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## A. SPECIFIC AIMS

**Aim 1: To test whether embedding anticipatory guidance in baby books is an effective method for increasing maternal knowledge of child development and parenting strategies.** Research on the dissemination of anticipatory guidance has shown that pediatricians often do not provide anticipatory guidance information and when they do, it is often narrow in scope, omitting many topics (Saunders & Shouldice, 2000; Schuster et al., 2000). This application seeks to determine if providing anticipatory guidance material through the use of books read to babies is an effective method for increasing maternal retention of anticipatory guidance. Presentation of this material will be visually interesting, written at a low reading level, and read repetitively.

**Aim 2: To determine if increases in knowledge of child development and parenting strategies results in changes in parenting behavior.** Although the research on anticipatory guidance and parenting behavior is promising (e.g. Clamp & Kendrick, 1998; Sege et al., 1997), little is known of how changes in knowledge translate into changes in behavior. The proposed study will assess whether increases in knowledge result in more reasonable expectations, better parenting practices, and safer, more stimulating environments for children.

**Aim 3: To assess whether benefits of reading coupled with increased knowledge result in higher quality mother-child interactions.** Research has shown that reading aloud to infants contributes to positive interactions characterized by reciprocal communication (e.g. DeLoache & DeMendoza, 1987). We predict that appropriate expectations of the child's ability will increase the quality of such interactions, such that the child's expression of enjoyment of the joint book sharing is expected to reinforce maternal positivity and responsiveness. These maternal reactions are thus expected to elicit more favorable responses from the child.

**Aim 4: To determine if increased knowledge and improved maternal-child interactions result in less maternal stress and increased maternal self-efficacy.** Since research has demonstrated that parents' beliefs and knowledge affect the manner in which they rear their child (e.g. Huebner, 2002; Parush & Hahn-Markowitz, 1997) we predict that increased knowledge of child development and parenting strategies will reduce stress, promote positive attitudes towards parenting, and increase a sense of efficacy in parenting.

**Aim 5: To assess if better parenting practices, higher quality mother-child interactions, and reduced maternal stress result in better child outcomes.** If the intervention alters parenting practices, reduces maternal stress, and improves the quality of interactions between mothers and their children, we expect to find better child outcomes. For example, increased safety practices in the home and car and regular primary healthcare for infants should result in reduced child injury and illness. Since knowledgeable mothers create more developmentally appropriate environments (Benaisch & Brooks-Gunn, 1996) we expect children to have improvements in their cognitive, emotional, social and physical development.

**Aim 6: Assess the cost-effectiveness of the baby books intervention.** This assessment will be done in two sections, first we will estimate the direct costs of the intervention and second we will estimate the savings and quality life improvement this intervention may produce. The second section will estimate the impact the intervention might have in terms of reducing maternal stress, preventing childhood injuries, increasing parents productivity, promoting better parenting practices, and improving mother-child interactions. If the intervention via health education improves mother's parenting skills then we expect to find the following cost savings. First, the children from the baby book group will have fewer injuries and therefore will require fewer medical services. In addition, parents from this group will have less productivity costs (forgone working wage) to care for an injured child. Second, infants from the baby book group will be immunized on schedule and be healthier resulting in a more productive life, requiring fewer medical services, allowing their mothers to be more productive. Their mothers will spend less time seeking medical care for their children and therefore miss fewer working hours. Overall the quality of life of these families will be higher than of the comparison group. Children's health impacts how mothers allocate their time (Becker, 1965). Mothers of healthier children will

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spend less time taking their children to the doctor or emergency room and therefore will have less absenteeism and higher job performance. Third, information and knowledge on the advantages of breastfeeding, child nutrition, and physical development will teach mothers the importance of breastfeeding and the appropriate time to introduce solid food to their newborns. Besides improving children's own health, this nutritional knowledge will increase breastfeeding practices and reduce the demand for baby food. Fourth, the intervention baby books will inform mothers how to identify symptoms of depression and the importance of seeking appropriate treatment. Better information will help mothers with depression to get early treatment, which in turn will minimize the economic burden of depression. We realize that some of these aims may not be met within the time period of the study.

## **B. BACKGROUND AND SIGNIFICANCE**

Parental knowledge. Research in child development has established that parents' beliefs and knowledge affect the manner in which they rear their child. Interventions to increase parental knowledge of typical child development and effective parenting strategies have been associated with *parental benefits* such as reduced stress (e.g. Huebner, 2002) and positive attitudes towards parenting (e.g. Parush & Hahn-Markowitz, 1997), *child benefits* such as reduced child maltreatment (e.g. Honig & Wittmer, 1991) and improved cognitive, emotional, social and physical development (e.g. Fewell & Wheeden, 1998; Landry et al, 2001; Rivara & Howard, 1982), and *improved parent-child interactions* (e.g. Culp et al, 1998; Huebner, 2002; Widmayer & Fields, 1980). More knowledgeable parents are more likely to create an environment that is appropriate to a child's emerging abilities (Benaish & Brooks-Gunn, 1996; Miller, 1988).

Conversely, parents with inappropriate expectations of typical child development often overestimate the rate of development of their children. This overestimation contributes to impatience and intolerance of their child's behavior (de Lissoy, 1973). In the extreme situations, inappropriate beliefs about child development have been associated with child maltreatment (Azar et al., 1984; Peterson et al., 1997). Additionally, parenting behaviors and strategies have been shown to greatly affect infant attachment (Schmidt & Eldridge, 1986; Ward, Kessler & Altman, 1993), with harsh, inconsistent parenting behavior being highly correlated with poor attachment and future child psychopathology (Carter et al., 2001; Erickson, Sroufe, & Egeland, 1985; Greenberg, Speltz, & DeKlyen, 1993).

Investigation of the amount of knowledge about child development parents possess has primarily focused on adolescent mothers (e.g. Parks & Smeriglio, 1983; Stern & Alvarez, 1992; Tamis-LeMonda, Shannon & Spellmann, 2002). The studies that have explored adult parental knowledge have identified many inaccuracies in the order and timing of cognitive, physical, and emotional development. A recent national study showed that parents misjudge when and how development occurs in young children (Citivas Initiative Zero to Three, 2000). This finding was supported by our survey of 203 mothers about typical child development, safety, and parenting (Reich, 2004). Although parental knowledge of child development has been linked to many beneficial outcomes, many mothers lack this information.

Anticipatory guidance. A major effort to educate parents about typical child development and effective parenting is through the dissemination of anticipatory guidance. This form of health supervision information is intended to educate the parent and promote the health of the child (Dinkevich & Ozuah, 2002; Green & Palfrey, 2002). It is most commonly provided by clinical providers during routine well-child examinations and covers both injury prevention and health promotion.

Research findings on the efficacy of anticipatory guidance, as a method for altering parental behavior, have been promising. The majority of such research has narrowly focused on safety practices and injury prevention. In a review of the effectiveness of injury prevention counseling in primary care settings, Bass et al., (1993) found positive changes in the safety of the home and car environment. Clamp & Kendrick (1998) found an even

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greater increase in safety when anticipatory guidance was coupled with access to safety devices (e.g. car seats). In the area of nutrition and discipline, Sege et al., (1997) found an increase in the use of time-outs after receiving anticipatory guidance about disciplinary practices. Adam, Stern, & Stein (1985) found a reduction in early introduction of solid food to children less than 4 months of age after provision of guidance on the topic. However, little research has explored the relationship of knowledge of child development and parenting to parent-child interactions, richness of the environment, or infant cognitive, physical, emotional, or social development. Studies that have investigated the relationship of knowledge and parenting practices have typically targeted only one to three anticipatory topics (most commonly car seat use, hot water heaters, and smoke detectors), relied on self report, and did not follow families beyond a brief posttest period. While these findings suggest that anticipatory guidance may have positive effects, research is scant on the a) efficacy of providing anticipatory guidance on most topics (e.g. nutrition, safety, discipline, emotional development, crying), b) objective measures of changes in parenting behavior, and c) the duration of such changes over time.

The small amount of longitudinal research on anticipatory guidance shows potential. For example, Gutelius et al., (1977) found that providing 19 one-hour sessions on anticipatory guidance during the first 3 years of the child's life was related to better nutrition and fewer behavioral problems at 5 and 6 years of age. Macknin et al., (1987) found an increase in seat belt use one year later. More research into how increased knowledge of anticipatory guidance information translates into parental behavior over time is needed. Research in this area should involve subjective as well as objective measures and be sensitive to changes in the environment, parent, and child.

While the extant research is encouraging, research on the implementation of anticipatory guidance suggests many gaps and problems. Although parents who report discussing anticipatory guidance with their child's pediatrician typically report feeling more confident in applying such information (Bethell et al., 2001), many topics are not addressed during routine visits. In general, pediatricians devote less than 10% of the time of a well child visit on parent education (Adam et al., 1985). In an analysis of audiotaped pediatric visits, Gielen et al., (1997) found that only 47% of visits discussed accident prevention. Of that 47%, an average of two types of prevention activities were discussed for a total of *one minute* of the appointment. Studies of pediatric well-child visits have found that only 8.4-12.4% of pediatricians allocated time to anticipatory guidance discussions (Goldstein & Dworkin, 1997; Reisinger & Bires, 1980). A national survey of parents of children under three years old found that 37% reported never discussing any anticipatory guidance with their pediatrician. When asked about specific topics, over half of the parents reported never discussing each issue, with the exception of newborn care, which was discussed with 2/3 of the parents (Schuster et al., 2000).

Investigations into why anticipatory guidance is not discussed during routine well child visits have identified several barriers. The most common reason for the omission of some or all health supervision recommendations is attributed to lack of time during the pediatric visit. Often there is simply not enough time to address all of the health supervision guidelines in addition to the physical examination. There are many competing demands that the physician must manage (Klinkman, 1997). When pressed for time, providers must use clinical judgment to decide which topics are appropriate for a particular child and family (Goodwin et al., 1999).

Another potential barrier to the provision of anticipatory guidance during well-child visits may be due to unfamiliarity with the material. Surveys of graduates of pediatric residency programs have reported a lack of preparedness for providing anticipatory guidance in their practices (MacPhee, 1984; Roberts, Starr & DeWitt, 1997). Graduates perceived their behavioral and developmental pediatric education as not very useful (Bruenlin et al., 1990). Cheng et al. (2000) have suggested the development of competencies and curricula in pediatric training to address this issue. In our own work, only 21% of 64 pediatric residents reported familiarity with Bright Futures Guidelines for Health Supervision (Reich, Worley, & Bickman, 2004).

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Clearly relying solely on pediatric visits to educate parents is not adequate. Even under those rare conditions when anticipatory guidance is given, the information that providers report discussing and what parents recall being discussed are often incongruent (Morrongiello, Hiller & Bass, 1995). Perhaps pediatricians believe they discuss more than they actually do and/or parents are not retaining the information provided during the visit.

In response to inconsistent dissemination and/or retention of anticipatory guidance information, some pediatric practices have relied on alternative approaches. The most common mediums are written material such as a brochure or handout and parenting classes. Brochures are sometimes handed directly to parents or, more typically, are simply available in the waiting room of the medical practice. There are several drawbacks to providing anticipatory guidance in the form of a brochure. First, parents simply may not read the material. If brochures are only available in the waiting room, parents may not notice them or if they do, choose not to take one. Of those that do take the brochure with them, some may decide to read it later and then forget about the brochure. If parents do read the brochure, it is unlikely that they will read it more than once. This is unfortunate since learning theories stress the importance of repetition for retention (Surber, 2001; Yale University Library, 2000). Although pediatric brochures of anticipatory guidance material have not been subject to systematic evaluation, studies of brochures for other medical issues, such as stroke symptoms and exercise programs have been found to be too complex to be useful (Sullivan & O'Connor, 2001; Cardinal & Seidler, 1995).

Some primary care practices and community centers provide anticipatory guidance in the form of parenting classes. Although parenting classes have been shown to be highly effective in changing parent behavior (e.g., Crean, Hightower & Allen, 2001; Ralph, Oman, & Forney, 2001), they are often time consuming, expensive and/or difficult for many parents to attend (due to transportation, scheduling, and childcare problems). We need to develop easier, more accessible, and less expensive ways to educate parents. One option is to create an educational format that is easy to use, enjoyable, inexpensive, and is not time consuming. This application is aimed to fill this gap.

