the variables entered in blocks 1 and 2, was used to answer this research question.

2. What are the most significant knowledge technology (e.g. intensity of care) variables contributing to LBW in the population of DoD beneficiaries when structural variables are controlled?

Descriptive statistics were used to determine the variables that were entered into the LR equation. Logistic regression using the variables entered in block 3 was used to answer this research question.

Table 3.

Chosen Risk Factors: Placement in Verran's Framework and Availability in BPLR Data

VF Risk Factor		In BPLR	data set BPLR variable
<u></u>	Demographic		
MT	Age	Yes	Age
MT	Unmarried	Yes	Marital status
MT	Black	Yes	Race
MT	Low socioeconomic status	No	
	Pre-Existing Conditions		
MT	Prepregnant weight	Yes	Prepregnancy weight
MT	Small stature	No	
MT	Previous abortion	Yes	Total number of abortions
MT	Previous fetal death	Yes	Total number stillbirths
MT	Parity (high or low)	Yes	Total number of pregnancies
MT	Previous LBW infant	Yes	Previous obstetric history
	Medical Risks		5
MT	Multiple Gestation	Yes	Multiple gestation this pregnancy
MT	Urinary tract infection (UTI)	Yes	Combined Dx antepartum/upon admit
MT	Anemia	Yes	Present/Active Anemia on admit
MT	Fetal anomalies	Yes	Fetal anomaly or abnormality
MT	Abruptio placentae	Yes	Placenta abruption Dx on admit
MT	Placenta previa	Yes	Placenta previa Dx complete/partial
MT	Smoking	Yes	Tobacco use this pregnancy
MT	Heavy alcohol use	Yes	Alcohol use this pregnancy
MT	Drug abuse	Yes	Combined illicit drug use
MT	Absent/inadequate care	Yes	Gestation first antepartum visit
MT	Inadequate weight gain	Yes	Weight final visit minus pre-weight
MT	Pregnancy induced hypertension	Yes	PIH observed on prior to or on admit
A	dded variables		
KT	Total amniocentesis	Yes	Total number aminocentesis
KT	Total biophysical profiles	Yes	Total number biophysical profiles
KT	Total non-stress tests	Yes	Total number non-stress tests
KT	Total ultrasounds	Yes	Total number of ultrasounds
KT	Total antepartum visits	Yes	Total number of antepartum visits
IC	Level III NICU	Yes	Infant admit to NICU as proxy
EC	Medical Center	Yes	Having a NICU as proxy
EC	War contingencies	No	
EC	Area of the country	No	
EC	State policies	No	
EC	Environmental factors	No	

Note: VF = Verran's Framework (1997); NT = Knowledge Technology, MT = Materials Technology, IC =Internal Context, EC =External Context.

CHAPTER IV

RESULTS

Chapter Four includes a description of the sample and results on the most significant material technology and knowledge technology variables as they relate to the outcome of low birth weight (LBW) when structural variables are controlled. Logistic regression (LR) was used to answer the research questions.

Description of the Sample

Total Population

Beginning with the complete database, infant and mother pairs (7,732) were coded as to whether or not the mother gave birth in a facility with a neonatal intensive care unit (NICU). Those subjects coded for NICU availability totaled 3,581 subject pairs. The NICU available group will henceforth be referred to as the total population for ease of discussion. Table 4 lists descriptive characteristics of the total population.

The total population was coded as to whether or not the birth weight was less than 2,501 grams (LBW criteria). The total population contained 6.2 percent LBW infants or 220 subject pairs (Group 1) that met the LBW criteria. Group 1 had a mean birth weight of 1938 (SD=539) grams. The remaining subject pair files (3,361) were randomly sampled to produce a comparison group of 250 subjects. The larger number was selected to allow for missing weight variables. Those with missing weights were dropped and 223 subject pairs remained (Group 2). The combination of Group 1 and Group 2 resulted in 443 paired subjects.

Descriptive Statistics: Means of Total Population and Data Range

	Total Population (SD) Mean	Range	% Missing Data
Maternal age	26.12(5.44)	14 - 49	0
Parity	.86(.99)	0 - 8	3.4
Antepartum visits	10.05(4.12)	1 - 35	3.5
Pre-pregnancy weight (lbs.)	141.59(30.77)	80 - 340	24.7
Weeks gestation 1st visit	13.05(6.78)	4 - 40.30) 10.5
Birth weight (grams)	3364.46(469.77)	378 - 4735	14.6

Note: SD = standard deviation.

Group 2 Representative of Total Population

Group 2 was compared with the total population to determine if the randomized selection process resulted in a group similar to the total population. The mean age (26.61, SD=5.62) years, number of previous live births or parity (.92, SD=.95), total antepartum visits (10.02, SD=4.49), and birth weight (3476 grams, SD=470), were not statistically different from the total population using t-test at the .05 level. Group 2 was accepted as being representative of the total population.

Comparison of Group 1 and Group 2

Groups 1 and 2 were compared using the chosen variables listed in Table 3. Tables 5 (dichotomous variables) and 6 (continuous variables) list the results of the comparison between groups maintaining Verran's framework (1997) identification. Analysis of differences was accomplished using Chi-squared for the dichotomous variables and T-test for the continuous variables.

