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MATERNAL PASSIVE SMOKE EXPOSURE IN PREGNANCY AND NEONATAL MORTALITY

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MATERNAL PASSIVE SMOKE EXPOSURE IN PREGNANCY AND NEONATAL MORTALITY

By

Kathy Walker Mathis

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ABSTRACT

MATERNAL PASSIVE SMOKE EXPOSURE IN PREGNANCY AND NEONATAL MORTALITY

By

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The purpose of this study, a secondary data analysis of an infant mortality study (Tiedje, Green, Tannenbaum, and Stommel, 1994-1997), was to compare passive cigarette smoke exposure during pregnancy in women whose babies died within the first twenty-eight days of life with a matched group of women who had healthy babies. Questions addressing passive smoke exposure during pregnancy were asked of the participants using an interview format. Data were available from the primary study on 27 mothers, however, once active smokers were excluded from the sample, the sample size was reduced to 18 (13 mothers who had healthy infants and 5 mothers who had a neonatal death).

The mean passive smoke exposure score for the healthy infant group was 3.9231, and the mean score for the mortality group was 5.6000, indicating that the mortality group had more passive smoke exposure than the healthy infant group. This difference was not significant (t= -.63, df= 16, p = .54).

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Maternal Passive Smoke Exposure in Pregnancy and Neonatal Mortality

Despite efforts to reduce the number of infants who are born alive but die before age twenty-eight days of life, the decline in neonatal mortality in the United States slowed to 3.5 percent per year between 1981 and 1986 (U.S. Department of Health and Human Services, 1991). The decline in the neonatal mortality rate was essentially a result of increased sophistication in neonatal intensive care, not because of a reduction in the incidence of low birthweight births (Institute of Medicine, 1985, U.S. Department of Health and Human Services, 1991).

A suspected cause of low birthweight is passive smoke exposure during pregnancy (Haddow, Knight, Palomaki, & McCarthy, 1988; Zhang & Ratcliffe, 1993). Further evidence also suggests that infants weighing less than 2,500 grams at birth are most at risk for death during the first twenty-eight days of life (Institute of Medicine, 1985). Although previous research has scientifically defined passive exposure to cigarette smoke (Haddow et al., 1988) and linked maternal passive exposure to cigarette smoke to low birthweight outcomes (Zhang & Ratcliffe, 1993), the relationship between passive exposure to cigarette smoke and neonatal mortality has not been extensively studied.

Therefore, the purpose of this study, a secondary data analysis from another neonatal mortality study, is to examine maternal passive exposure to cigarette smoke during pregnancy and its relationship to neonatal mortality. Neonatal, as opposed to infant, mortality will be studied in the belief that neonatal mortality is more likely to be related to behaviors that can be avoided during pregnancy, such as passive smoke exposure (Hogue & Hargraves, 1993). After twenty-eight days, causes of infant death are more likely to be related to problems that occur after pregnancy, such as accidents, infection, or sudden infant death syndrome (Hogue & Hargraves, 1993).

This study is significant to nursing and nursing research, because if it is shown that maternal passive smoke exposure is greater in the mothers whose babies died than in the mothers who had healthy babies, nursing interventions can be developed to help reduce passive smoke exposure during pregnancy. Although women may be aware of the hazards of cigarette smoking during pregnancy, and may decrease or eliminate their own tobacco use, these same women may be unaware of the potential risks to the fetus of maternal passive smoke exposure. Since advanced practice nurses are present in a variety of health care settings in which prevention and intervention services are provided for

women, any contact with women of childbearing age could be used to discuss the risks associated with passive exposure to cigarette smoke during pregnancy. Anticipatory guidance could also occur.

Statement of the problem

Maternal passive exposure to cigarette smoke during pregnancy may contribute to neonatal mortality outcomes, however, there is little data available to substantiate the relationship. The purpose of this study is to compare passive cigarette smoke exposure during pregnancy in women whose babies died within the first twenty-eight days of life with a matched group of women who had healthy babies.

The research question:

Do non-smoking women whose babies die in the neonatal period (first twenty-eight days) have a greater amount of passive cigarette smoke exposure during pregnancy than non-smoking women who have healthy babies?

Literature Review

Conceptual definitions

There are two concepts that are conceptually defined: passive smoke exposure and neonatal mortality.

