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Universal Newborn Screening for Developmental Risk

Grace Cox Ashton
University of Rhode Island

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UNIVERSAL NEWBORN SCREENING FOR DEVELOPMENTAL RISK

BY

GRACE COX ASHTON

A DISSERTATION SUBMITTED IN PARTIAL FULFILLMENT OF THE

REQUIREMENTS FOR THE DEGREE OF

DOCTOR OF PHILOSOPHY

IN

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Abstract

This study examined the relationship between at-birth risk factors and three year child developmental outcome. The purpose of this study was to design a multifactor risk screening system to identify those children who are at risk for developmental delay and behavior problems in Rhode Island. The sample was drawn from three separate datasets: the Rhode Island Universal Newborn Screening (Level One) database (N=27,282), the Early Intervention (EI) database (N=1,793), and the Maternal Lifestyle Study Providence/Teen samples (N= 311). Study One investigated the predictive probability of Level One for EI eligibility by age three. Results showed that Level One has inadequate sensitivity (65%) and a high percentage of false negatives (35%) predicting eligibility for EI services. Study Two investigated the utility of Level One screening to predict EI eligibility and neurodevelopmental outcome by 36 months. Results showed that Level One screening identified 84% of the high-risk sample as Risk-Positive, double that in the general population. The large Risk-Positive rate translated into a corresponding sensitivity for EI eligibility of 88% and the percentage of false negatives of 12%. Level One risk designation did discriminate between children with behavior problems at age three. No significant differences were found between Risk-Positive and Risk-Negative groups in three-year cognitive, motor, adaptive, or communication development. Study Three investigated the design of a newborn screening for EI eligibility that did not rely on predictors heavily influenced by socioeconomic factors. Logistic regression analyses revealed that a socioeconomic insensitive risk algorithm included measures of biological risk. A second model of EI eligibility was designed that combined both biological and parental/environmental predictors. This model produced a screening with sensitivity rate of 70% and false negative rate of 30%. Study Four investigated the use of biological, and parental/environmental variables, and measures of infant behavior to predict age three developmental outcome. High sensitivity (99%) and low false positives (1%) were produced. Results showed that including measures of infant behavior reduced the percentage of false positives to create a more accurate screening. Related findings are discussed along with implications for policy and future research.

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Introduction

The past 25 years of research have expanded our understanding of the vulnerability of young children at risk for developmental problems due to parental, environmental, and biological risk factors. We also have a greater understanding of the vulnerabilities of those children with established developmental disabilities. Well-known risk factors that can significantly impact young children's development include: poverty, prematurity, low birth weight, and maladaptive parenting (Bendersky & Lewis, 1994; Sameroff, Seifer, Boracas, Zax, & Greenspan, 1987). Poverty, for example, is often a marker variable for numerous other risk factors such as poor nutrition, poor prenatal care, and chaotic home environment. Low birth weight infants may enter the world with serious biological disadvantages. Children with developmental disabilities such as Down Syndrome may be even more vulnerable to the impacts of biological, environmental and psychosocial stressors. Children exposed to multiple risk factors are thought to be at greater risk for adverse developmental problems than those children with few risk factors.

The challenge of researchers has been to advance developmentally and neurobiologically sound theories to understand risk in early childhood development and to propose methods of intervention. The challenge of makers of public policy has been to develop and provide Early Intervention services for these vulnerable infants and toddlers. At this time, primary, secondary and tertiary Early Intervention programs are widely available throughout the United States. A serious endeavor remains to find and identify those children who are at risk for developmental delay and disability. Research has shown that the earlier the intervention services are provided the better the developmental outcome (Ramey & Ramey, 1998). Often children are not identified as being in need of intervention until they are preschool or school aged. Likewise, specifically targeted Early Intervention services are needed to reduce the over-identification of children for intervention services that are not needed (Ramey & Ramey, 1998).

The newborn screening process poses a difficult challenge to researchers and policy makers due to the complex nature of the relationship between biological, psychosocial, and environmental factors. Rhode Island's Universal Newborn Screening program to find and identify newborns thought to be at risk for developmental problems is unique in that it screens all newborns for risk factors rather

than only targeting at-risk populations (e.g., only very low birth weight infants). The screening and tracking program continues through transition from Early Intervention at the child's third birthday.

Research in developmental risk suggests that a new newborn screening that accounts for factors in biological and parental/environmental domains will perform better than a screen that accounts for factors from only one domain. The Rhode Island Universal Newborn Screening (UNS) Level One screening algorithm is a biopsychosocial weighted risk assessment comprised of variables thought to be related to later child developmental problems. Although biological and environmental factors are included in the Level One screening, the selection of those factors has been a priori, informed by prior research. This dissertation will attempt to identify a new matrix of biological and parental/environmental at-birth risk factors, a posteriori. This will be done by deriving a combination of variables based upon Early Intervention eligibility for a three year birth cohort and detailed three-year developmental outcome from a high-risk sample.

To date, previous research on developmental risk assessed at birth has focused on identification of risk variables in biological and parental/environmental domains, but has inadequately addressed the domain of infant behavior. Although it is beyond the scope of the current dissertation to examine the influence of infant behavior on risk prediction in any definitive way, the intersection of the UNS, Early Intervention Exchange of Information Operation, and MLS-Providence/Teen databases provides an avenue to begin investigation in this area. This opportunity arises from the inclusion of a direct neurobehavioral assessment, the NICU Network Neurobehavioral Scale (NNNS) in the MLS-Providence/Teen database. To understand the potential value of the NNNS in building a developmental risk assessment, it is important to understand the developmental models upon which the NNNS is based; i.e., the transactional and mutual regulation models of child development.

This study examines the State of Rhode Island's Universal Newborn Screening Program's ability to identify at birth those children who were later eligible for Early Intervention services and those children who are experiencing developmental delay or behavior problems by age three. In addition, this study seeks to create a newborn screening algorithms that predict both Early Intervention eligibility and child developmental outcome by age three. This dissertation consists of four studies.

Study One investigates the predictive probability of Level One screening for Early Intervention eligibility by age three for two overlapping time frames. The first one year time frame (January 1, 1993 through December 31, 1993) was the subject of investigation for this author's masters thesis research (Ashton, 1997). The second time frame matches the Maternal Lifestyle Study (May 1, 1993 through May 31, 1995) recruitment window. The results from the previous investigation (Ashton, 1997) of the predictive probability of the Level One screening revealed that the sensitivity for Early Intervention eligibility was low (66%) while the percentage of false negatives was high (34%). These results supported the need for modifying the at-birth screening system to achieve improved sensitivity and reduced percentage of false positives. Before this effort is undertaken, the predictive probability of Level One for Early Intervention eligibility must be established for the second time frame. It is hypothesized that similar results for predictive probability will be found for Level One screening for these two birth cohorts.

Study Two investigates the utility of Level One screening to predict Early Intervention eligibility and neurodevelopmental and behavioral outcome by 36 months of age in a high-risk sample. Two predictions are investigated in Study Two. Prediction A: there will be a higher rate of individuals designated as Level One Risk-Positive in the high risk sample than in the corresponding Rhode Island population sample and a higher rate of children receiving Early Intervention services than in the corresponding Rhode Island cohort. Prediction B: For the high-risk sample, Level One Risk-Positive newborns will exhibit poorer outcome as indexed by standardized measures of child development and will be more likely to be eligible for Early Intervention than will Risk-Negative subjects.

In Study Three, two models of a newborn screening for Early Intervention eligibility are designed. The first model is one that does not rely on predictors heavily influenced by social class. The second model of Early Intervention eligibility combines both biological and parental/environmental predictors. The purpose of this study is to design new multifactor risk screening models with improved sensitivity and reduced false negatives relative to the Level One screening.

Study Four investigates the use of biological, and parental/environmental variables, and measures of infant behavior to create a prediction model of age three developmental outcome. It is hypothesized that a new risk screening algorithm could be created with improved sensitivity and

specificity over the Level One screening, and more precisely detect those children with developmental delays or behavior problems. In this study, the utility of adding infant neurobehavioral performance to reduce the percentage of false positives identified by the at-birth screen will be assessed. In this way, the measures of infant neurobehavioral performance will be used as a “triage” of the infants designated as Risk-Positive.

Historical Background

Research advances in the field of infant mental health have improved our understanding of the role of biological, behavioral, and environmental risk factors in the subsequent development of newborns. Research findings in medicine, psychology and special education also support the association between the provision of Early Intervention services (EI) and positive developmental outcomes. This body of research supports Federal legislation (Public Law 99-457 Education for All Handicapped Children Act Amendments, 1986) and recent updates (IDEA, 1997) for the provision of a comprehensive range of EI services for families with infants and toddlers who have disabilities, who are experiencing developmental delays, or who are at-risk for developmental delays if intervention is not provided.

Public Law 99-457 is a downward extension of PL 94-142 (Education for All Handicapped Children Act of 1975) that includes provision of services to families and young children with disabilities from birth. Understanding of the processes by which biological and environmental circumstances place infants at risk for adverse development is critical in the design of valid screening procedures, and should be informed by sound developmental theory and account for multiple domains of risk. Since the implementation of PL 99-457 few systematic studies were conducted examining how to accurately identify these children at birth or soon after birth and then refer those in need for further assessment and appropriate services.

This paper reviews those concepts from developmental risk research and developmental psychopathology that are fundamental to the construction of the screening algorithms described in the following pages. Also reviewed are the Federal regulations governing screening and intervention services for infants and young children, and the ways in which the State of Rhode Island has implemented these Federal Regulations.

The development and deployment of screening techniques that identify problems such as behavioral/emotional disturbances and mild cognitive delays is important in improving the physical and mental health of children. A successful screening procedure will accurately and inexpensively identify the individuals at risk for the outcome in question. At present, about 4% of RI infants and toddlers receive EI services. Aylward (1997) noted that 8% of a typical pediatric population between the ages of 2 and 6 years will experience significant developmental problems. Of United States children less than 18 years of age, 16.8% have experienced one or more developmental disabilities and 15.3 percent of these children have required special education services (Boyle, Decoufle, & Yeargin-Allsopp, 1994). The discrepancy between the numbers of children experiencing problems early and later in life is partially explained by the lack of adequate early childhood assessment measures or the nature of disabilities that manifest later in childhood (i.e., reading disabilities). One of the major objectives of preventive intervention is to ensure that all eligible infants and toddlers entitled to EI services are promptly and accurately identified, located, evaluated and have Individualized Family Service Plans developed which accurately reflect their needs. In order to achieve this goal, various avenues of child identification are essential.

Research on Developmental Risk Factors

Most risk and resiliency research of the past twenty-five years investigated either biological or environmental/psychosocial variables affecting child developmental outcome. These risk factors have been scrutinized to find factors that may predispose a child to experience later developmental delay. Questions common to this line of inquiry include the following: what are the etiologies of risk? What are the consequences of the risk factor on development? What characterizes resilient children? What are the identified protective factors? What intervention programs help ameliorate adverse developmental sequelae? Over the years research in this area has moved from the examination of single risk factors in isolated domains, to consideration of biological or environmental clusters of risk factors to multicausal risk models that include multiple factors from several domains.

Domains of Risk

In 1976, Tjossem defined three overlapping domains of risk that formed the basic nosology for subsequent research: established risk, biological risk, and environmental risk. Tjossem defined

established risk as diagnosed medical disorder with a known etiology that carries relatively well-known expectancies for subsequent developmental outcomes. Biological risk encompasses a single or collective prenatal, perinatal, neonatal or early developmental event or events resulting in injury to the developing central nervous system, thereby increasing the probability of a disability. Environmental risk includes early life experiences including child care, health care, nutrition, opportunities for expression of language, adaptive behavior, and physical and social stimulation, that increase probability of delayed development.

Biological Risk. The past twenty five years of research in risk prediction in child development have seen an expansion from the search for single biological risk factors (e.g., low birth weight) that may uniquely explain later child development to examination of multiple biological risk factors. However, biological risk factors alone adequately explained variance in developmental outcome only for severely impaired children (Sameroff & Chandler, 1975). Other research has suggested that biological risk factors are more strongly associated with developmental outcomes such as severe mental retardation than they are with more mild delay (Drews, Yeargin-Allsopp, Decoufle, & Murphy, 1995). Biological factors have been shown to account for only a small proportion of intellectually delayed children and are more strongly associated with severe rather than mild mental retardation (Sameroff & Chandler, 1975; Sameroff et al., 1987). Some studies suggest that, although early developmental outcome is more strongly associated with biological factors for medically compromised neonates, the impact of environment becomes powerful as the child ages and assessment of developmental outcomes increasingly becomes based on more sophisticated reasoning skills (Bendersky & Lewis, 1994; Brooks-Gunn et al., 1992).

In the study of low birth weight neonates, medical/biological factors have been studied in conjunction with social and environmental factors. Social and environmental risks are well known factors affecting the developmental outcome of low birth weight infants (Vohr & Msall, 1997). Vohr and Msall found that there is a high rate (44%-56%) of special education services for Very Low Birth Weight infants (VLBW, < 1500 grams & < 30 week gestation). Non-optimal medical or biological risk is associated with poor motor and perceptual developmental outcome (Aylward, 1995). Neurological findings such as hypertonicity, tremors and jerky movements may resolve by one year of age (Vohr &

Msall, 1997). Vohr and Msall also found that there are higher rates of cerebral palsy in Extremely Low Birth weight (ELBW, < 1000 grams) and VLBW cohorts.

In 1993 approximately 7% of all live births were <2500 grams and 1% VLBW (<1500 grams) (Msall, Bier, LaGasse, Tremont, Lester, 1998). Social disadvantage influences the outcome of VLBW infants and influences intelligence and academic achievement with a complex interaction. Biologically at risk infants are at greater risk if they are born into a socially disadvantaged family (Msall et al., 1998). For LBW infants, poverty, maternal education, and male gender are predictors of minor neurodevelopmental impairments and long-term educational and behavioral outcomes (Msall et al., 1998). Prenatal alcohol exposed children may display distractibility, poor organization, impulsivity, poor cooperation and less well developed spoken and written language skills (Msall, 1998). Cocaine use is often associated with other drug, alcohol, and tobacco use, medical factors and socio-demographic factors and is a marker variable for these factors. Premature, low birth weight and prenatally exposed infants experience a disproportionately large number of risk factors from biological problems, poverty and social risks (Msall et al., 1998).

Duncan, Brooks-Gunn, and Klebanov's (1994) study of low birth weight infants, supported that family income and poverty status were predictors of IQ at age 5 after controlling for maternal education, family structure, and ethnicity. They also found that poverty status at age three predicted children's IQ at age 5. SES and Income are also linked to children's socioemotional functioning but to a lesser degree than differences in their school achievement and their cognitive development.

Environmental Risk. Research on environmental risk factors has followed a similar history as the literature on biological risk, i.e., expansion from research on single risk factors to multiple risk factors in the domain. The effects of multiple environmental risks can have a profoundly negative impact on child development (Greenspan, 1982; Sameroff, Seifer, Boracas, Zax, & Greenspan, 1987). In a review of the literature, Aylward (1992) found that no single environmental factor is associated with adverse developmental outcome, and that cumulative effects of multiple risk factors increase the probability of developmental sequelae. Research has shown high stability in the number of environmental risk factors experienced by families (Sameroff et al., 1993). Poverty is the most frequently studied environmental risk factor, however, aspects and definitions of poverty vary.

Socioeconomic status is the single environmental variable with the best prediction of a child's cognitive development (Sameroff, 1998). More research on the effects of poverty is presented in the next section.

Multiple Risk. Because biological risk factors alone do not account for the wide range of developmental outcomes seen, researchers have concluded that combinations of environmental factors play the major role in producing developmental outcome (Sameroff & Chandler, 1975, Sameroff et al., 1987; Sameroff et al., 1993; Sameroff & Seifer, 1995; Seifer & Dickstein, 1993; Seifer, Sameroff, Baldwin & Baldwin, 1993). Several studies show that combining multiple risk factors leads to the more accurate predictors of outcome than can be achieved by examining single risk factors (Sameroff et al., 1987; Sameroff et al. 1993). Cumulative or multiple risk models incorporate a number of proximal and distal variables into a risk index (Rutter, 1979; Sameroff et al., 1993; Sameroff et al., 1987). If the transactional processes between multiple sources of risk are not directly investigated, it is theorized that as the number of risk factors increases the severity of adverse developmental outcome also increases. Models that utilize multiple risk factors in combination are the most successful in predicting outcome (Sameroff et al., 1987). These aggregate scales show more stability than any individual factor. Furthermore, by summing individual scores, errors of measurement decrease, thereby increasing power to detect effects. The cumulative model of Sameroff and colleagues (1987) utilizes variables that are correlates of low socioeconomic status (i.e., education, mental health, occupation, family size and support).

Understanding the processes by which economic disadvantage places children at risk for delayed cognitive and emotional development is important to inform prevention efforts (Sameroff & Seifer, 1995). In a study of social-environmental risk factors and IQ score at age four, Sameroff et al., (1987) find that a univariate risk factor cannot explain later cognitive outcome. Children living in the most disadvantaged families had the poorest development by four years of age (Sameroff & Seifer, 1995). However, the same study finds that multiple risk factors produce cumulative effects that increase the probability of adverse intellectual development. The number of risk factors rather than the nature of risk factors has also been shown to contribute to child psychiatric disorder (Rutter, 1979). Thus, for child development, the greater the number of non-specific risk factors, the higher the certainty of adverse outcome (Seifer et al., 1992). As the number of stressful life events and conditions

increases, home environments become less cognitively stimulating and preschool age children's IQ scores decrease (Sameroff, Seifer, Boracas, Zax & Greenspan, 1987).

In an examination of low income mother-infant dyad antecedents of early childhood behavior problems, Shaw and Vondra (1995) found that maternal depressive symptoms were related to behavior problems in three year old boys. One predictor assessed in this dissertation is maternal mental health problems including depression. Family adversity including low income has been shown to be predictive of behavior problems (Shaw et al., 1994).

Bendersky and Lewis's (1994) study investigated environmental and biological risk, related to two-year developmental outcome for high-risk preterm children. They found environmental risk could be broken down into family and social risk, and the standard SES measure added little to characterization of the environment as it relates to age two development. The family risk measure proved useful as a measure of environmental quality, and was as predictive as were measures of medical risk for overall two-year outcome. When the effect of medical status was removed, environmental variables accounted for much of the variance in mental development index scores and in receptive language ability but very little variance in motor scores. This finding suggested that the environment had a greater impact on cognitive skills than on motor skills. The overall conclusion was the higher the risk in the family environment, the worse the developmental outcome. Using the Bayley Mental Development Index (MDI), they found that both environmental and biological factors contributed equally to MDI outcome at 24 months. They found that biological risks were more powerful predictors of Perceptual Developmental Index (PDI) outcome. They found that environmental factors were more powerful predictors of Sequenced Inventory of Communication Development (SICD) Receptive Communication Age than biological factors. They found that relatively little of the variance in expressive language was explained by their biological and environmental risk factors model. The higher the risk, the poorer the outcome.

Early childhood internalizing and externalizing behavior/emotional problems have also been the subject of risk research. Attention processes are a modifying variable and a marker for risks of learning disabilities, behavior problems, and conduct disorders (Vohr & Msall, 1997). In an examination of low income mother-infant dyad antecedents of early childhood behavior problems,

Shaw and Vondra (1995) found that maternal depressive symptoms were related to behavior problems (as indexed by the Child Behavior Checklist) in three year old boys. One predictor assessed in this dissertation is maternal mental health problems including depression. Family adversity including low income has been shown to be predictive of behavior problems (Shaw et al., 1994). Research has also supported several predictive domains related to infant emotion regulation and preschool-age internalizing problems (Shaw et al., 1997).

Risk and Protective Factors. The interaction between risk and protective factors serves as a better predictor of developmental outcome than either alone. Lester and colleagues (1995) studied the interaction between risk and protective factors associated with poverty and their effect on developmental outcome by age four. They found that children with few risk factors and many protective factors scored the highest on measures of developmental outcome. Children with multiple risk factors and few protective factors scored the lowest among the groups across a range of developmental domains. Their results did not show a main effect for either risk or protection indicating that a simple risk scale or protection scale would not be as reliable. The interaction between risk and protective factors serves as a better predictor of developmental outcome than either alone (Aylward, 1992). Aylward considers the "risk route" concept of overall development as the product of three interrelated domains of influence: medical/biological, environmental/psychosocial, and behavioral/developmental. Aylward concludes that environmental variables most strongly influence verbal and cognitive abilities and medical/biologic risks are more strongly related to neurologic and perceptual functioning. Cognitive and communicative skills in preschool aged children are best predictors of later academic competencies (Vohr & Msall, 1997).

The analysis of multiple setting and multiple systems (Bronfenbrenner, 1979; Bronfenbrenner, 1989) is complicated by the need for multi-causal explanations of developmental processes (Sameroff & Seifer, 1995). These explanations have evolved from Bronfenbrenner's (1979) ecological model of development which supposes that child outcome is the result of the interaction among multiple ecological processes. This subsequent transactional model of development postulates that the infant's biology and caregiving environment combine to facilitate or disrupt the development of the child ultimately impacting on outcome. The transactional model places equal importance on the effects of

the child and his or her environment, and integrates environmental, biological and individual regulatory systems which influence each other to determine development at any point in time (Sameroff & Chandler, 1975; Sameroff & Fiese, 1990). One hypothesis of this model is that multiple risk factors in different combinations will affect child outcome in different ways. For example, the "goodness-of-fit" (Thomas & Chess, 1977) between characteristics of child temperament (e.g., an infant's arousal and tolerance for stimulation), parent temperament, and care-giving characteristics may facilitate healthy development or may "mismatch," resulting in childhood behavioral, social, and emotional disturbances (Seifer & Dickstein, 1993). Viewed in this light, the "goodness-of-fit" model can be seen as a more specific example of a transactional model which also views child development as a complex interaction between the child, caregiver and environment. In support of this model, Ricciutti and Scarr (1990) found that the effects of certain biological risk factors differ as a function of family/environmental risks.

Another specific example of a transactional model of child development is the mutual regulation model. The model posits that normal infant and child development is dependent on reciprocal interaction between individual regulatory potentials to control attention, affect and behavioral states, as well as on the caregiver's support of the infant's organization and regulation of behaviors (Tronick, 1989; Tronick et al., 1986). Behavioral regulation is characterized by the "Four A's of Infancy:" Attention (abilities used for processing visual and auditory stimuli), Arousal (state modulation and habituation to stimuli), Affect (regulation of social interaction) and Action (motor functioning) (Lester & Tronick, 1994). These early markers of temperament seem to be most affected by the infant's biological status. Multiple adverse biological and environmental risk factors are likely to negatively impact the biobehavioral regulation of the child; conversely maladaptive biobehavioral regulation, may negatively affect the infant's care-giving environment, including the potential of the caregiver to maintain his/her own biobehavioral homeostasis. For example, in the mutual regulation model, an infant must be able to regulate his or her arousal level in order to filter out stressful stimuli. The irritable or hypertonic infant who cannot maintain a well-organized behavioral state requires help from his/her caregivers in order to regain control. A caregiver who is well-attuned to the infant may then provide a helpful environmental armature such as swaddling which allows the infant to engage with his or her surroundings. In other instances a caregiver's efforts may further stress an infant and, in turn,

heighten the infant's level of irritability. If the infant's physical resources are expended in an attempt to regain homeostasis, he will not be able to actively engage with his environment. Significant growth and developmental consequences may result. Difficult infant temperament has been shown to be strongly related to both internalizing and externalizing behavior problems at age three (Shaw et al., 1994). Conversely, infants at little or no biological risk and who are good early-regulators, can elicit caregiving that promotes healthy development.

Screening for Developmental Risk

Effective screening for developmental risk should combine sensitivity and specificity with relative risk, and understand patterns of symmetry among cognitive, motor, language, and psychosocial domains (Aylward, 1997). With greater understanding of risk, resiliency, interactive and outcome processes, the field is now looking toward developing more sophisticated risk screening and assessment models for the purposes of prevention and intervention of increasingly specific outcomes. Infant neurobehavior and neurological profiles may also be assessed soon after birth to determine the infant's CNS function, attention/cognition/information processing, arousal/reactivity, regulation, and motor functioning. Infant and child regulatory capacities can place the individual at risk for negative infant-child/caregiver interactions. Prenatal drug exposure is likely to affect the regulation of attention, arousal, affect, and sociality (Lester & Tronick, 1994a). Regulatory processes need to be assessed in concert with environmental factors. Prenatal drug exposure may be a marker variable for multiple risk factors including poverty, poor nutrition, and a chaotic home environment.

Researchers have concluded that specific forms of dysfunction are usually associated with many different risk factors, and diverse disorders share fundamental risk factors in common (Coie, Watt, West, Hawkins, Asarnow, Markman, Ramey, Shure, & Long, 1993). Exposure to several risk factors has cumulative effects. Cumulative risk analyses have been designed to identify who is at risk and to what degree. Single environmental risk factors rarely explain large proportions of outcome variance although single factors are often statistically associated with differences in outcome. Combining risk factors allows for gains in predictive power with more risk factors being associated with larger percentages of negative outcome. Sameroff and colleagues (Sameroff, Seifer, Boracas, Zax, & Greenspan, 1987; Sameroff, Seifer, Baldwin, & Baldwin, 1993) examined the association between

multiple risk and intellectual and mental health outcomes. They found that families in the low risk group did not have any children in the low cognitive functioning group (IQ below 85). However, families in the high risk group had 24% of children with IQ scores below 85 at age four, and 44% below 85 by age 13. This research supported that it mattered more how many risk factors were present rather than the specific nature of the risk. Prevention programs are ideally designed from research on developmental risk and protective factors.