Dichotomous Variables: Cross Tab Results Comparing Group 1 with Group 2

VF	Variable Name	%Gr1 LBW	%Gr2	X²	р
	Demographic				
MT	Unmarried	14.1	9.9	1.877	.111
MT	*Black	17.7	10.8	4.404	.025
	Pre-Existing Conditions				
MT	Previous abortion	23.2	28.3	1.489	.133
MT	Previous LBW infant	0	0		
MT	*Previous fetal death	5.0	0.4	8.706	.003
	Medical Risks				
MT	*Multiple Gestation	21.8	5.8	23.843	.000
MT	Urinary tract infection	24.5	20.2	1.217	.305
MT	*Anemia	20.0	13.0	3.938	.031
MT	Fetal anomalies	2.3	0.9	1.729	.421
MT	Abruptio placentae	11.8	6.7	3.419	.064
MT	Placenta previa	10.0	6.3	2.055	.104
MT	Smoking	4.5	4.9	0.037	.513
MT	Alcohol use	2.7	6.3	3.239	.057
MT	Drug abuse	0.9	0.4	0.349	.495
MT	*Asthma*	12.7	4.5	9.595	.001
MT	*PIH	7.7	2.7	5.707	.014
MT	Migraines*	16.8	11.7	2.416	.078

Note: VF = Verran's Framework (1997), MT = Materials Technology, PIH = pregnancy induced hypertension, \star = variable added based on researcher's previous data mining pilot study, X² = Chi-squared, p = Significance.

* indicates variables selected.

<u>Continuous Variables:</u> Means and Results of ANOVA between Group 1 and 2

) F	p
1.255	.263
4.44	.036
1.30	.256
7.48	.007
9.75	.002
0.83	.363
7.78	.006
10.17	.002
16.51	.000
22.49	.000
) F 1.255 4.44 1.30 7.48 9.75 0.83 7.78 10.17 16.51 22.49

Note: VF = Verran's Framework (1997), NT = Knowledge Technology, MT = Materials Technology. F = ANOVA, p = Significance, # = measured in pounds, SD = standard deviation. ** indicates variables selected.

Inclusion criteria

Variables were not used if there was a high percentage of missing data or when there was no significant difference between groups. Pre-pregnancy weight and adequate weight gain had a 24.7 percent missing data rate in the total population. Based upon the drop in selected subject pairs and thus sample size, the decision was made to exclude these two variables from the LR equation. Also, those variables that were not significantly different between the two groups were not entered in the LR equation in order to keep extraneous variables to a minimum. Two other variables, history of asthma and migraines were added. These two variables were not in the MI's list of risk factors and were added based on the researcher's previous (Valley, 1998). The researcher conducted a data mining study on 30 LBW mother-infant subject pairs. Variables consisted of 196 medical and obstetric comorbidities. Frequencies of each comorbidity when all 30 subjects were totaled were used to compile a list of comorbidities thought to be associated with LBW. Out of the list compiled, asthma and migraines were the only comorbidities not on the MIs risk factor list.

Logistic Regression

The following describes variables chosen to enter the LR equation, variables that were significant enough to stay in the equation, and the results of the LR equation. Variable Entry

The variables remaining were placed in the three categories identified (material technology non-modifiable and modifiable variables, and knowledge technology variables), and are listed according to entry block (Table 7). The variables were entered, using the block format into the forward stepwise LR equation. Group 1 (LBW) with 220 subject pairs and Group 2 (> 2,500 grams) with 223 (subject pairs) were used in the LR equation. When combined, the subject pairs totaled 386 (180 with LBW and 206 without LBW) once cases with missing data were eliminated.

In LR, it is the combination of the variables within the model that influences the significance of each of the individual variables. Some variables that might be

significantly different between comparison groups will not enter the LR equation because their entry does not enhance the predictive capability of the model as a whole. In block 1, multiple gestation and being of the black race both entered the equation, previous fetal death did not. Upon adding Block 2, Block 1 variables remained in the equation and asthma and pregnancy induced hypertension (PIH) also entered; anemia did not. When block 3 variables were added, non-stress tests (NSTs), fetal ultrasound, and total number antepartum visits entered the equation along with the previous variables. Week of gestation at the first antepartum visit (adequacy of prenatal care) and biophysical profiles (BPPs) did not enter the equation.

Table 7

Non-modifiable	Modifiable	Knowledge Technology	
Block 1	Block 2	Block 3	
Multiple gestation	PIH	Total fetal U/S	
Black	Asthma	Total NSTs	
Previous fetal death	Anemia	Total prenatal visits	
Trevious tetar death	Adequate care	Total BPPs	

Variables Identified by Block That Where Entered into Logistic Regression Equation

<u>Note</u>: BPP = biophysical profiles, NST = non-stress test; PIH = pregnancy-induced hypertension, U/S = ultrasound, NST = non-stress test, BPP = biophysical profile. **Bold** indicates those variables that entered the equation.

Final Logistic Regression Results

The results of the LR are listed in Tables 8 and 9 including *b*-weights, sample error, significance, odds ratio, and lower and upper limits of the odds ratio at a 95 percent confidence interval. The *b*-weights listed in the first column were used to determine the

probability of a subject having the predicted outcome. If the coefficient is positive it indicates that the presence of a variable increases risk of the outcome, and vice versa for negative coefficients. Based on the *b*-weights, the material variables in the study that were most likely to predict LBW were multiple gestation (1.61), followed by asthma (1.22), having PIH (1.03) and being of the black race (.95). The most significant technology variables were total number antepartum visits (-.23), followed by fetal ultrasounds (.22) and NSTs (.18). Using the 0.05 level, six of the seven are significant. Pregnancy induced hypertension was not significant.