Passive smoke exposure

Passive smoking exists when nonsmokers are exposed to cigarette smoke in confined environments (Weiss, 1986).

There are two sources of environmental cigarette smoke exposure: mainstream and sidestream smoke (Fielding & Phenow, 1988). Mainstream smoke is the substance inhaled by the smoker, filtered in the lungs, and exhaled (Fielding & Phenow, 1988). Sidestream, or passive, smoke is defined as the smoke released directly in the air from the lit end of a tobacco product (Fielding & Phenow, 1988). For the purpose of this study maternal passive smoke exposure is defined as sidestream exposure of a non-smoking pregnant woman to the chemicals released from the lit end of a tobacco product, in a confined environment, creating a risk situation for the fetus. The effects of this chemical exposure are dose-dependent (Ahlborg & Bodin, 1991; Lazzaroni, Bonassi, Manniello, Morcaldi, Repetto, Ruocco, & Cotellessa, 1990), and over time cause fetal hypoxia, reduced fetal blood oxygen unloading, and vasoconstriction of maternal blood supply to the placenta (Ogawa, Tominaga, Hori, Noguchi, Kanou & Matsubara, 1991).

Neonatal mortality is described as infant death under twenty-eight days of age (Dever, 1991). Neonatal death is typically an indication that there has been an insult of some sort to the fetus, such as chemical exposure. The neonatal mortality rate is calculated as the number of deaths under twenty-eight days of age occurring during a

given time interval, divided by the number of live births reported during that same time interval (Dever, 1991). The resulting number is then multiplied by a constant of 1000, since deaths are calculated per 1000 live births (Dever, 1991). The neonatal mortality rate is significant as an index of the overall health of the community, and thus has widespread implications for advanced practice nurses (Dever, 1991).

Maternal passive exposure to cigarette smoke

The literature relative to passive smoke exposure in pregnancy can be grouped into three broad categories: measurement, birthweight outcomes, and fetal mortality outcomes. There are no studies in the literature directly correlating maternal passive smoke exposure in pregnancy and neonatal mortality, although passive smoke exposure has been linked to low birthweight outcomes, and 70% of neonatal mortality is due to low birthweight (Institute of Medicine, 1985).

Measurement of passive smoke

Although persons exposed to passive smoke are exposed to a smaller amount of smoke and a lower amount of chemicals known to have negative health effects than are active smokers, it is still possible to measure cigarette smoke exposure in nonsmokers (Fielding & Phenow, 1988). One

objective measure of cigarette smoke exposure is the cotinine (a metabolic derivative of nicotine) level (Haddow et al., 1988). A strong relationship has been found between self-reported exposure to cigarette smoke and urinary cotinine levels (Haddow et al., 1988). Therefore, most recent studies have used the self-report format to identify when passive smoke exposure has occurred (Lazzaroni et al., 1990; Ahlborg & Bodin, 1991; Ogawa et al., 1991).

The defined amount of exposure varies widely whether the self-report format or other measures are used. Following is a review of the definitions that have been used in previous studies: exposure to someone else's cigarette smoke for at least two hours per day during pregnancy, either at home or at work (Martin & Bracken, 1986; Ogawa et al., 1991), an affirmative answer to the question "Do you spend most of your time at work in rooms where other people are smoking?" (Ahlborg & Bodin, 1991), by identifying a minimum daily exposure of one hour (Lazzaroni et al., 1990), or by serum cotinine level (in a nonsmoker) of between 2 and 10 ng/ml (Eskenazi et al., 1995). The definition of passive smoke exposure used in this study will be a variation of these previous measures, with the smoke exposure categorized as daily, weekly, or infrequent contact.

Clearly, there has been no consistency in identifying duration of passive smoke exposure. In the literature, each study has established the significance of its definition of the duration of passive smoke exposure by linking the amount of exposure to low birthweight outcomes. This study will look at whether the amount of passive smoke exposure is greater in women whose babies die in the neonatal period as compared to women who have healthy babies.

Birthweight Outcomes

There were no studies in the passive smoke literature addressing the link between maternal passive cigarette smoke exposure in pregnancy and neonatal mortality. However, passive smoke exposure in pregnancy has been addressed by several studies in terms of birthweight outcomes. Two studies, both involving nonsmoking women, identified a reduction in birthweight when passive smoke exposure occurred during pregnancy.