Public Policy

In 1997 Congress enacted Part C (previously Part H) of Public Law 105-17 (the Individuals with Disabilities Education Act (IDEA) Amendments of 1997) in part to require individual states to design and implement comprehensive services for families with infants and toddlers who have disabilities or who are experiencing developmental delays. Part C also mandates states to locate and identify all children, birth through age two, who have disabilities or who are experiencing developmental delays in order to promptly and accurately identify children who are in need of further evaluation. Thus, a pressing economic and political need also motivated States to improve the ability to screen for these individuals. Early diagnosis and treatment of developmental delay and risk conditions impacts the ultimate outcome of those children. Identification of newborns with disabilities or at risk for delays through universal screening for developmental challenges is a critical first step in providing Early Intervention (EI) services to promote optimal infant and toddler development. Part C provides states with financial incentives to develop and deliver a range of comprehensive and coordinated programs of early intervention resources and services for disabled infants and toddlers from birth through their third birthday. Services are provided to children who are experiencing a developmental delay or who are diagnosed with a condition with a high probability of resulting in a developmental delay. Financial assistance is also available through Part C, at the individual state's discretion, to provide services for children who are at-risk for developmental delay due to environmental or other factors if intervention is not provided.

The development of screening techniques, applicable in infancy and early childhood, which can identify high-incidence, low-severity problems such as behavioral/emotional disturbances and mild cognitive delays are important in improving the physical and mental health of children. A successful

screening procedure will accurately and inexpensively identify the individuals at risk for the outcome in question. At present the percentage of Rhode Island infants and toddlers who receive EI services is around 3.5%. However, an average of 12% of children ages 3-21 receive special education services (Meisels & Wasik, 1990). The discrepancy between those numbers is partially explained by the lack of adequate early childhood assessment measures or the nature of disabilities that manifest later in childhood (i.e. reading disabilities). One of the major objectives of preventive intervention is to ensure that all eligible infants and toddlers entitled to EI services are promptly and accurately identified, located, evaluated and have an Individualized Family Service Plan developed which accurately reflect their needs. In order to achieve this goal, various avenues of child identification are essential. Understanding of the processes by which biological and environmental circumstances place infants at risk for adverse development, is critical in the design of valid screening procedures. Because IDEA Part H (now Part C) compels individual states to develop programs for the detection of infants and young children with potential developmental delay, beginning in 1992 Rhode Island Department of Health/Division of Family Health has implemented a Universal Newborn Screening program to identify those children in need of EI services.

Early Intervention

Much research has been conducted to assess the positive impact of Early Intervention services on developmental outcomes. Overall, results show that Early Intervention programs can produce modest to large effects on children's cognitive and social development (Ramey & Ramey, 1998). There is a great deal of variability among programs and in research methodology. Ramey and Ramey (1998) examined many studies of the effects of Early Intervention and described six principles associated with positive developmental outcomes. The first of these principles is that programs that start early in the child's life and last longer are more effective than those that start at an older age and do not last as long. Second is the principle of program intensity. More intensive programs produce greater positive effects than do less intensive program interventions. Third is the principle of direct versus intermediary provision of learning experiences. Direct educational experiences demonstrate larger and longer lasting benefits for children than indirect services such as parent training only. Fourth is the principle of program breadth and flexibility. Early Intervention programs that provide more comprehensive services

produce larger effects than more narrowly focused programs. Fifth is the principle of individual differences in program benefits. Individual children respond differently to the same program and that these individual differences may be related to factors of the children's initial risk status. Sixth is the principle of ecological dominion and environmental maintenance of development. The "initial positive effects of Early Intervention will diminish to the extent that there are not adequate environmental supports to maintain children's positive attitudes and behavior and to encourage continued learning in school" (Ramey & Ramey, 1998, p. 117).

Guralnick (1998) compared results from many scientifically rigorous research studies evaluating the effectiveness of Early Intervention programs on cognitive development. He found a general decline in the course of intellectual development for children at risk [.5 to 1.5 standard deviations (SDs) based on control group data], and for children with established disabilities (.5 to .75 SDs or approximately 8 to 12 IQ points) if Early Intervention services were not provided. Unequivocal evidence has been presented that these declines can be substantially reduced by Early Intervention services provided during the first 5 years of life. Overall, the decline in cognitive development was substantially reduced for children at risk and for children with established disabilities who participated in comprehensive Early Intervention programs.

The long-term impact of Early Intervention services remains an issue of debate. Gains in intellectual development have been shown to fade over time (Guralnick, 1998) after the end of the program. Ramey and Ramey's (1998) sixth principle supports that environmental supports must remain in place to maintain the positive effects of Early Intervention. Non-cognitive long-term benefits of Early Intervention have been shown such as better school attendance, reduced grade retention, special education service placements, and rates of juvenile delinquency (Guralnick, 1998). Guralnick proposes that Early Intervention programs must be intensive in both comprehensiveness and duration, and specific for the population being served. Some comprehensive intervention projects such as the Abecedarian Project have continued to demonstrate long-term cognitive benefits for the intervention group compared with the control group (Campbell & Ramey, 1994). Guralnick (1998) and Ramey and Ramey (1998) support that timing may be very important for the best impact of Early Intervention on

short and long-term positive effects. Specifically, intervention programs must be initiated at the earliest time possible and continued through intensive programs to achieve positive long-term outcomes.

Identifying newborns at risk through universal screening for developmental challenges is a critical first step in providing Early Intervention (EI) services to promote optimal infant and toddler development. Rhode Island's Universal Newborn Screening program is unique in that it screens all families at birth for developmental risk factors rather than only for targeted populations (e.g., low birth weight, low SES). This screening and tracking program continues through transition from EI to preschool special education services. However, its utility as a first stage screening program is hindered by inadequate sensitivity. Previous research has shown that combinations of biological and psychosocial variables are predictive of later child outcome (Sameroff & Chandler, 1975; Sameroff & Seifer, 1995). Delineation of the patterns of interaction among biological, behavioral and environmental factors will greatly improve our ability to estimate risk and resiliency during early childhood development, and will inform the design of theoretically valid screening instruments.

Rhode Island's Universal Newborn Screening Program

Concordant with the objective of population-wide screening, the Rhode Island Department of Health, Division of Family Health (RIDOH/FH) developed the Universal Newborn Screening program that has been part of state policy since 1992. RI's Early Intervention Program, including Universal Newborn Screening (UNS), is administered through an Interagency Agreement sponsored by RIDOH/FH, the lead agency for IDEA, Part H (now Part C). The UNS program gathers infant and family information that provides risk disposition data for two levels of screening known as Level One and Level Two. The Level One algorithm is a subset of UNS information abstracted into a weighted, multifactor screening model that utilizes both biological and psychosocial variables. Level One screening is conducted in all RI birthing hospitals by Maternal and Child Health (MCH) visiting nursing staff. All RI infants are screened at birth (99.9% capture rate) from a chart review of perinatal medical record. The current Level One screening algorithm evaluates all newborns and assigns one of three Risk Disposition categories, i.e., Risk-Positive, Risk-Suspect, and Risk-Negative. The primary goal of this screening is to identify infants and families in need of a multidisciplinary team evaluation by an EI program and to assess the other needs of families in order that referrals to appropriate agencies may be

made. Level One identifies infants who automatically qualify for Early Intervention referral through state Early Intervention eligibility guidelines or may lead to immediate referral for comprehensive in-home Level Two screening. Through interview and direct observation Level Two screening gathers information on the infant's developmental competence, family strengths, needs, support systems and the quality of the caregiving environment. This information helps inform decisions about family referral to appropriate community-based agencies including Early Intervention. In 1995 there were 14,380 newborns screened in RI, of which 5,764 (41.1%) had positive risk factors indicating the need for referral directly to EI or for follow-up through home visiting. Of this cohort only about 3.5% of newborns required subsequent EI services.

Level One Screening

The Level One Screening was developed by the Rhode Island Department of Health, Division of Family Health and has been part of State policy since June, 1992. Level One Screening uses discrete infant and family characteristic variables assumed to be useful in determining risk abstracted from empirical and clinical literature. The Level One data collection instrument contains parental demographic variables, infant-centered characteristic variables (e.g., metabolic diseases, hemoglobinopathies, and hearing problems), parent-centered characteristic variables, and prenatal care information. The perinatal Level One Screening instrument is designed in part to help determine which infants have certain diagnosed conditions known to result in developmental problems and which infants are experiencing a combination of factors which place an infant at increased risk for having a developmental delay. Identified children are referred for a more detailed evaluation. The Level One screening is also the initial step toward enrollment in Rhode Island's Early Intervention Program.

Risk refers to the likelihood that a given event, usually a negative one, will occur (Molfese, 1989). Effective follow-up procedures for at-risk infants are very important to improve the physical and mental health of these children (Allen, 1993; Parkyn, 1985). In 1995, the State of Rhode Island screened 14,380 children. A large proportion of infants (5,764; 41.1%) had a Risk-Positive disposition indicating the need for follow-up through home visiting, and 1,739 (12.1%) had a Risk-Suspect disposition. Two hundred sixty-three new cases, or approximately 3.5% of the 7503 screened, were referred to Early Intervention programs.

The Level One Screening data form the foundation of the Rhode Island Children's Access Program (KIDS NET). KIDS NET is a tracking and outreach system designed to go beyond assessment and referral, integrating UNS, outreach, home visiting, and follow-up through an automated tracking system and a coordinated, comprehensive follow-up system. Several Rhode Island Health Department divisions, other state agencies, and children's services primary providers collaborate on the KIDS NET program. Universal newborn screening (Level One), and KIDS NET are Maternal Child Health Title V funded programs.

Level One risk criteria. Specific child and family characteristics are used to place an infant into one of three categories at birth: risk-positive, risk-suspect, or risk-negative. The criteria for a Risk-Positive disposition include any one of the following:

- Developmental Disabilities or certain other Known Established Conditions
- Birth weight less than 1500 grams (3.3 lb.)
- Intensive care hospitalization greater than 48 hours

or, any two of the following:

- Caregiver's education less than 11th grade
- Mother's age less than 19 or greater than 37
- Single caregiver living with child
- Number of children in mother's home greater than 5 or 0
- A parent characteristic, e.g., chronic illness, developmental disability, mental illness, substance abuse, Department of Children Youth and Families (DCYF) involvement
- Fewer than 6 prenatal care visits before 36 week or total number less than 10
- Absence of prenatal care visits before 5 months
- Gestational age greater than 37 weeks and birth weight 1500 - 2500 grams (3.3 - 5.5 lb.)
- Apgar scores less than 7 at 1 and 5 minutes

Any one of the above indicates a Risk-Suspect determination. Clinical information is included in the determination. When no child or parental Risk-Positive factors are identified at birth, a Risk-Negative disposition results.

Level Two Screening

A Level One Risk-Positive determination calls for an automatic referral for Level Two screening and can also trigger automatic referral to Early Intervention for children with single established conditions. Level Two screening is an in-home screening, which is a comprehensive process that includes gathering information on the child's developmental competence, family strengths, needs and support systems, and the general quality of the caregiving environment. The primary goal of this evaluation is to identify children and families in need of a multidisciplinary team evaluation by an Early Intervention program or to refer the families to other appropriate agencies. Other Level One disposition decisions may be made by the nurses for a risk-positive disposition, including: no evidence of child or family risk and Level Two Screening is not recommended; Level Two Screening not recommended, but referral to other programs is recommended based upon identified needs. A visiting nurse conducts the Level Two Screening as part of the Family Outreach Program. A primary care provider may also refer for Level Two screening directly. An infant determined to be Risk-Suspect may require Level Two Screening, surveillance and/or program referral with a review date in three to six months.

Many studies have addressed issues related to the validity of perinatal risk scales in predicting infant morbidity and mortality, as well as predicting behavioral measures obtained during the neonatal period, later infancy and early childhood (Molfese, 1989). The most successful measures predicting developmental problems in early childhood, are those which combine child-centered characteristics and environmental factors (Allen, 1993; Haber, 1991; Meisels & Wasik, 1990; Parkyn, 1985; Sameroff & Fiese, 1990; Shonkoff & Hauser-Cram, 1987). Single-factor approaches, e.g., birth weight alone, are not recommended. Benn conducted an extensive review of research related to 27 biological and environmental risk conditions to determine criteria for eligibility for Early Intervention services in the State of Michigan. "In general, this review revealed no definitive information as to which risk factors, in and of themselves, were most predictive of developmental delay" (Benn, 1993, p.32).

Eligibility for Rhode Island Early Intervention Services

Eligibility for Rhode Island Early Intervention is based upon information as determined by a MDT evaluation using standardized instruments, caregiver interview and clinical observation. Infants and toddlers are eligible for Early Intervention if they are experiencing one or more delays in specific

developmental domains. These domains are cognition, physical development (including vision and hearing), communication, adaptive, and social or emotional development. Young children are also eligible if they have a diagnosed physical or mental condition known to result in a developmental delay or disability. These discrete diagnoses are referred to as single established conditions (e.g., Down Syndrome). The RIDOH did not choose to serve all children “at risk,” but did define a constellation of factors which occurring together make a child eligible for Early Intervention. These constellations of risk factors are known as multiple established conditions. Multiple established conditions include diagnoses, events and conditions that, in combination, have a high probability of resulting in developmental delay.

States must concretely define eligibility for Early Intervention according to criteria set forth by IDEA Part C. Infants and toddlers are eligible if they are experiencing one or more delays in specific domains of development as determined by qualified personnel. These domains encompass cognition, physical development (including vision and hearing), communication, adaptive, and social or emotional development. Young children are also eligible if they have a diagnosed physical or mental condition known to result in a developmental delay or disability (i.e., a Single Established Condition).

IDEA Part C also allows, at the state’s discretion, services to children who are “at risk” of having developmental delays if Early Intervention services are not provided. The lead agency responsible for Early Intervention, The Rhode Island Department of Health, does not serve the “at risk” population but does define a constellation of factors which occurring together allows for eligibility, i.e., multiple established conditions. These include diagnoses, events and conditions that, in combination, have a high probability of resulting in developmental delay.

Children eligible for Early Intervention services include all infants and toddlers, birth through their third birthday, who have received a multidisciplinary team evaluation and meet the following criteria:

- 1) Developmental Delay: Children who are experiencing significant developmental delays (25% delay or greater than or equal to 2 SD below the mean in one area, or 1.5 SD below the mean in 2 areas) in one or more developmental domains of cognition, communication development, physical development including vision and hearing, social or emotional, or adaptive development. Delays may

be evident with or without an established diagnosis or known etiology, as measured by multi-disciplinary evaluation. Specific diagnoses accompanied by delays are sufficient but not necessary for eligibility determination.

Multiple and Single Established Conditions: Children are eligible who have a diagnosed physical or mental condition which has a high probability of resulting in developmental delay. These diagnoses apply to all conditions with known etiologies and adverse developmental consequences. Children may not necessarily be demonstrating significant delays at the time of referral to Early Intervention and subsequent eligibility determination. Established conditions may include single established conditions or multiple established conditions. Both criteria must result in a high probability of developmental delay or adverse developmental consequences. Examples of single established conditions include chromosomal anomalies or genetic disorders, inborn errors in metabolism, infectious diseases, neurological disorders, central nervous system congenital malformations, sensory disorders, or fetal alcohol syndrome. To meet the criteria of multiple established conditions guidelines are used which include four or more positive findings considered sufficient to deem a child eligible for early intervention services. A representative list of conditions includes child-centered conditions such as feeding difficulties, low birth weight, sleep disturbances, prematurity, etc., and parent-centered conditions such as mother's age less than 19, developmental disabilities, parental education level less than 10th grade, substance addiction, no/inadequate prenatal care, etc.

Summary

The research on screening for developmental risk has moved from a focus on isolated biological or environmental factors to a consideration of multiple factor models and the ways in which individual and environmental factors interact to produce developmental delays and disabilities. Although public policy demands a broad based and accurate identification of children at risk, the research on the effectiveness of state's attempts to achieve this end has been limited. The Rhode Island Universal Newborn Screening database provides the raw material for the systematic analysis of one state's attempts at compliance with Federal law for Early Intervention.

Method

Subjects

Subjects were selected from three different data sets: the State of Rhode Island Level One Universal Newborn Screening (UNS) database, the state's Early Intervention Exchange of Information Operation (EIEIO) database, and the Maternal Lifestyle Study (MLS) Providence and Teens samples (MLS-PT). Universal Newborn Screening including the Level One risk designations and EIEIO data were provided by the Rhode Island Department of Health/Division of Family Health, Office of Data and Evaluation. The Universal Newborn Screening (UNS) program has a 99.9% capture rate of all births in Rhode Island. MLS and EIEIO are comprised of prospectively gathered cohort data. This dissertation is an ancillary project of the multi-site Maternal Lifestyle Study (Principal Investigator – Barry Lester, Ph.D.). This study assesses two cohort time frames. Time Frame A: January 1, 1993 through December 31, 1993 and Time Frame B: May 1, 1993 through May 31, 1995. Subjects from the UNS and EIEIO databases were included if date of birth fell within the two study time frames.

Universal Newborn Screening. The subjects include all (99.9%) newborn Rhode Island residents delivered in any one of the eight birthing hospitals (Time Frame A: N=13,379, Time Frame B: N=27,282) during a three year time frame from May 1, 1993 through May 31, 1995. Universal Newborn Screening has a capture rate of 99.9% of all live births in Rhode Island. Infants who were born in Rhode Island but who were not Rhode Island residents were excluded from this study since they would be more likely to receive intervention services through their home state.

EIEIO. Early Intervention information was utilized for both time frame birth cohorts. During time frame A 807 children were included in the Early Intervention database. For time frame B there were 1,793 children reported in the EIEIO database. EIEIO was designed, in part, to provide information for Rhode Island State and Federal reporting requirements, standardized documentation and data reporting, resource and funding analyses and EI program effectiveness. The present study utilizes a very small fraction of available information.

Maternal Lifestyle Study. Child outcome information was provided by the Maternal Lifestyle Study. MLS is a National Institutes of Health developed and funded prospective study of prenatal substance exposure and child developmental outcome, supported in conjunction with National Institute

of Child Health and Human Development, National Institute of Drug Abuse, Administration on Children Youth and Families, and Center for Substance Abuse Treatment. MLS is a large, multi-site cohort study of infants exposed to cocaine/opiates compared to a non-cocaine/non-opiate exposed group at birth and after discharge from their initial hospitalization.

MLS screened 19,079 mothers from May 1993 to May 1995 at four clinical centers (Brown University, University of Miami, University of Tennessee, and Wayne State University). Of 11,811 eligible mothers who consented to study participation, 1185 (10%) infants were identified as substance exposed (MLS Phase I). The Brown University site screened 4,942 infant-mother dyads resulting in 3,338 (72%) enrolled in MLS Phase I. For MLS Phase II longitudinal outcome study, the Brown University site is following 211 mother-infant dyads in addition to 100 teenage mother-infant dyads recruited in parallel. The specific substance exposure status of these subjects is unknown to this author. Approximately half of the 211 MLS-P subjects are substance exposed. The teenage mothers did not use cocaine during pregnancy, however, some did use tobacco, alcohol and marijuana. This cohort of children is being followed through school age. Infants were excluded from Phase I if they were unlikely to survive, were multiple gestation, had a congenital anomaly, chromosomal abnormality or TORCH infection, or if their mothers were institutionalized or exhibited psychosis. Other exclusionary criteria included parental refusal, unavailability of mother, maternal language problem, or sibling in study. Spanish speaking interpreters were available for Spanish speaking mothers. The MLS screening plan included screening infants from 23 through 42 weeks gestational age and sought to enroll a sample of infants with a distribution of birth weights from less than 1500 grams (12%) to over 2500 grams (60%). Although the MLS is studying the effects of prenatal substance exposure, the specific exposure status of subjects was unknown to this investigator.

Cross-Matched Sample. By matching individuals in the UNS and EIEIO databases by mother's and child's names and dates of birth, a subset of children who existed in both databases was identified. Of the 13,375 infants born in RI during time frame A (January 1, 1993 through December 31, 1993), 807 were referred to an Early Intervention program at some point before their third birthday. During time frame A, 582 individuals were uniquely cross-matched and 499 were eligible for Early Intervention services. During time frame B (May 1, 1993 through May 31, 1995) 1793 were referred to

an Early Intervention program and 1523 individuals were identified who uniquely existed in both databases. Of the 1523 individuals matched, 1173 were eligible and enrolled in Early Intervention. Some records could not be uniquely matched between the Level One and EIEIO databases because of incomplete identifying data, duplicate records, and other reasons (e.g., immigration into the state, name changes after birth).

A subset of children whose data existed in the UNS, EIEIO and MLS databases were identified by matching individuals by mother's and child's names and dates of birth. This was done for Time Frame B only. During the MLS recruitment time frame (May 1, 1993 through May 31, 1995), 1,793 children were referred to an Early Intervention program and 1,523 individuals were identified who uniquely existed in both databases. Of the 1,523 individuals matched, 1173 were eligible and enrolled in Early Intervention. Some records could not be uniquely matched between the UNS and EIEIO databases because of incomplete identifying data, duplicate records, and other reasons (e.g., immigration into the state, name changes after birth). Of the 311 children in the MLS-Providence and Teen samples, 285 were successfully matched with UNS data (MLS-PT). One hundred eighty seven children were matched out of the 211 MLS-Providence sample and 98 out of 100 for the Teen sample. The unmatched individuals represent mother/infant dyads who live in neighboring states but were born in Rhode Island.

Not all children who are referred to an Early Intervention program for an evaluation are determined eligible or have parents who agree to an evaluation or Early Intervention services. Approximately 85% of children evaluated by an Early Intervention program are eligible for some type of Early Intervention service of which 5% of parents refuse services. A very small percentage of children evaluated for Early Intervention are found not eligible for services (2%) however, an estimated 8% of children are referred out for other services. Most of the children that are referred to Early Intervention just before their third birthdays are then referred to their local education agency. Not all of the children receiving Early Intervention services could be matched to corresponding Level One data. Some of these children were not born in Rhode Island and others may not have been matched due to data entry errors of birth date or name changes. After information from the three databases were linked, child and mother's names were permanently deleted from the data files used in this study.

Demographic Characteristics. Infant and parental characteristics of the two study time frame samples are shown in Table 1.

Table 1

Infant and Parent Characteristics for the Rhode Island Cohorts and MLS-PT Cohort

		Time A % N= 13,379	RI Cohort % N = 27,282	MLS-PT % N = 285
Mother's age	Less than 19	6.9	7.1	37.2
	19 to 37	89.2	88.7	59.9
	38 or older	3.9	4.3	3.0
Mother's marital status	Married	64.5	64.8	19.3
	Single	31.0	31.0	73.7
	Other	4.5	4.3	7.0
Mother's ethnicity	White	75.9	78.3	50.4
	Black	7.5	7.3	26.8
	Hispanic	10.7	11.1	20.1
	Other	5.9	3.2	2.9
Mother's education	≤ 8 th grade	5.9	5.0	12.1
	9 th to 11 th grades	15.1	14.1	39.5
	≥12 th	78.9	80.9	48.4
Father's education	≤ 8 th grade	3.0	2.9	2.9
	9 th to 11 th grades	10.5	9.9	19.7
	≥12 th	70.9	72.6	47.1
	Unknown	15.6	14.6	30.5
Birth weight	<999 g	.6	.6	1.4
	1000 – 1499 g	.5	.5	2.5
	1500 – 1999 g	1.3	1.1	4.2
	2000 – 2499 g	4.3	4.1	13.8
	>2500 g	93.3	93.7	78.1
Gestational age	< 37 weeks	8.0	7.9	23.2
	≥37 weeks	92.0	92.1	76.8

These data show that the majority of mothers were white, aged 19 to 37, married, and at least high school graduates. More than 64% of mothers are married. More than 6% of infants weighted less than 2500 grams at birth and 8% were born prior to 37 weeks gestational age. The majority of mother's and father had reported education levels of at least high school graduates. The unknown rate of father's education level is included because it is substantial. Information regarding mothers and infants have very low rates for missing or unknown with the exception of parental risk factors. Universal Newborn

Screening also gathers information on other parental risk factors. Parental risk factor information includes: chronic illness, substantiated child abuse/neglect [confirmed Department of Children Youth and Family (DCYF) involvement], developmental disabilities, inpatient and outpatient mental health history, substance abuse history, or other pertinent psychosocial information. Very large percentages of missing/unknown information were identified for these variables for both mothers and fathers (over 95%). Missing/unknown information is due to the UNS data being abstracted from current hospital and obstetric records, where this information is often not included.

The high-risk MLS Providence and Teen (MLS-PT) sample is not representative of the general Rhode Island population sample of newborn-mother dyads (Time Frame B). The distribution of subject characteristics for the two samples is shown in Table 1. The MLS-PT sample compared with the Rhode Island sample, has fewer Caucasian mothers (50% vs. 78%), and has more teenage mothers (37% vs. 7%). The MLS-PT mothers are more likely to be single and are less well educated, both of which was due in part to younger maternal age because of the high percentage of teenage mothers. Striving for a greater percentage of smaller newborns than is representative of the normal population was part of the MLS recruitment design, thus the MLS-PT sample has a larger percentage of premature newborns. The MLS recruitment criteria resulted in a difference between the MLS-PT sample and the Rhode Island sample in terms of certain known established conditions and parental risk factors (e.g., chromosomal abnormalities and maternal psychosis).

Prediction Measures

Universal Newborn Screening. Universal Newborn Screening including Level One screening is a population-based effort developed in Rhode Island and endorsed by an Interagency Agreement. This process begins with the birth of an infant. Information is gathered on the infant and his or her family then decisions are made regarding the need for follow-up services upon discharge from the hospital or direct referral to Early Intervention. Decisions of risk designation are first made through a computer risk algorithm and then reviewed by nurses to include any clinically relevant information. This Level One screening (reviewed in detail below) is conducted in all Rhode Island birthing hospitals by Maternal and Child Health staff and may serve as an entry point to Early Intervention for infants with established conditions. Infants with a Risk-Positive designation are followed after discharge.

Follow-up screening, known as Level Two screening, is comprised of an in-home evaluation conducted by Maternal and Child Health staff in the Family Outreach Program. In-home Level Two screening is a comprehensive process that includes information on the child's individual developmental competence, as well as the family's strengths, needs, support systems, and the overall quality of the caregiving environment. One of the goals of the screening is to identify children and families in need of a multidisciplinary team evaluation by an Early Intervention program. Level Two screening also assessed whether or not referral to other appropriate agencies should be made. After Level Two screening is completed, families with unmet needs are presented at an interagency case review meeting. This multidisciplinary committee meets regularly to review the identified needs and make appropriate referrals. Direct referrals are also made to Early Intervention programs by families, health care professionals, childcare providers, and other sources. A standard referral process has been instituted and information is shared with all primary referral coursed to encourage referrals to Early Intervention.