Table 8

Block VF	Variable	Ь	S.E.	р	R
1				· · · · · · · · · · · · · · · · · · ·	
MT	Multiple Gestation	1.6106	.3947	.0000	1635
MT	Race = Black	.9531	.3225	.0031	.1108
2			`		
MT	Asthma	1.2218	.4198	.0036	.1086
MT	PIH	1.0256	.5620	.0680	.0492
3					
KT	Total NSTs	.1841	.0567	.0012	.1248
KT	Total antepartum visits	2294	.0327	.0000	2930
KT	Total fetal ultrasounds	.2158	.0731	.0031	.1107
	Constant	.8338	.2662	.0017	

Results of Forward Stepwise Logistic Regression Analysis by Block Entered

<u>NOTE</u>: VF = Verran's (1997) framework, MT = Material Technology, KT = Knowledge Technology, PIH = pregnancy induced hypertension, b = beta or b-weight, S.E. - sampling error, p = significance, R = partial correlation.

Block VF	Variable	Odds Ratio	Lower 95 % C	Upper I for OR
1	an ann an Ionna Ionn an Ionna Ionn an Ionna			
MT	Multiple Gestation	5.0056	2.3095	10.8490
MT	Race = Black	2.5938	1.3787	4.8799
2				
MT	Asthma	3.3934	1.4904	7.7264
MT 3	PIH	2.7887	.9269	8.3902
КТ	Total NSTs	1.2022	1.0757	1.3435
КТ	Total antepartum visits	.7950	.7456	.8477
KT	Total fetal u/s	1.2409	1.0753	1.4320

Logistic Regression: Odds Ratio and Lower/Upper 95 Percent Confidence Interval

<u>NOTE</u>: VF = Verran's (1997) framework, MT = Material Technology, KT = Knowledge Technology, CI = confidence interval, OR = odds ratio.

The R statistic (partial correlation) is the correlation of one independent variable with the dependent variable while the other variables are held constant. A positive value indicates that as the variable increases in value, so does the likelihood of the event occurring with a negative value, the opposite (Munro, 1997). The only variable with a negative R was total antepartum visits. R² will result in the percentage of variance explained by the variable to the outcome. Total antepartum visits represented 8.5 percent of the explained variance, while NSTs explained 1.5 percent and fetal ultrasounds 1.2 percent. With the material technology variables, multiple gestation explained 2.7 percent of the variance, followed by race being black with 1.2 percent, asthma also with 1.2 percent, and PIH with less than 1 percent.

Framework Prediction Results

Odds ratios (OR) listed in Table 9 can be defined as the probability of occurrence over the probability of nonoccurrence. To obtain this figure the base of the natural logarithm (2.72) is raised to the power of the *b*-weight. In LR it is important to remember that it is the odds of an outcome occurring, not a <u>change in the dependent</u> <u>variable</u> for a one-unit change in the independent variable as in linear regression. In LR, the *b*-weight is the <u>change in the log odds</u> associated with a one-unit change in the independent variable with the other variables held constant. Also listed in Table 9 is the confidence interval (CI). The 95 percent CI values, upper and lower, are used to demonstrate more clearly the odds ratio. An exponentiation is performed on the usual formula; that is, the natural logarithm (2.72) is raised to a power derived from the *b*weight +/- 1.96 multiplied by the standard error (Munro). Because the odds ratio for each variable is directly associated with the *b*-weight, the results regarding the significance of the material and technology variables mirrors the *b*-weight results.

The overall model predicted the birth of a LBW infant at rate of 65 percent and normal birth weight at a rate of 74 percent. Overall the model's prediction rate was 70 percent. The Hosmer and Lemeshow Goodness-of-fit Test resulted in a Chi-square of 9.48 with 8 degrees of freedom and a significance of 0.30. When the significance is large for the test of -2LL or the goodness of fit statistic, the null hypothesis that the model fits can't be rejected. A significant result indicates that the model does not fit a nonsignificant result indicates that the model does fit (Munro, 1997). The results indicate that the model does fit.

CHAPTER V

DISCUSSION

The purpose of this study was to determine the most significant material technology and knowledge technology variables as they relate to the incidence of low birth weight (LBW) when the primary structural variables are controlled. The discussion of the results, limitations of the study, recommendations for further research, and implications for nursing are presented in this chapter.

Results in Relationship to Literature Review

Randomization was used to gather the subject data in the original study and as part of the present study. Based on the premise that randomization is useful for generalizing results to the entire population, the results indicate a unique list of factors associated with LBW for the Department of Defense (DoD) population. The results also indicate that some risk factors found in other populations are not significant factors in the DoD population.

Question 1: Significant Materials Technology Variables

The 1985 Institute of Medicine's (IM) compiled listing of significant risk factors related to LBW was used to guide variable selection for the category of materials technology. Two other variables (asthma and migraines) were selected based on the researchers previous data mining study (Valley, 1998). Out of 22 risk factors screened (20 from the MI list and two added), seven factors were entered into the LR equation based on analysis of differences (one-tailed T-test and Chi-square) at the .05 level. The

variables using maternal pre-pregnancy weight and total weight gained were significantly different but were dropped due to missing data.

The seven variables entered in Block 1 and 2 included multiple gestation, previous fetal death, race being black, anemia, pregnancy induced hypertension, asthma and adequacy of prenatal care. Of the seven variables added to the equation, four variables remained significant based on the entire model and entered the logistic equation. Based on the *b*-weights and odds ratio of this study, the material variables that were most likely to predict LBW were, in order of highest to lowest predictive ability, were multiple gestation, asthma, pregnancy induced hypertension, and being of the black race.