We propose to test an innovative way to provide anticipatory guidance through the use of baby books in which the educational material is embedded in the text. It is hypothesized that as mothers read to their children, they will learn about age appropriate development, injury prevention, and effective parenting strategies. These books could easily be disseminated during pediatric visits, when anticipatory guidance is ideally discussed, but does not rely on the clinical provider to present this information. The books could also be mailed to families, thus including those who do not visit their provider regularly. In addition to improving parental knowledge, we believe that such an approach will have other positive effects on both the mother and child's quality of life.

Benefits of reading. Research has shown that reading to children has many benefits (e.g. Honig & Shin, 2001; Kupetz & Green, 1997; Shore, 1997). According to the National Commission on Reading (Anderson et al., 1985), reading to children is one of the most important interventions for developing reading skills. The American Academy of Pediatrics (AAP) has mirrored this sentiment by recommending reading be prescribed to all children during well-child visits (AAP, 2000). Reading aloud models reading, builds vocabulary, introduces representational media, and associates the reading process as an enjoyable activity (Walsh, 1995; McMahon, 1996). Research by DeLoache & DeMendoza (1987) has shown that reading aloud provides teaching experience for the mother in which she elicits the best possible performance from her child. In a review of 100,000 studies of reading, the National Reading Panel (2000) found that reading aloud helps teach children about phonemic awareness, phonics, and strategies to guide and improve reading comprehension.

Unfortunately, the majority of children do not experience parental reading. A telephone survey of parents with children under the age of three years found that only 39% with children less than one year of age reported reading or looking at a picture book with their child on a daily basis. This number increased to 48% for parents of children between 1-3 years (Young et al., 1998). In a randomized study designed to increase reading High, Hopmann, & LaGasse, (1998) found that dissemination of children's books with educational material on age-

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appropriate reading strategies increased bedtime reading activity, child-centered literacy activities, and child's enjoyment of being read to.

The Reach Out and Read (ROR) program has found that simply providing children's books increases reading. In a randomized study Golova et al. (1999) found that parents who were given books were 10 times more likely to read than those that were not given a book. An increase in reading practices and literary orientation has been found in several studies of the ROR program (e.g. High et al., 2000; Mendelsohn et al., 2001), suggesting that parents are eager to read if the materials are available. This is encouraging for the application of our proposed intervention since simply providing books appears to promote reading them.

Given that providing books increases reading, providing anticipatory guidance in the form of baby books should both increase the frequency of reading and knowledge. Increases in knowledge are expected for several reasons. First, there is evidence that adults absorb health information best when presented as simply worded written material (Byrne & Curtis, 2000). Secondly, the use of visual aids for educating parents has shown success. Cardenas & Simon-Morton (1993) found that parents retained more information about water heater safety when viewing anticipatory guidance with a cartoon visual aid, rather than text alone. Additionally, Showers (1989) found that the use of pictorial behavior management cards were effective in educating parents about anticipatory guidance material. Thirdly, cognitive research has demonstrated that people retain information longer when exposed to it repetitively (Castaeda et al., 1987; Woltz, 1990). Since children's books will be read again and again, providing anticipatory guidance through children's books would provide the information repetitively with simple text and visual aids.

In order to read, mothers will need to set aside time to spend one-on-one with their child. This process should not only educate parents about typical child development and effective parenting strategies, but provide opportunities to improve parent-child interactions. Routine interactions, especially those that promote physical contact (e.g. being held, cuddled), support healthy emotional development and secure attachments (Honig, 1998; Tracy & Ainsworth, 1981).

Parent-child interaction. There is growing support for early mother-child relationships playing a fundamental role in the development of the child and influencing his or her later relationships and mental health outcomes (Greenberg et al., 1993; Sroufe, Egeland, & Kreutzer, 1990). From the first day of life, new mothers and their babies learn how to interact with one another. Their relationship is a dynamic bidirectional system with each member of the dyad affected by the other (Bell, 1979). Put simply, mothers and children are influenced by one another.

Although parent-child interaction styles are not static, some mother-child dyads learn patterns that persist through childhood. Maccoby, Snow & Jacklin, (1984) found that infant gender and temperament at 12 months did not correlate with maternal teaching effort and style at 12 months, but predicted it at 18 months, demonstrating a predictive influence of child characteristics on later maternal behavior. Additionally, insecure attachment of the child to her mother at the age of 2 years has been associated with lower sociability, increased anger, poorer peer relations, and reduced self-control in the preschool years (Greenberg & Speltz, 1988).

The interaction patterns that mothers and their children adopt can have beneficial or detrimental influences on child development. Parents who show greater warmth, responsivity, and sensitivity are more likely to have children who develop secure working models of relationships (Ainsworth et al., 1978; Egeland & Sroufe, 1981). Shared positive affect between the mother-child dyad has been linked to multiple favorable early developmental outcomes (Kochanska, 1997; Landry et al., 2001). Kochanska and Aksan (1995) found that mutually positive affect was a predictor of child compliance. Matas et al., (1978) found that secure attachment (warm, positive, responsive relationship) at 18 months predicted enthusiasm, persistence, and cooperativeness at 2 years of age. Landry and colleagues (1997) found that parenting behaviors that were sensitive to the child's interests and did

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not restrict or control child behaviors predicted increases and faster rates of cognitive, linguistic, and social development. Interactions that are supportive, stimulating, and loving have been shown to be important to child development (Parpal & Maccoby, 1985).

On the other hand, negative parent-child interactions have been associated with poor child outcomes including increased prevalence of externalizing disorders (Greenberg et al., 1993; Patterson, 1986). Shaw and colleagues (1994) noted stability of patterns in which parent-child interactions at 6 months were predictive of difficulties at 18 months and internalizing and externalizing behaviors at 36 months. In another study, Shaw (1998) found that noncompliance and rejection in mother-child dyads was related to externalizing problems. Patterson (1982) cautioned that poor parent-child interaction could develop into coercive cycles in which parents and children behave in ways that are aversive to the other in attempts to control that other's behavior. In the worst cases, this pattern can provide direct training in antisocial behavior, known as the early starter model (Patterson et al., 1991). In the first year of life this coercive pattern is most often the result of an irritable, demanding infant coupled with an unresponsive mother (Shaw, Bell & Gillion, 2000). In a review of the development of externalizing behaviors, Campbell (1995) found support for a transactional model in which mother and child interactions contribute to the stability of negative child behaviors.

This proposed intervention is expected to improve the quality of parent-child interactions and launch mothers and their infants on positive trajectories. First, mothers will be asked to hold the child while they read, encouraging physical contact and one-on-one communication. Second, the content of the book will address many topics relevant to parent-child interactions. For example, issues of social-emotional development, consistent discipline, and modeling good behavior will be covered. Third, the process of implementing the intervention (i.e., reading the books to a child) should promote positive interaction since the text provides questions and words the mother can say to engage the child. Fourth, we hypothesize that the child will respond favorably to the process of being read to, thus reinforcing both the reading and the information conveyed.

Research has shown that there are several parental and child factors that contribute to the quality of parent-child interactions and subsequent child outcomes. Maternal factors include race/ethnicity (Capage, Bennett & McNeil, 2001), education (Brooks-Gunn, Klebanov, & Duncan, 1996), social support (Izzo et al., 2000), stress (Mulsow et al., 2002), mental health (Carter et al., 2001), personality (Ispa, Fine & Thornberg, 2002; Kochanska, Clark, & Goldman, 1997), knowledge (Benasich & Brooks-Gunn, 1996), parenting efficacy (Teti & Gelfand, 1991), attitudes (Katainen, Raikkonen, & Keltikangas, 1997), perceptions and motivation (Froman & Owen, 1989). Additionally, some maternal factors are difficult to separate from the overall ecology of the home such as income (Portes, Cuenteas, & Zadt, 2000), stimulation of the environment, and domestic conflict (Wissow, 2001) but also demonstrate a relationship. Child characteristics that have been demonstrated to influence parent-child interactions are infant health (Magill-Evans & Harrison, 2001; Ward et al., 1993), temperament (Clark, Kochanska, & Ready, 2000; Lee & Bates, 1985), difficulty (Bates, Freeland, & Lounsbury, 1979), emotionality (Kochanska, 1993), and compliance (Parpal & Maccoby, 1985). The proposed study will measure and test these variables as moderators of the expected outcomes.

Although mother-child interactions are dynamic with both members learning how to relate to one another, first time mothers have less parenting experience. The proposed intervention targets primiparous women because they do not yet have established parenting behaviors. Due to this lack of familiarity with parenting, these mothers have a greater likelihood of wanting to acquire information on child development and parenting. Research has shown that the transition to parenthood is marked with an increase of information seeking both formally (e.g. books) and informally (e.g. conversations with others) (Deutsch et al., 1988). Women tend to be eager to learn more about their pregnancy, child development, and parenting (Hudson, Elek, & Fleck, 2001; Salmela-Aro et al., 2000). The proposed study does not include fathers, although they are important contributors to infant health and development. Pilot work with this population has found that only 57% of pregnant women in our sample report contact and/or assistance from a husband, boyfriend, or partner. Therefore the

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dissemination of anticipatory guidance through baby books is geared towards first time mothers in hopes of increasing maternal knowledge of child development, safety, and parenting. This study will test whether this knowledge translates into better parenting and increased child safety while also encouraging positive parent-child interaction. In addition to promoting positive child outcomes, we expect the intervention to contribute to reduced maternal stress and increased maternal self-efficacy.

Maternal Stress. Maternal prenatal and postnatal stress has been linked to many child outcomes. Research has shown that maternal prenatal stress results in behavioral and neurological changes in offspring (Streissguth et al. 1993). Strong relationships between maternal stress and poorer birth outcomes have been established in human, primate, and rodent studies (e.g. Field et al. 1985; Grimm V.E., Frieder, 1897; Morishima et al. 1978; Orr & Miller, 1995). After birth, maternal stress has been associated with poor parent and infant outcomes (Crnic et al, 1986; Wallander et al. 1990). In a study by Hart, Bax, & Jenkins (1984), maternal stress was significantly related to physical illness and behavior problems in children. In a study of maternal stress and child development Essex et al. (2002) found that exposure to maternal stress in infancy predisposes children to increased hypothalamic-pituitary-adrenal function. This same study also found that children with high levels of cortisol at age 4.5 years are at increased risk for mental health symptoms at the end of first grade.

Cost-effectiveness. Preventable injuries are costly to society. In 1996, 13% of all medical spending on children ages 1 to 19 was used to treat unintentional injuries. These injuries accounted for 11% of hospital admissions, 39% of nonadmitted emergency department visits, and 9% of physician office visits for this age group (Bureau of the Census, 1997). The prevalence-based medical spending on unintentional injury during that year totaled over \$13 billion (Future of Children, 2000). In terms of lost productivity, unintentional injuries are more costly than child illnesses. During 1996, 43% of all deaths and related future work-loss costs among children resulted from unintentional injury, while only 35% resulted from illness (with the remaining 22% resulting from intentional injury). Thus, fatal unintentional injuries caused greater work-related productivity losses than all fatal childhood illnesses combined (Future of Children, 2000). Injuries among children impose a financial burden on numerous aspects of society such as victims, families, government, insurers, and taxpayers. In 1996, children injuries in the U.S. cost about \$14 billion in lifetime medical spending, \$1 billion in other resource costs, and \$66 billion in present and future work losses (Miller et al.2000). These costs include resource costs, productivity costs, and quality of life losses. Different types of injuries result in different economic costs. Among the leading and more costly types of injuries for children 0 to 4 were falls, burns, cuts or piercing, motor vehicle traffic accidents, and being struck by or against an object.

The American Academy of Pediatrics has strongly advocated for the use of anticipatory guidance to help prevent child injuries. The Injury Prevention Program (TIPPS), an office based counseling program, has been shown to be cost-effective even when only a small percentage of parents heed the advice. For example, Miller & Galbraith (1995) estimated only a 17% increase in smoke detector use, 12% increase in car seat use, and 54.7% active prevention of falls produces a savings of \$880 per child (0-4 years of age) and \$3.4 billion annually, if extended to the 19.2 million children in the US. Unfortunately, most cost-effectiveness injury prevention programs adopt the societal perspective where a large effort is placed in the estimation of direct costs, which represent a small subset of the total injury costs and more importantly underestimate the possible saving costs prevention programs might have in the short and long run.