Passive smoking in pregnancy has been suggested to double a non-smoker's risk of having a low birthweight infant, approximately the same risk as active smoking (Martin & Bracken, 1986). In a large prospective study of 3,891 prenatal patients, passive smoke exposure was defined as a nonsmoker being exposed to someone else's cigarette smoke for at least two hours per day during pregnancy,

either at home or at work (Martin & Bracken, 1986). Passive smoke exposure was significantly related to delivering a low birthweight (less than 2500 grams) newborn - a relative risk of 2.17 (95% confidence interval) (Martin & Bracken, 1986).

A second study identified a mean reduction of 16 grams in birthweight for each hour of maternal passive smoke exposure during pregnancy (Lazzaroni, Bonassi, Manniello, Morcaldi, Repetto, Ruocco, & Cotelessa, 1990). In this study, a prospective design was used, with an initial sample size of 1004, 25% of whom were nonsmokers exposed to passive smoke during pregnancy (Lazzaroni et al., 1990). Data were gathered about cigarette smoke exposure by means of a questionnaire, and mothers of newborns with a gestational age below 36 weeks, birthweight less than 2000 grams, congenital defects or serious illnesses were excluded (Lazzaroni et al., 1990).

In contrast, two studies have suggested that although the risk for low birthweight due to passive smoking exists, it may be small (Ogawa et al., 1991, Eskenazi, Prehn, & Christianson, 1995). Of the 6831 women surveyed by Ogawa, et al. (1991), 35% reported passive smoke exposure during pregnancy (Ogawa et al., 1991). Passive smoking was defined as a nonsmoker's exposure to other persons' cigarette smoke for at least two hours per day at home, work or in other

locations (Ogawa et al., 1991). Data were gathered by means of a semistructured questionnaire, (Ogawa et al., 1991). Infants below 37 weeks gestational age were excluded from the sample, although there was no exclusion of infants weighing less than 2000 grams, as done by Lazzaroni et al. (1990). A small effect on birthweight was observed, with a mean reduction of 10.8 grams (Ogawa et al., 1991).

Similarly, in 1995, Eskenazi et al. reported a non-significant reduction of 45 grams in birthweight in infants of mothers exposed to passive smoke. Smoking status was assessed by interview of a group of 3896 pregnant women between 1964 and 1967 (Eskenazi et al., 1995). Approximately twenty years after data collection, serum cotinine analysis was performed as well (Eskenazi et al., 1995). Although the sera samples were old when studied, the authors maintain that cotinine remains stable over time (Eskenazi et al., 1995). A strength of this study is that because the interviews were done so many years ago, before women were as aware of the hazards of cigarette smoke as they are now, self-reported exposure may have been more accurate (Eskenazi et al., 1995). However, it was not clear whether infants weighing less than 2000 grams were excluded from the sample, as done by other researchers (Lazzaroni et al., 1990). Women who delivered a singleton live birth

between 20 and 44 weeks gestation were included in the sample (Eskenazi et al., 1995).

Although the results of these particular studies do not indicate that the effect of passive smoke on birthweight is as significant as that described in the previously mentioned studies, the trend of birthweight reduction associated with passive smoke exposure during pregnancy is still verified.

Fetal Mortality

The risk of fetal death (spontaneous abortion or stillbirth) for nonsmoking women exposed to passive smoke at work has also been explored, and has been found to be increased (relative risk=1.53, 95% confidence) (Ahlborg & Bodin, 1991). Conducted in Sweden, this study had a sample size of 678 women, 267 of whom reported passive exposure to tobacco smoke at work (Ahlborg & Bodin, 1991). Data were collected by means of a self-administered questionnaire (Ahlborg & Bodin, 1991). Passive exposure to cigarette smoke at work was defined as "an affirmative answer to the question, ' Do you spend most of your time at work in rooms where other people are smoking?'" (Ahlborg & Bodin, 1991, p. 339). The phrase "most of your time at work" was not defined, making it difficult to determine the actual amount of passive smoke exposure that occurred.

Conceptual and Methodological Shortcomings in the Literature

There are multiple gaps in the literature related to maternal passive smoke exposure during pregnancy and its outcomes. Although studies have identified a relationship between passive smoke exposure and low birthweight (i.e. Martin & Bracken, 1986), the issue of causality has been difficult to settle, because neonatal mortality is a multifactorial concept. A major problem has been the difficulty in controlling for the large number of biological and social factors that also may affect birthweight, such as fetal gender and mother's education (Lazzaroni et al., 1990).