In this study, multiple gestation was the most predictive of LBW. Those subjects with multiple gestation were five times (odds ratio = 5.01) as likely to have a LBW infant as those subjects with singleton births (CI 95%, 2.31 - 10.85). Multiple gestation is a risk factor well known to produce smaller infants. In this sample, 22 % of the LBW group were multiple gestation so it is not surprising that this variable carried the greatest risk. Also, the average gestation for a twin pregnancy is shorter as opposed to the 40-week average of a singleton birth (Pons, et al., 1998). Over the past ten years an increasing incidence of multiple gestation has been reported by the National Center for Health Statistics (1997). The report suggests that the increase is related to increase use of fertility agents and methods that have a corresponding increase risk of multiple gestation. The only way to reduce the incidence of multiple births would appear to be to reduce the use of subjects' fertility options. This intervention strategy would be highly opposed by

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those subjects that are aware of the risks and chose to use one or more of the fertility options. Perhaps focusing intervention strategies on this risk factor is not optimal for success in reducing the incidence of LBW. Future research controlling for multiple gestation is needed to examine how important the other factors examined are in relation to this factor.

The literature also supports the findings of this study that being black is a risk factor for LBW. The National Center for Health Statistics (1997) reported, based on nationally aggregated data, that women of the black race are almost twice as likely to have a LBW infant as compared to white women. It would appear from the results of this study that black women in the DoD beneficiary group are two and half times (odds ratio = 2.59) as likely to have a LBW infant compared to the composite of other races (CI 95 %, 1.38 - 4.89). Assuming access to health care was not an issue for this population, the results indicate that having access to health care does not decrease the risk of black women having LBW infants. Shiono and Behrman (1995) who contend that prenatal care may not provide significant benefits with respect to LBW and preterm birth support this premise. The subjects' economic status could not be analyzed in the data set due to the limitations of the original study. It is possible that this factor might have helped explain the increased risk of LBW in the black population, as it has previously been suggested as a confound (Institute of Medicine, 1985).

Asthma, one of the variables selected based on a previous study done by the researcher did enter the LR equation. The results of this study indicate that women with a history of asthma have a three and a third (odds ratio = 3.39) times higher chance of

having a LBW infant as do those women without asthma (CI 95%, 1.49 -7.73). Since the compilation of the MI's LBW risk factor list, asthma has been recognized as a risk factor for LBW (Witlin, 1997). The increased incidence and treatment variations for asthma in the general population possibly answers why asthma has only recently been studied as a risk factor for LBW. It is thought that asthmatics decreased oxygenation during asthmatic episodes may lead to IUGR or preterm labor. Schatz, et al. (1995), working out of the Department of Allergy and Obstetrics, Kaiser-Permanente and Jana, Vasishta, Saha, and Khunnu, working with the Institute of Medical Education and Research, Chandigarh, India, (1995) report that by controlling asthma during pregnancy the risk of poor neonatal outcomes like LBW can be reduced to that of patients without asthma. The results seen in the present study indicate that asthma was a factor in the incidence of LBW, which is consistent with the two studies just mentioned. Potentially, improved management of asthma in the DoD population may reduce the incidence of LBW.

Pregnancy induced hypertension (PIH) is currently used to define what was previously referred to as toxemia of pregnancy or pre-eclampsia. The significance of this variable (p=.068) related to the total model was not significant at the .05 level. It also explained less than one percent of the variance. The results would indicate that that subjects with PIH are two and three quarters times (odds ratio = 2.79) as likely to have a LBW infant as those without PIH (CI 95%, .92 - 8.39). The lack of significance of the PIH variable and its wide confidence interval makes interpretation of the results difficult. The results may indicate that the condition is being partially controlled in this population. Although the literature does not indicate a clear method of predicting or preventing adverse outcomes caused by PIH, recent advances in research into the pathophysiology of pre-eclampsia have greatly enhanced our understanding of this condition. Therefore, new strategies to predict and prevent this disorder are sought for and are emerging (Erkkola, 1997).

The four material technology variables that entered the LR equation explained little of the variance. This may lower the impact that these findings may have in regards to clinical significance. However, considering the price, both monetary and emotional, of having just one LBW infant, the percentage of explained variance may not be the deciding factor when focusing intervention strategies. Selecting risk factors that have proven management strategies such as asthma may be a better place to focus initial intervention strategies than those risk factors with greater explained variance that have no clear proven management strategies.

Migraines

The other added material variable, history of migraines, identified through data mining of 196 medical and obstetric comorbidities, did not prove to be significantly different at the p<.05 level. However, the analysis did identify a trend (p<.10). Migraines have been linked to hormone levels. Migraine onset, frequency and severity are influenced by hormonal changes throughout the various female reproductive life events, including pregnancy (Neurology Associates, Sioux Falls, SD, USA, 1995). It is conceivable that the same unstable hormone levels that are related to migraines are somehow linked to the incidence of LBW. Migraines are also being treated with newly marketed drugs. Perhaps the connection, if it truly exists, is in this direction. The lack of a previously reported correlation between migraines and LBW may be because patients without access to medical care would not be diagnosed with migraines, and as such would not self-identify themselves as suffering from migraines when queried regarding medical history. Even with access to medical care, forms filled out by obstetric patients may not be comprehensive enough to actually ask whether the patient had ever suffered from migraines. Some forms are structured by systems, such as in "list any neurological problems." Depending on the subject's medical knowledge migraines may not be listed even if present. Even when patients are verbally queried as to neurological problems, the average provider may not list migraines. Also, where asthma has defined objective diagnostic criteria (peak flows, pulmonary function tests), the diagnosis of migraines is often based on subjective information. Further research is needed to determine if a patient's history of migraines has any relationship to the outcome of LBW.