Maternal depression and stress can have grave effects on child and maternal outcomes and subsequent societal cost as well. Post-partum depression affects 13-15% of women within the first few months after childbirth (Angst, 1995; O'Hara & Swain, 1996). The prevalence of depression is higher in lower income women (de Groot et al. 2003; Deal & Holt, 1998). Depression following birth is associated with early termination of breastfeeding, difficulty with infant crying and sleeping, harsh discipline practices, and poor child cognitive and physical development (e.g. Chung et al. 2004; Hiscock & Wake, 2001). Few studies have examined the economic burden of depression (Berto et al. 2001; Hu & Rupp, 1993). In the US in 1990, depression accounted

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for US\$ 43.7 billion in both direct and indirect costs (US\$ 65 billion, at 1998 prices; Berto, 2000). Within direct costs, the major cost driver was hospitalization, which represented something in between 43 and 75% of the average per patient cost, drug cost accounted for 2% to 11%. In a comparison of depressed and non-depressed primiparous mothers in Great Britain, Petrou et al. (2002) found direct costs for services utilization of depressed mothers and their infants in the first 18 months to be significantly higher. These costs included hospitalization, medication, and opportunity costs for professionals treating the dyad. In a study of low-income mothers in the US, Cheng et al. (2004) found that women with persistent depressive symptoms were less likely to obtain well-child care for their child, use a smoke alarm, or use the back to sleep position. These women were twice as likely to use corporal punishment and 3 times more likely to have their child hospitalized. However, exploration into the costs of these results of depression has yet to be explored.

The goal of this project cost-effectiveness analysis is to determine the costs and outcomes of the use of baby books compared to using commercial children's books and no books. It will determine which intervention yields the greatest health and productivity improvements per dollar invested. Following the recommendations of the Panel on Cost-Effectiveness in Health and Medicine (Gold et al. 1996), this analysis adopts the societal perspective, estimating the direct and indirect costs and possible savings that may result from the baby books intervention. In this program the economic definition of "cost" represents both the value of the *consumed resource* and also the value of *lost resources* that result from the intervention. For instance, the cost of a child injury is equivalent to the value of medical cost and resources associated with caring for the injured victim (right after the injury incident) and by the value of any forgone wages due to the injury.

*Direct* costs are due to primary objectives of a project and indirect costs are spillovers and externalities due to an intervention. The Direct costs of this intervention are the costs of the books and their distribution. Potential cost savings include such things as reducing frequency and severity of accidents and injuries per child, outpatient visits to pediatricians, visits to the emergency room, and spending for baby food. *Indirect* costs are "lost output due to the reduced or lost parent's working productivity due to their children illness, disability, or injury" (Hargreaves et al. 1998). Indirect costs are mostly estimated by using the opportunity cost concept. The opportunity cost of any resource is its value in its best alternative use. When we use a resource to provide a specific health service, we give up the opportunity to use that resource in another way. Thus, the opportunity cost of that resource is the value, or societal cost, of the same resource if it were used for the next best purpose. Cost estimation based on the opportunity cost concept is not an easy task. It does however, provide a valuable standard for evaluating price and cost data available for indirect cost-outcome analysis. The importance of using the opportunity cost of a resource as a methodology of valuation comes when measuring social costs and productivity costs due to the intervention. Later, the analytical plan explains the measures this project uses to capture the direct and indirect costs; we will use parent's self-reported questionnaires and medical chart reviews to measure mother's work absenteeism and job productivity, frequency, severity and type of children's injuries, medical services used, timing of children's immunization, hospitalization, emergency visits, etc. In addition of measuring the quantitative costs of this intervention, this project will also measure its impact the intervention may have in the quality of life families experienced during the intervention.

### C. PRELIMINARY STUDIES

*The mothers learned.* In order to test the feasibility of such an intervention, a baby book was created that incorporated anticipatory guidance about physical, cognitive, socio-emotional development, safety, nutrition, crying, and sleep. This book was given to 15 mothers to read to their infants (3–10 months of age) for three weeks after completing a pretest knowledge questionnaire. No training about reading was provided and no contact was made with the participants with the exception of a reminder phone call two days before the scheduled focus group. Each page of the book was color coded with a corresponding color table on the back for the women to track which pages they had read. At the conclusion of the 3-week period, mothers were asked to complete an alternate form posttest knowledge questionnaire and participate in a one of three focus groups.



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From the table on the back of the book, women reported reading the book to their child at least every 3 days, with half of the women reading at least once a day. Comparison of pretest and posttest scores showed an improvement of the women's level of knowledge. Further analysis demonstrated that the increase in correct answers corresponded to topics addressed in the books. A comparison of book-relevant questions and those that were not covered in the book showed a significant difference (t-test,  $p < .001$ ). Additionally, all women reported feeling they had learned something from the book. One woman stated, "After I read it, I knew what the answer is on the questionnaire. It was very effective in that sense."

The three focus groups centered on four main topics: 1) ability to read in regards to time and other barriers, 2) overall enjoyment of the book for both mother and child, 3) usefulness of the information, and 4) opinion of using baby books as way to provide information.

*They found time to read.* Unlike the proposed intervention, no information on how or when to read to young children was provided. Instead, women were asked to identify the times and methods they used with the book. Every mother reported being able to find time to read. Most mothers reported creating a regular time to read to their child. The most common choices were in the morning after feeding or in the afternoon after naptime. As one woman described, "I read this right after she got up from her nap, which is just about 2 or 3 when her energy level is much higher...it was fun because it started me a whole new routine...This is a fun routine to do."

*They enjoyed reading the book.* The book was viewed as very enjoyable. However some sections were viewed more favorably than others. Mothers reported more engagement by their child when viewing pages that were brightly colored with large pictures. As one mother stated, "I did enjoy reading it to her. I liked seeing how she acts to different things." Half of the mothers discussed interactive techniques they employed while reading the books. For example one mother reported that the section about physical and cognitive development was her favorite. "These are what are read to her over and over again because it was really to interact with her. The feelings, the routines, the exploring your world...this was really fun. I mean I spent a good 30 minutes sitting her up, rowing her back and forth, bouncing her. I went through each one and would point to the picture. It was fun, you know."

*The information was useful.* All of the mothers found the book to be very useful. They noted that the book was not only educational for them but an additional opportunity to spend time with their child. One woman mentioned that she has a parenting book but has yet to find the time to read it. "Well they sent me one, this mother and child book I haven't gotten around to reading it." She reported high levels of satisfaction with being able to learn while reading to her child. Another woman in the group described the book as useful for learning more. "I was very interested in getting information because this is my first and only child so I definitely wanted to know as much as I could know to prepare myself basically for what was going on."

*Mothers thought the books were a good way to provide information.* All of the women in the focus group were very excited by the prospect of an educational baby book. Each woman reported wanting a book of this type to be available, especially if the book targeted particular points of child development. Examples of their responses included: "This is a good idea because it's hard to take the time for yourself and if you were reading to your child then you and your child are both receiving some information, so it is good."

"There is a lot of mothers- to- be out there that don't research and rely on asking their moms and friends that don't really have the information that's needed. I am amazed that since I have a niece that having a baby and she is not doing any research. And a book like this, if it's presented in the right way for her to buy to read for her baby, she might learn from it...unfortunately there is a lot of moms out there that don't know any better."

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“Yes, definitely [create books] because I don’t really feel like it matters what you read to your child, it could be information for us or just a little kid’s book, ‘cause I think its helping them in the speaking and understanding regardless of what you’re reading. Whether it’s about a monkey or a choking hazard, I still think it’s helping them. I think the parents need as much information as they can get.”

Overall, the pilot of the proposed intervention was very favorable. Women were able to find time to read, enjoyed the process of reading, and had an increase in knowledge.

#### D. RESEARCH DESIGN AND METHOD

Overview. The project will provide an intervention, in the form of baby books, designed to educate and persuade mothers to follow the anticipatory guidance advocated by the American Academy of Pediatrics. The books are designed to educate mothers on child development and childhood injury prevention, promote reading and better health practices, and provide opportunities for high quality mother-child interactions. Primiparous women in their third trimester of pregnancy will be recruited for the study and retained until their child is 18 months old.

Design. A three group randomized design will be used with 60 mothers in each group. We will utilize two control groups, one group will receive commercial children’s books to control for effects of simply offering reading material and the second group will not receive any book. The only difference between the two book conditions will be the type of book the mother is given. A comparison between the experimental (baby book) and commercial book condition will tell us if there are any effects caused by the type of book. Comparisons with the no book condition will inform us if reading, regardless of the type of book, had any effect. Data collection time intervals, payment, and the amount of researcher contact will be equivalent among all groups.

Participants. One hundred and eighty pregnant women will be recruited from the Vanderbilt University Obstetric Clinic. Based on the characteristics of pilot research with this same population, we anticipate an ethnically diverse and low-income population. See Table 1 for details of race/ethnicity and income. Eligible women must be over 17 years of age, pregnant with their first child, conversant in English, and able to read (2<sup>nd</sup> grade level). There are no restrictions on the health of the fetus or the number of gestational fetuses (e.g. twins).

Table 1. Expected Class, Racial, and Ethnic Compositions of Mothers in the Study

	American Indian or Alaskan Native	Asian or Pacific Islander	Black, not of Hispanic Origin	Hispanic	White, not of Hispanic Origin	Other or Unknown	Total
<\$15,000	.01	.01	.15	.01	.12	.02	<b>.32</b>
\$15,000-\$25,000	.01	.01	.11	.01	.12	.01	<b>.26</b>
\$25,000-\$35,000	0	.0	.05	.01	.12	.01	<b>.19</b>
\$35,000-\$45,000	0	0	.02	0	.05	0	<b>.07</b>
>\$45,000	0	0	.01	0	.06	.01	<b>.09</b>
Unknown	.01	0	.04	0	.02	0	<b>.07</b>
<b>Total</b>	<b>.03</b>	<b>.02</b>	<b>.38</b>	<b>.03</b>	<b>.49</b>	<b>.05</b>	<b>1.00</b>

Recruitment. All visibly pregnant women in the waiting room of the hospital obstetrics clinic will be approached by a researcher and invited to participate in a study of new mothers’ reading practices. Eligibility for participation will be ascertained and a log kept of all women who were not eligible or who refused to provide the information needed to judge eligibility. For those women who are eligible and willing to participate in the study, the informed consent process will be initiated and a one-page background form (in Appendix A)

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will be completed. At that point, an appointment will be made to visit the potential participant in her home. Before the home visit, the woman will be called to verify the appointment. Based on our experience in conducting research with this population we expect that approximately 20% of the women will not be home for this initial visit. We will return to the woman's home two additional times (a total of 3 home visits) before dropping her from the study and replacing her with a new potential participant. We have found the repeat visits to be successful in retaining half of the women who were not present during the initial visit. Thus, we expect to collect baseline data on 90% of the women who consent to participate. Since brief background information will be collected in the clinic, comparisons of attrited and continuing participants will be possible. In order to minimize differential attrition, the random assignment to conditions will not occur until the first visit is made and baseline data are collected. After the baseline data are collected in the home, the interviewer will consult a sealed envelope to determine to which experimental condition the subject is assigned. This will help protect against differential attrition by condition since any attrition between recruitment and baseline data collection will occur prior to assignment. Participants will be randomly assigned to one of three groups. Randomization will be performed through the use of a computerized randomization program. Recruitment will take place over 15 months beginning in month 9 of grant year 1. Approximately 12 women per month will be recruited.

Since there is no way to keep the data collector "blind" to the experimental condition, it is possible that bias can be introduced in the data collection procedure. The researcher may want the experimental group to do better and collect the data in such a manner to help confirm the study's hypotheses. We will attempt to minimize such bias through training and random observations of the data collection process. If such bias were present, it would be expected to manifest itself more on instruments that are completed by the researcher than the mother. We will analyze our data to check for the presence of such a bias. In addition, the psychologist administering the Bayley and Mastery Motivation assessments will be blind to the participant's experimental condition.