Another major problem is that it has proven difficult to find a consistent definition of passive smoke exposure. The most precise definitions use serum cotinine level to identify the beginning of passive smoke exposure, defining passive smoke exposure as present at the point where cotinine can be identified in the serum (1-2 ng/ml) (Eskenazi et al., 1995). The recommended upper limit of passive smoke exposure is 10 ng/ml, the point at which active smoking is presumed to have occurred (Eskenazi et al., 1995). However, no scientific basis for this determination is presented. Other studies define passive smoke exposure in hours per day of self-reported exposure,

and justify the definition by showing reductions in birthweight at that amount of exposure. The lack of a consistent definition of passive smoke exposure makes it difficult to compare and replicate studies.

In the studies investigating the link between passive smoke exposure and low birthweight outcomes, birthweight and gestational age were not uniformly used as either inclusion or exclusion criteria. Lazzaroni et al. (1990), excluded from their sample infants weighing less than 2000 grams, but Ogawa et al. (1991) and Eskenazi et al. (1995), did not. Additionally, Lazzaroni et al. (1990) excluded infants of gestational age below 36 weeks, and Ogawa et al. (1991) excluded those infants less than 37 weeks gestation, but Eskenazi et al. (1995) included infants born between 20 and 44 weeks gestation in their sample. Since neonatal mortality outcomes are influenced both by birthweight and gestational age (Institute of Medicine, 1985), this lack of consistency in the literature is particularly problematic.

Another shortcoming in the literature is that no study has been able to quantify how other factors such as the type of cigarette smoke (filter or nonfilter, low tar or nicotine, etc.) smoking rate, room size, ventilation rate or other factors influence the effect of the passive exposure to cigarette smoke (Fielding & Phenow, 1988). To date, only

duration or amount of exposure have been measured.

Lastly, no studies directly relating maternal passive smoke exposure during pregnancy directly to neonatal mortality were found. Therefore, certain conclusions have been drawn from the literature for this study - i.e. low birthweight can be attributed to maternal passive smoke exposure during pregnancy, and low birthweight has been associated with increased infant mortality rates (Institute of Medicine, 1985), therefore it is possible that passive smoke exposure and neonatal mortality are related. The proposed study was aimed at addressing this gap in the literature.

Neonatal mortality

The leading causes of death in the neonatal period are congenital anomalies, respiratory distress syndrome, low birthweight, and effects of maternal complications (U.S. Department of Health and Human Services, 1991). The future direction of efforts to reduce neonatal mortality, as outlined in the Healthy People 2000 objectives, is to focus attention on reducing the incidence of infants born who are low birthweight and have congenital abnormalities (U.S. Department of Health and Human Services, 1991). Low birthweight remains the major determinant of neonatal death, with the risk of neonatal death being two hundred times

greater for a low birthweight infant than for a normal birthweight infant (Institute of Medicine, 1985). Since low birthweight has been linked to passive smoke exposure, (Haddow et al, 1998; Martinez, Wright, Taussig, Wright, Taussig, & the Group Health Medical Associates, 1994; Zhang & Ratcliffe, 1993), it is logical and important to investigate the relationship between maternal passive cigarette smoke exposure during pregnancy and neonatal mortality. This is the purpose of the study. It is acknowledged that although maternal passive smoke exposure is being studied separately, neonatal mortality is a multifaceted concept, and passive smoke exposure is only a piece of a multifaceted causative model.

Theoretical Model

To achieve further reductions in neonatal mortality, health care providers and individuals must focus on modifying behaviors that affect birth outcomes (USHHS, 1991). Furthermore, an understanding of the possible factors that contribute to the identified behaviors is essential to the development of any interventional model. In the infant mortality study that has provided the data for this secondary analysis, a model, Effects of Behavioral Factors on Infant Mortality, was hypothesized. This model aims to explain infant outcomes such as neonatal mortality

in terms of pregnancy behaviors and the factors that contribute to the development of these behaviors (Tiedje, Green, Tannenbaum, & Stommel, 1996). It is important to note that the model implies relationships between factors as opposed to causality. These relationships are depicted in Figure 1.