Universal Newborn Screening gathers a great deal of information on all infants born in Rhode Island. A subset of these UNS variables makes up the Level One screening. The following variables were identified among the variables assessed during the Universal Newborn Screening. Each variable was selected on the basis of the scientific literature supporting the variable's potential negative impact on child development or because the factor was included in the current Level One screening. In some cases the cut-points or criterion of the predictor variables differ from the criteria used in the Level One screening based upon a review of cut-points used in similar scientific literature.

Birth weight. Three birth weight variables are used in this study. Very low birth weight (< 1500 grams), and low birth weight (<2000 grams or < 2500 grams). The criteria for both low birth weight and very low birth weight are commonly found in the literature (e.g., Msall, Bier, LaGasse, Tremont & Lester, 1998, Rogers & Graves, 1993). The classification for very low birth weight is the criterion used to represent risk in the Level One screening.

NICU Hospitalization. NICU hospitalization greater than 48 hours is the criterion for risk of hospitalization included in the Level One screening.

Small for Gestational Age. Small for gestational age (SGA) is based upon the Level One criterion to represent risk. This criterion is gestational age greater than 37 weeks and birth weight between 1500 – 2500 grams.

Apgar Score. Rather than use the Level One criterion of Apgar score less than seven at one and five minutes. This analysis incorporates another Apgar risk variable based on the medical literature. In this variable, risk is indicated by a five minute Apgar score less than seven (Blackman, 1988; Rogers & Graves, 1993). The Apgar scoring system measures the effect of several complications of labor and delivery on the newborn and helps indicate the need for resuscitation at birth. The Apgar score has a long history of use as a predictor of later child disability, however it has significant limitations as a predictive measure for this purpose. Although a normal Apgar score is highly predictive of normal neurodevelopment, a low score is less predictive of later developmental problems (Batshaw, 1997).

Known Established Conditions. This variable is part of the Level One risk algorithm. The Maternal Lifestyle Study excluded infants from enrollment if they had certain established conditions such as chromosomal anomalies/genetic disorders, inborn errors in metabolism, or TORCH infections. Therefore this risk factor will continue to include central nervous system congenital malformations, other infections diseases, and substance exposure. A summary variable was created indicating presence/absence of a known established condition.

Maternal Age. Maternal age was first stratified into three groups based on age at the time of the child's birth: Mothers less than 19 (risk), 20 through 37 (no risk), and 38 and older (risk). This criterion is that specified in the Level One algorithm. Mother's age was then dichotomized into teenage (<18) or older mothers (>= 18) variable for further investigation.

Parental Education. Parental education was classified based on the Level One criterion to indicate risk: education levels less than 11th grade, make up the risk group.

Single Mother. Mother's marital status was dichotomized into either married or single (single, separated, divorced, or widowed). This classification is based on Level One criterion to represent risk.

Family Size. The number of children in the family was based upon criterion used by Sameroff, Seifer, Boracas, Zax, and Greenspan (1987). Families with 4 or more children were placed in the risk

group. A large number of children in the family may create a competition for social and physical resources and thus be a risk factor for intellectual competence. The Level One criterion for family size risk is greater than 5 children in the home or no previous births to mother (this infant is her first child).

Prenatal Care Visits. Risk of inadequate prenatal care was defined by the Level One criteria as less than six prenatal care visits before 36 weeks or total number of visits less than 10.

Prenatal Care Visits Before 5 Months. A second variable indicating risk of inadequate prenatal care is also included in the Level One algorithm: no prenatal care visits prior to the fifth month of pregnancy.

Parental Risk Factors. The parental risk factors include: parental developmental disability, chronic illness, substance abuse history, Department of Children Youth and Families (State protective services) involvement, parental inpatient or outpatient mental health treatment, or other risk factor. Any one of these factors indicates a parental risk characteristic. This classification is based on Level One screening criterion. Parental mental illness is part of the Level One criteria for parental risk, however, maternal psychosis was an exclusionary factor for the Maternal Lifestyle Study recruitment.

Delivery. This variable is not currently included in the Level One risk algorithm. Risk criterion was dichotomized into vaginal birth (no risk) or risk (cesarean, forceps, or vacuum extraction).

Feeding. This variable is not currently included in the Level One risk algorithm. Type of feeding method was dichotomized into breast fed (no risk) or bottle fed (risk). Including this variable is based on the health and economic benefits of breastfeeding (Splett & Montgomery, 1998).

Level One Screening. The risk status of newborns is evaluated using the Rhode Island Universal Newborn Screening Level One risk criteria. The Level One screening, developed by the Rhode Island Department of Health, includes discrete infant and family variables abstracted from the professional literature, from both empirical evidence and clinical perceptions, to be useful in determining risk status. The Level One screening is a neonatal screen designed in part to help determine which infants have certain diagnosed conditions known to result in developmental problems, and which infants are experiencing a combination of factors which places the infant at increased risk for developmental problems. Identified children are referred for a more detailed evaluation. The Level One screening is also the initial step toward enrollment in Rhode Island's Early Intervention programs.

Level One is weighted, multifactor instrument contains parental demographic and psychosocial variables, and infant-centered biological variables. Specific child and family characteristics are used to place an infant into one of three risk disposition categories at birth: Risk-Positive, Risk-Suspect, or Risk-Negative. The screening procedure is designed to identify and ensure timely and appropriate follow-up for those infants at risk for developmental and behavioral problems. Universal Newborn Screening Level One has been Rhode Island Department of Health policy since June, 1992.

The Risk-Positive disposition is determined if there is any One of the following factors:

- Known Established Conditions*
- Birth weight less than 1500 grams
- Intensive care hospitalization greater than 48 hours

or any Two of the following factors:

- Caregiver's education less than 11th grade
- Mother's age is less than 19 or greater than 37
- Single caregiver and child lives with that parent
- Number of children in mother's home is greater than 5 or 0
- Parental risk characteristic**
- Less than 6 prenatal care visits before 36 week or total number less than 10
- No prenatal care visits before 5 months
- Gestational age greater than 37 weeks and birth weight 1500 - 2500 grams
- Apgar scores at 1 and 5 minutes, less than 7

* chromosomal anomalies/genetic disorders, inborn errors in metabolism, infectious diseases, neurological disorders, central nervous system congenital malformations, sensory disorders including vision and hearing, and toxic exposure

** parental developmental disabilities, inpatient or outpatient mental health care, substantiated child abuse/neglect, substance abuse history, chronic illness or other significant parent risk factor

Any One of the above indicates a Risk-Suspect determination. Clinical information may be included in the risk determination.

The Risk-Positive determination calls for an automatic referral for Level Two screening and can also trigger automatic referral to an Early Intervention program for children with single established conditions. Other disposition decisions may be made by the nurses for a Risk-Positive disposition. It may be decided that there is no evidence of child or family risk and Level Two Screening is not recommended. If Level Two Screening is not recommended, referral to other programs may be

recommended based upon identified needs. Risk-Suspect infants may require surveillance and/or program referral with a review date in three to six months. The Risk-Negative dispositions results when no infant or parental risk positive factors are identified at birth.

The Universal Newborn Screening Level One procedure produces two risk disposition categorizations for each infant. One is automatically generated by a computerized algorithm, the other by visiting nurse personnel (VNA). The computer calculated risk disposition code for each infant is reviewed by the nurse who enters the information who then reviews any other relevant clinical information and records his or her risk disposition categorization. Both of these categorizations are present in the final Level One infant record. The VNA risk disposition categorization is used for determining what follow-up services if any are needed for each newborn. Results of the nurse's risk designation triggers referral to Early Intervention or other services. For this study, the nurse's risk designation is utilized. The Risk-Positive newborns are followed-up either by direct referral to an Early Intervention program or for Level Two screening. The Risk-Suspect newborns are only referred for a Level Two evaluation if a case review process reveals some compelling reason to do so.

Predictor Measure of Infant Neurobehavior. The neurobehavioral status of infants was assessed at age one month using the NICU Network Neurobehavioral Scale (NNNS) (Lester & Tronick, unpublished manuscript). The NNNS was designed to assess three components of neurobehavioral function: neurologic, behavioral, and stress or abstinence in substance exposed infants. The neurologic aspect includes passive and active tone, primitive reflexes, and items that reflect central nervous system integrity and maturity of the infant. The behavioral aspect includes items from the Brazelton scale with modified scoring (Brazelton, 1984). The stress or abstinence from withdrawal symptoms aspect is a list of items marked "yes" or "no," organized by organ system that indicates stress or abstinence from withdrawal symptoms. These items are based on the work of Finnegan (1984). The NNNS examination starts with a period of pre-examination observation, and is followed by neurologic and behavioral components. The stress or abstinence from withdrawal symptoms scale is based on observations made throughout the examination.

For data analysis, the NNNS items were collapsed to reflect clinically-defined categories of neurobehavioral functioning. Missing data precluded the reduction of some of the NNNS summary

variables. The following summary variables followed by their variable names were available for the current study: Orientation/Attention; Types of Handling required to get good orientation; Quality of Movement; Arousal; Self Regulation; Abnormal Reflexes; Stress Signs; Hypertonicity; Hypotonicity; Asymmetric Reflexes; Excitability, and Lethargy.

Outcome Measures

Communication Development. Communication development was assessed using the Sequenced Inventory Communication Development-Revised (SICD-R) (Hedrick, Prather, & Tobin, 1984) at approximately 30 months of age (see Table 2). The SICD-R is a norm-referenced diagnostic test of communication abilities of children 4 months to 4 years of age. The SICD-R profiles both receptive and expressive child language skills. Receptive Communication Age (RCA) and Expressive Communication Age (ECA) Domain scores are derived using three sources of information: parent report, and elicited child behavioral responses. The RCA is derived from behaviors such as awareness, discrimination, and understanding. The ECA is derived from communicative behaviors and responding behaviors such as motor responses, vocal responses, verbal responses, imitating behaviors, initiating behaviors, responding behaviors and verbal output. The 12 age levels are divided into three discrete age groups per year from 4 months to 48 months of age (4 months, 8 months, 12 months, 16 months, and so on to 48 months). A clinically significant cut off between the child's chronological age and RCA or ECA is not provided in the SICD-R manual. For the present study, a significant delay is defined as being less than or equal to 20 months RCA or ECA.

Developmental Skills. The developmental skills of children at 36 months of age (see Table 2) was assessed using the Bayley Scales of Infant Development-II (Bayley, 1993). The Bayley is a commonly used evaluation instrument to compare a child's level of development to same aged peers. The Bayley Scales of Infant Development-II is composed of three separate scales: the Mental Development Index (MDI), the Psychomotor Development Index (PDI), and the Infant Behavior Record (IBR). Only the MDI and the PDI were used in the present study. The Bayley Mental Scale is designed to measure memory, learning, problem solving, early communication, classification and generalization. The Bayley Motor Scale is designed to measure both gross motor and fine motor development. The Bayley Manual cites studies confirming the ability of the BSID (Bayley, 1969) to

identify children who will demonstrate developmental delay on ability or achievement measures when they are school age. In general, the later the BSID scores are obtained, the more predictive they are of later childhood developmental functioning. The BSID-II has a standardization mean of 100 and standard deviation of 15. Scores of 85-114 are classified as "Within Normal Limits." Scores of 70-84 are "Mildly Delayed Performance" and scores of 69 and below are "Significantly Delayed Performance." Scores of 115 and above are classified as "Accelerated Performance."

Adaptive Functioning. Child adaptive behavioral functioning was assessed at 36 months of age (see Table 2) using the Vineland Adaptive Behavior Scales-Interview Edition (Sparrow, Balla, & Cicchetti, 1984). VABS is a semi-structured interview that assesses personal and social competence of individuals from birth through age 19. Child adaptive behavior is measured in four domains: Communication, Daily Living Skills, Socialization, and Motor Skills. Adaptive behavior is defined as the ability to perform daily activities required for personal and social sufficiency (Sattler, 1988). The Adaptive Behavior Composite score is the combination of the four domains. Each adaptive behavior domain is designed to evaluate certain capabilities. Receptive, expressive and written communication skills are expressed in the Communication domain. The Daily Living Skills domain samples personal living skills, domestic living skills and behavior within the community. The socialization domain evaluates social interactions, play and leisure activities and coping skills. The motor domain samples fine and gross motor coordination. The VABS domain scores have means of 100 and SD = 15.

Behavior. Children's behavior problems were assessed using the Child Behavior Checklist 2-3 (CBCL/2-3) (Achenbach, 1992) at 36 months (See Table 2). The CBCL was designed to assess children's behavioral/emotional problems based on parent/caregiver rating and was derived in an empirically based taxonomic method. The CBCL/2-3 provides scales for scoring six narrow-band syndromes, and three broad-band categories, Internalizing, Externalizing, and total problems. The six narrow-band syndromes include: anxious/depressed, withdrawn, sleep problems, somatic problems, aggressive behavior, and destructive behavior. Caregivers rate their child's behavior on 99 items scored from 0 to 2 to indicate frequency of occurrence within the previous two months. Broad-band subscales for Internalizing problems (anxious/depressed, withdrawn), and Externalizing problems (aggressive behavior, destructive behavior) are obtained in addition to a Total problems score. Severe behavior

problems are indicated by a score of >63 for Internalizing, Externalizing, and Total problems scales. Scores of 60 to 63 are in the borderline clinical range for problem behaviors.

Neurobehavioral Outcome Composite. A composite variable was created from the measures of communication development, cognitive functioning, motor functioning, adaptive functioning and behavior. This bivariate composite variable was created to indicate a delay of two standard deviations below the mean in one or more areas, or a delay of 1.5 standard deviations below the mean in at least two areas. This mirrors the eligibility criteria for Early Intervention programming in Rhode Island in terms of demonstrated child developmental delay. Some of the assessment measures have overlapping domains (e.g., Bayley PDI and Vineland Motor). The composite variable is made up of the following scores: Bayley MDI and PDI; Vineland Adaptive Behavior Composite; CBCL Internalizing, Externalizing and Total Problems Score; and SICD Receptive and Expressive communication. Not all children were evaluated by all measures. If no outcome information was available, the neurobehavioral composite variable was coded as missing. If outcome information was only available for one measure (e.g., SICD) and these results were negative, the neurobehavioral composite variable was coded as missing rather than zero indicating no delay. If outcome information was only available for one measure and those results were two standard deviations below the mean, then the composite variable was coded as one, indicating developmental delay. If data were available for two outcome assessment measures and the results were within normal limits for both, the neurobehavioral composite variable was coded as zero, indicating no delay. In the case of the CBCL, if the child falls in the borderline clinical range, that is the equivalent of the 1.5 SD criterion. The composite variable was based on t-scores for CBCL and standard scores for Vineland and Bayley, and age scores for SICD.

EIEIO Database. The Early Intervention Exchange of Information Operation (EIEIO) database was designed to provide information for state and federal reporting requirements, quality assurance, public awareness, standardized documentation and data reporting, streamlined billing, interagency tracking, resource and funding analyses and Early Intervention program effectiveness. At the time of initial referral to Early Intervention for an evaluation, the child is given an identification number and an EIEIO record of that child is established. This record is continually updated throughout the referral, intake, evaluation, eligibility, enrollment, provision of services, and discharge process. Nine forms

make up the EIEIO system. The present study utilizes a very small fraction of available information. The following information was abstracted from the EIEIO database for children who had birthdays within the study timeframes: ID number and identifying information, eligibility status (e.g., eligible, not eligible, family refused), eligibility disposition (e.g., single established condition, multiple established conditions, significant developmental delay), date of referral, intake and discharge, and discharge status (e.g., services no longer required, special education services planned for age three).

Early Intervention Enrollment. Early Intervention Enrollment information was obtained from the Early Intervention Exchange of Information Operation (EIEIO) database. Early Intervention program eligibility information is determined by a multidisciplinary team evaluation using standardized instruments, caregiver interview and clinical observation. Infants and toddlers are eligible for Early Intervention if they are experiencing one or more delays in specific developmental domains as determined by qualified personnel. These domains are cognition, physical development (including vision and hearing), communication, adaptive, and social or emotional development. Infants and young children are also eligible if they have a diagnosed physical or mental condition known to result in a developmental delay or developmental disability. Federal legislation Individuals with Disabilities Education Act allows at the state's discretion, services to children who are at risk of having developmental delays if Early Intervention services are not provided. It is up to the state lead agency for Early Intervention to define the "at-risk" category. This is a conceptual change in federal policy from previous legislation which allows states to specify risk factors as a condition of eligibility. The lead agency responsible for Early Intervention, the Rhode Island Department of Health, did not choose to serve the "at-risk" but did define a constellation of factors which occurring together places them at risk for developmental delay or developmental disability.

Rhode Island Early Intervention program eligibility information, as determined by a Multidisciplinary Team evaluation using standardized instruments, caregiver interview and clinical observation. Infants and toddlers are eligible for Early Intervention if they are experiencing one or more delays in specific developmental domains. These domains are cognition, physical development (including vision and hearing), communication, adaptive, and social or emotional development. Young children are also eligible if they have a diagnosed physical or mental condition known to result in a

developmental delay or disability. These discrete diagnoses are referred to as single established conditions (e.g., Down Syndrome). These constellations of risk factors that when occurring together allows for Early Intervention eligibility are known as multiple established conditions. Multiple established conditions include diagnoses, events and conditions that, in combination, have a high probability of resulting in developmental delay. Children may not demonstrate significant delay at the time of referral to Early Intervention and subsequent eligibility determination. To meet the criterion of multiple established conditions guidelines are used which include four or more positive findings considered sufficient to deem a child eligible for Early Intervention services. A representative list of conditions includes child-centered conditions such as feeding difficulties, low birth weight, sleep disturbances, prematurity, etc. Parent centered conditions include adolescent maternity, developmental disabilities, low parental education level, substance addiction, inadequate prenatal care, etc. Table 2 presents a summary of the prediction and outcome measures used in this study.

Table 2

Infant Predictor and Outcome Measures

Predictor		Outcome	
Birth	ne Month	30 Month	36 Month
Biological/environmental predictor variables Universal Newborn Screening (Level One)	ICU Network eurobehavioral Scale	Communication skills SICD: Receptive language Expressive language	Developmental Skills Bayley mental Bayley motor Early Intervention EIEIO Adaptive functioning Vineland Behavior CBCL

Study One

Study of the Rhode Island Universal Newborn Screening (UNS) database and the Rhode Island Early Intervention database presents a unique opportunity to empirically test a biopsychosocial screening procedure. The present study investigates the predictive utility of the UNS Level One screening procedure for predicting Early Intervention enrollment during two overlapping time frames. Results of this study will be used to evaluate the need for modifying or retaining the present method of screening. The present study addresses the hypothesis that there are no differences between the two time frames in terms of predictive probability for Early Intervention enrollment.

Statistical Analyses

Data analysis consisted of two major parts, with the goal to evaluate the predictive probability of the level one screening system for Early Intervention enrollment. The first part describes the characteristics of the Level One screening. The second part investigates differences in the predictive probability of the Level One screening on Early Intervention enrollment outcome for the two study time frames. This section also examines the predictive probability of the level one screening for time frame B in greater detail in order to provide a comparison point for later investigation into creating a screening algorithm with better utility. These areas were addressed using descriptive and epidemiological statistics and logistic regression analyses. The procedures for logistic regression analyses were consistent with guidelines outlined by Hosmer and Lemeshow (1989). This investigation into the predictive probability of the Level One screening focused on the results for the VNA risk categorization. The Risk-Positive newborns determined by the VNA categorization are followed up by either Level Two screening or direct referral to Early Intervention. The VNA Risk-Positive group, compared to the Risk-Positive group determined by the computer are the infants who are more likely to be referred and subsequently enrolled in Early Intervention.

Results

The results of this study are presented in 2 sections: (a) descriptive characteristics of the Level One screening system, risk disposition categories, and Early Intervention enrollment compared to risk disposition categories; and (b) comparison of the two time frames for cohort effects on the predictive

probability of the screening system, and the predictive probability of the Time B Level One Screening. The subjects that are the focus of Study One are drawn from the UNS and EIEIO databases described in the previous method section.

Characteristics of the Level One Screening

Variables included in the Level One screening are presented in Table 3. The incidence rates for the infant biological variables (e.g., birth weight, Apgar score) are low compared to the parental risk factors (e.g., number of children in mother's home, single caregiver). The high incidence of parental risk factors contribute to the high Risk-Positive and Risk-Suspect identification rates (Table 4). Results for the two cohorts were very similar. The number of children in mother's home variable is very high because this variable includes first time mothers (zero previous births to mother). The prenatal care risk variable is also quite high. This variable is sensitive to inaccurate prenatal care information in the obstetric record.

Table 3

Prevalence of Newborn Psychosocial and Biomedical Risk Factors for Two Time Frames

Level One	Time A % N=13,379	Time B % N=27,282
Known established condition	1.4	1.7
Birth weight less than 1500 grams	1.1	1.1
ICU hospitalization greater than 48 hours	2.1	4.6
Caregiver education less than 11 th grade	14.6	13.2
Mother's age less than 19 or greater than 37	10.8	11.4
Single caregiver	35.5	35.3
Number of children in mother's home greater than 5 or 0	42.6	44.0
Parent risk characteristic & child lives with that parent	9.6	10.5
No prenatal care visits before 5 months	5.7	7.6
Prenatal care risk*	12.3	11.0
Small for gestational age**	1.6	1.3
Apgar scores at 1 and 5 minutes, less than 7	1.7	1.7

Note. percentages represent valid percent

*Less than 6 prenatal care visits before 36 weeks or total number of prenatal care visits less than ten

** Gestational age greater than 37 weeks and birth weight between 1500-2500 grams

A comparison of the percentages for the VNA and Computer risk disposition categories are presented in Table 4. The VNA categorization is based on the same information as the computer algorithm but also incorporates clinical judgement. Table 4 illustrates how clinical judgement affects the final risk disposition categorization. The Risk-Negative category contains the greatest number of individuals for both the VNA and Computer risk disposition categorization for either time frame (approximately 46%).

Table 4

Comparison of Computer Algorithm Versus VNA Risk Disposition Classification by Time Point

	VNA		Computer	
	Time A	Time B	Time A	Time B
Risk-Positive	41.8%	41.3%	40.1%	40.3%
Risk-Suspect	11.6%	12.1%	15.0%	13.5%
Risk-Negative	46.5%	46.7%	44.9%	46.2%

Predictive Probability of Level One Screening System

The Level One screening system was analyzed for its predictive probability of determining which children would eventually be eligible for Early Intervention services. This was done through Logistic Regression analyses and statistics commonly used in epidemiology studies. The cell percentages for each risk disposition category were examined in terms of Early Intervention program enrollment outcome (Table 5). Very few (5.9%, 6.8%) of the Risk-Positive newborns were subsequently referred and determined eligible for Early Intervention services before their third birthday. The percentage of Risk-Positive children who were not eligible for Early Intervention (Percentage of False positives) is high (time A=41%, time B=40%). Because the Risk-Suspect infants are not routinely followed up by the VNA, these children are added to calculations of the false negative rate. A large percentage (more than 25%) of Early Intervention eligible children were designated Risk-Negative at birth for both time frames which contribute to percentage of false negative rates of 34% and 35% for times A and B.

Table 5

VNA Risk Disposition Categorization and Early Intervention Enrollment Outcome

	VNA	Time A	VNA	Time B
	EI Eligible	Not Eligible	EI Eligible	Not Eligible
Risk-Positive	328	6097	768	10491
% within EI enrollment	65.7%	40.9%	65.5%	40.2%
Risk-Suspect	41	1516	107	3181
% within EI enrollment	8.2%	11.8%	9.1%	12.2%
Risk-Negative	130	5266	298	12435
% within EI enrollment	26.1%	47.3%	25.4%	47.6%

Results for the times A and B VNA Risk Disposition criteria for Risk-Positive versus Risk-Negative dispositions (Table 6) showed almost identical sensitivity (time A=66%, time B=65%) and almost identical specificity (time A=59%, time B=60%). These sensitivity rates indicate that only 65 or 66% of the Early Intervention eligible children are screened Positive at birth. The specificity rates indicate the proportion of children correctly identified at birth as not at risk. Sensitivity is defined as the capacity of a screening instrument to yield a positive result for a person with the diagnostic characteristic of interest. Sensitivity is the proportion of children who are correctly identified as at-risk for a developmental disability or delay (Risk-Positive), who are ultimately eligible for Early Intervention services. Specificity is the capacity of an assessment instrument to yield a negative result for a person without a diagnostic condition or characteristic. Specificity is the proportion of Risk-Negative children who were not subsequently enrolled in Early Intervention. Both sensitivity and specificity are independent of sample size and population base rates, and represent the external validity of a screening test (Glaros & Kline, 1988). The low positive predictive value (PV+) means that for all infants who are Risk-Positive, approximately 6 or 7 percent will be expected to be eligible for Early Intervention. A negative predictive value (PV-) of 98% means that 98% of Risk-Negative newborns would be expected not to be enrolled in Early Intervention prior to their third birthday. A large negative predictive value is to be expected in any screening for a rare disease or condition because the majority of those screened will by definition be free from the disease (Hennekens & Buring, 1987). For rare

conditions such as eligibility and enrollment for Early Intervention (base rate approximately 4% of the population in RI for both time frames), the major determinant of the positive predictive value is the prevalence of the preclinical developmental delay/disability in the screened population. With such a low base rate for Early Intervention enrollment, a negative test finding should warrant more confidence than a positive test finding. The base rate of a condition is defined here as all children in Early Intervention divided by the population. Base rate or prevalence is important in evaluating a screening test's effectiveness. Low base rates typically produce a low positive predictive value and high negative predictive value. Another important statistic is the percentage of false negatives (FN). Thirty four percent or 35% of children eventually eligible for Early Intervention were not found to be at risk at birth. However, the odds ratio for Risk-Positive disposition shows that they are approximately 3 times more likely to be eligible for Early Intervention than those who were risk negative at birth.