The intervention. The intervention books target the relevant anticipatory guidance for the prenatal period, and when the child is 2, 4, 6, 9, and 12 months of age as cited by the Bright Futures Guidelines for Health Supervision (Green & Palfrey, 2002) and AAP Guidelines for Health Supervision III (AAP, 1997). The books are designed to appeal to age-appropriate cognitive and sensory development of the child. For example, the 6-month book is a board book with many pictures and few words, whereas 12-month book is interactive with flaps and hidden pictures. These books not only contain text and pictures that educate the mother about child development and safety, but also elicit child behaviors that demonstrate the content. For example, the two-month book will discuss the types of sensory stimuli infants find most appealing while the infant is attending to these stimuli, thus supporting the information in the books and encouraging parent-child interaction while reading. The content of each book is focused on age relevant issues such as safety, nutrition, physical, cognitive, motor, and socio-emotional development, crying, and maternal emotional and physical self-care. Table 2 describes the content and structure of each book. Appendix B contains the book used in our pilot test, which is similar but of lower quality to the actual books that will be used in the study. Funds have been requested for the assistance of a professional children's book author/editor and a graphics design expert to produce professionally appearing books that will be equivalent in attractiveness and presentation to the commercial books that will be used in the reading control condition. The commercial books will serve as controls for reading books that are not specially designed to convey anticipatory guidance information. We expect that experimental books with educational content will make a critical difference in the mother's knowledge and behavior and her impact on her child.

Almost all data collection will occur in the participant's home with the exception of the short background form and medical chart audit. At the completion of each data collection home visit (prenatal, 2, 4, 6, 9, 12, and 18 months), a researcher will give the mothers in the books conditions a new book and discuss the need to read to her child at least once a day. The researcher will then show the mother a video (DVD) that demonstrates how to read that book to a similar aged child. This video models reading to a similar aged infant or toddler and focuses

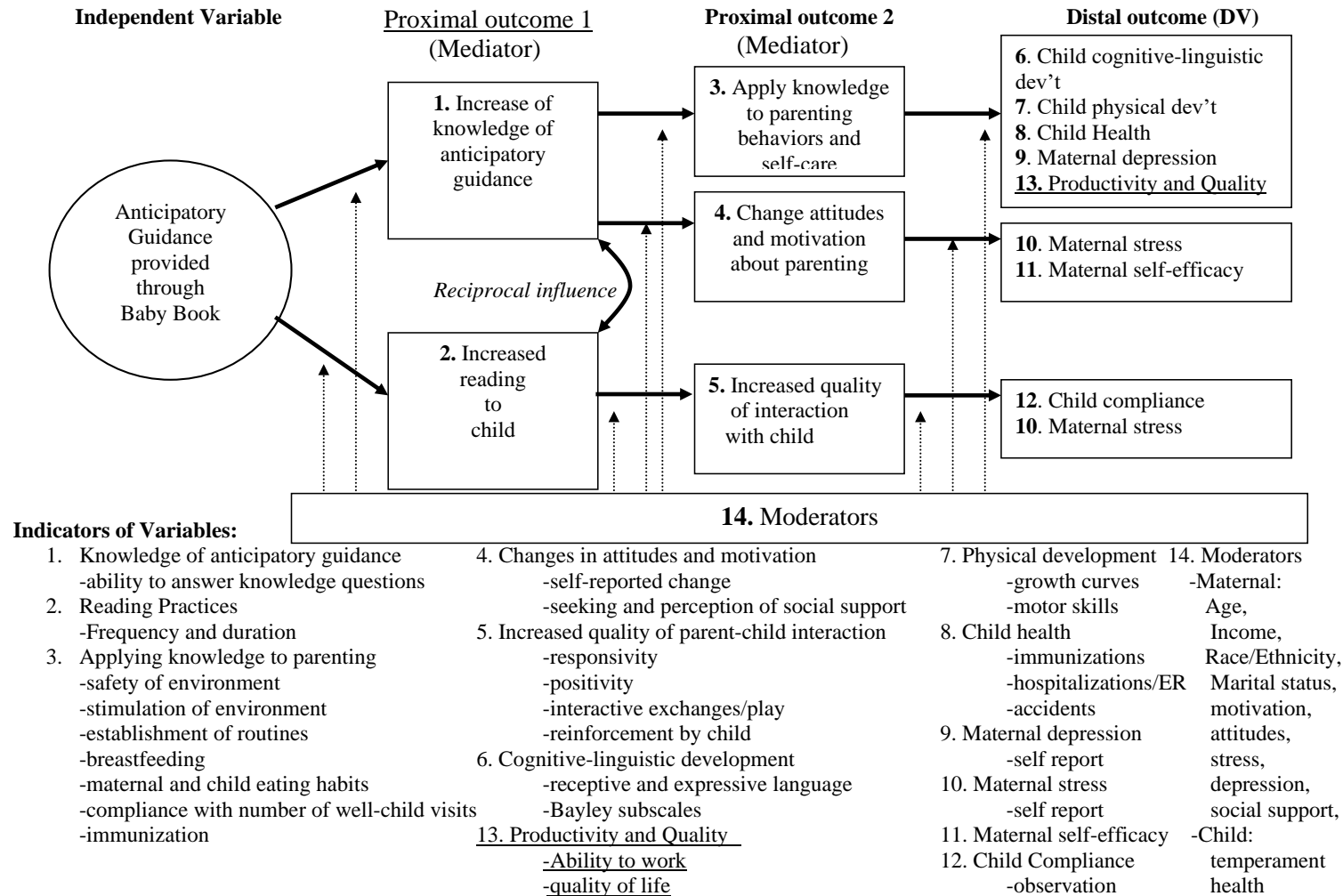


Figure 1 is a graphic representation of the relationships between the variable in Table 1

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on the important aspects of effective reading. Specifically, the video will stress the importance of physical contact during reading time (e.g. putting an arm around the child or placing him/her on a lap), the value of voice and rhythm (e.g. avoiding monotone reading, using inflection and accentuation), the need to involve the child (asking questions, pointing to pictures), and the importance of understanding the child's developmental abilities (e.g. being aware states of alertness, supporting a newborn's body while reading, helping a 8-month old turn the pages). Following the video, the researcher will encourage the mother to 'try it out' and read aloud to her child. Since reading to a child is a skill that must be cultivated, the intervention will ensure that women have the ability to effectively participate in this project. The instruction on how to read will occur in all three conditions in order to keep them equivalent. Even though no book will be given to the mother in the no book condition, she will receive the same instruction as in the other two conditions. Since mothers are told that the study is about reading behaviors, the reading instruction should not seem unusual. We think that it is more important to have the 3 conditions as equivalent as possible than to have a completely no treatment control group. Women will be allowed to keep previous books and encouraged to read them as often as they like in addition to the current book.

Figure 1 provides a model of the logic underlying the intervention. Primiparous mothers will receive anticipatory guidance information in the form of a baby book. The information in the books as well as the books themselves should result in two proximal outcomes: 1) mothers have an increased knowledge of anticipatory guidance and 2) mothers spend more time reading to their child. These two proximal outcomes should lead to several additional outcomes. Increased knowledge is expected to lead to the application of such knowledge to parenting behavior. Increased knowledge coupled with reading activities is expected to result in more favorable attitudes and motivations for parenting as well as higher quality mother-child interactions. These three outcomes are expected to result in many favorable maternal and child outcomes such as reduced maternal stress, improved child health, and better physical, cognitive, and social development for the child, and higher work productivity and less work absenteeism for the mother. All of these proximal and distal outcomes might be moderated by such factors as maternal demographic characteristics (e.g. age, income, education, race), attitudes, motivation, stress, depression, social support, child temperament, and child physical health. Based on previous research, we expect levels of knowledge of anticipatory guidance material, the quality of parent-child interactions, and maternal and child outcomes will be correlated positively with maternal income, education, marriage, motivation, positive attitudes, social support, and child health and negatively correlated with minority status, maternal stress, maternal depression, and difficult child temperament. How these moderators will be explored is described in greater detail in the analysis section.

Tests and Measurement. Data collection methods and timing will be equivalent for the baby book, commercial book and no book conditions. Almost all data will be collected in the participants' home through self-report and observational methods. A short background questionnaire will be completed in the obstetric clinic waiting room when the women are recruited and if they agree to participate. A retrospective medical chart review will be conducted at the office of the child's pediatrician at the conclusion of the study. All other measurement will occur during the prenatal, 2, 4, 6, 9, 12, and 18-month home visits. The interviewers will be trained in the administration of the measures to assure a high level of reliability for instruments before allowed into the field. The researcher will be accompanied on randomly selected visits by the project's pediatrician to maintain reliability and to prevent interviewer "drift" or differences between interviewers. Although interventions that utilize home visits by nurses (e.g. Olds, 2002) have shown beneficial effects simply from the visitation, this confound should be distributed equally among all groups. Additionally, the interviewers will not be clinical providers nor will they provide education about parenting. Our previous work with this population has found that home visits result in higher subject retention than data collection that occurs at our center. Finally, since some measures require special training (e.g. Bayley) we will use some testers who are not part of the project and thus will be "blind" to the condition to which the mother was assigned. Below is a description of each measure and frequency of data collection. See Table 3 for more details.

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Table 2. Baby book topics and structure

Time	Title	Pages	Style	Main Topics	Additional Topics
Prenatal	“Getting to Know You” and Maternal Health	Glossy Paper	First person text	Maternal self-care (social support, rest, diet, exercise, depression signs); Breastfeeding; Infant Development	Safety; Newborn development (sensory, motor, cognitive); Sleep patterns; Routines
2 month	“Routines”	Boards Book	See and Point	Establishing routines; Sleep	Safety; Cognitive and Physical development; Nutrition; Parenting; Maternal Care
4 month	“Introducing Solids”	Boards Book	See and Point	Nutrition; Safety	Parenting; Discipline; Routines; Sleep; Oral Hygiene
6 month	“Baby Proofing”	Boards Book	Rhyming	Safety; Development	Routines; Sleep; Nutrition; Maternal Social Support and Rest
9 month	“Setting Limits”	Boards Book	Rhyming	Discipline; Parenting	Safety; Routines; Nutrition; Development
12 month	“Maternal and Family Health”	Boards Book	Interactive (flaps and texture)	Maternal Self-Care; Parenting	Development; Nutrition; Safety; Routines
*The last page of all books provides a space for questions for next well child visit.					

*Parenting Stress Index (PSI)*. The PSI, normed on a large sample (N=2,633), was designed to measure general stress related to parenting. The measure may be used as a screening or a diagnostic instrument. The Total score is derived from questions regarding the domains of parent, child, and parent-child interactions with the assumption that stress is always an interaction of the person by situation. The parent domains include: health, depression, isolation, attachment, role restriction, competence, and spouse. Child domains include: adaptability, acceptability, demandingness, mood, distractibility/hyperactivity, and reinforcement of parent. The scale has 101 items and has been used in hundreds of studies as a correlate and as an outcome (Goldberg et al., 1997; Lutzker et al., 1998). The PSI publisher reports the coefficient alpha to be .90 for the child domain, .93 for the parent domain, and .95 for the total scale. The test-retest reliabilities for the total score range from .65 for a 1-year time period to .96 for 1-3 months. The PSI will be administered 3, 6, 12, and 18 months.

*Pregnancy Experience Scale (PES), low SES version*. The PES (DiPietro et al., 2002) is a maternal report scale of pregnancy specific hassles and uplifts. It has a demonstrated relationship with fetal activity in a large middle class sample. It has been modified and employed in a low SES, predominately minority sample (DiPietro et al., 1999; Hawkins, DiPietro, & Costigan, 1999). In that form it has 31 phenomena that must be rated according to the positive and the negative valence they afford. The reliability data on the PES is good (Cronbach’s alpha = .91 - .95) (DiPietro et al, 2003). Measurement will occur at Baseline.

*Brief Symptom Inventory-18 (BSI-18)*. The BSI –18 is a short form of the 25 SCL-90-R (Derogatis, 1994) consisting of 1 broad factor (Global Severity Index) and 3 subscales (Somatization, Depression, Anxiety). Symptoms are rated on a 5-point Likert scale, with values ranging from 0 (not at all) to 4 (extremely) rating degree of distress experienced due to each symptom over the past seven days. The purpose of the scale is to screen for psychological problems in normal populations, to evaluate symptoms changes over time, and to support managed care decisions (Derogatis, 2000). The subscales of the BSI-18 have correlated highly with the

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SCL-90-R (>.90). The BSI has adequate internal consistency (Cronbach's alpha = 0.89). Measurement will occur at baseline, 2, 6, 12 and 18 months.

*Maternal Self-Efficacy Scale.* This 9-item instrument measures specific self-efficacy for parenting behaviors as conceptualized by Bandura (Teti & Gelfand, 1991). It measures feelings of confidence in domains of infant care, such as getting the baby to know what the mother wants, disengaging from the baby, and knowing what the baby enjoys. The scale has been related to environmental, child, and dyadic variables in mothers living in poverty (Raver & Leadbeater, 1999). Coefficient alpha was reported as .65 for a sample of 44 mothers (Raver & Leadbeater, 1999). Self-efficacy will be measured at 2, 4, 9, 12, and 18 months.