Question Number 2: Significant Knowledge Technology Variables

The variables selected for knowledge technology were chosen to measure the intensity of care given to a subject, such as fetal tests or provider encounters. The intensity of care variables included four variables, total non-stress tests (NST), bio-physical profiles (BPP), antepartum visits, and fetal ultrasounds. The results of the LR equation show NSTs and fetal ultrasounds with positive *b*-weights indicating that an increase in these variables would result in a higher prediction of LBW. Total number of antepartum visits had a negative *b*-weight and indicates that a decrease in the number of visits would result in a higher prediction of LBW. The variables BPP did not enter the equation related to the dropped significance in relation to the other variables in the

model. The odds ratio for NSTs (1.20), fetal ultrasounds (1.24), and antepartum visits (.80) showed only a slight increased risk for LBW.

Patients who are identified with preterm labor, and do not immediately deliver, are often placed on periodic fetal monitoring surveillance to check for further uterine activity. Fetal heart tones are also monitored and a NST (a check that analyzes fetal heart rate acceleration trends corresponding with fetal movement) is often a bi-product of such monitoring activity. When uterine measurement or other diagnostic procedure identifies possible fetal growth retardation, serial ultrasounds are used to closely monitor fetal growth. Ultrasounds are more accurate than fundal height (measuring the uterus externally from pelvic bone to the top of the uterus) for measuring fetal growth. Those infants identified with possible interuterine growth retardation (IUGR) are also monitored for well-being via NSTs. The increase of both fetal ultrasounds and NSTs could be explained by the foregoing arguments. The database did not extend to the reason behind each test, and as such, further research would be necessary to fully understand the relationship between material technology variables and knowledge technology variables as they relate to the outcome of the birth of a LBW infant.

The results related to the knowledge technology variables indicate that as the number of NSTs and fetal ultrasounds increase so does the risk of LBW. Fetal ultrasounds and NSTs are often ordered on patients with IUGR and NSTs are often a biproduct of monitoring for pre-term labor. Fetal surveillance tests are used to identify fetuses at risk for adverse outcomes such as fetal death. Without evidence that the pregnancy was medically terminated based on fetal surveillance, it is difficult to know

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how much effect the tests had on the outcome of LBW. It does not seem plausible to contend that the increased fetal surveillance has a definite causal effect on the risk for LBW, but rather the increase testing resulted from the identification of factors indicating either IUGR or preterm labor. However, it would make sense that some infants are being delivered early and with LBW based on evidence obtained from the increased fetal surveillance. For example, the decision to accept the risks of a live LBW infant as opposed to the risks of a fetal death might be made if a fetus' growth was extremely stunted.

The third variable, total antepartum visits, has a negative *b*-weight that indicates that as the number of prenatal visits decreases, the risk of LBW increases. On first glance, this result might be interpreted as the need to increase the number of visits for those mothers at high risk for LBW. Although this interpretation might be correct, the selection of this variable was approached incorrectly and subsequently the results can not be used to base intervention strategies. Based on literature findings, the etiology of LBW is a mixture of premature infants, IUGR infants, and a combination of the two. A percentage of the LBW population had a shortened gestation and subsequently fewer provider encounters. A variable that contained the number of prenatal visits adjusted by the estimated weeks of gestation at birth may be helpful in determining the actual relationship of the total number of prenatal visits to the outcome of LBW. Further research would be necessary to determine the usefulness of the suggested new variable.

None of these variables are particularly useful for predicting the outcome of LBW because their numbers are only collected retrospective to the outcome. Perhaps if the

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framework is used to measure practice changes, the knowledge technology variables selected in the present study may be of more usefulness. Another noteworthy finding was that total number of antepartum visits and number of NSTs had a correlation of >.30 (-.36). Normally with a correlation of >.30 one of the variables would be dropped from the model. Because of the descriptive nature of the study, both variables were kept in the LR equation so future research would have a reference point for both variables.

Significant Differences Between Groups

Three risk factors, anemia, previous fetal death, and adequacy of care were found to have significant differences between groups, but did not enter the LR equation. In LR, a combination of risk factors is used to form a prediction model. These three variables did not add to the predictive capability of total model so were not entered into the LR equation. Although these two variables did not seem useful in predicting LBW, one reason may be due to the rare nature of the variable and not its significance. Previous fetal death affected only twelve subjects out of a possible 443. It is noteworthy that eleven of the twelve were found in Group 1 (LBW). Anemia can not be explained with the same argument. The risk factor of anemia is not rare in the sample with 73 subjects affected out of 443 possible. Perhaps anemia is being managed through intervention strategies (i.e. iron supplementation, nutritional counseling) but the effects have not eliminated it from the list of risk factors currently related to the outcome of LBW. Further research would be necessary to explore this contention. Inadequacy of care using the proxy variable of weeks gestation at the first visit did not enter the equation either. The LBW group was seen on average a week and a half earlier than the comparison group. Although significant statistically, the difference between the groups is probably not clinically significant.

Risk Factors Not Found Significant

The results of this study can not be used to do an analysis of risk management effectiveness in the obstetric population. It is noteworthy that in this sample of the DoD's population the vast majority of the MI's risk factors were not found significant. The small list of significant risk factors could be the result of sampling error or lack of true variable identification. The MI's risk variables not predictive of LBW could be the result of risk management strategies that are already in place. For example, with the risk factor of urinary tract infections the DoD policy is to follow the American College of Obstetricians and Gynecologists recommendations for patients to be screened via urine culture during baseline testing of new obstetric patients. Those with positive cultures are treated and followed via monthly urine cultures. If the risk management process to reduce the effect of urinary tract infections is in place, it may explain why having a urinary tract infections are sub-clinical and would not have been reported in the database, even if these infections were causing the preterm labor.