Table 6

Comparison of VNA Risk-Positive Screening Categorization for Early Intervention Outcome

	Sensitivity	Specificity	FN %	FP %	PV+	PV-	OR	95% CI
Time A	66%	59%	34%	41%	6%	98%	2.92	(2.37-3.59)
Time B	65%	60%	35%	40%	7%	97%	3.05	(2.66-3.50)

Note. the percentage of false positive (FP) includes rates for the Risk-Suspect and Risk-Negative. Odds ratio is Risk-Positive versus Risk-Negative.

Both Risk-Negative and Risk-Suspect newborns are being referred to Early Intervention at a significantly older age than Risk-Positive newborns. Results of a One-Way ANOVA are significant comparing the mean age at referral for each risk disposition category $F(2, 1517) = 76.02, p < .0001$. Risk-Positive children were referred to Early Intervention at the youngest age ($M = 15.52$ months, $SD = 10.36$). Risk-Suspect newborns were referred to Early Intervention at an average of 22 months of age ($M = 22.07, SD = 9.08$) as were Risk-Negative newborns ($M = 22.12, SD = 8.68$).

An important consideration of this investigation into the effectiveness of the Level One screening is if the results are stable across time. Logistic regression analyses were modeled variously including risk disposition, then adding cohort then adding the risk by cohort interaction, to answer the

question of if there is a difference in the predictive probability between time points. Table 7 displays the estimated logistic regression coefficients, -2 log-likelihood, the likelihood ratio test statistic (G) and p value for three models on the combined Time A and Time B data. The process began by contrasting a constant-only model against a model containing the risk disposition predictor variable, then adding the cohort predictor then adding the interaction term. The results of each model are shown in Table 7. For model 0, the program generated the -2 log-likelihood of the constant-only model (i.e. 13945.57). This value was compared with the univariate model (-2 log-likelihood = 13524.91) in model 1, and yielded a likelihood ratio test ($G = 420.65$, $p < .01$). Model 2 added cohort, thus statistically adjusting risk for cohort. The likelihood ratio test for the difference between model 1 and model 2 was also significant ($G = 8.12$, $p < .01$). The likelihood ratio test for the difference between model 2 and model 3 was not significant ($G = .25$, $p = .88$). Model 2 displays evidence of confounding by cohort, however the estimated coefficients changed very little with the addition of cohort into the model. The log-likelihood ratio test for the difference between Model 1 and Model 2 is statistically significant. This tests for the significance of the coefficients added to the model. There is no evidence of an interaction between risk disposition and cohort, thus cohort is not an effect modifier. The non-significant p-value means that no change in the estimated coefficient is found when the interaction term is added to the model. This confirms what was shown in the previous table, that there were no noticeable differences in classification rates between the two study time frames.

Table 7

Logistic Regression Models of Risk Disposition and Cohort on Early Intervention Enrollment Outcome

Model	constant	Risk +/-	Risk +	Cohort	Risk +/- x Cohort	Risk + x Cohort	-2 log- likelihood	G	p
0	-3.15						13945.57		
1	-3.77	.31	1.10				13524.91	420.65	.001
2	-3.87	.31	1.10	.16			13516.80	8.12	<.01
3	-3.85	.24	1.07	.12	.10	.05	13516.55	.25	.88

Closer Examination of Time Frame B

Table 8 contains the results of the model containing the VNA risk disposition categorization of infants born in time B ($N = 27,282$), and shows: (a) the estimated coefficients (β); (b) the estimated standard error [$SE(\beta)$] of the estimated coefficients; (c) the Wald statistic associated with each variable; (d) the alpha level associated with the Wald statistic; (e) the estimated odds ratio (ψ); and (f) the 95% confidence intervals for the odds ratio. The odds ratio indicates that Risk-Positive children are three times more likely to be eligible for Early Intervention than those who are Risk-Negative at birth. Risk-Suspect newborns are also significantly more likely to be eligible for Early Intervention than Risk-Negative newborns.

Table 8

Univariate Logistic Regression Model for Early Intervention Eligible Data for Time B

Variable	β	$SE(\beta)$	Wald	p	ψ	95% CI
Risk-Negative (referent group)			227.25	.0000'		
Risk-Suspect	.34	.11	8.76	.0031	1.40	(1.12,1.76)
Risk-Positive	1.12	.07	257.83	.0001	3.05	(2.66,3.50)
Constant	-3.73	.059	4052.45	.0001		

Discussion

Utility of the Level One Screening

The Level One screening procedure is administered to the entire population of Rhode Island children, with the purpose being early identification of those who will need additional assessment and Early Intervention services. Screening allows for the detection of risk that is not readily apparent, and allows for systematic follow-up of children in need. Approximately four percent of Rhode Island children require Early Intervention services to promote positive developmental outcome. The risk factors that make up the Level One screening are associated with Early Intervention program enrollment by age three. However, the screening procedure could be more effective as the first phase of Rhode Island's preventive intervention program. In addition to the burden placed upon the system of

large numbers of newborns inappropriately identified as at-risk ($N=10,491$), direct referrals to Early Intervention are routinely made by parents, medical professionals and child care providers. The high false-positive rate (40%) also results in many unnecessary referrals for the more costly and personnel-intensive in-home Level Two assessments.

Sensitivity and Specificity. The low sensitivity of the Level One screening does not measure up to the state and federal mandates. Although the Rhode Island department of Health has not stated acceptable criteria, 65% sensitivity and 35% false negative rates are clearly less than optimal for a universal screening procedure that seeks to capture all appropriate infants and toddlers. The concept behind the Level One screening prefers high sensitivity and accepts lower specificity. The reduced specificity (60%) is expected because Risk-Positive infants will have follow-up with later developmental screening before referral for an Early Intervention evaluation and receipt of intervention services. In addition, many adverse events may happen to the child after the newborn screening to adversely affect development. Lead exposure, traumatic brain injury, acute illness are a few examples of adverse developmental events.

The state of Rhode Island seeks to cast a wide net and capture all children who are in need of Early Intervention services at the earliest age possible. The serial screening procedures that are Rhode Island State policy should result in an increased specificity with the more detailed and rigorous Level Two screening. With such a large false positive rate, a higher rate of sensitivity would be expected. The inclusion of clinical information into the risk disposition categorization did not greatly improve on the sensitivity of the screening measure. If the specificity of the Level One screening could be raised, the positive predictive value would also increase. The large percentage of false negatives is important because these children were referred to Early Intervention at a significantly older age than the Risk-Positive newborns. Research into the effectiveness of Early Intervention shows services that begin at a younger age and last longer are more beneficial for positive child development. Risk suspect newborns are significantly more likely to be eligible for Early Intervention than Risk-Negative newborns (time B only) yet they are referred at an average of 22 months of age.

Odds Ratio. An odds ratio was calculated that indicates the increased probability of a child later requiring Early Intervention services if results of the Level One screening were positive or suspect.

Risk-Positive newborns were three times more likely to be enrolled in Early Intervention than those children who were Risk-Negative at birth. The odds ratio for the Risk-Suspect newborns indicate that they are also more likely to be enrolled in Early Intervention than Risk-Negatives. The Risk-Suspect newborns are not routinely followed at this time, however more than 9% are enrolled in Early Intervention programs. Ideally, all children who are eventually eligible for Early Intervention should be captured at birth through the universal screening procedure. The Risk-Negative and Risk-suspect children are being referred to Early Intervention through other sources.

Replicability. After the validity of the screening test has been evaluated, it is necessary to consider its replicability. Results of this study show that the predictive probability of the Level One screening system has not changed significantly from 1993 through 1995. The large at-birth over-identification rate (40% false-positive) and the low sensitivity (65%) motivate an effort toward designing a new screening algorithm.

The "Child Identification" stipulation of Part C of IDEA has prompted state efforts to locate and identify all children birth through two who are disabled and in need of Early Intervention program services. Rhode Island has responded to this mandate via a population newborn screening and tracking program as the first phase in providing Early Intervention services. Results of this study show Rhode Island's current Level One system to have inadequate sensitivity (65%) and specificity (60%) to identify newborns at risk based on subsequent Early Intervention program enrollment. In addition, 35% of those infants and toddlers eventually enrolled in Early Intervention programs were characterized as Risk-Negative or Risk-Suspect at birth. Improvements in the sensitivity and specificity of the screen may be made by removing some variables in the risk algorithm and adding others with a relation to Early Intervention enrollment outcome. The objective of an improved, empirically-derived newborn screening is to facilitate the design of efficient intervention and prevention strategies. This study evaluated the current Level One weighted, multifactor, screening algorithm that incorporates a combination of newborn biological and parent/environment psychosocial variables to identify those newborns at greatest risk for developmental problems. The purposes and design of this study were informed by prior research into developmental risk prediction, viewed through theoretical models of child development, i.e., the transactional model (Sameroff & Chandler, 1975).

Federal public policy mandates states to locate and identify all children from birth through two who are in need of Early Intervention program services. Unfortunately, the current Level One screening has a large at-birth over-identification rate and more importantly, low sensitivity. As such, there is a pressing need for a new and improved universal newborn screening algorithm. It is expected that a more sensitive and specific developmental screen will account for risk in biological and environmental domains, and that a new state-wide risk assessment can be informed by detailed examination of a known high-risk sample.

Study Two

In Study One, the utility of the current Level One Universal Newborn Screening to predict Early Intervention program enrollment was established for two overlapping timeframes. Results supported the need for a more sensitive and specific at-birth screening algorithm to predict which children are in need of intervention services. Towards this aim, the present study investigates the utility of the Level One screening algorithm to predict Early Intervention enrollment and neurodevelopmental outcome by 36 months in a high-risk sample of 285 children.

The present study addresses the following predictions:

- A) There will be a higher rate of individuals designated as Level One Risk-Positive in the high risk sample than in the corresponding Rhode Island population sample and a higher rate of children receiving Early Intervention services than in the corresponding Rhode Island cohort.
- B) For the high-risk sample, Level One Risk-Positive will exhibit poorer outcome as indexed by standardized measures and will be significantly more likely to be eligible for Early Intervention than will Level One Risk-Negative subjects.

Statistical Analyses

Data analysis are presented in two major sections, with the goal to evaluate the predictive utility of the Level One screening system for Early Intervention eligibility and child developmental outcome for the MLS-PT sample. The first section of results compares characteristics of the Level One screening risk disposition and Early Intervention eligibility for the MLS-PT sample and for the entire Rhode Island sample. The Level One screening variables were examined descriptively then the risk algorithm was analyzed for its predictive probability of determining which children would eventually be eligible for Early Intervention services. Logistic regression analysis was used to determine if the Risk-Positive newborns were more likely to be eligible for Early Intervention than those who were Risk-Negative at birth. The second section of results presents T-tests used to compare the rates of Risk-Positive versus Risk-Negative for each area of developmental outcome (Communication, Cognitive and Motor Development, Adaptive Functioning, Behavior Problems, and Early Intervention Program Enrollment).

Results

The subjects in this study were drawn from the cross-matched (UNS, EIEIO, MLS) sample described in the method section. Variables included in the Level One Universal Newborn Screening are presented in Table 9 for the Rhode Island population sample and MLS-PT samples. The incidence rates for the infant biological variables (e.g., birth weight, gestational age, Apgar score) are lower compared to the rates of parental risk factors (e.g., number of children in mother's home, single caregiver). The high incidence of parental risk factors contributes to the high Risk-Positive identification rate. The higher percentage of teenage mothers in the MLS-PT sample is reflected in the variables identifying risk by maternal age, education risk and marital status. The higher percentage of newborns meeting criteria for Known Established Conditions is due all or in part to substance exposure because some of the criteria for identification in this category are exclusionary criteria for the MLS study recruitment design (e.g., congenital malformation).

The percentages for each Level One risk disposition category were examined to test the first prediction that there will be a higher rate of individuals designated as Risk-Positive in the MLS-PT sample than in the Rhode Island sample. The percentages of each risk disposition for both samples are presented in Table 10. The rate of Risk-Positive Newborns in the MLS-PT cohort is roughly double the rate in the Rhode Island sample born in the same timeframe (83.9% versus 41.3%). This leads to a false positive rate of 83% for the MLS-PT sample compared with a false positive rate of 40% for the Rhode Island cohort. The percentage of Risk-Negative newborns in the Rhode Island sample (46.7%) is more than five times the rate for the MLS-PT sample (8.4%). Chi-square analysis was performed to compare the rate of Risk-Positive newborns for each sample. Chi-square assumes that there is no difference between the cohort groups in the proportions of the factor of interest (risk designation). Because Risk-Suspect newborns are not routinely followed up they were added to the Risk-Negatives for this analysis. As predicted, the MLS-PT cohort had a significantly greater proportion of Risk-Positive newborns and significantly fewer Risk-Suspect or Risk-Negative newborns than the state-wide sample, $X^2(1, N=27,280) = 215.51, p<.001$.

Table 9

Prevalence of Newborn Psychosocial and Biomedical Risk Factors for Both Cohorts

Level One	1993-93 % N=27,282	MLS-PT % N=285
Known Established Condition	1.7	8.4
Birth weight less than 1500 grams	1.1	3.9
ICU Hospitalization greater than 48 hours	4.6	13.7
Caregiver education less than 11 th grade	13.2	42.9
Mother's age less than 19 or greater than 37	11.4	40.2
Single caregiver	35.3	80.7
Number of children in mother's home greater than 5 or 0	44.0	54.0
Parent risk characteristic & child lives with that parent	10.5	43.5
No prenatal care visits before 5 months	7.6	21.1
Prenatal care risk*	11.0	30.2
Small for gestational age**	1.3	4.2
Apgar scores at 1 and 5 minutes, less than 7	1.7	3.9

*Less than 6 prenatal care visits before 36 weeks or total number of prenatal care visits less than ten

** Gestational age greater than 37 weeks and birth weight between 1500-2500 grams

Table 10

Comparison of Risk Disposition Classification by Cohort

	RI sample N=27,280	MLS-PT N=285
Risk-Positive	41.3%	83.9%
Risk-Suspect	12.1%	7.7%
Risk-Negative	46.7%	8.4%
EI Eligible	4.3%	14.7%

Table 11

VNA Risk Disposition Categorization and Early Intervention Enrollment Outcome

	VNA 1993-95		VNA MLS cohort	
	EI Eligible	Not Eligible	EI Eligible	Not Eligible
Risk-Positive	768	10491	37	202
% within EI Enrollment	65.5%	40.2%	88.1%	83.1%
Risk-Suspect	107	3181	3	19
% within EI Enrollment	9.1%	12.2%	7.1%	7.8%
Risk-Negative	298	12435	2	22
% within EI Enrollment	25.4%	47.6%	4.8%	9.1%

Predictive Probability of Level One Screening Algorithm

Next, Prediction B was examined. The Level One Risk-Positive MLS-PT newborns were expected to be enrolled in Early Intervention at a significantly greater rate than those who were Risk-Negative at birth. First, the cell percentages for each risk disposition category were examined in terms of Early Intervention program enrollment outcome (Table 11). More than 15% of the MLS-PT Risk-Positive newborns were subsequently referred and determined eligible for Early Intervention services before their third birthday, twice the percentage in the corresponding Rhode Island cohort. The percentage of Risk-Negative children who were eligible for Early Intervention is much lower in the MLS-PT sample than in the Rhode Island cohort (4.8% v 25.4%). Because the Risk-Suspect infants are not routinely followed up by the Visiting Nursing Association, these children are added to calculations of the false negative rate. Less than 12% of Risk-Negative combined with Risk-Suspect newborns were eligible for Early Intervention (Percentage of False Negatives, FN%). This represents a much lower false negative rate than for the Rhode Island sample cohort. Overall, in the Rhode Island cohort, 4.3% of children are eligible for Early Intervention compared with 14.7% of the MLS-PT cohort (Table 10).

Next, the predictive probability of the Level One screening for the MLS-PT sample was compared with the Rhode Island cohort. Results of logistic regression analyses revealed that the MLS-PT Risk-Positive newborns were not significantly more likely to be enrolled in Early Intervention programs at some time before their third birthday than Risk-Negative newborns (Table 12). The odds

ratio for MLS-PT Risk-Positive disposition shows that they are approximately 2 times more likely to be eligible for Early Intervention than those who are risk negative at birth, however, this rate does not reach statistical significance. The odds ratio for MLS-PT Risk-Positive disposition shows that they are only 1.5 times more likely to be eligible for Early Intervention than those who are Risk-Negative or Risk-Suspect at birth. Prediction B was not supported for prediction of Early Intervention program enrollment.

The sensitivity of the Level One screen to identify the newborns who would eventually be eligible for Early Intervention was higher (88%) in the MLS-PT sample than for the Rhode Island sample cohort (65%). These sensitivity rates indicate the percentage of the Early Intervention eligible children who were Risk-Positive at birth. The specificity rates indicate the proportion of children correctly identified at birth as not at risk. The specificity of Level One for the MLS-PT cohort was very low (17%). Fourteen and seven tenths percent of the MLS-PT cohort were enrolled in Early Intervention at some time before their third birthday compared with 4.3% enrolled in Early Intervention for the Rhode Island sample cohort. Although the sensitivity of the screen was quite high and the specificity was low, the Risk-Positive newborns were not more likely to be in Early Intervention than those screened as Risk-Suspect or Risk-Negative at birth. Both sensitivity and specificity are independent of sample size and population base rate, and represent the external validity of a screening test (Glaros & Kline, 1988). The positive predictive value (PV+) means that for all infants who are Risk-Positive, approximately 15% will be expected to be eligible for Early Intervention. A negative predictive value (PV-) of 89% means that 89% of Risk-Negative newborns would be expected not to be enrolled in Early Intervention prior to age three. A large negative predictive value is to be expected in any screening for a rare disease or condition because the majority of those screened will by definition be free from the disease (Hennekens & Buring, 1987). For rare conditions such as enrollment for Early Intervention (base rate approximately 4% of the population in Rhode Island, 14.7% for MLS-PT), the major determinant of the positive predictive value is the prevalence of the preclinical developmental delay/disability in the screened population.

Table 12

VNA Risk-Positive Screening Categorization for EI Outcome for Two Cohorts

	Sensitivity	Specificity	FN %	FP %	PV+	PV-	OR	95% CI
1993-95	65%	60%	35%	40%	7%	97%	3.05	(2.66-3.50)
MLS	88%	17%	12%	83%	15%	89%	2.01	(0.45-8.93)

Note. the percentage of false positive (FP) includes rates for the Risk-Suspect and Risk-Suspect/Negative. Odds ratio (OR) is Risk-Positive versus Risk-Negative. Positive predictive value (PV+), negative predictive value (PV-), false positive (FP).

Risk Disposition and Neurodevelopmental Outcome

T-tests were conducted to test the hypothesis that MLS-PT Risk-Positive infants perform more poorly than Risk-Negative infants on measures of child outcome. Table 13 presents the descriptive statistics by group for the child outcome variables. The hypothesis was supported for the measures of behavior (CBCL) only. On the CBCL, the Risk-Positive group functioned significantly more poorly than the comparison group. Other measures of child neurodevelopmental outcomes (cognitive, motor, adaptive behavior, and receptive and expressive language) were equally developed for both the Risk-Positive and Risk-Suspect/Negative newborns.

Table 13

Risk-Positive and Risk-Negative for Neurodevelopmental Outcome Measures

Outcome		Total	Risk-Positive	Risk-Suspect & Negative	P
Bayley MDI, 36 months	N	156	125	31	Ns
	Mean (SD)	85.13 (13.67)	84.2 (13.41)	88.9 (14.24)	
Bayley PDI, 36 months	N	153	122	31	Ns
	Mean (SD)	90.24 (14.39)	90.27 (14.0)	90.1 (16.06)	
CBCL Internalizing T-Score , 36 months	N	179	144	35	**
	Mean (SD)	56.87 (8.76)	57.94 (8.96)	52.46 (6.28)	
CBCL Externalizing T-Score, 36 months	N	179	144	35	**
	Mean (SD)	55.57 (9.11)	56.80 (9.12)	50.51 (7.21)	
CBCL Total Problems T- Score, 36 months	N	179	144	35	**
	Mean (SD)	56.58 (8.76)	57.55 (8.94)	52.57 (6.74)	
Vineland – Communication Standard Score, 36 months	N	163	131	32	Ns
	Mean (SD)	101.18 (12.89)	100.99 (12.52)	101.97 (14.51)	
Vineland – Daily Living Skills Standard Score, 36 months	N	163	131	32	Ns
	Mean (SD)	88.73 (12.06)	88.94 (11.75)	87.88 (13.44)	
Vineland – Socialization Standard Score, 36 months	N	162	131	32	Ns
	Mean (SD)	93.04 (10.41)	92.97 (10.34)	93.34 (10.85)	
Vineland – Motor Skills Standard Score, 36 months	N	162	130	32	Ns
	Mean (SD)	87.85 (14.41)	87.75 (14.23)	88.28 (15.35)	
Vineland – Adaptive Behavior Composite SS, 36 months	N	162	130	32	Ns
	Mean (SD)	90.10 (12.00)	90.02 (11.74)	90.44 (13.21)	
SICD – Receptive, 30 months	N	160	131	29	Ns
	Mean (SD)	26.70 (4.80)	26.66 (4.59)	26.90 (5.75)	
SICD – Expressive, 30 months	N	154	128	26	Ns
	Mean (SD)	28.21 (4.38)	28.09(4.30)	28.77 (4.80)	

** p<.01

Discussion

The present study examined at-birth characteristics for the Rhode Island cohort and the high-risk MLS Providence and Teen samples. The MLS-PT samples showed a greater percentage of all at-birth risk factors that make up the Level One newborn screening. The biological variables of birth weight and gestational age were influenced by MLS recruitment design to select an enriched sample of high-risk infants. Teenage maternity was also considerably higher because of recruitment design. Results of the present study supported Prediction A, that a higher percentage of risk positive infants and a higher percentage of Early Intervention eligible infants are present in the high-risk sample. This high rate of identification at birth for the MLS-PT sample leads to both a high sensitivity rate (88%) and a huge over-referral rate (83%), double that in the general population. The high sensitivity may be an artifact of identifying newborns based upon social strata criteria such as maternal age, occupation and ethnicity. This is explored in the next study by creating a screening algorithm that is more independent of socioeconomic indicators. Although the sensitivity of Level One for the MLS-PT sample was very high, the Risk-Positive newborns were not significantly more likely to be eligible for Early Intervention services than those who were Risk-Negative at birth.

The Level One risk algorithm is designed to identify those children at birth who are at risk for developmental problems if Early Intervention services are not provided. Results of the present study indicate that no significant differences between Risk-Positive and Risk-Negative newborns are seen in terms of later cognitive, motor, adaptive behavior and speech and language development by age three. It may be argued that providing intervention services has helped those children at risk, thus reducing the disparity between those receiving the services and those who are not eligible for the services. However, the Level One screening is identifying those children who will have behavior problems (internalizing, externalizing and total problems) as indexed by the CBCL/2-3. These results are very interesting because the behavior problems that are indexed by the CBCL would primarily be evident after the child is two years of age. Children exhibiting only behavior problems and not other delays may be referred to Early Intervention at a later age than those children with other developmental or biological problems. Therefore these children receive Early Intervention services for a limited amount of time. Nevertheless, Level One screening is identifying those children who will have behavior problems by age three. Most

studies of risk factors for early childhood developmental outcome focus on measures of cognitive development. However, Shaw and Vondra (1995) found that maternal depressive symptoms were related to early childhood behavior problems in low-income three year old boys. Family adversity including poverty has been shown to be predictive of behavior problems (Shaw et al., 1994). The level One screening includes maternal mental health and several variables that are strongly related to economic disadvantage (e.g., limited prenatal care, large family size, low maternal education). It may be these distal variables that are contributing to the prediction of childhood behavior problems.

Study Three

Study Two examined the utility of the Level One screening to predict child developmental outcome. The results revealed that the Level One risk algorithm was greatly over-identifying newborns at risk for later developmental problems. Children identified as at risk by the Level One risk identification are significantly more likely to be enrolled in Early Intervention than those who are risk negative at birth. However, the sensitivity of the Level One screening to identify those who will later be eligible for Early Intervention is not high (65%) while the percentage of those not identified at birth (% of false negatives) who will later be enrolled in Early Intervention programming is quite high (35%). The Level One risk algorithm did not reliably predict child developmental outcomes by age three in a high risk sample, with the exception of parent report of child behavioral problems. Therefore the goal of this section is to create a risk algorithm for Early Intervention enrollment with higher sensitivity and lower percentage of false negatives than the current Level One screening procedure studied in the previous study. This risk algorithm will be more generalizable to the population at large than most risk indices that have been developed for specific groups of children.

It was predicted in study two that a higher rate of Risk Positive newborns would be identified in the high-risk sample of newborns (MLS Providence/Teen sample). This prediction was supported with the results that children in the MLS-PT sample were identified as risk-positive at a rate double that in the general Rhode Island cohort. However, Risk-Positive infants were not significantly more likely to be eligible for Early Intervention services than those who were Risk-Negative at birth. Post-hoc analysis indicated that the Level One risk algorithm was identifying newborns based upon social class factors (i.e., level of caregiver education, amount of prenatal care). Indeed, children living in poverty (as indexed by poverty census tract) are eligible for Early Intervention programming at a larger rate than those who are living in non-poverty areas (5.3% versus 3.9%, odds ratio for poverty 1.37, 95% CI = 1.18 – 1.60). This investigation sought to determine if factors independent of social class could be found that predicted Early Intervention enrollment so that a set of risk factors would be determined in a low socioeconomic class group that would be predictive of Early Intervention enrollment for all social classes.

The present study details the development of an empirically and theoretically designed model of perinatal risk that controls for the influence of poverty alone on prediction of Early Intervention enrollment. Predictor variables are included to assess both biological and parental/environmental risk. The utility of this design will be established on a non-poverty group, then on the entire Rhode Island cohort. This prediction model will be compared to the Level One prediction algorithm in terms of commonly used epidemiological statistics to determine predictive utility of the model.