*Parent/Caregiver Involvement Scale.* This scale is designed to describe caregiver behaviors during active play with an infant or toddler ages 6 months to 5 years (Farran et al., 1987) and is considered an indicator of maternal involvement. Eleven types of caregiver behavior are measured on Likert scales (e.g., physical involvement, verbal involvement). Three aspects of each behavior are measured: amount, quality, and appropriateness. All measurement is based on a 20-minute interaction between mother and child. The scale has been used in many studies of mother-toddler interactions (Hagan & Myers, 1997; McGrath, Sullivan, & Seifer, 1998) and to test the concept of 'goodness of fit' between parent and child in early intervention research (Simeonsson et al., 1986). The G-coefficient of this measure has been estimated to be between .53 to .93 (Farran et al., 1987). Seifer et al. (1996) reported inter-rater reliability of .95 and an alpha of .87. The PCIS will be administered at 6, 9, 12, and 18 months. The interaction will be videotaped and scored by 2 independent observers to ensure reliability. These individuals will be trained to have acceptable inter-rater reliability before scoring data and will be blind to the mother's experimental group assignment.

*Anticipatory Guidance Knowledge Questionnaire.* This measure is designed to correspond with the knowledge imparted from reading each baby book. The questionnaire assesses knowledge gain of age-appropriate anticipatory guidance. Therefore a different version is utilized at each wave of data collection. This questionnaire will be created in conjunction with the baby books. Measurement will occur at all waves.

*Modified Parent Reading Belief Inventory.* This 43-item self-report instrument measures beliefs that parents have about reading and the benefits of reading (DeBaryshe & Binder, 1994). Questions are organized into 7 scales: efficacy, affect, participation, instruction, knowledge, resources, and environment. In a modified form it has been used in a study promoting literacy in a pediatric setting (Celano et al., 1998). This version has a coefficient alpha of .91. This will be measure will be used at baseline, 6, 12, and 18 months.

*Parenting Attitudes Towards Childrearing Questionnaire.* This 51-item self-report measure assesses parental attitudes regarding parental warmth, strictness, aggravation, and child independence on a 7-point Likert scale (Easterbrooks & Goldberg, 1984). Although this instrument has most commonly been used with parents of toddlers, it is applicable to parents of infants as well (Halpern et al., 2001; Holden & Edwards, 1989). Internal consistency validity is adequate, ranging from .57-.87. Test-retest reliability reported by the authors was .76. It will be used at 2, 6, 12, and 18 months.

*Multidimensional Personality Questionnaire-Brief Form.* The Multidimensional Personality Questionnaire (Tellegen et al., 1988) is a self-report instrument has been used in many studies of personality including epidemiological studies of adults (Kruger et al., 2000) and children (Roberts et al., 2001) and clinical studies (Raymond et al., 2002). The MDQ-BF consists of 155 items and measures 11 primary dimensions and 3 higher-order traits related to emotional and behavioral regulation: Positive Emotionality, Negative Emotionality, and Constraint. It was normed on a large sample (N=1,350) of adults. The coefficient alphas for the primary trait scales range from .75 to .84. When the scales were prorated to full length the Spearman-Brown split half reliabilities ranged from .83 to .91. This will be administered at baseline.

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*The Maternal Background Questionnaire.* Two background measures have been created specifically for this study by the applicant: Maternal Background Questionnaire-Short Version and Maternal Background Questionnaire-Full Version. Both forms include information on age, race, ethnicity, marital status, income, current employment, and receipt of public assistance. The Full version also includes information household composition, maternal health and employment history. The Short version will be given to all women at the first contact in the clinic who consent to participate. Women will complete the full version at the baseline data collection home visit.

*The Incurred Costs Interview.* Developed by the applicant, this measure identifies sources of cost incurred by the mother between data collection periods. These costs include maternal health problems (e.g. illness, depression), child health problems (e.g. doctor visits, medication), frequency, severity and type of child injury, mother's working productivity (e.g. current working condition, employment status, number of working hours, missed working hours due to child illness or injury), and expenses for infant care (e.g. formula, baby food). Measurement will occur at every wave.

*The Preschool Language Scale-Fourth Edition.* This well known norm-referenced scale is used to measure receptive (auditory) and expressive language for subjects aged 0 to 7 years. Standard scores and percentiles are available by a 6-month age range. Behavioral assessment of language skills is made through elicited interactions and responses. The scale also uses spontaneous scoring of behaviors if exhibited at any time during the test session. Coefficient alpha ranges from .47 to .94 across age groups and subscales. The two primary scales, auditory comprehension and expressive communication, had coefficients of at least .80. Test-retest reliability ranged from .81 to .94 across 3-month age groups for 30 subjects. A good estimate of inter-rater reliability was not available for this instrument. This measure will be used at 6, 12, and 18 months.

*Revised Infant Temperament Questionnaire.* This scale is designed to measure nine aspects of infant behavior that are inferred to be representative of temperament: activity level, regularity, adaptability, initial approach-withdrawal, intensity, mood, persistence, sensory threshold and distractibility (Carey & McDevitt, 1978; Carey, 1983). It has been used to relate parenting to child behaviors (Simeonsson et al., 1986). The coefficient alpha and test-retest reliability have been reported as adequate for this measure (Bohlin, Hagekull, & Lindhagen, 1981; Persson-Blennow & McNeil, 1979; Rothbart, 1981). Infant temperament will be measured at 6 months.

*Bayley Infant Neurodevelopmental Screener (BINS).* The BINS assesses neurological processes, neurodevelopmental skills, and developmental accomplishments such as imitation and language. This instrument uses 10-13 items per 3-6 month age range. It is designed for use with infants aged 3-24 months. The BINS was normed on 600 children stratified by age, race, region, and parent education. Four scores are obtained from the screener: neurological functions-intactness, receptive functions, expressive functions, and cognitive processes. Sensitivity is from 75% to 85% across age groups. Coefficient alpha ranges from .73 to .85 depending on the age group. Test-retest reliability was calculated as .71 for 3 month-old infants and .84 for 18 month-old infants (N=150). The BINS will be used at 4, 6, and 9 months.

*Bayley Scales of Infant Development (BSID-II).* This well-known scale is designed to children from birth to 42 months of age and was normed on a large sample (N=1,700). The scale includes Mental Development Index, Psychomotor Developmental Index, and Behavioral Rating Scales. The instrument is recommended for research as well as clinical assessment applications. The average coefficient alpha for the Mental Development Index has been reported as .88 (range .78-.93), for the Motor Development Index as .84 (range .75-.87) and for the Behavior Rating Scales .88 (range .82 to .92). Test-retest reliability estimates are acceptable, although tend to be lower for the Behavioral Rating Scales. The Bayley Scales will be used at 12 and 18 months.

*Home Observation for Measurement of Environment (Infants/Toddlers, HOME).* This highly utilized 45-item instrument is designed to measure aspects of the home environment that have been linked to child development



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(Caldwell & Bradley, 1984). The scale measures learning and language stimulation, organization of the environment, and provision of warmth, acceptance and discipline. The majority of data collected with this instrument is based on observation with approximately 1/3 based on parent report. Coefficient alpha for the scales ranges from .44 to .89. The alpha for the total score is .89. The test-retest reliability of the scales range from .27 to .77 across 6, 12, and 24 months. The HOME correlates positively with SES and is sensitive to change. Scores on this measure have been used to predict cognitive development (Totsika & Sylva, 2004). This will be used at 2, 9, 12, and 18 months.

*Home Literacy Questionnaire.* This 5-item questionnaire is designed to measure parent initiatives to enhance the home literacy environment (Frijters, Barron & Brunello, 2000) and has been used by several authors to do this (Bus & van Ijzendoorn, 1995; Scarborough & Dobrich, 1994). The Spearman-Brown split-half reliability coefficient is .77 for a sample of 95 families. Measurement will occur at baseline, 6, 12, and 18 months.

*Mastery Motivation Assessment.* This observational measure of toddler self-efficacy (Jennings & Abrew, 2004) relies on the videotaping of a child's interaction with six mastery toys that vary in task demands. One toy is an exploratory toy, 2 are effectance toys, and 3 are goal directed toys. The child's persistence, engagement, mastery pleasure, and pride displays are coded. Kappas are .80 for persistence, .66 for mastery pleasure, .77 for pride, and .82 for prompts by researcher. A psychologist, "blind" to which group the mother was randomly assigned, will administer this measure at 18 months.

*Infant Home Safety Assessment.* This instrument corresponds to the anticipatory guidance safety information recommended by Bright Futures and the American Academy of Pediatrics. Different versions of this instrument will be used at each wave of data collection to correspond to the content of each baby book. Measurement will occur at every wave.

*Infant Nutrition Interview.* This brief maternal report questionnaire documents maternal provision of nutrition to her child. Questions apply to infants consuming food other than breast milk or formula. It has been created specifically for this project. Measurement will occur at every wave.

*Medical Chart Review.* Children's health (e.g. immunizations, hospitalizations, ER visits, growth curve) information will be assessed through a chart review in the pediatric clinic. The instrument will be developed once funded since it is not needed until the end of the data collection phase. It will be based on our experience in developing a coding form for our NIMH study of pediatrician practices.

*Unobtrusive and self-report of Reading Behavior.* A major intervening variable in this study is the amount of reading that the mother does with the child. We will ask the mothers at each visit what she has read to the child in the last week. For both conditions two measures of fidelity of reading will be used. The mother will be asked to move a sticker (star) from the front cover to the back cover every time she reads the book to her child. The back cover will have spaces indicated by dates so we can tell what day she read to the child. However, this method has some limitations. Mothers may forget to move the star or move the star when she did not read due to social desirability. The star method will also not provide information about the duration of the reading episode. To deal with these measurement issues we have developed an unobtrusive measure that uses a specially designed "smart card" that will be placed in the cover of the book. When decoded the card will provide information about when the book was opened (including date) and the amount of time it was open. A block diagram of the device may be found in the Appendix C. Mothers will be thoroughly debriefed about the card at the end of the study and given the option to not have their data retained.

Duration of data collection. Administration of the measures described above will be spaced out over the duration of the study to ensure that no episode of data collection exceeds 2 ½ hours. Surveys of knowledge, cost, nutrition, and safety of the home environment will be used at every wave of data collection after the child

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is born. Two of the data collection episodes (4 and 9 months) will last 45 minutes. All other episodes will be between 2-2 ½ hours. Several of our previous NIMH-funded studies with comparable samples have used data collection periods of this length with less participant compensation. These studies experienced less than 9% attrition in the second year and did not exceed 12% attrition for the three years of data collection. Although measurement is extensive, we do not expect it to be burdensome to participants nor contribute to dropout.

Assumptions about attrition. The first step in the analytic plan is estimating the effective sample size based on the following assumptions about attrition: 1% drop out permanently (e.g. by moving or refusing); additionally, each month 5% temporarily miss a wave. None will miss the baseline wave, since randomization will not occur until baseline data collection is complete. However, we anticipate 10% of women who consent to participate to not complete wave 1 data. This pattern of attrition is based on our pilot work with mothers of newborns and the extensive research we have conducted with parents and children in NIMH-funded studies. Table 4 shows how this attrition reduces the sample to 80% at the endpoint, with an average  $N$  of 89% of the initial number recruited. Conservatively, we will use 80% as the effective  $N$  for power calculations. To reduce dropout, four strategies will be used. Since we have found that initial participation predicts later attrition, women who miss the first home visit, and after 3 attempts, will not be included in the study. We will also employ tracking methods used in our previous research: a) obtaining the names and contact information of persons who would know the whereabouts of participants; b) use of a commercial locating service when we are unable to find the mother; and c) providing mothers with further payments for continued participation.

Sample Size and Statistical Power. We plan to start with 180 mothers, 60 in each of 3 randomly assigned groups (no books, commercial books, anticipatory guidance books). According to assumptions about attrition, 60 cases would attrite down to about 48 at the end. Power estimates assume  $48+48+48=144$  participants, as shown in table 4.