A review of the literature supports the concepts in the model and their relationships. Pregnancy behaviors that have been previously associated with low birthweight outcomes, and thus an increased risk for neonatal mortality, are poor nutrition, alcohol and drug use, and cigarette smoking (Struk, 1994). According to the model, multiple factors contribute to these behaviors. For example, one contributing factor is difficult life circumstances (DLC) (Barnard, 1988). Difficult life circumstances can lead to problems such as poor nutritional status, which in turn may contribute to low birthweight (Hogue & Hargraves, 1993). Secondly, a woman's attitudes and beliefs about her susceptibility to poor infant outcomes, the seriousness of the behavior she is engaging in, the barriers to reducing the behavior, and the benefits of reducing the behavior can also have an influence on whether she has good nutrition during pregnancy or uses alcohol, cigarettes, or drugs (Rosenstock, 1990).

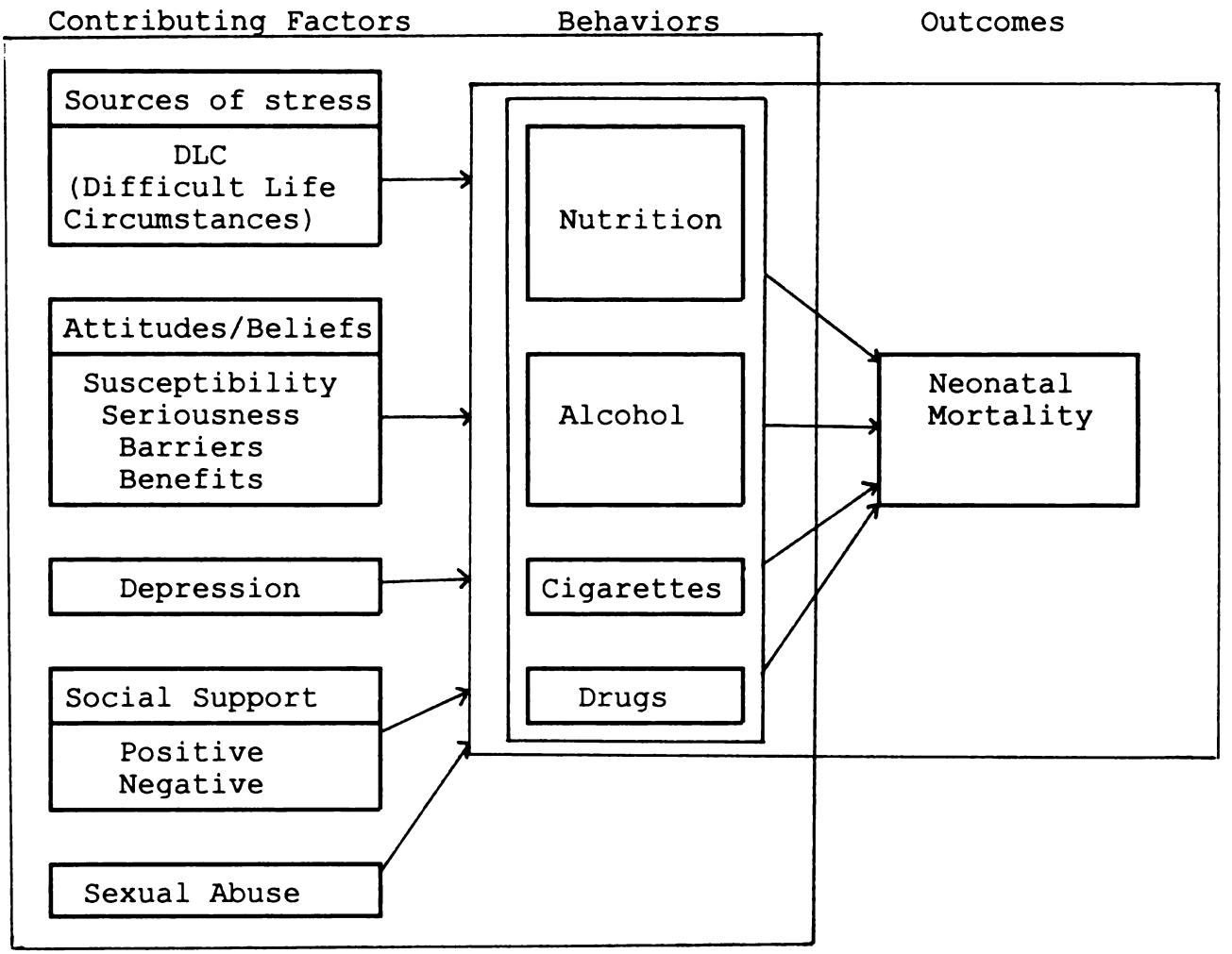

Figure 1. Hypothesized Model of Effects of Behavioral Factors on Infant Mortality (Tiedje, Green, Tannenbaum & Stommel, 1996).