Statistical Analysis

Data analysis is reported in two major sections. The first section (Results One) focuses on creating a risk algorithm that determines the component risk variables within low social class. The analyses involved building a screening model using SPSS logistic-regression procedures to identify the predictors of Early Intervention enrollment in a poverty census tract sample. The second major section (Results Two) involves empirically developing a risk algorithm on Early Intervention enrollment independent of poverty status with the goal of increasing sensitivity and decreasing the percentage of false negatives from that of the Level One screening. Towards this end, certain variables were examined in a more detailed manner to determine more sensitive cut-points for analysis. The procedures for variable selection and model building through logistic regression analysis were concordant with those outlined by Hosmer and Lemeshow (1989).

Results One

Results One include (a) demographic characteristics of the poverty and non-poverty subsamples; (b) results of the univariate logistic regression analysis on poverty status; (c) results of the univariate logistic regression analysis on Early Intervention enrollment in a poverty cohort, (d) multiple logistic regression analysis on Early Intervention enrollment in a poverty cohort and non-poverty cohort, and (e) comparison of the poverty cohort-optimized risk algorithm with the current Level One prediction algorithm.

Demographic Characteristics

Newborns and families living in poverty (poverty $N=4995$) are represented in Early Intervention programming at a larger rate than those who live in non-impovertised (not-poverty $N=14,347$) homes (OR=1.36, 95% CI 1.18 – 1.59). There are also differences between Caucasian and

minority families in terms of poverty status, $X^2(1, N=19342) = 4699, p < .01$. Within the poverty sample approximately 39% of mothers are Caucasian while 60% are minority. Mothers living in poverty are younger ($M = 25.4$ years) than mothers not living in poverty ($M = 28.6$). Mothers living in poverty also have a significantly greater number of children ($M = 1.2$ versus $M = .8$). Mothers living in poverty also are less well educated ($M = 11.1$ grade level) than non-impoveryed mothers ($M = 13.5$ grade level), and have fewer prenatal care visits ($M = 9$ versus $M = 10$). Children living in poverty were referred to Early Intervention at roughly the same age (17 .5 months) as children not living in poverty. Young age of referral to Early Intervention is important for a longer duration of intervention services provided to the child and family.

Univariate Logistic Regression Analyses

The logistic-regression model-building process began with the selection of predictor variables following the recommendations of Hosmer and Lemeshow (1989). Univariate analysis was conducted for each variable, using likelihood ratio chi-square tests with contingency tables comparing outcome by level of each variable. Likelihood-ratio chi-square tests were performed for the entire cohort of Rhode Island residents for poverty status as the dichotomous outcome variable (poverty versus low-medium-high census tracts) to identify variables with strong associations with poverty status as indexed by census tract. The goal is to inform a multivariable model that is less globally social-class sensitive. Table 14 shows the results of the univariate logistic regression analyses for predictor variables that are theoretically important for model inclusion, and displays (1) the estimated slope coefficients (β) for the univariate logistic regression model containing this variable; (2) the estimated standard error [$SE(\beta)$] of the estimated slope coefficient; (3) the estimated odds ratio [$Exp(B)$], which is obtained by exponentiating the estimated coefficient; (4) the 95% confidence intervals for the odds ratio; (5) the value of the -2 log-likelihood for the model; (6) the likelihood-ratio test statistic (G) for the hypothesis that the slope coefficient is zero; and (7) the alpha level associated with G (p).

Results of the univariate analyses for poverty status identified eleven of fourteen variables that were significantly associated with poverty status ($p < .01$): Mother's Age, Caregiver Education, Single Caregiver, Family Size, Small for Gestational Age, Established Conditions, Number of Prenatal Care

Visits, No Prenatal Care Visits Prior to the Fifth Month, Parental Risk Factor(s), Delivery Method, and Infant Feeding Method. The variables with negative estimated slope coefficients and corresponding estimated odds ratios less than one (mother's age greater than 37, and non-vaginal delivery method) are less likely to be associated with poverty status than with non-poverty status. Variables with positive estimated logistic regression coefficients are more likely to be associated with poverty status than with non-poverty status.

Hosmer and Lemeshow (1989) suggest using a $p < .25$ as the screening criterion level for selection of predictor variables for model inclusion. This is because a more stringent criterion level often results in rejection of a variable that might be important in the multivariable model building process. By using the recommended criterion level for selection of variables that are not associated with poverty ($p > .25$), three variables are identified as not associated with poverty status: Birth weight, 5 minute Apgar Score, and NICU hospitalization. Unfortunately these three variables all represent biological risk factor variables. Because developmental risk theory such as the transactional model (Sameroff & Chandler, 1975) emphasizes the importance of including environmental variables with measures of biological risk, these three biological variables alone are theoretically insufficient predictors of developmental risk. So as not to prematurely truncate the influence of environmental variables, all fourteen predictor variables were included in univariate analyses for Early Intervention enrollment within the poverty subsample ($N=4995$).

Table 15 shows the results of univariate logistic regression analyses of Early Intervention enrollment within a poverty group. Based on the inspection of the confidence interval estimates, there is evidence that most variables have some association with the outcome, Early Intervention enrollment. The data indicate that eleven out of fourteen variables met the screening criterion for model inclusion ($p < .25$): Caregiver Education, Single Caregiver, Family Size, Birth weight, Small for Gestational Age, 5 minute Apgar Score, Established Conditions, Prenatal Care Visits Risk, Parental Risk Factor(s), NICU hospitalization, and Infant Feeding Method. Although Maternal Age did not meet screening criterion for inclusion, the theoretical importance of maternal age on child developmental risk is known. Thus, maternal age was included in the multiple logistic regression model building process. Prenatal care prior to the fifth month and delivery type were excluded from further analysis because these factors

did not meet univariate criteria for further investigation. The caregiver education variable was excluded from the multivariable model because it was moderately correlated with maternal age ($r=.46$). This correlation indicates a substantial association between these variables. Caregiver education was also excluded because of the association with social class. Thus, eleven predictor variables were considered for the multivariable model building process.

Table 14

Univariate Logistic-Regression Models for Poverty Status

Risk Variable	β	SE(β)	Exp (B)	95% CI	-2 log-likelihood	G	p	Referent Group
Mother Age 38 and Over	-.38	.09	.68	.57 - .82	21686.88	376.41	.01	Mother's Age: 19 - 37
Mother Age < 19	1.04	.06	2.82	2.54 - 3.14				
Caregiver education < 11 th grade	1.54	.04	4.69	4.31 - 5.10	20074.67	1282.99	.01	Caregiver Education: $\geq 11^{\text{th}}$ grade
Marital Status = Single	1.60	.03	4.94	4.61 - 5.29	19881.20	2206.34	.01	Marital status = married
Previous Births > 2	.93	.05	2.53	2.27 - 2.81	21805.22	268.24	.01	Previous births ≤ 2
Birth weight < 1500 g	.04	.15	1.04	.77 - 1.41	22026.03	.07	.79	Birth weight: ≥ 1500 grams
Small for Gestational Age	.38	.130	1.46	1.13 - 1.88	21950.04	7.98	.01	Not Small for Gestational Age
Apgar < 7	-.04	.12	.97	.76 - 1.22	21958.06	.08	.77	Apgar Score 5 minute: 7 or higher
Known Established Conditions	.32	.12	1.37	1.09 - 1.73	16589.01	6.81	.01	No Established Conditions
Inadequate # of Prenatal Visits	1.12	.05	3.36	3.06 - 3.69	18442.45	618.81	.01	Adequate # of prenatal visits
No Prenatal Care < 5 Months	1.14	.05	3.14	2.83 - 3.48	20623.89	444.54	.01	Any prenatal visits < 5 months
One or More Parental Risk Factors	.61	.05	1.83	1.67 - 2.02	21948.51	148.36	.01	No parental risk factor
NICU Hospitalization > 48 Hours	.12	.16	1.13	.818 - 1.563	1300.59	.56	.45	NICU Hospitalization ≤ 48 hours
Non-Vaginal Delivery	-.32	.040	.73	.67 - .79	22035.44	64.13	.01	Vaginal Delivery
Bottle Fed	.37	.03	1.45	1.36 - 1.56	21702.69	125.64	.01	Breast fed

Table 15

Univariate Logistic-Regression Models for Early Intervention in a Poverty Group

Risk Variable	β	SE(β)	Exp (B)	95% CI	-2 log-likelihood	G	p	Referent Group
Mother Age 38 and Over	.30	.34	1.35	.70 – 2.6	2076.38	.74	.69	Mother's Age: 19 – 37
Mother Age < 19	.00	.18	1.00	.70 – 1.42				
Caregiver education < 11 th grade	.36	.13	1.43	1.09 – 1.85	1944.25	6.84	.01	Caregiver Education: $\geq 11^{\text{th}}$ grade
Marital Status = Single	.50	.15	1.64	1.23 – 2.18	2059.34	12.34	.01	Marital status = married
Previous Births > 2	.35	.168	1.41	1.02 – 1.96	2061.63	3.96	.05	Previous births ≤ 2
Birth weight < 1500 g	2.49	.28	12.03	6.96 – 20.77	1983.29	58.30	.01	Birth weight: ≥ 1500 grams
Small for Gestational Age	.58	.38	1.79	.857 – 3.74	2038.13	2.07	.15	Not Small for Gestational Age
Apgar < 7	1.42	.28	4.14	2.41 – 7.12	2036.58	19.97	.01	Apgar Score 5 minute: 7 or higher
Known Established Conditions	1.76	.245	5.82	3.60 – 9.41	1489.77	38.41	.01	No Known Established Conditions
Inadequate # of Prenatal Visits	.53	.14	1.70	1.29 – 2.24	1907.19	13.37	.01	Adequate # of prenatal visits
No Prenatal Care Visits < 5 Months	-	.18	.93	.65 – 1.33	1878.98	.17	.68	Any prenatal visits < 5 months
One or More Parental Risk Factors	1.01	.138	2.74	2.09 – 3.59	2030.44	47.33	.01	No parental risk factor
NICU Hospitalization > 48 Hours	2.87	1.02	17.57	2.38 – 129.4	255.56	20.26	.01	NICU Hospitalization ≤ 48 hours
Non-Vaginal Delivery	.00	.16	1.00	.74 – 1.36	2083.63	.00	.98	Vaginal Delivery
Bottle Fed	.48	.13	1.61	1.24 – 2.10	2000.06	13.29	.01	Breast fed

Multiple Logistic Regression Analyses

There are many model-building strategies available for fitting a logistic regression model. For this study, both a manual fitting strategy and a backward stepwise log-likelihood ratio procedure were used. The results of this process are shown in Tables 16 through 18. For the stepwise regression procedure, the alpha level for entry (i.e. p_E) was set at $p_E \leq .15$ and for removal (i.e. p_R) at $p_R \geq .20$. Significance was assessed using the likelihood ratio chi-square test. The procedure began by contrasting a constant-only model against a full multivariable model comprising the eleven predictor variables determined by the univariate logistic regression analyses.

After determining the fit of the multivariable model, the importance of each variable included in the model was verified. This included an examination of the Wald statistic for each variable and a comparison of each estimated coefficient with the coefficient from the univariate model containing only that variable. Variables that did not contribute to the model based on these criteria were eliminated and a new model fit. The new model was compared to the old model through the likelihood ratio test and the estimated coefficients for the remaining variables were compared to those from the full model. Because there are many variables to test, a stepwise logistic regression procedure was used in this study as recommended by Hosmer and Lemeshow (1989).

The logistic regression coefficients may be interpreted using the Wald test statistic. Under the hypothesis that an individual coefficient is zero, the Wald statistics will follow the standard normal distribution. The Wald critical value of 2 leads to an approximate level of significance of .05. However because of multiple degrees of freedom, one must be careful in the use of the Wald statistics to assess the significance of the coefficients, especially in the case of design variables such as the levels of mother's age. Hosmer and Lemeshow (1989) suggest testing one model with and one model without the variable using the likelihood ratio test such as has been done with the stepwise logistic regression procedure. The p -values calculated in stepwise procedures are not p -values in the traditional hypothesis-testing context. They are thought of as indicators of the relative importance among variables.

Eleven variables were considered in the model-building process. Table 16 shows a full multivariable model containing variables identified by univariate logistic regression analyses for Early Intervention enrollment in a poverty group. On the basis of the output displayed in Table 16 it appears that several of the variables do not demonstrate importance in the multivariable model when controlling for the other variables: Family Size, 5 Minute Apgar Score, Parental Risk Factor, and Infant Feeding Method. The two levels of maternal age show a very different association with the outcome variable. Older mothers are significantly more likely to have children enrolled in Early Intervention, however younger mothers are not.

Table 16

Full Multivariable Model of Early Intervention Enrollment for Poverty Cohort

Variable	β	SE(β)	Wald
CONSTANT	-5.51	1.35	16.74
Mother's Age: 19 – 37 (referent group)			4.34
38 and over	1.77	.85	4.33
Under 19	.20	.68	.09
Single Caregiver: Married (referent group)	.97	.62	2.50
Family Size: 0-2 (referent group)	-.36	.66	.29
Birth weight: ≥ 1500 grams (referent group)	2.51	.67	13.86
SGA: >37 weeks and >2500 grams (referent group)	1.65	.75	4.89
Apgar Score 5 minute: 7 or higher (referent group)	-.17	.71	.06
Known Conditions: none (referent group)	3.23	.78	17.10
Prenatal Care Risk: no (referent group)	.65	.48	1.85
Parental Risk Factor: No (referent group)	-.13	.59	.05
NICU Hospitalization: ≤ 48 hours (referent group)	2.44	1.14	4.62
Infant Feeding Method: Breast (referent group)	-.14	.47	.09
-2 Log Likelihood = 141.339			

These results suggest that a new model be fit which does not contain these variables. This may be done manually or through a stepwise logistic regression procedure. The final results were derived by stepwise model backward likelihood ratio procedure in which all variables that demonstrated a substantial univariate association to the outcome were included in the first step. These results are given in Table 17.

The likelihood ratio test for the difference between the models in Tables 16 and 17 (a test for the significance of the excluded variables) yields a value of $G = [141.921 - 141.339] = .592$. Comparing this to a Chi-square distribution with 4 degrees of freedom yields a non-significant p-value, indicating that the excluded variables add little to the model once the other variables have been included. Variable exclusion was further supported by the similarities between the model's values of the estimated coefficients, with the exception of birth weight. A jump in magnitude of the estimated coefficient for birth weight indicates that one of the excluded variables was important in providing a needed adjustment of the effect of birth weight.

Table 17

Backward Stepwise Logistic Regression Results for Early Intervention Enrollment

Variable	β	SE(β)	Wald	Exp(β)	95% CI	p
Mother's Age: 19 – 37			4.43			
38 and over	1.76	.84	4.39	5.79	1.11 – 30.03	.04
Under 19	.28	.67	.18	1.33	.36 – 4.90	.67
Single Caregiver	.88	.59	2.26	2.42	.77 – 7.62	.13
Birth weight	2.43	.59	17.23	11.35	3.61 – 35.75	.01
SGA	1.70	.75	5.12	5.46	1.25 – 23.72	.02
Known Conditions	3.09	.73	17.85	21.87	5.23 – 91.50	.01
Prenatal Care Risk	.65	.47	1.95	1.92	.77 – 4.79	.16
NICU Hospitalization	2.49	1.15	4.70	12.06	1.27 – 114.57	.03
CONSTANT	-5.64	1.33	17.88			.01
-2 Log Likelihood = 141.921						

An inspection of the change in estimated coefficients at the various steps of the backward stepwise regression procedure indicated that 5 minute Apgar score provided the adjustment for birth weight. The residual Chi-square value of the variables excluded from the equation was not significant ($G = .574, p = .97$).

Examining the results of the stepwise procedure indicates that mother's age over 37, single caregiver, birth weight, small for gestational age, known established conditions, and NICU hospitalization all demonstrate a critical value of 2 for the Wald statistic.

At the conclusion of the stepwise procedure, a collection of variables which seem to be statistically important is produced. Before proceeding with the final model, Hosmer and Lemeshow (1989) suggest that any known theoretically important variables should be added or theoretically unimportant variables removed. At this point the variable Prenatal Care Risk was deleted from the final multivariable model. This variable represented the weakest association with Early Intervention enrollment and was also known to be associated to poverty status. Table 18 presents the results of the manually fit final multiple logistic regression model for Early Intervention enrollment.

Table 18

Final Prediction Model (Model One) for Early Intervention Enrollment in the Poverty Cohort

Variable	β	SE(β)	Wald	Ψ	95% CI	p
Mother's Age			4.69			.10
38 and over	1.55	.73	4.46	4.71	1.12 - 19.81	.04
Under 19	3.45	.49	.48	1.41	.53 - 3.74	.49
Single Caregiver	.74	.45	2.34	2.10	.81 - 5.43	.13
Birth weight Risk	1.94	.73	18.83	6.94	2.89 - 16.63	.01
SGA	1.55	.54	4.48	4.72	1.12 - 19.82	.03
Known Conditions	1.81	1.05	11.06	6.11	2.10 - 17.76	.01
NICU Hospitalization	2.14	1.12	4.18	8.52	1.09 - 66.40	.04
CONSTANT	-4.80	1.12	18.45			.01
-2 Log Likelihood = 189.138						

The mothers age variable was again found to have differential rates of Early Intervention enrollment between age groups. Mother's who are over 37 are over four times more likely to have children in Early Intervention programming than those mother's who are between the ages of 19 and 37. The teenage group is not strongly associated with the outcome variable, however, the overall age variable does meet criterion for model inclusion. This final multivariable model was then tested for utility on the non-poverty group. The results are presented in Table 19. The comparison of rates of identification between the various multivariable models produced in this study to each other and the Level One algorithm are presented in Table 20.

Table 19

Model One for Early Intervention Enrollment in the Non-Poverty Cohort

Variable	β	SE(β)	Wald	Ψ	95% CI	P
Mother's Age			.002			.99
38 and over	.01	.51	.00	1.01	.37 – 2.76	.99
Under 19	-.02	.47	.00	.98	.39 – 2.46	.97
Single Caregiver	.21	.25	.69	1.23	.75 – 2.03	.41
Birth weight Risk	1.78	.27	43.14	5.93	3.49 – 10.09	.00
SGA	-.67	.80	.69	.51	.11 – 2.47	.41
Known Conditions	1.74	.29	35.69	5.70	3.22 – 10.10	.00
NICU Hospitalization	.45	.35	1.62	1.56	.79 – 3.09	.20
CONSTANT	-2.77	.33	69.94			
-2 Log Likelihood = 536.079						

As can be clearly seen in the results in Table 19, the group of variables that were strongly related to Early Intervention enrollment in a poverty group produced quite different results in a non-poverty group. The variables within the multivariable model that were associated with Early Intervention enrollment when controlling for the other variables for the non-poverty group were very low birth weight and known established conditions. The results of the poverty group optimized model

one for non-impoveryshed families showed that biological risks represent the strongest predictors of Early Intervention enrollment for these families. Non-impoveryshed families with environmental risks alone are less well represented in the Early Intervention eligible population.

A composite variable produced by indicated risk among the selected factors was produced (Model One). The utility of the multivariable model optimized on the poverty group to predict Early Intervention enrollment (Model One) was tested on the non-poverty group and on the total Rhode Island sample. The comparison of utility of this model for different samples is presented in Table 20. The poverty-optimized risk algorithm produced increased sensitivity and decreased percentage of false positives compared to the Level One prediction algorithm. These results indicate a substantial increase in predictive utility over using poverty status as a predictor alone. Model One demonstrated reduced sensitivity and increased percentage of false negatives in the non-impoveryshed group compared to the Level One screening cohort. The poverty-optimized multivariable model tested on the entire Rhode Island cohort was nearly identical to the Level One screening in terms of sensitivity, specificity, percentages of false positive and false negatives and odds of Early Intervention enrollment. Because the model did not represent an improvement in the identification of children at risk for Early Intervention enrollment by age three, an Early Intervention optimized risk model was designed. The Early Intervention optimize model is described in Results Two.

Table 20

Multivariable Models for Poverty and Non-Poverty Groups and Level One Risk Algorithm

Group	Sensitivity	Specificity	FN%	FP%	OR	95% CI
Model One poverty	82%	30%	18%	70%	2.02	1.47 – 2.79
Model One non poverty	61%	64%	39%	36%	2.79	2.35 – 3.32
Model One for all	66%	58%	34%	42%	2.70	2.38 – 3.05
Poverty census tract alone	32%	74%	68%	26%	1.37	1.18 – 1.59
Level One risk disposition	65%	60%	35%	40%	2.82	2.49 – 3.19

Discussion One

Children living in poverty are represented at a larger rate in Early Intervention programming in Rhode Island than those who are not impoverished. However, these children are at risk and are sometimes underrepresented in mental health and educational services nation-wide. Many reasons account for this disparity including frequent moves, language and economic barriers. Studies of delayed development may represent environmental risk in terms of socioeconomic status rather than identifying the specific component risk factors. The high-risk sample (MLS-PT) was identified as risk-positive by the Level One screening at a rate double that in the general Rhode Island cohort (see Study Two). Post-hoc examination of the Level One screening revealed that the screening may be overly influenced by social class sensitive factors, such as educational level and amount of prenatal care.

This study examined the association between a set of predictor variables and Early Intervention enrollment, with the goal of designing a risk algorithm with improved sensitivity and reduced percentage of false-negatives as compared to the current Level One prediction algorithm. An effort was made to find predictor variables that were better predictors of Early Intervention enrollment than global socioeconomic status.

Univariate Models

The univariate logistic regression analyses for poverty status identified eleven of fourteen variables that were significantly associated with economic disadvantage. Surprisingly, most of the factors that were tested for their association with poverty were found to have a univariate association with poverty. Only three variables were not significantly associated with poverty status: birth weight, NICU hospitalization greater than two days, and five minute Apgar score less than seven. A risk screening based solely on the three measures of biological risk that were independent of poverty status showed one that is not supported by developmental theory (i.e., the Transactional Model). Therefore additional univariate analyses were calculated for Early Intervention enrollment in a poverty group.

The second set of univariate logistic regression analyses indicated that eleven out of fourteen variables demonstrated an association with Early Intervention enrollment within the poverty sample. Maternal age, prenatal care before the fifth month of pregnancy, and delivery type were not found to be related to Early Intervention enrollment. Maternal age was included in the multivariable model based

on the theoretical importance of maternal age, especially teenage mothers, on child developmental outcome. Caregiver education level was not included in the next phase of analyses because it was found to be moderately correlated with maternal age ($r = .46$). Eleven predictor variables were considered for the multivariable model building process.

Multivariable Models

The results of the full multivariable model containing all eleven variables indicated through univariate logistic regression analyses yielded some interesting results. When controlling for other variables included in the model, family size, five minute apgar score, parental risk factor, and infant feeding method were not predictors of Early Intervention enrollment in a poverty group. In addition, teenage mothers were also not associated with the outcome.

The results of the backward stepwise logistic regression procedure indicated that seven of the original variables best predicted Early Intervention enrollment in a poverty sample: mother's age over 37, single caregiver, birth weight, small for gestational age, known established conditions, prenatal care risk, and NICU hospitalization. A final model (Model One) was fit that excluded the prenatal care variable because of its association with low economic status. In the final model, mother's age, continued to demonstrate different levels of association with Early Intervention depending on age. Teenage mothers were not more likely to have children in Early Intervention than mothers between the ages of 19 and 37. Inspection of the confidence intervals for the estimated odds ratio indicated that single mothers, when controlling for other variables in the model, were not more likely to have children in Early Intervention than mothers who were married. Predictors of Early Intervention enrollment in a poverty group were mothers over age 37, very low birth weight children, small for gestational age newborns, newborns with known established conditions such as congenital malformations or inborn errors in metabolism, and newborns who were hospitalized in the neonatal care unit for more than two days.

Model One was run for the non-poverty group and the results were quite different when examining the individual estimated coefficients and odds ratios. In this case only two variables had odds ratios that were significantly greater than one: very low birth weight and known established conditions. These findings support that biological variables alone may represent the best risk factors of

Early Intervention enrollment for non-impoveryished families. Non-impoveryished families with environmental risk factors but not biological risk factors are not well represented in the Early Intervention population. Model One was tested for its predictive probability for the poverty group, non-poverty group and the total Rhode Island cohort. The poverty-optimized risk algorithm produced increased sensitivity (82%) and decreased percentage of false positives (18%) even though there was a substantial reduction in the number of predictor variables compared to Level One (6 versus 12). The Early Intervention-optimized model was much more sensitive than the use of poverty status alone as a predictor of eligibility and enrollment.

Using Model One for a non-poverty group produced a less sensitive model and one with a higher percentage of false negatives than the Level One screening. The poverty-optimized multivariable model tested on the entire Rhode Island cohort was nearly identical to the Level One risk disposition algorithm in terms of sensitivity, specificity, percentages of false positive and false negatives and odds of Early Intervention enrollment. Therefore the risk factors that were predominantly found reliable for a poverty sample were not good predictors of Early Intervention enrollment for non-impoveryished families. For the entire Rhode Island cohort, Model One produced very similar results with fewer predictors than the Level One screening.

The goal of this investigation was to design a risk algorithm that was less social-class sensitive and with higher sensitivity and with a lower percentage of false negatives. The combination of predictor variables indicating biological risk and family risk produced by the model-building procedure is supported by the transactional model of developmental risk (Sameroff & Chandler, 1975). Model One did not represent an improvement in the identification of children who would be in need of Early Intervention services by age three for the general population. Therefore an Early Intervention enrollment-optimized risk model was designed. The performance of the Early Intervention optimized model is reported in Results Two.

Results Two

This section provides (a) an overview of the demographic characteristics of the randomly selected sample of one-third the population compared with the remaining two-thirds sample; (b) results of univariate analysis of Early Intervention enrollment; (c) results of multivariable analysis of Early

Intervention enrollment; and (d) comparison of the new Early Intervention-optimized model with the current Level One prediction algorithm. The randomly selected sample of one third the Rhode Island cohort was generated through the SPSS random sample procedure.

Demographic Characteristics

A randomly selected one-thirds sample ($N=8966$, 32.8%) of the entire cohort ($N= 27,312$) was compared to the remaining two-thirds ($N= 18,346$) on demographic criteria and predictor variables. T-tests and Chi-square analyses were performed between the two samples. The samples did not significantly differ in terms of any child/biological or parental/environmental predictor variable.