Statistical power. Outcomes as reported in Table 3 range from proximal (e.g. knowledge of book content) to intermediate (maternal attitudes), to distal (maternal behavior and child development). Some measures will be observed at all 7 waves, such as knowledge of anticipatory guidance. Others appear at fewer waves, e.g. maternal self-efficacy at 5 waves (2, 4, 9, 12, & 18 months), Preschool Language Scale waves (0, 2 & 6), or Bayley Development 2 waves (12 & 18). An “intensive” longitudinal design with many repeated measures offers greater power than pre-post designs (Kraemer, 1991; Kraemer & Thiemann, 1989; Lambert, Doucette, & Bickman, 2001). Outcomes with many repeated measurements should be more sensitive to detecting treatment effects than those that are measured only twice.

All estimates of statistical power will follow Cohen’s (1988) conventions: two-tailed tests done at the 5% level of significance; minimum adequate power an 80% probability of detecting an effect if it occurs. Effect sizes are measured in standard deviations (SDs) by Cohen’s  $d = (M_1 - M_2) / SD_{pooled}$ . Effect sizes are evaluated with Cohen’s norms, which define small, medium, and large effects as 0.2, 0.5, and 0.8 SDs respectively. For simplicity, estimates of statistical power will use common two-group models because the study asks two questions: a) Are enhanced books better than ordinary books? and b) Are ordinary books better than no books?

We begin with the lowest powered case: With 2 groups of 48 each, what would be the statistical power to detect differences in a pre-post change score, such as the Bayley Motor Scale or the Bayley Behavior Rating Scale? This would be a  $t$ -test between groups; the outcome would be a difference score or a residual change score. A traditional Cohen-based power curve appears in Figure 2 and suggests that for a  $t$ -test to detect differences between any two groups, the effect size would have to be at least 0.57 SDs, slightly larger than a medium effect (.5 SDs). For example, if small differences occurred on the Bayley, the study would be underpowered to detect them. The two-wave test is the worst case. For the BINS there are 3 repeated measures, and power would be slightly better. For outcomes like knowledge of anticipatory guidance, measured at every visit (prenatal, 2, 4, 6, 9, 12, 18 mo), the increased number of observations should make power to detect small effects substantially

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better. To evaluate the power of repeated measures, we must use longitudinal power analysis estimates (Diggle, Liang, & Zeger, 1994). Using Cohen's popular power analysis for a *t*-test would badly underestimate the power of an outcome measured 7 times.

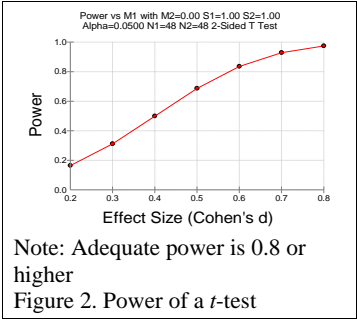
Table 3. List of measures			
Variable	Measurement	Frequency	Variable Type
Maternal Knowledge	Anticipatory Guidance Knowledge Questionnaire (Applicants)	Every visit	Proximal Outcome 1 (Mediator)
Maternal Attitudes and Motivations	Parents Attitudes towards Childrearing Questionnaire (Easterbrooks & Goldberg, 1984)	2, 6, 12, 18	Moderator Proximal Outcome 2 (Mediator)
Maternal Social Support and Stress	Parenting Stress Index (Abidin, 1995)	2, 6, 12, 18	Moderator Dependent (distal Outcome)
	Pregnancy Experience Scale (DiPietro, 2002)	Baseline	
Maternal Self-Efficacy	Maternal Self-efficacy Scale (Teti & Gelfand, 1991)	2, 4, 9, 12, 18	Moderator Dependent (distal outcome)
Maternal Personality	Multidimensional Personality Questionnaire (Patrick, Curtin, & Tellegen, 2002)	Baseline	Moderator
Maternal Depression	Brief Symptom Inventory-18 Derogatis (2000)	Baseline, 2, 6, 12, 18	Moderator Dependent (distal outcome)
Maternal Reading	Parental Reading Belief Inventory (DeBaryshe, Barbara, & Binder, 1994) Unobtrusive Spine Monitor (Applicants)	Baseline, 6, 12, 18 Every wave	Mediator (proximal outcome 1)
Infant Nutrition	Infant Nutrition Interview (Applicants)	Every visit	Mediator (proximal outcome 2)
Infant Temperament	Infant Temperament Questionnaire (Carey & McDevitt, 1978)	6	Moderator
Infant Cognitive-Motor Development	Bayley Scales of Infant Development (Riverside Publishing)	12, 18	Dependent (distal outcome)
Infant Language Development	The Preschool Language Scale-4 (Psychological Corporation)	6, 12, 18	Dependent (distal outcome)
Infant Neurodevelopment	Bayleys Infant Neurodevelopment Screener (The Psychological Corp.)	4, 6, 9	Dependent (distal outcome)
Infant Health	Chart Review (immunization, doctor visits, emergency room visits, hospitalizations)	After 18 months	Dependent (distal outcome)
Infant Self-Efficacy	Mastery Motivation Assessment (Jennings & Abrew, 2004)	18	Dependent (distal outcome)
Parent-Child Interaction	Parent-Caregiver Involvement Scale (Farran, Kasari, Comfort, & Jay, 1987)	6, 9, 12, 18	Mediator (proximal outcome 2)
Environmental Stimulation	Home Observation for Measurement for Environment Caldwell & Bradley, 1984)	2, 9, 12, 18	Mediator (proximal outcome 2)
	Home Literacy Questionnaire (Frijters, Barron, & Brunello, 2000)	Baseline, 6, 12, 18	
Environmental Safety	Infant Home Safety Assessment (Applicants)	Every visit	Mediator (proximal outcome 2)
Cost Variables	Incurred Costs Interview (Applicants)	Every Visit	Dependent (distal outcomes)

Longitudinal outcomes are often evaluated with changes in slope or growth curves, as shown hypothetically in Figure 3, where an experimental and control group start about equal, but one group improves over time. We

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expect mothers who read the intervention books will have a gradual improvement in outcomes such as self-efficacy, whereas those with ordinary commercial books will not.

Since data collection can occur from 2 to 7 times, Table 5 displays the different patterns ranging from every visit (7 waves) down to 4 or 2 waves. Rather than calculate every possible case, we estimated longitudinal power on 3 key examples: 7 waves, 4 waves, and 2 waves. Power calculations were done on a hypothetical outcome with an SD=10. As before we assume 48 per group. Temporal stability (average cross-wave correlation) was assumed to be  $r = 0.60$ , somewhat lower (and more conservative) than we typically observe with mental health tests such as the Child Behavior Check List.

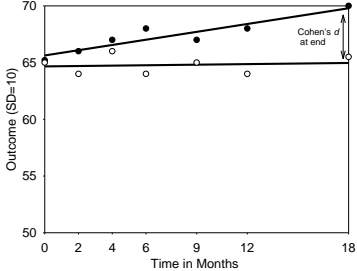


The first longitudinal power analysis assumed 7 repeated measurements (Time = 0, 2, 4, 6, 9, 12, 18 months) and a slope-as-outcome, as shown in Figure 3. The figure shows growth lines for two groups, with hypothetical means appearing as points and linear growth models as lines.

According to the longitudinal power model, a rate of change of 0.23 points/month could be detected with 80% power. This difference in slope produces a difference between groups of 0.38 SDs at the endpoint, and an effect size between small (.2) and medium (.5) -- we expect to detect small-to-medium differences on 7-wave slope outcomes. This power is considerably better than that of a  $t$ -test, which is one of the main reasons why Kraemer and Thiernann (1989) advocate multi-wave studies so strongly.

The longitudinal power estimate was repeated in a 4-wave model (Time = 0, 6, 12, 18 months). For adequate power, a difference in slopes between the two experimental groups would have to produce a difference of  $d = 0.46$  SDs at the end, a medium effect. Table 6 summarizes the power analysis, showing the effect sizes that can be detected with adequate power (80% at  $p < .05$ ). The two-wave power, presented above, is .57.

Figure 3. Longitudinal outcomes



Expected effect sizes. The outcomes in Table 3 can be ordered from proximal to distal. For example, maternal knowledge of material in the enhanced books is proximal. Outcomes like maternal self-efficacy or maternal depression would be intermediate. Parent-child interactions or child medical treatment from the pediatrician's chart would be distal, indicating whether enhanced books influenced behavior. Distal outcomes, such as the child's scores on the Bayley Scales of Infant Development could occur, but they are not the main outcome of the study. We expect large effects in the proximal outcomes, such as maternal knowledge of book material, and medium effects in the intermediate outcomes, including better maternal self-efficacy and compliance with guidelines for pediatric care. Some studies have shown large changes in the Bayley over the time period we are studying. For example, Farran and Ramey (1980) randomly assigned 23 high-risk infants to 40 hrs/week of day care starting when they were 3 months old. Compared to 23 random controls, treated infants had higher Bayley scores at 18 months ( $p < .003$ , ES = 0.94 SDs). In another

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random trial of an educational treatment (3 parent lessons in 18 weeks) Metzler (1980) found significant differences in Bayley scores with treatment groups containing 20 participants. So it is possible to see experimental effects with small samples. However, the present study would be a success if intermediate outcomes (e.g. maternal behavior) improve more with the enhanced books.

Table 6. Effect Sizes Needed

Wave Times	Difference in SDs
0, 2, 4, 6, 9, 12, 18	.38
0, 6, 12, 18	.46
6, 18	.63

Data management. Raw data are captured in the most convenient source, including MS Access, MS Excel, Teleform scans, and computer-programmed interviews. As data are gathered, highly confidential information (e.g. name, address, phone number) is kept in password-encrypted files and locked file cabinets. Data are then arranged in orderly hierarchy on our Netware-6 server, which has daily tape backups and daily security checks by our Novell-certified manager. An anonymous identification number links the data files, and highly confidential information is removed. Quantitative data are then exported into SAS data sets, either by directly reading (e.g. Excel) or export software (StatTransfer and DBMScopy). Then an array of SAS programs are written by research associates and graduate assistants to clean, label, and transform the raw data, mark missing values, and enforce consistent statistical coding (e.g. no-yes 0-1). Finally, the SAS datasets are merged into analytic files that are either wide (1 line per participant) or tall (7 lines per participant for longitudinal analysis). The project manager will perform random checks of the concordance between paper surveys and their corresponding electronic entry each month.

Analytic model. A longitudinal random coefficients slopes-as-outcome model (Gibbons, Hedeker, & Davis, 1993) will be used because repeated measurements often violate the independence assumption that traditional analysis of variance (ANOVA) requires. This dependency should be modeled, not ignored. Longitudinal multilevel models offer important advantages over older models (Nich & Carroll, 1997), such as better handling of missing values and unequal time intervals between waves and subjects. Repeated measurements offer increased statistical power, describe the shape of change over time, and avoid the psychometric problems with pre-post change scores (Lambert et al., 2001a).

Having examined power and the general analytic approach, we will illustrate a few examples of the study's hypotheses, which are summarized here. Compared with mothers in the commercial book condition, mothers in the enhanced book group will have: 1) Greater knowledge of guidelines; 2) Better parenting behavior; 3) Better self-care/health and social support, less stress; and 4) More positive parent-child interactions and greater child development. These relationships are moderated by mother and child characteristics and they are mediated by maternal knowledge of the guidelines.

Hypothesis 1, better knowledge of guidelines, is an immediate effect showing improvement in the treated group and no change in the control group. Repeated scores on the Anticipatory Guidance Knowledge Score would be analyzed in a 7-wave random coefficients model, **Outcome = F(Group, time, group\*time)**. In this case we expect flat slopes (time and group\*time nonsignificant). The important parameter is Group, which if positive, indicates a higher average score over time. Before examining group differences, we would first inspect individual and whole-sample timelines graphically to check our assumptions. Then we would estimate the model for intercept coefficients comparing the 2 treatment groups. This hypothesis and most others could be tested with intent-to-treat samples (all cases) or efficacy samples (only mothers who read the books).

Hypotheses 2, 3, and 4 describe long-term outcomes. Estimates of each family's slope of improvement would be estimated so that the average slopes for each treatment group would be compared. The model would again be **Outcome = F(Group, time, group\*time)**, but in this case **group\*time** is the important parameter. The Group effect compares the two groups at time zero to check the assumption that the randomized groups started equally before treatment. Significant slope coefficients, combined with 3-group charts showing observed and model scores for each treatment group, would help us interpret the results.