Depression (Boyd, 1993), social support (both positive and negative (Struk, 1994), and sexual abuse (Boyd, 1993) are also known factors that contribute to unhealthy pregnancy behaviors and subsequently, a risk for poor infant outcomes. For example, researchers estimate that approximately 67-75% of alcoholic women who enter treatment have a history of sexual abuse (Boyd, 1993). Up to 80% of substance abusers have depressive and anxiety disorders, as well (Boyd, 1993).

Finally, social support, (either positive or negative) from individuals, family, and society is also identified as a contributing factor that may influence a woman's tendency to smoke, use drugs, or use alcohol during pregnancy (Struk, 1994). For instance, lack of social support, or support from those who drink or smoke, may act as a barrier to reducing unhealthy pregnancy behaviors, but positive social support, especially related to good nutrition and not smoking or drinking in pregnancy, may reinforce positive pregnancy behaviors.

Using the concepts identified in the model developed by Tiedje et al.(1996), the effects of one of the behavioral factors (passive exposure to cigarette smoke) on infant outcomes (neonatal mortality) will be examined (Figure 2).

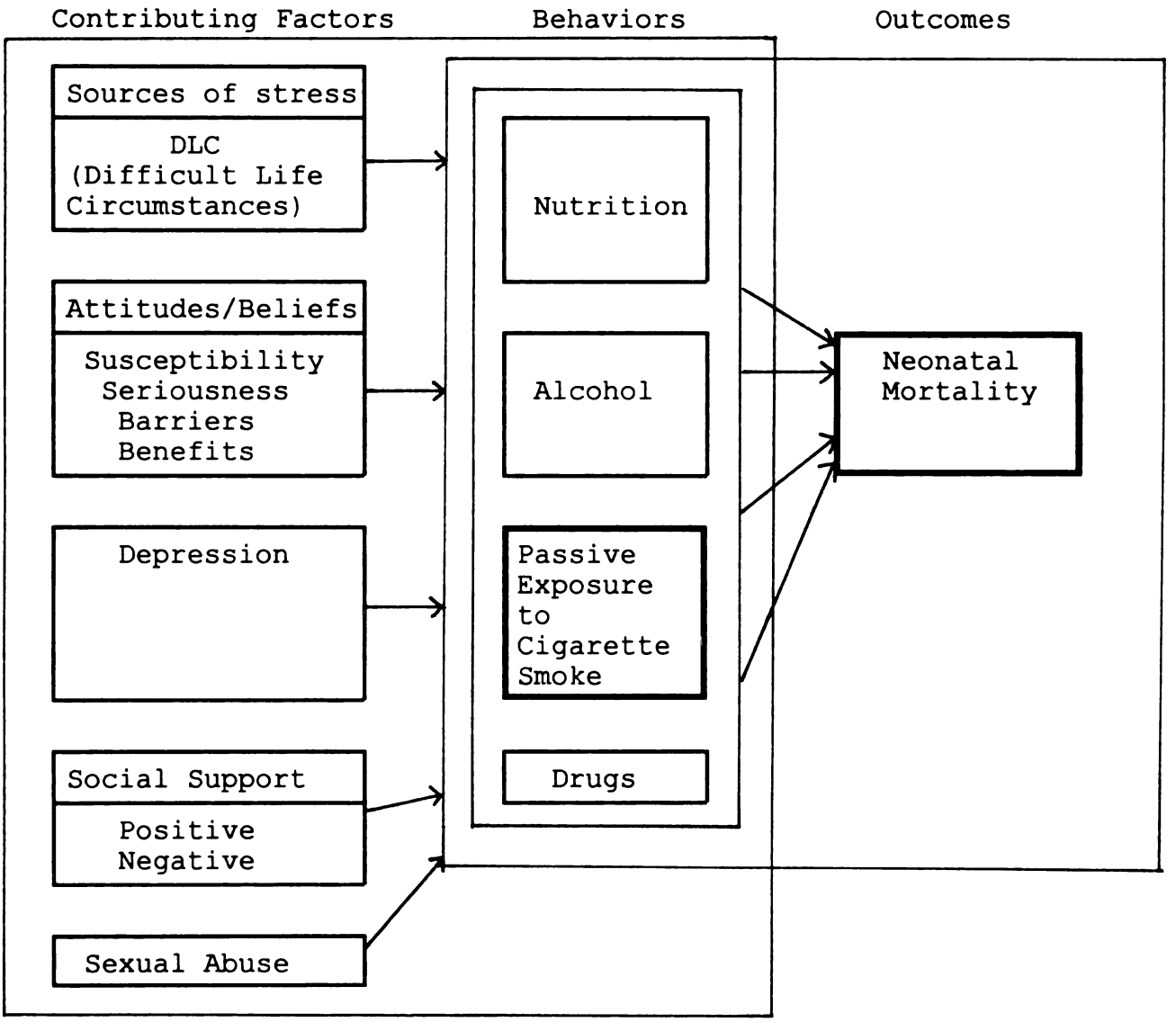

Figure 2. Hypothesized Model of Effects of Maternal Passive Exposure to Cigarette Smoke on Neonatal Mortality.

Methods

This study is a secondary data analysis of information gathered from an infant mortality study by Tiedje et al.(1994-1997). The purpose of the primary study was to describe the factors associated with infant mortality in a sample of women whose infants die during the neonatal period (first 28 days of life) with a matched sample of women with healthy infants (matched by race, age, week of delivery and hospital of delivery). Using an interview schedule, maternal demographic characteristics, factors affecting behavior in pregnancy (depression, sexual abuse, and stress) and behavior in pregnancy (alcohol, tobacco, and other drug use) were measured.

Sample

The entire sample from the primary study (10 mothers who had a neonatal death and 17 matched mothers who had a healthy infant) were utilized for this study, except for the mothers who identified themselves as having actively smoked cigarettes during their pregnancy. All subjects were recruited for the primary study from the Ingham County hospital that has the neonatal intensive care unit (NICU). The reason for collecting data from this hospital is because approximately 70% of the births and 80-90% of the neonatal deaths in the county occur within it, presumably related to