Univariate Logistic Regression Analyses

The logistic regression model building process began with careful univariate analysis of each variable. The goal was to create a prediction model based on Early Intervention enrollment for a randomly selected one-third sample, then test this model on the remaining sample. Table 21 shows the results of the univariate analyses for predictor variables that are theoretically important for model inclusion, and displays (1) the estimated slope coefficients (β) for the univariate logistic regression model containing these variables; (2) the estimated standard error [$SE(\beta)$] of the estimated slope coefficient; (3) the estimated odds ratio [$Exp(B)$], which is obtained by exponentiating the estimated coefficient; (4) the 95% confidence intervals for the odds ratio; (5) the value of the -2 log-likelihood for the model; (6) the likelihood-ratio test statistic (G) for the hypothesis that the slope coefficient is zero; and (7) the alpha level associated with G (p).

Results of the univariate analyses for Early Intervention enrollment indicated that twelve of fifteen variables were significantly associated with enrollment status ($p < .25$). All variables had positive logistic regression coefficients indicating a positive association with outcome (i.e. the lighter the newborn, the more likely that newborn will be in Early Intervention). Also, based on inspection of the confidence interval estimates, there is evidence that these twelve variables are associated with the outcome, Early Intervention enrollment. Maternal age did not meet the screening criterion for inclusion as a predictor variable. However, there is evidence that teenage maternity is a risk factor for developmental problems. Therefore the variable indicating teenage (<18) or not teenage was tested.

Table 21

Univariate Logistic-Regression Models for Early Intervention Enrollment

Risk Variable	β	SE(β)	Exp (B)	95% CI	-2 log-likelihood	G	p	Referent Group
Mother Age 38 and Over	.08	.24	1.08	.67 – 1.73	3219.14	.11	.95	Mother's Age: 19 – 37
Mother Age < 19	.02	.20	1.03	.69 – 1.52				
Caregiver Education < 11 th grade	.07	.24	1.07	.81 – 1.69	3219.53	.08	.77	Caregiver Education: $\geq 11^{\text{th}}$ grade
Marital Status = Single	.57	.10	1.77	1.45 – 2.17	3194.96	30.24	.01	Marital status = married
Previous Births > 2	.48	.17	1.62	1.16 – 2.25	3217.45	7.22	.01	Previous births ≤ 2
Birth weight < 2500 g	.89	.19	2.44	1.68 – 3.55	3053.90	163.26	.01	Birth weight: ≥ 2500 grams
1500 – 1999 g	1.11	.32	3.04	1.61 – 5.73				
1000 – 1499 g	2.79	.31	16.29	8.95 – 29.65				
<999 g	3.11	.28	22.49	12.89 – 39.26				
Small for Gestational Age	.95	.28	2.59	1.50 – 4.46	3205.55	9.28	.01	Not Small for Gestational Age
Apgar < 7	1.84	.20	6.28	4.24 – 9.30	3155.68	59.86	.01	Apgar Score 5 minute: 7 or higher
Known Established Conditions	2.24	.19	9.37	6.43 – 13.66	2458.32	96.83	.01	No Known Established Conditions
Inadequate # of Prenatal Visits	.70	.14	2.02	1.55 – 2.64	3010.47	23.41	.01	Adequate # of prenatal visits
No Prenatal Care Visits < 5 Months	.16	.19	1.17	.81 – 1.69	3043.60	.67	.41	Any prenatal visits < 5 months
One or More Parental Risk Factors	.82	.13	2.26	1.75 – 2.93	3191.69	33.60	.01	No parental risk factor
NICU Hospitalization >48 Hours	1.56	.47	4.75	1.87 – 12.05	411.91	15.92	.01	NICU Hospitalization ≤ 48 hours
Non-Vaginal Delivery	.29	.11	1.33	1.07 – 1.67	3218.11	6.29	.01	Vaginal Delivery
Bottle Fed	.35	.10	1.41	1.15 – 1.74	3136.14	10.96	.01	Breast fed

The results indicated that this variable did not meet the univariate criterion for inclusion in the model, however the variable for teenage mother was included in the multivariable model based upon theoretical importance. The variable any visits before five months was also not significantly related to Early Intervention enrollment ($p=.41$). The birth weight risk variable was reduced to two categories for multivariable analysis (less than 2500 grams or 2500 grams or greater). The estimated odds ratio for the new birth weight risk variable was 4.45 (95% CI 3.45 – 5.75).

Multiple Logistic Regression

Thirteen variables were considered for model-building process. Table 22 shows a full multivariable model containing variables identified by univariate logistic regression analyses for Early Intervention enrollment. On the basis of the output displayed in Table 22, it appears that five of the variables do not demonstrate importance in the multivariable model: single caregiver, small for gestational age, five minute apgar score, prenatal care risk, and infant feeding method. This suggested that a new model be fit which does not contain these variables. The final model was derived by forward stepwise log-likelihood ratio logistic regression procedure. The results of the last step in the forward process are given in Table 23. For the stepwise regression procedure, the alpha level for entry (i.e. p_E) was set at $p_E \leq .15$ and for removal (i.e., p_R) at $p_R \geq .20$. The variables specified in the model are tested for entry into the model one by one, based on the significance level of the score statistic. The variable with the smallest p_E is entered into the model. After entry, variables already included in the model are tested for possible removal based on the significance of the likelihood ratio chi-square test. The procedure began by producing a constant-only model and assessing the significance of each of the thirteen predictor variables. The final step occurs when all variables have entered the model or all variables in the model have p-values to remove which are less than p_R and the variables not included in the model have p-values to enter which exceed p_E . The following are the results of each step in this process:

Step 0: Step (0) begins with a fit of the “intercept only model” and an evaluation of its log-likelihood, followed by fitting each univariate logistic regression models and comparing their respective log-likelihoods. At step (0) the program selects as a candidate for entry at step (1) the variable with the

smallest p-value. This was the variable known established conditions with a p-value of .001. Since the p-value is less than .15, the program proceeds to step (1).

Step 1: At step (1) the program will not remove the variable just entered since $p_R > p_E$ and the p-value to remove at step (1) is equal to the p-value to enter at step (0), which is true for a variable at any step. The value of the likelihood ratio test for the model at step (0) compared to that containing known established conditions at Step (1) is $G = 23.26$. The p-value of G is $< .001$. The variable with the smallest p-value to enter at step (1) is birth weight Less than 2500 grams with a p-value of .001, which is less than 0.15 so the program moves to step (2).

Step 2: Step (2) begins with a fit of the model containing both known established conditions and birth weight less than 2500 grams. It is possible that once birth weight has been added to the model, known established conditions is no longer important. In this way step (2) checks for backward elimination. At step (2) the program did not remove any variables and selects the smallest p-value to enter among the remaining variables not in the model which is caregiver education risk ($p = .028$). This value is less than .15 so the program proceeds to step (3). The likelihood ratio test for the model at step (2) was also significant ($G = 35.98$, $p = .001$).

Step 3: Step (3) begins with the fit of the model containing known established conditions, birth weight less than 2500 grams, and caregiver education risk. The likelihood ratio test for the model at this step is significant ($G = 40.33$, $p = .000$). The program selected delivery risk ($p = .036$) for entry at step (4). No variables were selected for removal at this step.

Step 4: The likelihood ratio test for the model at step (4) was also significant ($G = 44.70$, $p = .001$). The program selected parent risk characteristic(s) ($p = .055$) for entry at step (5). No variables were selected for removal at this step.

Step 5: The likelihood ratio test for the model at step (5) was also significant ($G = 48.10$, $p = .001$). The program selected NICU hospitalization greater than 48 hours ($p = .076$) for entry at step (6). No variables were selected for removal at this step.

Step 6: The likelihood ratio test for the model at step (6) was also significant ($G = 51.59$, $p = .001$). The program selected family size ($p = .058$) for entry at step (7). No variables were selected for removal at this step.

Step 7: The likelihood ratio test for the model at step (7) was also significant ($G = 55.81$, $p = .001$). The program found the minimum p-value for entry was .18 for teenage mother. This value is greater than .15 so teenage mother was not entered into the model, and the program stopped. No variables met the criteria for removal at this step. The residual chi-square for the variables excluded from the model was not significant ($G = 4.95$, $p = .61$).

Table 22

Full Multivariable Model of Early Intervention Enrollment

Variable	β	SE(β)	Wald
CONSTANT	-3.809	.585	42.35
Teenage mother: 18+ (referent group)	-1.150	.799	2.07
Single Caregiver: Married (referent group)	.379	.373	1.03
Caregiver Education: $\geq 11^{\text{th}}$ Grade (referent group)	1.090	.481	5.14
Family Size: 0-2 (referent group)	-1.508	.779	3.75
Birth weight: ≥ 2500 grams (referent group)	.778	.364	4.58
SGA: >37 Weeks and >2500 Grams (referent group)	-.045	.632	.01
Apgar Score 5 Minute: 7 or Higher (referent group)	.393	.420	.88
Known Conditions: None (referent group)	2.510	.504	24.83
Prenatal Care Risk: No (referent group)	1.38	.412	.11
Parental Risk Factor: No (referent group)	.875	.424	4.25
NICU Hospitalization: ≤ 48 Hours (referent group)	1.035	.551	3.53
Delivery Method: Vaginal (referent group)	.483	.331	2.13
Infant Feeding Method: Breast (referent group)	-.267	.327	.67
-2 Log Likelihood = 263.341			

The p-value for teenage mother was .18, just met the cut-off for entry into the model of 0.15.

Therefor this variable was included in the final multivariable model presented in Table 23.

The likelihood ratio test for the difference between the models in Tables 22 and 23 yields a value of $G = [317.93 - 263.34] = 54.59$. Comparing this to a chi-square distribution with 6 degrees of freedom yields a p-value of .001, demonstrating that the reduced model is reliably different from the full multivariable model. In comparing multiple logistic regression models, the question is “does the log-likelihood value decrease/increase significantly with the addition/deletion of predictor(s)?” In this case, the log-likelihood value significantly increases with the deletion of predictors. Tabachnick and Fidell (1996) support that if the sample size is very large, almost any difference between models is likely to be statistically significant, even though the multivariable model deviates significantly from the perfect (hypothetical) model. The log-likelihood value of the final model compared to the constant only model yields a likelihood ratio test ($G = 71.09, p < .001$). This confirms the finding that the variables included in the reduced model are reliable predictors of Early Intervention enrollment. The estimated coefficients for each variable included in the reduced model were compared to the full multivariable model. No substantial changes in the values of the estimated coefficients were found indicating that the excluded variables did not significantly impact the remaining variables.

Table 23

Model Two for Early Intervention Enrollment for the One-Third Sample

Variable	β	SE(β)	Wald	Ψ	95% CI
Teenage Mother	-1.016	.70	2.11	.36	.09 – 1.43
Education Risk	1.076	.43	8.34	2.93	1.27 – 6.77
Family Size	-1.454	.69	3.74	.23	.06 – .90
Low Birth weight	.950	.32	5.86	2.59	1.39 – 4.82
Known Conditions	2.654	.45	27.30	14.21	5.93 – 34.08
Parent Risk	.960	.38	5.20	2.61	1.25 – 5.47
NICU Hospitalization	1.198	.54	3.83	3.31	1.14 – 9.61
Delivery Method	.548	.29	2.58	1.73	.97 – 3.08
CONSTANT	-3.953	.57	48.98		
-2 Log Likelihood = 317.931					

Examination of the odds ratios shows that each predictor variable is associated with likelihood of eligibility and enrollment for Early Intervention services on the basis of one unit change in each predictor variable. The odds ratio value less than one for Family Size indicates that when statistically adjusting for the other predictors, children in large families are less likely to be in Early Intervention than are children in small families. Teenage maternity is negatively associated with Early Intervention enrollment when controlling for other variables in the model. Known established conditions demonstrates the strongest predictor in the multivariable model, followed by NICU hospitalization, education, parent risk, very low birth weight and delivery method.

At the conclusion of the stepwise procedure, a collection of variables that seem to be statistically important was produced. All variables were associated with Early Intervention enrollment with the possible exception of teenage maternity which produced inconsistent results in this analysis. This final multivariable model was then tested for utility on the remaining two-thirds sample. The results are presented in Table 24.

Table 24

Model Two for Early Intervention Enrollment for the Two-Thirds Sample

Variable	β	SE(β)	Wald	Ψ	95% CI
Teenage Mother	.413	.457	.819	1.51	.62 – 3.70
Education Risk	-.035	.332	.011	.97	.50 – 1.85
Family Size	.703	.303	5.39	2.02	1.12 – 3.66
Low Birth weight	.742	.202	13.47	2.10	1.41 – 3.12
Known Conditions	1.81	.265	46.38	6.08	3.62 – 10.22
Parent Risk	.535	.259	4.28	1.71	1.03 – 2.84
NICU Hospitalization	1.45	.415	12.24	4.27	1.89 – 9.64
Delivery Method	.296	.195	2.31	1.34	.92 – 1.97
CONSTANT	-3.87	.411	89.08		

-2 Log Likelihood = 707.645

Variables in this sample demonstrate very different estimated logistic regression coefficients than for the one-third sample. Teenage maternity now displays a positive association with Early Intervention enrollment and education risk a negative association when controlling for the other predictors in the model. Education and teenage maternity are not statistically important in predicting Early Intervention enrollment when controlling for the remaining variables. Known established conditions continues to display the strongest association with outcome, followed by NICU hospitalization, very low birth weight, family size, parent risk and delivery method. The comparison of rates of predictive probability of Early Intervention enrollment between Model Two and the Level One screening are presented in Table 25.

Table 25

Comparison Multivariable Risk Models

Group	Sensitivity	Specificity	FN%	FP%	OR	95% CI
Model Two 1/3 sample	70%	51%	30%	49%	2.46	1.98 – 3.07
Model Two 2/3 sample	70%	51%	30%	49%	2.49	2.13 – 2.91
Model Three 1/3 sample	89%	25%	11%	75%	2.71	1.96 – 3.75
Model Three 2/3 sample	93%	13%	7%	87%	1.98	1.50 – 2.60
Level One Risk Disposition	65%	60%	35%	40%	2.82	2.49 – 3.19

The utility of this model to predict Early Intervention enrollment in the two samples compared to the results of the Level One risk algorithm is presented in Table 25. In addition, the results of a multivariable model (Model Three), obtained by including all variables that shows an univariate association with the Early Intervention outcome in the one-third sample, was calculated. The Early Intervention-optimized multivariable model (Model Two) represents an improvement over the Level One algorithm both in terms of greater sensitivity (70% versus 65%) and in a reduction in the percentage of False Negatives (30% versus 35%). Model Two represents an improvement in the identification of children at risk for developmental problems as indicated by Early Intervention

enrollment by age three. Clearly the multivariable model (Model Three) obtained through adding univariate predictors of Early Intervention enrollment produced a risk algorithm that had improved sensitivity and has greatly reduced percentage of False Negatives. This demonstrates that improved sensitivity carries with it the burden of a large rate of false positives.

Discussion Two

Univariate Models

The goal of Results Two was to design a risk algorithm with improved sensitivity and reduced percentage of false-negatives compared to the current Level One prediction algorithm. Results of the univariate analyses indicated that twelve of fifteen variables were significantly associated with Early Intervention enrollment ($p < .25$). The variables that were not significantly associated with enrollment were mother's age and prenatal care visits prior to the fifth month of pregnancy. Teenage maternity less than 18 was included in the multivariable model based on the theoretical importance of maternal age on child developmental outcome. Dropped from further consideration as a predictor variable was any prenatal care visits before five months. Thus, thirteen predictor variables were considered for the multivariable model building process.

Multivariable Models

The result of the forward stepwise logistic regression procedure indicated that eight variables best predicted Early Intervention enrollment. Closer examination of the final logistic regression model in the one-third sample indicates some interesting results. Both teenage mother less than 18 and family size had negative estimated coefficients when statistically adjusting for the other variables included in the model. The effect of controlling for other variables will mean that the other variables display greater importance in predicting Early Intervention enrollment than family size or age of the mother alone. Known established conditions represents the variable with the greatest influence on Early Intervention enrollment when included in a multivariable model. Children with established conditions that place them at risk for developmental problems are more than 14 times more likely to be enrolled in Early Intervention than those without these conditions. The risk factors for education and parental risk were also strongly associated with the outcome. This model represents a combination of child centered biological predictor variables and environmental/parental predictor variables. For Model Two tested on

the remaining two-thirds sample, both teenage maternity and family size had positive estimated logistic regression coefficients. Teenage maternity displayed limited importance in prediction when controlling for the other variables in the model and is strongly associated with poverty status.

This Early Intervention-optimized algorithm (Model Two) was tested for its predictive utility in terms of sensitivity, specificity, percentages of false negative and false positive, and associated odds ratios. In addition, the results of a multivariable model (Model Three) obtained by including all variables that show a univariate association with the Early Intervention outcome in the one-third sample was calculated. Model Two represents an improvement over the Level One algorithm both in terms of greater sensitivity and in a reduction in the percentage of false negatives. Model Two represent an overall improvement in the identification of children at risk for developmental problems as indicated by Early Intervention enrollment by age three. This model also demonstrated identical predictive utility in both the one-third and two-thirds samples. The multivariable model (Model Three) obtained through adding univariate predictors of Early Intervention enrollment produces a risk algorithm that has greatly improved sensitivity and greatly reduced percentage of false negatives. However, this model would produce so large a rate of false positives that it would be ungainly to service in the current follow-up procedure. Model Two will be tested in the next study on age three neurodevelopmental outcome in a high-risk sample.

Model One and Model Two included different combinations of predictor variables. Very low birth weight, known established conditions and NICU hospitalization were included in both models. Teenage maternity was included in both models for theoretical reasons. Model One, optimized on a poverty sample, also included small for gestational age and single caregiver status. Model Two also included caregiver education, family size, parent risk and delivery method risk. No previous research investigating the predictor variables for Early Intervention enrollment was found in a literature search. Thus, no direct comparisons can be made to such a screening model. Research on the factors that are commonly considered when determining a child to be at risk for developmental problems and therefore eligible to receive Early Intervention services supports including biological and parental/environmental predictors in an eligibility/enrollment model (Benn, 1993). Comparisons to screening models of developmental delay and disability are presented in the next study.

These findings support that a new risk algorithm could be utilized in Rhode Island that has increased sensitivity and decreased percentage of false negatives compared to the current algorithm being employed, Level One screening. The goal of the universal newborn screening program in Rhode Island is to cast a wide net and capture all of those children at birth who will be in need of services during their first three years of life either because of delayed development or risk for delayed development/behavior/adaptive problems in the future.

This study was limited to the predictor variables currently gathered by the Rhode Island Universal Newborn Screening procedure. Many children who are in Early Intervention programming in Rhode Island qualified not because of child developmental delay or behavior problems, but because they were determined to be at risk, in part based on the criteria used to determine newborn risk status. Children with true developmental delays and/or behavior/adaptive problems could not be distinguished from those at risk. The next study will establish if biological variables, environmental variables or a combination are the best predictors of actual developmental delay or behavior/adaptive problems as assessed by norm referenced measures of child development.

Study Four

Study Three examined the design of a risk model that best predicted Early Intervention enrollment. Children are eligible for Early Intervention if the child experiences delayed development/behavior problems or, under Rhode Island enrollment guidelines, the child has a combination of risk factors that places him/her at risk for developmental/behavioral problems. The best prediction model of Early Intervention enrollment (Model Two) included the following variables: teenage maternity, low parental education, large family size, very low birth weight, certain established conditions such as chromosomal abnormalities, parental risk factors such as mental illness, NICU hospitalization and non-vaginal delivery method. This model produced better sensitivity (70% versus 65%) and lower percentage of false negatives (30% versus 35%) than the current Level One screening for Early Intervention enrollment. The question remained if the child was eligible for Early Intervention services because of perceived risk or because of true delay, and if the Level One screening would be effective in identifying those infants at birth who would later experience delayed development.

This study examines the use of biological, parental/environmental, and infant behavioral information to create a prediction algorithm of child developmental delay at age three. It is hypothesized that a new risk algorithm can be developed with improved sensitivity and specificity over the current Level One that more precisely detects those children with developmental delays or behavior problems. It is also hypothesized that neurobehavioral information gathered at age one month will add to the prediction model for developmental delay by age three.

The present study details the development of an empirically and theoretically derived at-birth screening that predicts developmental outcome data. The utility of the model developed to predict Early Intervention enrollment in the previous study will be tested. A new prediction model will then be optimized on developmental outcome. Finally, the utility of using infant neurobehavioral information to reduce the high percentage of false positives identified by the at-birth screening will be assessed.

Risk Algorithm

A risk prediction algorithm (Model Two) was developed to predict Early Intervention enrollment in the Rhode Island cohort (see study three). Model Two included the following variables: teenage mother, caregiver education, family size, birth weight less than 2500 grams, known established conditions, parent risk, NICU hospitalization, and delivery method. This risk algorithm represents the group of variables that best predicts which children will be in need of Early Intervention services prior to their third birthday, while reducing the percentage of false negatives missed at birth. This model also does not increase the percentage of false positives to a level that would not be feasible to follow up with Level Two screening.

Statistical Analyses

Data analysis consisted of two major parts. First, the predictive utility of the prediction Model Two for child developmental outcome will be determined through chi-square and epidemiological statistics. The goal is to evaluate its predictive utility for developmental outcome as indexed by the composite variable and each of the separate outcome variables: Vineland Adaptive Behavior Composite, Bayley MDI and PDI, CBCL Internalizing, Externalizing and Total problems Score, and SICD Receptive and Expressive age. The evaluation of predictive utility will be performed through sensitivity, specificity, negative and positive predictive values, percentages of false negatives and false positives, and odds ratios. Then the utility of the NNNS summary variables to discriminate those infants who later demonstrated developmental problems will be assessed through SPSS univariate logistic regression procedure. Useful variables were added to the prediction algorithm in order to screen for those infants who were not likely to be in need of further evaluation for Early Intervention referral. The NNNS adjusted Model Two will be assessed by epidemiological statistics.

The second section presents an empirically developed model of developmental outcome based on the results of the composite outcome variable. The results of this empirically-derived model will be compared to the results of Model Two. NNNS summary variables will be added to the outcome-optimized model and the utility of this new model for predictive utility will be assessed. The

procedures for variable selection and model building were concordant with those outlined by Hosmer and Lemeshow (1989).

Results One

Demographic Characteristics

The demographic characteristics of the delayed versus not delayed groups were assessed. For continuous variables, and the means and standard deviations for the delayed versus no delay groups were calculated followed by *t*-tests to evaluate sign. For categorical variables, univariate logistic regression analyses were performed and estimated odds ratios are presented. For the composite variable Outcome, the two groups, delayed versus not delayed did not differ in terms of mothers age, birth weight or gestational age. Non white mothers (OR = 1.86) and mother's with less than 11th grade education (OR = 2.94) were significantly more likely to have children with some developmental delay. For the Bayley Mental Development Index, no significant differences between delayed and not delayed groups were found in terms of mother's age, birth weight and gestational age. Mothers with less than 11th grade education were three and one half times more likely to have children with a cognitive delay (OR = 3.46). For Bayley Psychomotor Developmental Index, mothers of children with delays were significantly older than mothers of children without delays (29.37 v 26.69 years). PDI groups did not differ in terms of ethnicity or mother's education. Mothers of children with internalizing behavior problems were significantly younger compared to the mothers of children without internalizing behavior problems (23.48 v. 26. 81 years). Minority group mothers were significantly more likely to have children with internalizing behavior problems (OR = 2.24), or Child Behavior Checklist Total Problem Score (OR = 3.01) in the clinically significant range. Mother's with less than 11th grade education were significantly more likely to have children with externalizing behavior problems (OR = 2.67), internalizing behavior problems (OR = 3.02), or Child Behavior Checklist Total Problem Score (OR = 3.01) in the clinically significant range. Children with Vineland Adaptive Behavior Composite scores in the <2 SD below the mean delayed range had significantly older mothers than children with non-delayed composite scores (30.06 v. 25.95 years). Children with Receptive Communication Age delays were significantly heavier weight at birth (*M* = 7.25, 1.23 SD) than those with non delayed Receptive Communication (*M* = 6.58, 1.58 SD). Minority mothers (OR = 3.80) and mother's with less

than 11th grade education (OR = 3.42) were significantly more likely to have children with Receptive Communication delays. No significant differences between delayed and non delayed groups were found for Expressive Communication Age.

Predictive Utility of Model Two for Delayed Developmental Outcome

The predictive utility of Model Two was assessed through chi-square analysis and epidemiological statistics. Table 26 presents the results for Model Two predicting the Developmental Composite variable and each of the developmental outcome variables that make up the composite. The sensitivity of Model Two for the developmental composite was very high (96%), and the percentage of false negatives was extremely low (4%). Only three of the 85 subjects with Developmental Composite delay were classified as risk negative by Model Two. The utility of Model Two for the individual outcome measures was also very good with sensitivity ranging from 96% to 100%, and percentage of false negative ranged from 0 to 4%. The odds ratio could not be calculated for outcomes where the sensitivity was 100%, because of a zero cell in the two by two analysis.

Model Two risk positive infants were almost eight times more likely to exhibit delayed development by age three than those who were classified as risk negative at birth. The results of the chi-square test for Model Two predicting Developmental Outcome Composite score was significant ($\chi^2 = 13.8, p < .01$). The results of the chi-square test for Model Two predicting delayed Bayley MDI, Bayley PDI, CBCL Externalizing, Vineland Adaptive Behavior Composite, and SICD Receptive and Expressive Communication Age scores could not be interpreted because one cell in each analysis had an expected count less than 5. The results of the chi-square test for Model Two predicting delayed CBCL Internalizing score was significant ($\chi^2 = 6.37, p < .01$). The results of the chi-square test for Model Two predicting delayed CBCL Total Problems score was significant ($\chi^2 = 7.36, p < .01$). These results show that Model Two, optimized on Early Intervention enrollment, performs very well for prediction of Developmental Delay and better than it performed for Early Intervention enrollment (96% versus 70% sensitivity, 4% versus 30% false positives).