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Hypotheses 5 & 6 (moderators and mediators) would add theory-driven extensions to the basic model we have just discussed. For example, perhaps maternal depression reduces maternal learning and also reduces the impact of special books. We would center depression around zero and define depression either a continuous z-score or a dichotomy (depressed 0-1). If depression\*time were significantly negative, it would appear that depressed mothers have shallower growth slopes. If the group\*time\*depression coefficient were significant, we could conclude that depression changes the impact of the treatment. While both moderators and mediators would be used in the same way in the longitudinal model, this random clinical trial (RCT) would offer an opportunity to use Kraemer's et al method to "... identify and distinguish between moderators and mediators in RCTs when outcomes are measured dimensionally" (2002, p. 877). Having presented the main analytic plan, we discuss very briefly some additional analyses.

Econometric modeling of attrition artifacts. Most threats to validity have been controlled by random assignment, but this section mentions very briefly how some threats to validity might trigger special analyses. For example, with different treatments, participant dropout could differ between groups, confounding attrition and outcome. We always do an attrition analysis (Foster & Bickman, 1996) to detect such artifacts. If differential attrition affects outcomes, a variable representing the completeness of each case can be added to the longitudinal model to monitor and control this potential bias (Hedeker & Gibbons, 1997). If either differential attrition or failed random assignment lead to too many significant differences to control with a covariate or two, propensity scoring (Rosenbaum & Rubin, 1985; Rubin, 1997) offers a parsimonious way to control for all known differences. Rubin suggests doing a logistic regression between treatments, estimate the differentiating equation, and then estimate the probability (propensity) of each case to be in a given treatment group. Then divide the propensity score by rank into quintiles, and add this as a category to the analysis to correct for potentially confounding differences by adding a single nominal control variable, the propensity quintile.

Descriptive longitudinal analyses. Since little is known about the growth curve of this study's outcomes over time, we plan descriptive longitudinal analysis using longitudinal mixture models. With up to 7 repeated measurements there are many possible trajectories (e.g. linear, diminishing returns, etc.). In our past studies linear sloping outcome models often failed to fit the data, so we used other shapes, such as a quadratic curve, (Hamner, Lambert, & Bickman, 1997) or piecewise linear (Lambert et al. 2001b). To determine whether the outcomes in this study are linear or some other shape, we will use a mixture model we have used before (Bickman, 2002). A longitudinal mixture model still under development at Carnegie Mellon (Jones, Nagin, & Roeder, In press) sorts timelines into common patterns based on a semi-parametric statistics (Nagin & Tremblay, 1999; Nagin, 1999; Nagin & Tremblay, 2001). This procedure, called "PROC TRAJ" resembles a cluster analysis of cases, which sorts cases into common types based on the shape of their timeline of outcome. We also have experience with MPLUS, which can do longitudinal latent-class modeling (Muthen, 2001; Muthen & Muthen, 2000). Both programs can estimate the new dual trajectory models in which trajectories on one outcome (e.g., maternal reading) are related to growth on another (e.g., ratings of mother-child interaction).

Cost Analysis: Direct Costs of Implementation. The implementation program costs are part of the direct cost and include book production and distribution (e.g. curriculum, materials, personnel, office supplies, communication), personnel's time introducing and distributing the baby books, office space (in square footage), office supplies, electricity use, and other administrative and implementation costs, and mother's time reading the baby books to their children. Instead of accounting for simple expenditures paid, we will value all resources used during the implementation of the program using standard costs to the society. All personnel time will be valued by using the median earning per hour of a comparable worker published by the Bureau of Labor Statistics 2002 (Eiserman et al., 1990). This way, differences in human capital endowment will not affect the implementation costs of the program. We will report the program implementation costs at aggregate level, intervention vs. control groups, and at the child level to show how much it would cost to reproduce this program in similar settings.

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Indirect and Saving Costs. The indirect and saving costs analysis will inform whether the experimental group is less costly than the control groups by reducing mother's absenteeism from work and improving their job performance, requiring fewer health services and medication (these are healthier children), requiring fewer health and care services due to children's injury and by increasing breastfeeding practices and reducing the demand for baby food.

Children's Health Service and Medication Costs. Children in the demonstration group may be healthier and therefore use fewer medical services and be less costly to the society. This source of potential cost offset may be of importance for this project. Health service costs will be classified into: 1) doctor visits (due to accident, injury, regular visit, and other concerns), 2) emergency room visits, 3) hospitalization, and 4) medication costs. To avoid the distortion of charges, we will value the physician and other health services by using standardized regional medical care cost averages published by the Statistical Reports by the U.S. Department of Health and Human Services. The price of a single medication can vary dramatically depending on the source of distribution and ordered quantity. To value prescribed drug cost and avoid artificial regional variation this project will use the wholesale drug prices from commercial databases (e.g. Medi-span, regional Medical Care Price Index).

Seven interviews with mothers and medical chart audits will provide the variables include as the amount of care (e.g. number of visits, bed days), type of service, total cost market of similar services per level of care, length of treatment (e.g. date treatment started and ended), name of the medication, dosage, and length of treatment in the project. The children's health information will be assessed through chart reviews in which our previous experience creating a coding form for our NIMH study of pediatrician practices will be utilized. The *Incurred Cost Interview* questionnaire includes questions on maternal and child health problems, service utilization, and medication use between each wave.

Children's Breastfeeding Patterns and Baby Food Expenses. Information in the baby books on advantages of breastfeeding, child nutrition, and cognitive and physical development will teach mothers the importance of breastfeeding and the appropriate time of introducing solid food to their newborns. If mothers modify their behavior due to the new information, they will increase breastfeeding practices and reduce the demand for baby food. This project has created the *Incurred Costs Interview*, which documents use of baby food other than breast milk. In addition we will also use the *Infant Nutrition Interview* to document breastfeeding practices. To avoid price differentiation across different supermarkets and charge distortions, we will value the baby food by using average regional prices deflated by the consumer price index (CPI) published by the Bureau of Labor Statistics.

Treatment for Maternal Depression. In 1990, both direct and indirect costs of depression accounted for US\$ 43.7 billion in the US (US\$ 65 billion, at 1998 prices; Berto, 2000). Within direct costs, the major cost driver was hospitalization, which represented something in between 43 and 75% of the average per patient cost, drug cost accounted for 2% to 11%. To measure how much maternal depression costs to society, this project will assess 1) depression treatment costs (increasing the direct costs) 2) effects of depression on the mother's labor market productivity and their job absenteeism.

To assess depression treatment costs we will ask mothers questions on service use such as number of doctor visits, outpatient visits, hospitalization (bed days), type of service, length of treatment, medication, and other health services they may have required due to post-natal depression between each wave. To avoid the distortion of charges, we will value the physician and other health services by using standardized regional medical care averages published by the Statistical Reports by the U.S. Department of Health and Human Services. To value prescribed drug cost and also avoid artificial regional variation this project will use the wholesale drug prices from commercial databases Medi-span and the regional Medical Care Price Index (MCPI).

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Estimates of social costs of mental illness used by the federal government focus primarily on the effects on the parent's labor productivity. Since labor productivity is approximated by earned income, estimating productivity loss requires a model of income loss. This model will only apply to working mothers. The income loss model is the difference between the average income of a group of women sharing symptoms of depression and the average income of a group without the illness. Then, this project will use an earning model where productivity loss will be associated with having or not having maternal depression. The earning model uses regression analysis on earnings to control for socioeconomic, demographic, and educational factors, household characteristics, and the existence of other health problems. Given the longitudinal nature of our data (7 waves and where an individual may have a depressive episode in some, but not all waves), the presence or absence of maternal post-natal depression will be introduced as moving covariate into the equation to capture income group differences, and whether income group differential change over time. Mothers will be asked the domains described in this paragraph, measures will occur at every wave. To measure the symptoms of maternal depression and stress, this project uses the *Brief Symptom Inventory-18* (at baseline and when the child is 2, 6, 12 and 18 months) and the *Parenting Stress Index* (at 2, 6, 12 and 18 month visits). We recognize that these measures are only proxies for clinical depression and do not provide a clinical diagnosis. The Maternal Background Questionnaire and Incurred Cost Interview will gather information on mother's earnings, socioeconomic, demographic variables, household characteristics, frequency, severity and type of the child's injury, and mother's health status.

Loss of Mother's Productivity. There is a little question that most mothers invest a large amount of their time caring for their children and looking for better services to meet their needs. According to our hypothesis, children's health impacts how mothers allocate their time (Becker, 1965). Our study will then focus on estimating the time value mothers spent seeking medical care for their children. The underlying theoretical basis of this section is the human capital paradigm. Individuals have personal characteristics, assets, and skills for hire. Mothers' time allocation and productivity of these characteristics and assets change when their children's wellbeing is at stake. If mothers' productivity decreases (e.g. declining punctuality, quantity and quality of performance, increasing absenteeism) firms in response would pay less, reduce responsibility, make fewer human capital investments in the individuals, and dismiss faster (Becker, 1967).

There are two well known approaches of estimating the individual's loss productivity: valuing time at the opportunity cost of the family member providing care and valuing the time at the substitution cost of the actual care giving tasks performed. The opportunity cost method is most appropriate from a societal perspective, since it reflects the value of the productivity loss society incurs when a mother gives up competitive employment to care for her child. The opportunity cost method is applied using individual wage rates. This kind of estimate, however, may distort cost-effectiveness analysis. Consider, two mothers, one is a lawyer and the other a bank teller. The opportunity cost of the first mother, the lawyer, will be represented by her earnings of \$100,000 per year, and by the bank teller's earnings of \$30,000 per year. Unless we have a good reason to assume that the quality of the lawyer's care giving is significantly superior, this valuation does not provide any meaningful information about intervention cost and its magnitude may have a noticeable impact on the overall cost-effectiveness relationship.

The second approach uses either an aggregate wage rate as an estimate of the opportunity cost or use a substitution cost, calculated as the specialist cost of paid caregivers, such as home health workers or mental health workers. This project uses the second approach where parent's time is given a monetary value per hour equal to the median weekly earning for full time work given by the U.S. Department of Labor, Bureau of Labor Statistics 2002 (Eiserman, McCoun, & Escobar, 1990).

Variables include the number of hours the primary care provider spends looking for medical services, the number of hours traveling to treatment, time spent in child's treatment, hours working in paid jobs (per week), number of hours missed from work due to children's health problems, the number of hours missed from work



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due to own illness, mother's labor market characteristics such as years of job experience, complete schooling, age, occupation, ethnicity, language spoken at home, etc. Data sources are the mother's interview when child turns 2, 3, 4, 9, 12, and 18 months old and post hoc pediatrician's chart audits.

Cost Analysis. One of the main strengths of this project is that children will be followed from the third trimester of gestation until they are 18-months of age. Six repeated measures on costs will let us examine the incremental costs on each group at different time points, when the child turns 2, 4, 6, 9, 12, and 18 months old. The examination of significant cost and outcome differences between groups will be done in two steps depending on the stage of the data collection. As a first step, after the wave 2 data collection we will examine pre and post group cost differences and services received by children. After adding up all service utilization, medication, and mother's time value we will determine the impact of the intervention on costs by estimating the equation:  $C = \beta_0 + \beta_1 T_1 + \beta_2 T_2 + \beta_3 X + v$ . Where C is total cost per child;  $T_1$  is a dichotomous variable equal to 1 for the intervention and zero for the control groups;  $T_2$  is a dichotomous variable equal to 1 for the no-book group and zero otherwise, the reference group will be the commercial children's book group; X is a vector of variables controlling for client socio-demographic and health status at intake differences, and v is the error term.

According to the hypothesis  $\beta_1$  will be negative and significantly different from zero indicating that reading baby books lowers the costs or have significant cost savings than the commercial children's book group. If both groups are cost equivalent, an effective treatment would be preferred.

As a second step, after collecting longitudinal data (more than 3 waves), we will use a longitudinal analytic model (Diggle et al., 1994), in this case a random coefficients or hierarchical linear model recommended for psychiatric outcome research (Gibbons et al., 1993; Hedeker, Gibbons, & Flay, 1994). The dependent variable will be the direct and indirect costs over time as a function of group (kids book, children's commercial books, no books), individual and mother's characteristics (demographic and socioeconomic differences), and group by time interactions. With this model we will test whether total costs and average costs are different among groups, whether the costs change over time, and whether changes over time are any different among groups.

Given the longitudinal nature of our data, this project will have cost and outcome measures at six different time intervals (when the child turns 2, 4, 6, 9, 12, and 18 months). We will use a growth curve model to evaluate the relation of treatment on cost and outcome. This method is recommended by Rogosa and Willett (1985) and used in a study of cost-effectiveness of case management program by Jerrell and Hu (1989). With the growth curve model, we will estimate an individual cost-effectiveness growth rates in a regression model that includes a binary variable controlling for the intervention vs. the control groups and other socio-demographic characteristics. From this analysis, we will determine whether the intervention is less costly and more effective.