Results in Relationship to Conceptual Framework

Verran's framework (1997) provided the structure for this study. Verran's framework was useful because it took into account both process and structure. Structure is an important aspect to outcome studies as illustrated in the literature review. It is important for outcome research to investigate just how important structure is to the outcome and which structural components result in the best outcome. Giving birth at a medical center may be the most significant factor for some outcomes such as the mortality of very low birth weight infants. For other outcomes, structure may have limited impact. If further research could identify whether receiving care in a medical center environment decreased the incidence of LBW, then perhaps those patients with significant risk factors should be transferred from a small clinic setting to a environment that offers the structural components found at a medical center. The prevention of one LBW infant would probably be cost beneficial.

Framework's Usefulness for Predicting LBW

Using Verran's framework to select and control for variables, the framework's overall predictive capability was 70 percent. However, as discussed under knowledge technology variables, the variables selected were for tests that happened during the pregnancy and would not be useful in predicting LBW at the onset of pregnancy. Lovell, et al. (1997) ascertained that modeling or the statistical method does not change the predictive capability of negative outcomes in obstetrics. They argue that more discriminative clinical information is needed to improve the model's ability to predict an outcome. For example, variables for the present study could not measure how severe the patient's chronic condition was, just that the variable was part of their medical history.

The predictive quality of the framework used for this study potentially could have been increased by several factors. First, the selection criteria used in the study eliminated those variables that were linked to only one of the two etiologies of LBW, prematurity or IUGR. By adding these variables the framework's ability to predict may be improved.

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Also, knowledge is still limited on the underlying causes of LBW. The lack of risk factors not yet identified may partially be responsible for the low predictive rate. Finally, the choice of knowledge technology variables was not useful in predicting LBW. Because the framework was designed to monitor practice changes the inclusion of these variables might be more useful in intervention studies. A variable such as total dollars spent on health care the year prior to conception may be useful in predicting LBW prior to pregnancy.

Further Defining the Framework

The results would indicate that Verran's framework might be lacking subgroups within the category of knowledge technology. These subgroups might be titled low intensity and high intensity of care. Subjects requiring a low intensity would probably require a structure similar to a community hospital setting. When subjects require high intensity care, at some point there may be a need for a particular structural element like a medical center. The intensity correlates with the needed structural element. For the outcome of LBW, the increase in the intensity of care may be related to early cues of future problems like preterm labor and inter-uterine growth retardation (IUGR). In the present study, LBW infants had a higher rate of NSTs and fetal ultrasounds than the comparison group. The higher level of fetal surveillance may have had a direct relationship with LBW related to an identified fetal mortality risk. If this were the case, the structural element of a medical center would be considered to reduce the risks of neonatal outcomes related to the birth of a LBW infant. The difficult question to answer is at what point is it cost effective (monetary, neonatal and maternal outcomes) to transfer a patient from a community hospital environment to a medical center environment. The database did not extend to the reason behind each test and as such further research would be necessary to fully understand the relationship between material technology variables and knowledge technology variables as they relate to the outcome of the birth of a LBW infant.

Limitations of the Study

The study was limited by the following factors:

1. The structural variable was limited to those subjects giving birth at a facility with an NICU, thus limits the generalizability of the results to that population.

2. The unavailability of potentially key variables (i.e. economic status, height of subject, and area of the country variables) limits the completeness of the risk factor list.

- 3. The exclusion of variables related to only one of the two etiologies limited the list of risk factors analyzed, possibly decreasing the predictive power of the framework.
- 4. A high percentage of missing data for some variables (i.e. pre-pregnancy weight, weight gain) led to their absence in the LR equation, possibly decreasing the predictive power of the framework.
- 5. The majority of material technology variables were based on subject selfreport and may not have been totally accurate or complete.

6. Two variables, parity and age were not coded correctly and could not be analyzed.

Recommendations for Further Research

Test the Structural Component

The present study controlled for structure by limiting the selection criteria to those subjects that gave birth at a facility with a NICU. Databases such as the one used in this study are very expensive to collect and "wasting" any subjects unnecessarily would be something any future researcher should try to avoid. If structure is a significant variable, as contended, there should be a difference when this structural variable is not controlled. If there is no significant difference found between controlling for NICU or not controlling for it, then the available LBW subjects was limited to 220 from a possible 340 in the database needlessly.

Choose Different Knowledge Technology Variables

Now that data is becoming more readily available regarding a patient's usage of the medical system and the associated cost attached to the care received, it may be reasonable to use this information as a variable to predict risk in obstetrics. The dollar amount spent on a patient's health care for the year prior to pregnancy may be a good proxy for severity of illness and access to health care. If the figure is in the high range of normal, the patient might have been in poor health the year prior to conception. If the dollar amount is in the low range, problems with access to medical care (either selfinflicted or structurally inflicted) could be considered as a risk factor for LBW. Further research would have to be done to define the usefulness of this variable.

Increase the Sample Size and Improve Variable Collection to Limit Missing Data

Although the sample size was adequate, many of the risk factors identified had low incidence in the sample. The BPLR data has been collected for three years. By adding the databases together, the sample size would be approximately tripled and allow greater generalizability and strengthen the findings. In addition, if the structural variable of NICU were not found to be significant, by adding the databases together the LBW subjects would also be increased to approximately 1000 LBW subjects.