Table 26

Predictive Utility of Level One and Model Two for Three Year Developmental Outcome

Outcome	Delay N	No delay N	Sensitivity	Specificity	FN%	FP%	OR	95% CI
Level One predicting Developmental Composite	85	103	88%	24%	12%	76%	2.40	1.08 – 5.34
Model Two predicting Developmental Composite	85	103	96%	22%	4%	78%	7.86	2.27 – 27.12
Model Two – Bayley MDI	23	133	100%	18%	0%	82%		
Model Two – Bayley PDI	12	141	100%	17%	0%	83%		
Model Two - CBCL Internalizing	40	139	98%	19%	3%	81%	8.92	1.18 – 67.49
Model Two - CBCL Externalizing	31	148	97%	18%	3%	82%	6.35	.83 – 48.41
Model Two - CBCL Total Problems	43	123	98%	20%	2%	80%	10.12	1.33 – 77.05
Model Two - Vineland – Adaptive Composite	8	154	100%	16%	0%	84%		
Model Two - SICD – Receptive	24	136	96%	15%	4%	85%	4.19	.54 – 32.65
Model Two - SICD – Expressive	12	142	100%	15%	0%	85%		

Univariate Analysis of NNNS Summary Variables to Predict Developmental Outcome

Model Two produced very high rates of sensitivity and extremely low rates of false negatives. Therefore the twelve NNNS summary variables were explored for their utility in reducing the percentage of false positives identified by Model Two. Unfortunately large amounts of missing NNNS data meant that many NNNS summary variables that may have proved useful in this study could not be calculated. The NNNS summary variables are continuous scale, the directions of which vary. A higher score sometimes indicates better performance or more of the component being measured and sometimes a higher score indicate worse performance. Hosmer and Lemeshow (1989) support the univariate analysis of continuous variables that include the estimated coefficient (β), the estimated standard error

[SE(β)], the univariate Wald statistic, the likelihood ratio test for the significance of the coefficient (G), and its associated p-value. Hosmer and Lemeshow (1989) also suggest using two sample t-test to determine mean and standard deviation for each group. The results of the univariate logistic regression analyses with associated means and standard deviations are presented in Table 27.

Table 27

Univariate Analysis of NNNS Summary Variables for Developmental Outcome Composite

Variable	Mean (SD) Delay No Delay	β	SE(β)	Wald	G	p
Orientation/Attention	5.97 (.86) 5.70 (1.08)	.28	.16	3.00	3.11	.08
Amount of Handling	.63 (.21) .72 (.22)	-2.08	.74	7.94	8.36	.01
Quality of Movement	4.27 (.54) 4.39 (.56)	-.38	.28	1.85	1.88	.17
Arousal	4.27 (.54) 4.31 (.53)	-.12	.29	.19	.19	.67
Self Regulation	4.84 (.73) 4.79 (.62)	.09	.23	.16	.16	.69
Bad Reflexes	4.38 (1.76) 4.23 (1.46)	.06	.10	.39	.39	.53
Signs of Stress	.24 (.0056) .22 (.0059)	4.30	2.67	2.59	2.65	.10
Hypertonic	.68 (.92) .56 (.80)	.16	.18	.76	.77	.38
Hypotonic	.10 (.31) .007 (.26)	.41	.54	.57	.58	.45
Asymmetric Reflexes	1.41 (1.43) 1.50 (1.43)	-.05	.11	.17	.17	.68
Excitable	3.97 (2.39) 3.94 (2.10)	.01	.07	.01	.01	.92
Lethargic	2.42 (1.41) 2.58 (1.74)	-.06	.10	.43	.43	.51

Hosmer and Lemeshow (1989) suggested using a $p < .25$ as the screening criterion level for selection of predictor variables for model inclusion. Because a more stringent criterion level often results in rejection of a variable that might be important in the multivariable model building process. The data indicated that four out of twelve NNNS variables met the screening criterion for model inclusion ($p < .25$): Orientation, Amount of Handling required to get good orientation, Quality of Movement, and Signs of Stress. Close examination of the direction of the NNNS variables that show a

association with the composite outcome variable yield some interesting results. The delayed group showed better orientation and required less handling to achieve good orientation than the non-delayed group. This may seem counter-intuitive at first. For very irritable infants, examiners will move directly to the most intensive handling procedure, swaddling, to achieve good orientation. Thus, the number of handling procedures tried by the examiner will be less than that for less irritable infants. This situation may be influencing the orientation scores as well. Swaddling may be very effective for both irritable and not-irritable infants to achieve good orientation responses.

The non-delayed group showed better Quality of Movement and fewer Signs of Stress than the delayed group. The direction of the association between these NNNS summary variables and outcome for these variables was expected. Investigating the association between the NNNS summary variables and developmental outcome among the Model Two risk group yields the same four variables, each with the same direction in the association. The negative estimated coefficient for handling indicated that the predicted odds of delayed outcome decreased as the amount of handling increased. The positive estimated coefficient for orientation means that the predicted odd of delay increased as the amount of orientation increased.

To determine if any of the NNNS summary variables were highly correlated, Pearson r correlation procedures were performed. Correlations among the four NNNS summary variables are presented in Table 28. Although all correlations showed an association, only Quality of Movement and Signs of Stress show a moderate negative correlation indicating a moderate associations among variables.

Table 28

Correlations Among NNNS Summary Variables

	Orientation	Handling	Movement	Stress
Orientation	---			
Amount of Handling	-.31**	---		
Quality of Movement	.13*	-.19**	---	
Signs of Stress	-.13*	.17**	-.45**	---

* $p < .05$, ** $p < .01$.

Multivariable Analyses

Next, the Model Two composite variable was entered into a separate multiple logistic regression procedure with the goal of statistically adjusting the estimated effect of Model Two for differences in the distribution of and association with each NNNS summary independent variable. Each estimated coefficient provides an estimate of the log odds adjusting for the other variable included in the model. Each multivariable situation examines two independent variables, one dichotomous and one continuous, with the primary interest focused on the effect of the dichotomous variable (Model Two). In this way the results of Model Two risk classification statistically adjusted for NNNS performance. Analyzing the data with a bivariate model and then a multivariable model yields the estimated logistic regression coefficients shown in Tables 29 - 32, and displays (1) the estimated slope coefficients (β) for the univariate logistic regression model containing this variable; (2) the estimated standard error [$SE(\beta)$] of the estimated slope coefficient; (3) the Wald statistic, (4) the estimated odds ratio [$Exp(\beta)$], which is obtained by exponentiating the estimated coefficient; (5) the 95% confidence intervals for the odds ratio; (6) the value of the -2 log-likelihood for the model; (7) the likelihood-ratio test statistic (G) for the prediction that the slope coefficient is zero; and (8) the alpha level associated with G (p).

Table 29

Results of Statistically Adjusting Model Two for Orientation

Variable	β	$SE(\beta)$	Wald	$Exp(\beta)$	95% CI	-2 log-likelihood	G	p
Model Two	2.04	.64	10.26	7.65	2.20 – 26.57	220.996	15.12	.01
CONSTANT	-2.04	.61	11.01					
Model Two	1.99	.64	9.71	7.29	2.09 – 25.42	218.911	2.09	.15
Orientation	.24	.17	2.04	1.27	.92 – 1.75			
CONSTANT	-3.38	1.13	8.86					
-2 Log Likelihood = 236.112								

The value of the likelihood ratio test of Model Two at steps one (univariate) and two (multivariate) indicated that adding orientation to Model Two does not significantly improve on the prediction of Model Two alone. Therefore no improvement in prediction was found when orientation was added to Model Two. The NNNS adjusted estimated logistic regression coefficient and associated odds ratio for Model Two barely changes with the inclusion of orientation (Table 29). The goodness-of-fit chi-square process used to evaluate the predictor added to the model was not significant ($G = 2.09, p = .15$). Thus, little of the apparent difference between the two groups was in fact due to differences in level of orientation. Examination of the estimated coefficient, Wald statistic and the estimated odds ratio for orientation shows that orientation has a association to developmental outcome which was also seen in the univariate analysis of orientation on developmental outcome. The positive predictor coefficient indicates that the predicted odds increases as the predictor increases. Univariate analysis of orientation on developmental outcome for the Model Two risk group only revealed that orientation does not have an association with outcome (Wald = 1.38).

With the addition of Amount of Handling, the NNNS adjusted estimated logistic regression coefficient and associated odds ratio for Model Two showed an improvement in prediction over Model Two alone. The estimated logistic regression coefficient decreased slightly with the inclusion of Amount of Handling (Table 30).

Table 30

Results of Statistically Adjusting Model Two for Handling

Variable	β	SE(β)	Wald	Exp(β)	95% CI	-2 log-likelihood	G	p
Model Two	2.04	.64	10.27	7.65	2.20 – 26.56	223.768	15.14	.01
CONSTANT	-2.04	.61	11.01					.
Model Two	1.94	.64	9.06	6.95	1.97 – 24.57	217.718	6.05	.01
NHANDLE	-1.86	.77	5.85	.16	.03 - .70			
CONSTANT	-.70	.81	.74					
-2 Log Likelihood = 238.911								

The goodness-of-fit chi-square process used to evaluate the predictor added to the model was significant ($G = 6.05$, $p = .01$). Thus, some of the apparent difference between the two groups was in fact due to differences in Amount of Handling required for good orientation. Examination of the estimated logistic regression coefficient, Wald statistic and the estimated odds ratio for Amount of Handling in the multivariable model revealed that Amount of Handling has a association to developmental outcome. The odds of delayed outcome predicted by Model Two decreased when Amount of Handling is added to the multivariable model. The negative predictor coefficient for Handling showed that the odds of delayed outcome decreases as the Amount of Handling increases. Therefore, the use of a categorical variable to indicate high Amount of Handling versus low amount of handling should be useful in reducing the percentage of false positives found with Model Two. This composite variable for Amount of Handling will be added to an NNNS adjusted prediction model detailed in the next section.

Improvement in prediction of outcome by the addition of Quality of Movement was found. The NNNS adjusted log odds ratio and associated odds ratio for Model Two significantly increased with the inclusion of Quality of Movement (Table 31). The goodness-of-fit chi-square process used to evaluate the predictor added to the model was significant ($G = 4.28$, $p = .04$). Thus, some of the apparent difference between the two groups was in fact due to differences in Quality of Movement displayed at one month and the addition of Quality of Movement enhances prediction by Model Two. Examination of the estimated coefficient, Wald statistic and the estimated odds ratio for Quality of Movement showed that movement has a negative association with developmental outcome. The odds of delayed outcome predicted by Model Two increased when Quality of Movement is added to the multivariable model. The negative predictor coefficient for Quality of Movement showed that the odds of delayed outcome decreases as the Quality of Movement increases. Univariate analysis of Quality of Movement on developmental outcome for the Model Two risk group only revealed that Quality of Movement has an association with outcome ($G = 5.88$, $p = .02$, Wald = 5.52). Therefore, the use of a categorical variable to indicate good Quality of Movement versus poor Quality of Movement should be useful in reducing the percentage of false positives found with Model Two. The composite variable for Quality of Movement will be added to an NNNS adjusted prediction model detailed in the next section.

Table 31

Results of Statistically Adjusting Model Two for Quality of Movement

Variable	β	SE(β)	Wald	Exp(β)	95% CI	-2 log-likelihood	G	P
Model Two	2.02	.64	10.14	7.55	2.18 – 26.19	225.148	14.93	.01
CONSTANT	-2.04	.61	11.01					
Model Two	2.21	.65	11.67	9.11	2.57 – 32.38	220.866	4.28	.04
NQMOVE	-.61	.30	4.11	.54	.30 - .98			
CONSTANT	.45	1.36	.11					
-2 Log Likelihood = 240.075								

No enhancement to prediction of outcome with the inclusion of number of Signs of Stress was found (Table 32). The NNNS adjusted log odds ratio and associated odds ratio for Model Two barely changed with the inclusion of Signs of Stress. The goodness-of-fit chi-square process was used to evaluate the predictor added to the model ($-2 \text{ Log-likelihood } 226.541 - 223.468 = G = 3.07, p = .08$). Thus, little of the apparent difference between the two groups was in fact due to differences in amount of stress signs.

Table 32

Results of Statistically Adjusting Model Two for Signs of Stress

Variable	β	SE(β)	Wald	Exp(β)	95% CI	-2 log-likelihood	G	p
Model Two	2.04	.64	10.28	7.65	2.21 – 26.54	226.54	15.17	.01
CONSTANT	-2.04	.61	11.01					
Model Two	2.08	.64	10.57	7.97	2.28 – 27.85	223.47	3.07	.08
NSTRESS	4.82	2.79	2.99	124.44	53 – 29479.32			
CONSTANT	-3.18	.92	12.05					
-2 Log Likelihood = 241.71								

Examination of the estimated coefficient, Wald statistic and the estimated odds ratio for Signs of Stress shows that the amount of stress signs has a positive association with developmental outcome. The positive predictor coefficient for Signs of Stress shows that the odds of delayed outcome predicted increases as the number of stress signs increases. The odds of delayed outcome predicted by Model Two increased slightly when Signs of Stress was included in the multivariable model. Univariate analysis of Signs of Stress on Developmental Outcome for the Model Two risk group only revealed that Signs of Stress had an association with outcome ($G = 3.97$, $p = .05$, $Wald = 3.83$). However, because amount of stress signs did not add to the overall prediction of the model from that of Model Two alone, this variable will not be included in the NNNS adjusted prediction model analyses.

NNNS Adjusted Prediction Algorithm

The goal of this section was to reduce the percentage of false positives identified by Model Two while not greatly reducing the sensitivity or increasing the percentage of false negatives. The NNNS summary variables identified in the previous section were dichotomized into low risk and high risk groups. This was done by taking the highest 10 percent of scores for Amount of Handling and Quality of Movement indicating low risk. Infants with risk positive Model Two scores were recoded as risk negative if they had Amount of Handling scores or Quality of Movement scores in the top ten percent, and then entered into a new risk model (Model Four). Table 33 shows the predictive probability of the Level One, Model Two and Model Four screenings for developmental outcome.

The predictive utility of Level One (risk positive versus risk suspect/risk negative dispositions) and Model Four is assessed through chi-square analysis and epidemiological statistics. Table 33 presents the results for Model Four predicting the Developmental Composite variable and each of the developmental outcome variables that make up the composite variable. The sensitivity of Model Two to predict developmental outcome was 96% and the percentage of false positives was 78%. These rates of sensitivity and false positives for Model Two were better than that of the current Level One screening. Model Four has comparable sensitivity and percentage of false negatives to Level One, and the specificity and percentage of false positives was greatly improved. These results show that adding NNNS summary variables for Amount of Handling and Quality of Movement greatly reduced the number of infants who would require follow-up screening via Level Two and referral for early

intervention services. Therefore, the use of the relatively quick NNNS assessment to identify those infants who may not need follow-up assessment or referral to Early Intervention, could translate into a large financial and time cost savings for the state and families.

Table 33

Predictive Utility of Level One and Model Four for Developmental Outcome

Outcome	Delay N	No delay N	Sensitivity	Specificity	FN%	FP%	OR	95% CI
Level One – Developmental Composite	85	103	88%	24%	12%	76%	2.40	1.08 – 5.34
Model Two – Developmental Composite	85	103	96%	22%	4%	78%	7.86	2.27 – 27.12
Model Four – Developmental Composite	85	103	86%	40%	14%	60%	4.02	1.95 – 8.32
Model Four - Bayley MDI	23	133	91%	33%	9%	67%	5.19	1.16 – 23.14
Model Four - Bayley PDI	12	141	90%	35%	10%	65%	2.19	.46 – 10.44
Model Four - CBCL Internalizing	40	139	90%	35%	10%	65%	4.75	1.60 – 14.13
Model Four - CBCL Externalizing	31	148	90%	33%	10%	67%	4.62	1.34 – 15.95
Model Four - CBCL Total Problems	43	123	93%	35%	7%	65%	7.17	2.09 – 24.53
Model Four - Vineland – Adaptive Composite	8	154	88%	31%	13%	69%	3.17	.38 – 26.48*
Model Four - SICD – Receptive	24	136	75%	29%	25%	71%	1.25	.46 – 3.38
Model Four - SICD – Expressive	12	142	75%	27%	25%	73%	1.14	.29 – 4.42

The sensitivity of Model Four for the developmental composite was much lower (86%) than for Model Two (96%), and the percentage of false negatives was low (14% versus 4%). Sixteen subjects were incorrectly classified as risk negative by Model Two (4% false Negative rate). The percentage of false positives was greatly reduced in Model Four from Model Two (60% versus 78% for

Model Two). Model Four proved useful in decreasing the percentage of false positives while not greatly increasing the percentage of false negatives. Because of the specificity, model four represented an improvement over Level One for three-year developmental delay and behavioral problems. The utility of Model Four for individual outcome measures varied from 91% for Bayley Cognitive, to 71% for SICD Receptive Age. The Percentage of false positives for Model Four (60% to 73%) was reduced substantially from that of Model Two (78% to 85%). Odds ratios were calculate for all outcomes, however, when the two by two analyses had one cell with expected count less than 5, the confidence intervals were adversely affected.

Model Four risk positive infants were over three times more likely to exhibit delayed development by age three than those who were classified as risk negative at birth. The results of the chi-square test for Model Four predicting Developmental Outcome Composite score was also significant ($\chi^2 = 13.14$, $p < .001$). The results of the chi-square test for Model Two predicting Developmental Outcome Composite score was significant ($\chi^2 = 13.8$, $p < .01$). The results of the chi-square test for Model Four predicting delayed Bayley MDI was also significant ($\chi^2 = 7.69$, $p < .01$). The results of the chi-square test for CBCL Internalizing score was significant ($\chi^2 = 7.93$, $p < .01$) as were the results of the chi-square test for CBCL Externalizing score ($\chi^2 = 7.15$, $p < .01$) and CBCL Total Problems score ($\chi^2 = 11.55$, $p < .01$). SICD Receptive Communication Age did not produce a significant chi-square result ($p = .66$). The chi-square results for Bayley PDI, Vineland Adaptive Behavior Composite, and SICD Expressive Communication Age scores could not be interpreted because one cell in each analysis had an expected count less than five.

Discussion One

Study Two reported no differences at age three between Bayley, Vineland, and SICD scores for Level One risk positive and risk negative newborns. However, Level One has very good ability to predict significantly delayed development for the developmental composite variable. This is surprising considering that the sensitivity and percentage of false-negatives of Level One screening for Early Intervention eligibility was poor. Model Two was designed with Early Intervention enrollment as the outcome in an effort to improve upon the predictive probability of the Level One screening. Model

Two proved to have even greater sensitivity and lower percentage of false negatives than the Level One screening for three-year developmental outcome. The very high sensitivity of Model Two for developmental outcome resulted in a large percentage of false positives. In an effort to reduce this number, NNNS summary variables were included in univariate and multivariable analyses. Two summary variables proved important in the reduction of false positives: amount of handling and Quality of Movement. These variables were added to Model Two and the resulting prediction algorithm (Model Four) proved effective in reducing the percentage of false positives while not greatly inflating the percentage of false negatives. False negative newborns would not be referred for Early Intervention or follow-up screening and therefore may not receive timely Early Intervention services. Model Four produced similar rates of sensitivity and greatly improved specificity than Rhode Islands current Level One screening. The result of using a screening system such as Model Two, and then NNNS evaluation at one month, could greatly reduce the financial burden of too large a percentage of false positives. Please refer too the Conclusion section for further discussion of the practical and policy implications of the use of this screening.

Results Two

Results Two include (a) results of univariate analysis of developmental outcome; (b) results of multivariable analysis of developmental outcome; and (c) comparison of the new developmental outcome-optimized model with the current Level One prediction algorithm, Model Two and Model Four.

Univariate Logistic Regression Analyses

The logistic regression model-building process began with careful univariate analysis of each variable. The goal was to create a prediction model based on developmental outcome for the 285 MLS-PT subjects. Table 34 shows the results of the univariate analyses for predictor variables that are theoretically important for model inclusion, and displays (1) the estimated slope coefficients (β) for the univariate logistic regression model containing this variables; (2) the estimated standard error [$SE(\beta)$] of the estimated slope coefficient; (3) the estimated odds ratio [$Exp(B)$], which is obtained by exponentiating the estimated coefficient; (4) the 95% confidence intervals for the odds ratio; (5) the

value of the -2 log-likelihood for the model; (6) the likelihood-ratio test statistic (G) for the prediction that the slope coefficient is zero; and (7) the alpha level associated with G (p).

Results of the univariate analyses for developmental outcome indicated that eleven of eighteen variables were significantly associated with developmental outcome ($p < .25$): gender, caregiver education, single caregiver, family size, birth weight less than 1500 or 2000 grams, known established conditions, no prenatal care prior to the fifth month, parental risk factor, and infant feeding method. Gender was added to these analyses based upon the association between male gender and developmental problems in the scientific literature. Based on inspection of the confidence interval estimates, there is evidence that these eleven variables are associated with Developmental Outcome. Known established conditions met screening criteria, however, the negative logistic regression coefficient indicates that the predicted odds of delayed outcome is less likely in children with these established conditions. It is important to note that MLS study criteria excludes infants with most of the conditions that make up this risk variable (e.g., chromosomal abnormality) but does include prenatal substance exposure.

Many variables were tested that did not meet the criteria for model inclusion. Maternal age did not meet screening criteria for inclusion as a predictor variable ($p = .57$), nor did teenage maternity less than 18 ($p = .62$). Small for gestational age had a chi-square p -value of .46, and five minute Apgar score risk had a p -value of .54. Prenatal care risk, birth weight below 2500 grams, and delivery method also did not meet screening criteria. Two other birth weight variables were tested and did meet screening criteria. Birth weight below 2000 grams will be used for multiple logistic regression analyses because it will include more subjects than more restrictive criterion.

Table 34

Univariate Logistic-Regression Models for Developmental Outcome

Risk Variable	β	SE(β)	Exp (B)	95% CI	-2 log-likelihood	G	p	Referent Group
Male Gender	.91	.30	2.49	1.37 – 4.51	249.57	9.33	.01	Female gender
Caregiver Education < 11 th Grade	.07	.24	1.07	.81 – 1.69	3219.53	.08	.77	Caregiver Education: $\geq 11^{\text{th}}$ grade
Marital Status = Single	.92	.39	2.51	1.17 – 5.41	252.95	5.95	.02	Marital status = married
Previous Births > 2	1.00	.38	2.72	1.29 – 5.76	251.70	7.20	.01	Previous births ≤ 2
Birth weight < 1500 g	1.51	.82	4.55	.92 – 22.50	251.91	4.19	.04	Birth weight: ≥ 1500 grams
Birth weight < 2000 g	1.08	.52	2.93	1.06 – 8.08	251.45	4.65	.03	Birth weight ≥ 2000
Known Established Conditions	-.60	.52	.55	.20 – 1.52	244.28	1.40	.24	No Known Established Conditions
No Prenatal Care Visits < 5 Months	.54	.36	1.71	.85 – 3.43	241.06	2.28	.13	Any prenatal visits < 5 months
One or More Parental Risk Factors	.35	.30	1.42	.80 – 2.53	257.49	1.41	.24	No parental risk factor
NICU Hospitalization >48 Hours	1.29	.89	3.64	.63 – 20.96	51.68	2.36	.13	NICU Hospitalization ≤ 48 hours
Bottle Fed	.46	.30	1.58	.87 – 2.86	247.80	2.31	.13	Breast fed

Multivariable Logistic Regression

Ten variables identified above were considered for model-building process. Table 35 shows a full multiple logistic regression model containing variables identified by univariate logistic regression analyses for Developmental Outcome. The likelihood-ratio test for the model was significant ($G = 18.86, p = .04$). On the basis of the output displayed in Table 35, it appears that five of the variables do not demonstrate importance in the multivariable model: gender, birth weight less than 2000 grams, known established conditions, prenatal care before five months, and parental risk. This suggested that a new model be fit which does not contain these variables.

Table 35

First Full Multivariable Model for Developmental Outcome

Variable	β	SE(β)	Wald
Gender	-.67	1.21	.22
Education Risk	3.47	2.22	2.43
Single Caregiver	2.68	1.86	2.08
Family Size	5.05	2.12	5.65
Birth weight <2000 g.	1.28	1.48	.74
Known Conditions	1.10	2.18	.25
Any Visits < 5 Months	2.32	1.96	1.39
Parent Risk	-1.42	2.08	.46
NICU Hospitalization	3.30	2.17	2.32
Infant Feeding Method	2.52	1.76	2.05
CONSTANT	-8.16	3.63	5.07

-2 Log Likelihood = 24.07

Because of the known importance of very low birth weight, an additional multivariable model was fit with the birth weight Less than 1500 grams variable included and a second full multivariable model was tested. Those results are presented in Table 36.

Table 36

Second Full Multivariable Model for Developmental Outcome

Variable	β	SE(β)	Wald
Gender	-.41	1.22	.12
Education Risk	2.82	1.878	2.28
Single Caregiver	2.88	1.82	2.52
Family Size	4.81	2.13	5.11
Birth weight <1500 g.	.20	1.56	.02
Known Conditions	.37	1.99	.04
Any visits < 5 months	2.33	2.05	1.30
Parent Risk	-1.56	2.16	.52
NICU Hospitalization	3.57	2.17	2.71
Infant Feeding Method	2.55	1.67	2.34
CONSTANT	-7.70	3.42	5.07

-2 Log Likelihood = 24.887

On the basis of the output displayed in Table 36, it appeared that five of the variables do not demonstrate importance in the multivariable model: gender, birth weight less than 1500 grams, known established conditions, prenatal care prior to five months, and parental risk. The likelihood-ratio test for the model was significant ($G = 22.69$, $p = .03$). This suggested that a new model be fit that does not contain these variables and then a comparison of the models be made via a likelihood ratio chi-square test. The results of the reduced final multivariable model for developmental outcome are presented in Table 37.