Limitations. We recognize some of the mothers will not be employed and thus the cost estimates will be constrained. Although depression rates are higher in our target population, our sample size may be too low to adequately detect meaningful differences between treatment and control groups. However, there is the potential of detecting a relationship between depression and other outcomes when considering all 180 mothers, irrespective of group assignment. There may be other externalities that this project will not be able to capture. For instance, if the intervention has a long lasting effect on children reading skills and children's school performance increase significantly and are long lasting, we will not be able to measure its impact on the children's quality of life, we will not be able to estimate the impact this program might have on future high-school graduation rates, likelihood to attend college, children's earnings, decreasing welfare dependency, increasing taxation pool, better overall health during their lifetime, etc. There is a large body of literature asserting that individuals' human capital investments in terms of better health and higher school performance during infancy are strongly correlated with increasing labor productivity and higher standard of livings during the individuals working lifetime (Becker, 1976; Schultz, 1999, 1961; Weiss, 1995). The assessment of these and other potential externalities of the intervention are beyond the scope of this study.

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## **E. HUMAN SUBJECTS**

### **1. Potential Risks to Participants**

**Human subjects involvement characteristics:** The subject sample for the proposed research will be comprised of first time adult mothers and their infants. The only selection criterion for inclusion in this project is that the mother be over 17 years of age, conversant in English, and able to read at a second grade reading level. No exclusions will be made based on race, ethnicity, income, health status or infant or mother. Duration of inclusion in the study will be from the third trimester of pregnancy until the infant is 18 months old.

**Sources of Materials:** Data collection will predominately entail self-report questionnaires obtained solely for the purpose of this study. Observational measures will involve video taped interactions of mothers with their children. At the completion of the participant's last wave of data collection, a retroactive chart review of her child's birth record, health status, immunization record, growth record, doctor visits, hospitalizations, and emergency room visits will be conducted.

**Potential Risks:** There is minimal risk to mothers and their infants associated with participation. The greatest inconvenience to participation in this study is loss of time. Participants will be asked to read to their infant as often as possible and participate in 7 home data collection visits. There is also the possibility of the loss of confidentiality, although safeguards described below will be used to minimize this.

It is possible that certain aspects of this project may make participants feel uncomfortable. Having a researcher visit their home, answering questions, and being video taped may make some participants feel uneasy. For example, not knowing the answers to questions about typical child development and effective parenting strategies may be unsettling to participants. Additionally, women may feel uncomfortable reading to their baby. All participants will have an opportunity to discuss these feelings during the home visits or by calling us. We anticipate such discomfort to be minimal.

Participants may feel uncomfortable talking about their thoughts and feelings regarding parenting and their child. Participants will be informed that they may choose not answer any or all questions and may discontinue at any time.

Monitoring dropout rates from the study to determine if they are higher than expected or if there are any violations of confidentiality will minimize risks to the participant. The PI, the pediatrician Dr. Worely, Ms. Reich, and the project manager will conduct internal reviews. While there is little expectation that the study itself can be a source of risk it is possible that we will uncover a high-risk situation through either the home visits or from the questionnaire responses. It is likely that some of the women in the sample may suffer from depression. However, the instruments we use are not designed to provide a clinical diagnosis and our home visitors are not trained clinicians. Thus, we will treat all the women in the study as if they had the potential to develop depression. We will provide the subjects a list of mental health service providers and encourage them to seek help if they have any problem. If a participant explicitly states verbally or in writing that she will harm herself or another, we will report this to the local police department for a Mandatory Prescreening Agent to assess her mental health and potential need for hospitalization. Second, it is possible that the home visitor may see evidence of child abuse and/or neglect. All home visitors will be trained to follow the state of Tennessee law concerning reporting as described on the State's web page (<http://www.state.tn.us/youth/cps/index.htm>). If evidence of child maltreatment is found during the visits to the participants' home, this will be reported to Child Protective Services (CPS). Under such circumstances, this reporting will be a breach of confidentiality.

### **2. Adequacy of protection against risk.**

**Recruitment and informed consent:** Participants will be recruited from the Vanderbilt Obstetric Clinic waiting room. A researcher will approach visibly pregnant women awaiting their appointment. Women will be asked if they are interested in participating in a study about reading to their child. If women express interest, the

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researcher will describe the duration of the study, timing and place of data collection, duration of the home visit, payment for participation, and rights as a human subject. If the woman agrees to participate she will be asked to read, discuss, and sign an already IRB-approved consent form. The researcher will record her phone number and arrange by phone or at the clinic a time for baseline data collection.

**Protection against risk:** Participation in this study will be completely confidential. Women will be assigned subject numbers and no identifying information will appear on survey instruments. All surveys will be stored in a locked cabinet in which only the PI and project manager have a key. Electronic data will be password protected and stored by a unique identifier. Although women and their children will be videotaped, the digital images will be stored on a secure server and no names will be associated with the files. The digital images will then be erased from the cameras.

Enrollment and attrition will be monitored on a monthly basis. Adverse events that may be related to the study such as hospitalization for mental health problems or abuse will be reported immediately to our IRB. Any adverse effects that are associated with participation in the proposed research will be reported to the NICHD project officer. The Principal Investigator and Project Manager will provide oversight of the monitoring of data confidentiality and data storage for the project.

### **3. Potential benefits of the proposed research to the participants and others.**

Many benefits to the participants are expected if the intervention is efficacious. Women will know more about their child's development and effective parenting, experience less stress and depression, and interact with their child in higher quality ways. Although infants are not direct participants in this study, there is the potential for benefit from their indirect involvement. Infants may experience better parenting and safer and more stimulating environments as a result of this project. Additionally, reading to a child has been well documented to have beneficial effects on attachment and future expressive and receptive language skills (High et al., 2000; Pappalardo & Maccoby, 1985).

If during data collection, our developmental/behavioral pediatrician suspects any developmental delays or need of additional screening, we will share this information with the mother and refer her to the appropriate agency. This is a potential benefit as the child and family may be able to detect and treat special needs earlier.

### **4. Importance of the knowledge gained.**

Medical best practices recommend that pediatricians provide parent education about a variety of topics such as child development, safety, nutrition, and maternal self-care. However little research has explored whether increases in knowledge of this material translates into behavior. The investigation of this relationship is beneficial irrespective of the direction of the results. If increased knowledge leads to better parent and child outcomes than the efficacy of anticipatory guidance is supported. As such, the amount of resources targeted towards the development of education for health promotion and accident prevention is justified. Additionally, the method of dissemination will no longer be reliant on the physician. The education through the use of books would be less expensive, easier, and accessible to a greater number of families.

Conversely, if the relationship between increased knowledge and better parenting is not supported, then the tremendous time burden of education that primary care providers are suggested to hold is alleviated. Money allocated for the development, promotion, and dissemination of anticipatory guidance can be directed in other ways.

Principal Investigator: Bickman, Leonard



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Parent Consent Form-Reading Intervention

We at Vanderbilt University want to know if reading books is good for mothers and their babies. We are starting a study that will look at how reading affects women and babies over time. Women are asked to start reading when they are pregnant and continue until their baby is 18 months old. We will visit women in their homes while they are pregnant and when the baby is 2, 4, 6, 9, 12, and 18 months old. During these visits we will ask mothers questions about themselves and their child. We will also videotape 15 minutes of mothers and babies playing. We would like to invite you (and your baby) to take part in this study.

If you want to be a part of this study, you could get 6 books we made, 6 store-bought books, or no books at all. If we give you books, we ask that you read them to your baby as often as you can. If you do not get a book, it is up to you if want to read or not. We will come to your home 7 times to ask you questions about how you feel, your health, your baby's health, and how you are raising your child. We will also make a tape of you playing with your baby. Some visits will take 45 minutes and others may last up to 2 ½ hours. If the visit seems too long, you can ask to stop whenever you want to. You will get to keep the books and be paid \$290.00 for being in the study. The payments will be broken down like this:

While you are pregnant	\$40.00
Baby is 2 months	\$30.00
Baby is 4 month	\$40.00
Baby is 6 months	\$40.00
Baby is 9 months	\$40.00
Baby is 12 months	\$50.00
Baby is 18 months	\$50.00

You will be paid each time we come to your house. If you decide to not be in the study anymore, you will still keep the money you earned for each visit.

We are interested in everyone as a group and not in any one person. Your name will not be written on the questions you answer. Instead, a code that we make up will be used. If we publish anything about this study, we will talk about the whole group and not any single person. No one will be able to identify you individually.

The videotapes of mother and babies playing and all the written forms will be kept in a locked cabinet. When the study is over, they will be destroyed.

Other than giving your time and having us visit your home, there are no known risks for taking part in this study. There may be topics that you do not want to talk about. You do not have to talk about them. If you do not want to complete all of the forms, you do not have to. If you want to join now and change your mind, you can stop at any time. There will be no costs to you for taking part in this study and it will have no effect of the care you or your child receive.

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If you have any questions about this study, you can contact the principle investigator, Dr. Len Bickman at (615) 322-8694. If you have general questions about giving consent or your rights as a member in this study you can call the Vanderbilt Institutional Review Board Office at (615) 322-2918.

If you are willing to participate in this research, please sign the back of this page.

**Confidentiality and Privacy of Health Information:**

All reasonable efforts will be made to keep your protected health information (PHI) private and confidential. PHI is health information that is, or has been, collected or maintained by Vanderbilt University Medical Center and can be linked back to the individual participant. Use or disclosure of such information must follow federal privacy guidelines. A decision to participate in this research means that you agree to let the research team use and share your PHI as described below.

As part of the study, Dr. Bickman and his study team may provide the results of your study and/or non-study related the health status of your child, as well as portions of his/her medical record, to those groups named below. These groups may include representatives from the Federal Government Office for Human Research Protections and the Vanderbilt University Institutional Review Board. These agencies may not be governed by federal privacy regulations; however, they have their own policies and guidelines to insure that all reasonable efforts will be made to keep your personal health information private and confidential.

The study results will be retained in your research record for at least six years after the study is completed. No information will be added to your child's medical record.

Unless otherwise indicated, this authorization to use or disclose your PHI does not have an expiration date. If you decide to withdraw your authorization to use or disclose your PHI, we ask that you contact Dr. Bickman in writing and let him know that you are withdrawing your authorization. His mailing address is VIPPS 1207 18<sup>th</sup> Ave South Nashville, TN 37212. At that time, we will discontinue further collection of any information about you. However, the health information collected prior to this withdrawal may continue to be used for the purposes of reporting and research integrity.

**STATEMENT BY PERSON AGREEING TO PARTICIPATE IN THIS STUDY**

- [ ] I have read this consent form. All my questions have been answered, and I freely and voluntarily choose to participate. I understand that I may withdraw at any time.
- [ ] The material contained in this consent form has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to participate. I understand that I may withdraw at any time.

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of patient/volunteer

Consent obtained by: \_\_\_\_\_  
Signature

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#### **Inclusion of Women**

This proposal will recruit women in their third trimester of pregnancy. No exclusion will be made based on the health of the woman or her fetus. Each woman will be retained until her child is 18 months of age.

#### **Inclusion of Minorities**

The proposed study anticipated enrollment of ethnically and racially diverse participants. Data collection procedures for this study will include information about race and ethnicity as separate questions on the same demographic questionnaire. Information about race will be collected first. Respondents will be offered the option of selecting one or more racial designations.

#### **Targeted/Planned Enrollment Table**

<b>Racial Category</b>	<b>Total</b>
American Indian/Alaska Native	.03
Asian	.02
Native Hawaiian or Other Pacific Islander	.02
Black or African American	.44
White	.49
Total of all subjects	100
*Note all participants are female	

5% of the population identified themselves as Hispanic

#### **Inclusion of Children**

Children will be included in the study through their mothers' enrollment during the third trimester of pregnancy. Therefore children will be included from birth until they are 18 months of age.

#### **F. VERTEBRATE ANIMALS**

None

#### **G. LITERATURE CITED**

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#### **H. CONSORTIUM/CONTRACTUAL ARRANGEMENTS.**

None.

#### **I. CONSULTANTS**

Dr. Susan Landry and Dr. Kay Jennings have agreed to consult on the project and their letters of support follow.