Unfortunately, pre-pregnancy weight and weight gain, examples of potentially manageable risk factors were eliminated in this study based on missing data. It would be important to base the weight gain on estimated gestation at birth. Otherwise those having preterm birth would be expected to have gained the same as those giving birth at term. Perhaps splitting the weight gain into trimesters would be useful. Future research would benefit by improved data collection for the maternal weight variables.

Nursing Implications

Nurses need to be active participants in outcome research. Nurses have a broad understanding of both process and structural variables that might influence an outcome. Non-clinical research analysts may not have a full understanding of how the variables apply to the outcome. For example, understanding how NSTs and fetal ultrasounds were related to the etiology of LBW helped with interpreting the results of the study.

Nursing case management uses risk assessment to determine patient needs. The results of the study suggest that women who have the risk factor(s), a) multiple gestation, b) being black, c) pregnancy induced hypertension, and d) having asthma are at an

increased risk for having a LBW infant. Related to the limitations of the study, this list is not all-inclusive. Even with the study's limitations, the information is useful when developing a plan of care for these patients. As described earlier, improved asthma management may reduce the incidence of LBW infants.

Nursing case managers coordinating practice guidelines for DoD obstetric populations should identify a plan to evaluate and monitor all those patient's with a history of asthma during pregnancy. Hopefully, through the standardization of medical treatment plans, patients with asthma will receive the medical care their condition warrants. Nurse case managers can educate patients, who may have become scared to use any drugs during pregnancy, in the safety and need for treating asthma symptoms.

Summary

When assessment knowledge is collected on a specific population, then the problem identification and plan for intervention strategies can be directed for that population. The same nursing process that guides practice at the patient level can continue to guide nurses at the population level. In this way, care across the episode of obstetric care can be individualized and continuously improved. Despite the limitations of the study the results are still useful for nursing and healthcare in general. The results of the study found three maternal risk factors that were significant in the DoD population, multiple birth, being of the black race, asthma. Because of the limitations of the study these three factors are not all inclusive, but these results emphasized the uniqueness of the DoD population compared to other populations studied and the United States as a whole. Risk factors such as multiple births and race seem to be non-modifiable. But as

illustrated, multiple births are on the rise due to fertility treatments and medical research is being done to reduce the risk of multiple births with many of these pharmaceuticals and treatments. Being black may also have a key element, other than access to health care that has not been identified to reduce the incidence of LBW in this population. And finally, asthma has a proven intervention strategy and implementing the strategy DoD wide will possibly reduce the incidence of LBW in the DoD population. The analysis of the knowledge technology variables were interesting in that they helped define the total LBW outcome model that will become useful when evaluating future intervention strategies. Nurses are very important to outcome research because they combine expertise in both process and structure. It is worth noting that without previous research to base the adding of asthma and migraines as variables to the present study, the model would have been less complete and a modifiable risk factor would not have been identified. The building of knowledge regarding the risk factors for LBW allows healthcare providers to improve the care they can offer their patients.
APPENDIX A

APPROVAL FOR SECONDARY DATA ANALYSIS



1305 N. Martin PO Box 210203 Tucson, AZ 85721-0203 (520) 626-6154

College of Nursing

September 1, 1998

Major Florence A. Valley

Dear Major Valley:

Your request to complete a secondary analysis of data originally collected by William Strampel has been approved by the Office of Nursing Research. It is understood that this data will be used for your Master's thesis.

We wish you success with your research.

Sincerely,

Luy a Badgu Terry Badger, PhD, RN

Associate Professor

TB/ms

cc: Paula Meek William Strampel APPENDIX B

AGENCY APPROVAL OF SECONDARY DATA ANALYSIS



MANAGEMENT ACTIVITY

OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE HEALTH AFFAIRS SKYLINE FIVE, SUITE 810. 5111 LEESBURG PIKE FALLS CHURCH, VIRGINIA 22041-3206

2 0 AUG 1998

Major Valley

Dear Major Valley:

You have requested to do a secondary data analysis on a data set commissioned by the Department of Defense. You have identified yourself as an Active Duty Air Force officer on official orders to complete your Masters in Nursing at the University of Arizona, Tucson, Arizona. You have also identified that the University of Arizona, College of Nursing mandates a thesis as a degree requirement. It is my understanding that your purpose for this secondary analysis is to describe the relationship among the risk factors for low birth weight specific to the population of Department of Defense health care beneficiaries.

The 1996 compilation of data and report of the analysis titled <u>Birth Product Line Quality</u> <u>Management Review</u> by the FMAS Corporation were commissioned to discover within TRICARE "best practices" and to communicate the findings. "Best practices" are defined as those practices that result in superior patient outcomes with the most efficient use of resources. Your thesis proposal on the topic of low birth weight could be useful in future outcome research evaluating "best practices" for the prevention of low birth weight. Because the intent of your proposal matches the original intent of the Department of Defense, you are authorized to use the 1996 data with the following stipulations.

First, any publication of your findings other than that required by the University of Arizona and the College of Nursing will require pre-authorization IAW DoD Reg xxx-xx. Second, idenufying information regarding specific medical institutions or individuals will not be published in either your original thesis manuscript or any future publications.

The prevention of low birth weight is an important continuous quality management initiative. I look forward to reviewing your findings. If I can be of further assistance, please feel free to contact me.

Sincerely,

Villiam Strampel, COL, MC, USA Acting Chief Medical Officer

REFERENCES

American College of Obstetricians and Gynecologists and The American Academy of Pediatrics. (1992). <u>Guidelines for Perinatal Care</u>. (3rd Ed).