The final model was derived by manually fitting a reduced multiple logistic regression model based upon the results of the full multivariable model. Stepwise logistic regression procedure was not needed because of the limited number of variables being tested. The likelihood ratio test for the difference between the models in Tables 36 and 37 yields a value of $G = [31.282 - 24.887] = 6.395$. Comparing this to a chi-square distribution with 5 degrees of freedom yields a non-significant p -value at the .05 level, demonstrating that the excluded variables add little to the model once the other variables have been included in the model.

Table 37

Final Reduced Multivariable Model for Developmental Outcome (Model Five)

Variable	β	SE(β)	Wald	Ψ	95% CI
Education Risk	1.89	1.34	1.98	6.63	.48 – 92.36
Single Caregiver	2.60	1.37	3.59	13.47	.91 – 198.65
Family Size Risk	3.30	1.44	5.27	27.19	1.62 – 455.71
NICU Hospitalization	2.68	1.52	3.10	14.51	.74 – 284.70
Infant Feeding Method	1.29	1.11	1.36	3.64	.41 – 32.11
CONSTANT	-5.92	2.43	5.93		
-2 Log Likelihood = 31.282					

In comparing multiple logistic regression models, the question is “does the log-likelihood value decrease/increase significantly with the addition/deletion of predictor(s)?” Tabachnick and Fidell (1996) support that if the sample size is very large, almost any difference between models is likely to be statistically significant, even though the multivariable model deviates significantly from the perfect (hypothetical) model. The log-likelihood value of the final reduced multivariable model compared to the constant only model yields a likelihood ratio test ($G = 15.85$, $p < .01$). This confirms the finding that the variables included in the reduced model are reliable predictors of three year developmental outcome. The estimated coefficients for each variable included in the reduced model were compared to the full multivariable model. Substantial changes in the values of the estimated coefficients were found indicating that the excluded variables did impact the remaining variables. A jump in magnitude of the estimated coefficients indicates that one or more of the excluded variables were important in the sense of providing a needed adjustment of the effect of the included variables. All of the estimated logistic regression coefficients were positive in the final model, indicating that the predicted odds increase as the predictor increases. Examination of the odds ratios showed that each predictor variable is associated with likelihood of developmental delay on the basis of one unit change in each predictor variable.

The utility of Model Five to predict Developmental Outcome and associated outcome measures is presented in Table 38. Included in the table are also the results of the Level One risk algorithm to predict developmental outcome. The Developmental outcome-optimized multivariable model represents an improvement over the Level One algorithm, both in terms of sensitivity (99% versus 88%) and in a reduction in the percentage of false negatives (1% versus 12%). Infants identified by Model Five are more than three times more likely to have delayed development than those who are risk negative at birth. The rate of false positives is very high and would represent a large burden if this model were applied to the entire Rhode Island population. Therefore, NNS summary variables identified in the last section will be added to Model Five in an effort to reduce the percentage of false positives while not greatly increasing the percentage of false negatives.

Table 38

Comparison of Multivariable Risk Models

Group	Sensitivity	Specificity	FN%	FP%	OR	95% CI
Level One - Developmental Composite	88%	24%	12%	76%	2.40	1.08 – 5.34
Model Five - Developmental Composite	99%	14%	1%	86%	3.35	1.7 – 102.7
Model Five - Bayley MDI	100%	9%	0%	91%		
Model Five - Bayley PDI	100%	9%	0%	91%		
Model Five - CBCL Internalizing	100%	11%	0%	89%		
Model Five - CBCL Externalizing	100%	10%	0%	90%		
Model Five - CBCL Total Problems	100%	11%	0%	89%		
Model Five - Vineland – Adaptive Composite	100%	8%	0%	92%		
Model Five - SICD – Receptive	96%	9%	4%	91%	2.23	.28 – 18.0
Model Five - SICD – Expressive	92%	9%	8%	91%	1.11	.13 – 9.28

Note. Odds ratio could not be calculated for two-by-two analyses with a zero cell. In the case of SICD receptive and expressive communication age delay, only one case was missed for each by Model Five.

Adjusting Model Five Prediction for NNNS Summary Variables

Next, the Model Five composite variable was entered into a separate multiple logistic regression procedure with the goal of statistically adjusting the estimated effect of Model Five for differences in the distribution of and association with the NNNS summary independent variable. Each estimated coefficient provides an estimate of the log odds adjusting for the other variable included in the model. Each multivariable situation will examine two independent variables, one dichotomous and one continuous, with the primary interest focused on the effect of the dichotomous variable (Model Five). In this way the results of Model Two risk classification was statistically adjusted for NNNS performance. Analyzing the data with a bivariate model and then a multivariable model yielded the estimated logistic regression coefficients shown in Tables 39-42, and displays (1) the estimated slope coefficients (β) for the univariate logistic regression model containing this variable; (2) the estimated standard error [SE(β)] of the estimated slope coefficient; (3) the Wald statistic, (4) the estimated odds ratio [Exp(B)], which is obtained by exponentiating the estimated coefficient; (5) the 95% confidence intervals for the odds ratio; (6) the value of the -2 log-likelihood for the model; (7) the likelihood-ratio test statistic (G) for the hypothesis that the slope coefficient is zero; and (8) the alpha level associated with G (p).

Table 39

Results of Statistically Adjusting Model Five for Orientation

Variable	β	SE(β)	Wald	Exp(β)	95% CI	-2 log-likelihood	G	p
Model Five	2.55	1.05	5.93	12.80	1.64 – 99.69	224.68	11.43	.01
CONSTANT	-2.64	1.04	6.50					
Model Five	2.53	1.05	5.79	12.50	1.60 – 97.81	222.00	2.68	.10
Orientation	.27	.16	2.60	1.30	.94 – 1.80			
CONSTANT	-4.17	1.42	8.65					
-2 Log Likelihood = 236.112								

No improvement in prediction was found when Orientation was added to Model Five. The NNNS adjusted estimated logistic regression coefficient and associated odds ratio for Model Five barely changed with the inclusion of Orientation (Table 39). The goodness-of-fit chi-square process used to evaluate the predictor added to the model was not significant ($G = 2.68$, $p = .10$). Thus, little of the apparent difference between the two groups was in fact due to differences in level of Orientation. Examination of the estimated coefficient, Wald statistic and the estimated odds ratio for Orientation shows that Orientation has a association with Developmental Outcome which was also seen in the univariate analysis of orientation on developmental outcome.

Improvement to prediction of Developmental Outcome by the addition of Amount of Handling to Model Five was found (Table 40). The NNNS adjusted estimated logistic regression coefficient and associated odds ratio for Model Two decreased slightly with the inclusion of Amount of Handling (Table 14). The goodness-of-fit chi-square process used to evaluate the predictor added to the model was significant ($G = 6.24$, $p = .01$). Thus, some of the apparent difference between the two groups was in fact due to differences in Amount of Handling required for good orientation.

Table 40

Results of Statistically Adjusting Model Five for Amount of Handling

Variable	β	SE(β)	Wald	Exp(β)	95% CI	-2 log-likelihood	G	P
Model Five	2.55	1.05	5.93	12.82	1.65 – 99.78	227.46	11.45	.01
CONSTANT	-2.64	1.04	6.50					
Model Five	2.38	1.05	5.11	10.79	1.37 – 84.74	221.23	6.24	.01
Handling	-1.84	.75	5.97	.16	.04 - .70			
CONSTANT	-1.24	1.18	1.10					
-2 Log Likelihood = 238.911								

Examination of the estimated logistic regression coefficient, Wald statistic and the estimated odds ratio for Handling in the multivariable model revealed that amount of handling has an association with developmental outcome when Handling was included in the model. The odds of delayed outcome

predicted by Model Five decreased when Handling was added to the multivariable model. The negative predictor coefficient for Handling shows that the odds of delayed outcome decreased as the amount of handling increases. Therefore, the use of a categorical variable to indicate high amount of handling versus low amount of handling should be useful in reducing the percentage of false positives found with Model Two. The composite variable for Amount of Handling was added to an NNNS adjusted prediction model detailed in the next section.

Improvement to prediction of outcome by the addition of Quality of Movement to Model Five was found. The NNNS adjusted log odds ratio and associated odds ratio for Model Two increased with the inclusion of Quality of Movement (Table 41). The goodness-of-fit chi-square process used to evaluate the predictor added to the model was significant ($G = 4.28$, $p = .04$). Thus, some of the apparent difference between the two groups was in fact due to differences in Quality of Movement displayed at one month, and the addition of Quality of Movement enhances prediction by Model Two.

Table 41

Results of Statistically Adjusting Model Five for Quality of Movement

Variable	β	SE(β)	Wald	Exp(β)	95% CI	-2 log-likelihood	G	P
Model Five	2.54	1.05	5.88	12.66	1.63 – 98.58	228.755	11.32	.00
CONSTANT	-2.64	1.04	6.50					
Model Five	2.55	1.05	5.91	12.82	1.64 – 100.16	220.866	4.28	.04
Quality of Movement	-.40	.29	1.87	.67	.38 – 1.19			
CONSTANT	.45	1.62	.33					
-2 Log Likelihood = 240.075								

Examination of the estimated coefficient, Wald statistic and the estimated odds ratio for Quality of Movement showed that movement has a negative association with developmental outcome. The odds of delayed outcome predicted by Model Two increased when Quality of Movement was added to the multivariable model. The negative predictor coefficient for Quality of Movement shows

that the odds of delayed outcome decreased as the Quality of Movement increased. Univariate analysis of Quality of Movement on Developmental Outcome for the Model Two risk group only revealed that Quality of Movement has an association with outcome ($G = 5.88$, $p = .02$, Wald = 5.52). Therefore, the use of a categorical variable to indicate good quality of movement versus poor quality of movement should be useful in reducing the percentage of false positives found with Model Two.

No enhancement to prediction of outcome by number of Signs of Stress added to Model Five was found (table 42). The NNNS adjusted log odds ratio and associated odds ratio for Model Five barely increases with the inclusion of Signs of Stress. The goodness-of-fit chi-square process was used to evaluate the predictor added to the model ($G = 3.07$, $p = .08$). Thus, little of the apparent difference between the two groups was in fact due to differences in amount of stress signs. Examination of the estimated coefficient, Wald statistic and the estimated odds ratio for Signs of Stress showed that the amount of stress signs has a positive association with developmental outcome. The difference between the estimated logistic regression coefficient for the univariate and multivariable models of Signs of Stress on outcome and showed that Wald statistic increased in the multivariable model. The positive predictor coefficient for Signs of Stress showed that the odds of delayed outcome increases as the number of stress signs increases.

Table 42

Results of Statistically Adjusting Model Five for Signs of Stress

Variable	β	SE(β)	Wald	Exp(β)	95% CI	-2 log-likelihood	G	p
Model Five	2.55	1.05	5.94	12.83	1.65 – 99.86	230.237	11.47	.001
CONSTANT	-2.64	1.04	6.50					
Model Five	2.61	1.05	6.16	13.60	1.73 – 106.72	227.167	3.07	.08
Signs of Stress	4.81	2.78	2.99	122.38	53 – 28507.51			
CONSTANT	-3.80	1.25	9.27					
-2 Log Likelihood = 241.71								

NNNS Adjusted Developmental Outcome Prediction Algorithm

The goal of this section was to reduce the percentage of false positives identified by Model Five without greatly increasing the percentage of false negatives (1%). The NNNS summary variables identified in the previous section were dichotomized into low risk and high risk groups. This was done by taking the highest 10 percent of scores for Amount of Handling, and Quality of Movement. Infants with risk positive Model Five scores were recoded as risk negative if they had Amount of Handling scores or Quality of Movement scores in the top ten percent, and were entered into a new risk model (Model Six).

Table 43

Predictive Utility of Prediction Models for Three Year Developmental Outcome

Outcome	Sensitivity	specificity	FN%	FP%	OR	95% CI
Level One - Developmental Composite	88%	24%	12%	76%	2.40	1.08 – 5.34
Model Two - Developmental Outcome	96%	22%	4%	78%	7.86	2.27 – 27.12
Model Four - Developmental Composite	86%	40%	14%	60%	4.02	1.95 – 8.32
Model Five Predicting Developmental Outcome	99%	14%	1%	86%	3.35	1.7 – 102.7
Model Six Predicting Developmental Composite	88%	33%	12%	67%	3.70	1.70 – 8.04
Model Six - Bayley MDI	91%	26%	9%	74%	3.75	.84 – 16.82
Model Six - Bayley PDI	83%	24%	17%	76%	1.59	.33 – 7.61
Model Six - CBCL Internalizing	93%	29%	8%	71%	4.98	1.45 – 17.09
Model Six - CBCL Externalizing	94%	28%	6%	72%	5.56	1.27 – 24.35
Model Six - CBCL Total Problems	95%	29%	5%	71%	8.48	1.95 – 36.95
Model Six - Vineland – Adaptive Behavior Composite	88%	25%	13%	75%	2.37	.28 – 19.91
Model Six - SICD – Receptive	75%	24%	25%	76%	.96	.35 – 2.62
Model Six - SICD – Expressive	75%	24%	25%	76%	.94	.24 – 3.69

The predictive utility of Models Five and Six was assessed through chi-square analysis and epidemiological statistics. Table 43 presents the results for Models Five and Six, and Level One predicting the Developmental Composite variable. Also included in Table 43 are the results of Model Six for each of the developmental outcome variables that make up the composite. The sensitivity of Model Five for the developmental composite was very high (99%), and the percentage of false negatives was extremely low (1%). After the NNNS summary variables were included in the prediction algorithm, Model Six had very good sensitivity (88%) and low percentage of false negatives (12%). The percentage of false positives was reduced in Model Six to 67%.

The utility of Model Six for individual outcome measures varied from 95% for CBCL Total Problems Score, to 75% for SICD Receptive and Expressive Age. The Percentage of false positives for Model Six ranged from 71% to 76%. Model Six Risk Positive infants were almost four three times more likely to exhibit delayed development by age three than those who were classified as Risk Negative at birth.

Discussion Two

These results show that a very sensitive prediction model can be produced with a subset of variables from the Universal Newborn Screening. The increased sensitivity compared to the Level One carries with it the burden of many more infants to follow for additional screening and referral to Early Intervention services. The NNNS evaluation could be performed in the hospital prior to discharge. The results of the neurobehavioral assessment could inform the risk status of the infant. The importance of including information on infant behavior is supported by the transactional model. Positive results from the NNNS evaluation could be used to reduce the number of infants in need of follow-up evaluation. The increased sensitivity of Model Five with fewer predictors may be due to both single caregiver status and infant bottle feeding method, both of which are high-incidence occurrences.

The prediction variables included in Model Two (Early Intervention enrollment-optimized) and Model Five (Developmental Outcome-optimized) are quite different. Model Two included eight variables: teenage maternity (included for theoretical reasons), caregiver education, family size, low birth weight, known established conditions, parental risk characteristics, NICU hospitalization, and mode of delivery. Model Five included only five variables: caregiver education, single caregiver,

family size, NICU hospitalization and infant feeding method. It is surprising that very low birth weight did not represent a predictor of delayed development in the multivariable Model Five. The correlation between birth weight and NICU hospitalization was not significant ($p=.24$). The Level One screening weights biological predictor variables more heavily than environmental/parental risk variables. These results show that only NICU hospitalization is significantly associated with delayed outcome when controlling for parental/environmental risk factors. It is important to note that many of the factors that make up the known established conditions category are exclusionary criteria for the MLS study (e.g., chromosomal abnormalities, parental psychosis). This variable should remain part of a newborn risk algorithm in actual use.

Infant feeding method, breast versus bottle, was included in the model after controlling for other potential predictor variables. Studies have found that breast-feeding is associated with improved cognitive functioning. Anderson, Johnstone and Remley (1999) conducted a meta-analysis of observed difference in cognitive development between breast-fed and formula-fed children controlling for confounding variables such as socioeconomic status and maternal education. They concluded that significantly higher levels of cognitive functioning is seen in breast-fed children at 6-23 months of age and these differences are stable across successive ages and these results increased with duration of breast-feeding. In addition, low birth weight infants showed larger differences than did normal birth weight infants.

Because Model Two has such high sensitivity and low percentage of false positives, this model represents the best prediction algorithm for a new universal newborn screening system. Model Two used in conjunction with NNNS assessment prior to discharge would represent a more accurate analysis of newborn risk for developmental and behavioral problems by age three.

Unfortunately, large amounts of missing data caused there to be a limited number of NNNS summary variables to be assessed. However, Model Four reduced the percentage of infants designated as risk positive by approximately 15 percent. This could translate into a reduction of almost 2000 infants designated as Risk Positive during the two-year time frame for this study. These results need to be considered in conjunction with current state and federal child identification and Early Intervention efforts.

Conclusion

The effects of environmental, parental and biological risks support the profound negative impact of multiple risks on child development (Aylward, 1992; Msall et al., 1998; Sameroff et al., 1987; Sameroff & Seifer, 1995; Vohr & Msall, 1997). Researchers have extensively examined which risk factors predict developmental problems and the quality of risk factors needed before developmental problems occur. Less emphasis has been placed on researching what combinations of specific risk factors are most predictive of developmental delay. The primary purpose of this series of studies was to design an improved newborn screening algorithm with greater sensitivity and specificity for both Early Intervention eligibility/enrollment and developmental outcome by age three. The policy and practical implications of utilizing an improved screening system are discussed.

Federal requirements to find and identify those infants and young children who are at risk for developmental delay and disability promotes investigation in this area. Research has shown that the earlier intervention services are provided the better the developmental outcome (Ramey & Ramey, 1998). Often children are not identified as being in need of intervention until they are preschool or school aged. Likewise, specifically targeted screening and evaluation services are needed to reduce the over-identification of children for intervention services that are not needed (Ramey & Ramey, 1998). Overall, results show that Early Intervention programs can produce modest to large effects on children's cognitive and social development (Ramey & Ramey, 1998).

Non-cognitive long-term benefits of Early Intervention have been found as better school attendance, reduction in grade retention, special education service placements, and rates of juvenile delinquency (Guralnick, 1998). Guralnick proposes that Early Intervention programs must be intensive in both comprehensiveness and duration, and specific for the population being served. Some comprehensive intervention projects such as the Abecedarian Project have continued to demonstrate long-term cognitive benefits for the intervention group compared with the control group (Campbell & Ramey, 1994). Gurlanick (1998) and Ramey and Ramey (1998) support that timing may be very important for the best impact of Early Intervention on short and long-term positive effects. Specifically, intervention programs must be initiated at the earliest time possible and continued through intensive programs to achieve positive long-term outcomes.

The Level One screening algorithm produced low sensitivity and high percentage of false negatives for Early Intervention eligibility for both time frames studied in this investigation. More than one third of newborns who are determined to be Risk-Negative at birth are referred and determined eligible for Early Intervention services at some time prior to their third birthday. Risk-Suspect and Risk-Negative children are referred to Early Intervention services at an average of 22 months of age compared to Risk-Positive infants who are referred at an average of 15.5 months of age. Risk-Negative children who are referred to Early Intervention and found eligible at an older age will receive less services compared to Risk-Positive children.

The level One screening algorithm had better predictive utility in terms of child developmental outcome by age three. Although the average developmental performance of Level One Risk-Positive versus Risk-Negative children did not differ in terms of mental, motor, adaptive functioning and communication skills, Risk-Positive newborns displayed greater behavior problems at age three compared to Risk-Negative children. In addition, the Level One Risk-Positive screening produced good sensitivity and very low percentage of false-negatives for age three developmental outcome composite. This indicates that although the Level One screening misses one third of children who will later be in need of Early Intervention services, the system is identifying many children who will display developmental delay and behavioral problems by age three.

Several screening algorithms were produced in this investigation with very high sensitivity and very low percentage of false-negatives. Model Two was developed on Early Intervention enrollment as an outcome. This model had improved sensitivity and lower percentage of false negatives over the Level One screening for Early Intervention eligibility. Model Two included the following variables: education risk, family size risk, low birth weight, known established conditions, parental risk, NICU hospitalization and delivery method risk. Teenage maternity was also included for theoretical reasons although this was not supported empirically in this investigation. It could be decided that teenage maternity does not carry the risks that have been supported in the literature, and so teenage maternity could be dropped from a risk screening algorithm. Model Two also produced extremely high sensitivity and extremely low percentage of false-negatives for developmental outcome. Model Two Risk-Positive newborns were almost eight times more likely to have developmental problems by age three compared

to Level One Risk-Positive newborns. Level One Risk-Positive newborns are two and one half times more likely to have developmental problems than those who are Risk-Negative at birth. Overall, Model Two represents a substantial improvement in identification of infants at risk.

Model Five was developed on delayed development as the outcome category. This model produced extremely high sensitivity and extremely low percentage of false-negatives. Model Five Risk-Positive newborns were over three times more likely to have delayed development than those who were Risk-Negative at birth. Model Five included only five variables: education risk, single caregiver, family size, NICU hospitalization and infant feeding method. Known established conditions should be added to this model for practical application to identify those infants who would automatically be eligible for Early Intervention services (e.g., single established conditions). NICU Hospitalization was the only measure of biological risk included in this empirically-derived model. Biological factors have been extensively studied as risk factors for developmental problems and results support their inclusion as part of a biopsychosocial model. Biological factors have been shown to account for only a small proportion of intellectually delayed children and are more strongly associated with severe rather than mild mental retardation (Sameroff & Chandler, 1975; Sameroff et al., 1987).

Some studies suggest that, although early developmental outcome is more strongly associated with biological factors for medically-compromised neonates, the impact of the environment becomes more powerful as the child ages (Bendersky & Lewis, 1994; Brooks-Gunn et al., 1992). Medical/biological factors of low birth weight infants have been studied in conjunction with social and environmental factors. Social and environmental risks are well known factors affecting the developmental outcome of low birth weight infants (Vohr & Msall, 1997). Biologically at-risk infants are at greater risk of delayed intelligence and academic achievement if they are born into a socially disadvantaged family (Msall et al., 1998). Holloman, Dobbins, and Scott (1998) investigated the effects of birth weight and maternal education on special education placement at age ten. They found that the largest percentage of children receiving special education services had the single risk factor of low maternal education. Very low birth weight children with low education mothers were at high individual risk for receiving special education services.

Practical and Policy Implications

This investigation has shown that a screening algorithm with increased predictive utility can be derived from the variables currently gathered as part of Rhode Island's Universal Newborn Screening program. Improved sensitivity for developmental problems would allow Rhode Island to better fulfill the federal mandate to find and identify those children in need of intervention services. This increased sensitivity would result in more newborns being identified as at-risk who would then require follow-up screening for Early Intervention services. In time frame B, 11,259 infants were designated as Risk-Positive by the Level One screening (42%). Model Two identified 13,511 infants (50%) as Risk-Positive for the same two year time period. Teenage maternity is included in Model Two but did not demonstrate predictive utility in this investigation. The deletion of this variable from the prediction model would reduce the percentage of infants identified as Risk-Positive. Model Five identified 64% of newborns as Risk-Positive which would translate into a substantial increase in infants followed by Level Two screening.

The benefits of identifying more children for follow-up and referral for Early Intervention services are clear. More children being evaluated would lead to a higher percentage of children being served at an earlier age in Early Intervention programming. The initial costs of identifying more children as at-risk at birth, following them with Level Two screening, and providing Early Intervention services may save money in the long run by reducing the need for special education services and reducing the risk of school failure and mental health and behavioral problems later in the child's life.

The transactional model includes infant and child behavior as an equally important variable in determining the developmental outcome of the individual. This study investigated the predictive utility of the NNNS infant neurobehavioral assessment procedure to identify those infants who are likely to have later developmental problems. NNNS is an early indication of infant behavior and central nervous system integrity. Some compelling evidence was shown that the NNNS procedure may be useful as a "triage" of those infants who are at great risk or decreased risk for adverse development. Infants may be identified through this procedure who are Risk-Positive at birth for biological or environmental risk factors yet show very good neurobehavioral functioning. These infants may not be in need of services. Those infants with poor scores of infant neurobehavior, especially in terms of motor

functioning (e.g., quality of movement), may be referred for Early Intervention program evaluation directly, skipping the Level two screening. In this way using the relatively quick NNNS procedure (assessment time approximately 20-30 minutes) may reduce the large rate of false-positives produced by a very sensitive screening instrument and may reduce the need for the more lengthy Level Two screening. The NNNS procedure may be performed prior to discharge from the birthing hospital, however, it is unknown at this time how newborn NNNS results compare with NNNS assessed at one month of age.

Limitations

Several limitations to this research are acknowledged. The Universal Newborn Screening data are abstracted from birth hospital record reviews. The information contained in these may not be accurate, or some of the information that is gathered may not be included. The Early Intervention Exchange of Information Operation database has information on all children referred for Early Intervention services in Rhode Island. The Early Intervention eligibility status of Rhode Island newborns who subsequently move out of state is not known.

Much of this investigation centered on the Maternal Lifestyle Study Providence and Teenage maternity (MLS-PT) samples. The MLS-PT sample is not representative of Rhode Island's population characteristics. While this sample is not representative of the general population, it is an enriched sample of infants at great biological and psychosocial risk. Approximately half of the MLS-Providence mothers used cocaine during their pregnancy. Cocaine use is often associated with other drug, alcohol, and tobacco use, medical factors and socio-demographic factors and is a marker variable for these factors. Research has shown that premature, low birth weight and prenatally-exposed infants experience a disproportionately large number of risk factors from biological problems, poverty and social risks (Msall et al., 1998). None of the teenage mothers used cocaine during their pregnancies, however, some used tobacco, alcohol and marijuana. Some of the exclusionary criteria for participation in the Maternal Lifestyle Study are inclusionary criteria for Level One screening risk status and Early Intervention program eligibility (e.g. chromosomal abnormalities, maternal psychosis). Results based on age three child developmental and behavioral outcomes of this high-risk population may not be generalized to the population.

Directions for Future Research

The results presented in this series of studies indicate that it is possible to improve the sensitivity of the at-birth screening algorithm without changing the UNS system. However, there are a number of questions which remain. Does improving sensitivity have major effects on early and later costs of Early Intervention and special education services? Does improving the specificity using the NNNS procedure lead to earlier client identification and service implementation? Does an NNNS assessment performed soon after birth have predictive utility for later developmental outcome? Does providing intervention services earlier in a child's life offset later costs? Additional scientifically informed policy research should be undertaken to answer these and other questions.

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