Bird, S. T. & Bauman, K. E. (1995). The relationship between structural and health services variance and state-level infant mortality in the United States. <u>American</u> Journal of Public Health, 85, 26-29.

Department of Defense. (1997). <u>Birth Product Line Quality Management</u> <u>Review</u>. QMR97.002.

Detmer, D. E. & Tyson, T. J. (1978). Regional differences in surgical care based upon uniform physician and hospital discharge abstract data. <u>Annals of Surgery, 187,</u> 166-169.

Easterday, C. L., Grimes, D. A. & Riggs, J. A. (1983). Hysterectomy in the United States. <u>Obstetrics and Gynecology</u>, 62, 203-212.

Erkkola, R. (1997). Can pre-eclampsia be predicted and prevented? <u>Acta</u> <u>Obstetricia et Gynecologica Scandinavica, Supplement 164,</u> 98-100.

Fleschler, R, G. & King, B. P. (1995). Perinatal outcomes management: Balancing quality with cost. Journal of Perinatal and Neonatal Nursing, 9, 21–28.

Foust, R. F. (1997). Maternity management: From preconception to after delivery. <u>The Journal of Care Management</u>, 3, 22–28, 39–42.

Guyer, B., Martin, J. A., MacDorman, M. F., Anderson, R. N., & Strobino, D. M. (1997). Annual summary of vital statistics--1996. <u>Pediatrics</u>, 100, 905-918.

Hamill, P. V., Drizd, T.A., Johnson, C. L., Reed, R. B., Roche, A. F., & Moore, W. M. (1979). Physical growth: National Center for Health Statistics percentiles. American Journal of Clinical Nutrition, 32, 609-629.

Institute of Medicine. (1985). Committee to study the prevention of low birth weight. <u>Preventing Low Birth Weight.</u> Washington, DC: National Academy Press.

Jana, N., Vasishta, K., Saha, S.C., & Khunnu, B. (1995). Effect of bronchial asthma on the course of pregnancy, labour and perinatal outcome. Journal of Obstetrics and Gynaecology, 21, 227-32.

Kane, R. L. (1997). <u>Understanding Health Care Outcomes Research</u>. Gaithersburg, Maryland: Aspen Publishers Incorporated. Krebs G. (1993). Maternity medical case management: a study of employer attitudes. Presentation before the National Managed Health Care Congress; Dec. 9.

Lewit, E. M., Baker, L. S., Corman, H. & Shiono, P. H. (1995). The direct cost of low birth weight. <u>The Future of Children</u>, 4, 35 - 56.

Lynn, M., & Lyman, E. (1996). The nature of nursing administration research: Knowledge building or fire stomping? Journal of Nursing Administration, 26, 9 - 20.

Munro, B. H. (1997). <u>Statistical Methods for Health Care Research</u>. (3rd Ed.) Philadelphia, PA: Lippincott-Ravin Publishers.

Nageotte, M. P., Towers, C. V., Asrat, T., & Freeman, R. K. (1995). Perinatal outcome with the modified biophysical profile. <u>American Journal of Obstetrics and</u> <u>Gynecology, 170</u>, 1672-1676.

National Center for Health Statistics (1997). Online: http://www.whitehouse.gov/fsbr/health.html.

Neurology Associates, Sioux Falls, SD, USA (1995). Treatment of migraine during pregnancy and lactation. <u>South Dakota Journal of Medicine. 48</u>, 373-377.

Paneth, N. S. (1995). The problem with low birth weight. <u>The Future of</u> <u>Children, 5, 68-74</u>.

Phibbs, C. S., Bronstein, J. M., Buxton, E., & Phibbs, R. H. (1996). The effects of patient volume and level of care at the hospital of birth on neonatal mortality. <u>Journal of the American Medical Association, 276</u>, 1054-1059.

Schatz, M., Seiger, R. S., Hoffman, C. P., Harden, K., Forsythe, A., Chilingar, L., Suanders, B., Porreco, R., Sperling W., & Kagnoff, M. (1995). Perinatal outcomes in the pregnancies of asthmatic women: a prospective controlled analysis. <u>American Journal of Respiratory and Critical Care Medicine</u>, 151, 1170 - 1174.

Shiono, P. & Behrman, R. (1995). Low Birth weight: Analysis and recommendations. <u>The Future of Children, 5</u>, 1-14.

Taren, D. L. & Gaven, S. N. (1991). The association of prenatal nutrition and educational services with low birth weight rates in a Florida program. <u>Public Health</u> <u>Reports, 106, 426 - 436</u>.

United Nations Statistical Office. (1997). Population and Vital Statistics Report: Statistical papers, vol. XLIX, No.3 (United Nations publication, ST/ESA/STAT/SER.A/202). Valley, F., A. (1998). <u>Perinatal outcome: Low birth weight.</u> Unpublished manuscript.

Verran, J. A. (1997). The value of theory-driven (rather than problem-driven) research. <u>Seminars for Nurse Managers, 5,</u> 169 - 172.

Walker C.K. (1991). Healthy babies for healthy companies. <u>Business and</u> <u>Health</u>, May.

Witlin, A. G. (1997). Asthma in pregnancy. <u>Seminars in Perinatology. 21</u>, 284-297.

World Health Organization. (1948). <u>Manual of the International Statistical</u> Classification of Diseases, Injuries and Causes of Death, (6th Ed). Geneva, Switzerland.

World Health Organization. (1961). Expert committee on maternal and child health: Public aspects of low birth weight. <u>Third report of the Expert Committee on</u> <u>Maternal and Child Health</u>. Technical report series, 217: Geneva, Switzerland.