the presence of the NICU and the connection of low birthweight and neonatal mortality. All mothers delivering at the hospital were asked to participate in the study, so that matching of healthy mothers with infant mortality mothers could be done, and because it was not always possible to predict which babies would die within the first twenty-eight days of life. Mothers who were not able to read/understand English were excluded from the sample.

Women whose babies died during the first twenty-eight days of life were identified once the death occurred and matched with mothers who had healthy babies. One to two mothers who had healthy babies were matched with each neonatal mortality mother. Mothers were matched for race, age, week of delivery, and hospital of delivery.

Procedures

In the primary study, signed consent for study participation was obtained by birth records clerks at the hospital. Nurses at the hospital, funeral home directors, and the clerks in the medical examiners office were asked to report neonatal deaths to the study investigators during primarily the 1994 calendar year. After a neonatal death was identified, matching for race, age, week of delivery and hospital of delivery was completed. Data were available on

10 women who had a neonatal death and 17 matched mothers who consented to be interviewed. In the primary study, matching was not done on a large number of variables because this would have reduced the sample size and made the matching process more difficult. The characteristics used for matching were those that were considered most critical and relevant to the overall goals of the study. For the purposes of the secondary data analysis of passive smoke exposure, matching for race and age, as done in the primary study, is supported in the literature (Ahlborg & Bodin, 1991, Eskenazi et al., 1995). Additional matching would have been helpful if done on gravidity, educational level, and infant gender, for all of these variables are suspected to affect birthweight, and thus pregnancy outcomes such as neonatal mortality (Haddow et al., 1988, Ahlborg & Bodin, 1991, and Eskenazi et al., 1995).

Four to six weeks after the death occurred, the mother was contacted by telephone at home with a request for an interview. Mothers who did not have a telephone had previously identified (on the study consent form) a telephone number at which they could be reached. The 4-6 week delay was incorporated into the study design to allow some space between the time of the death and the interview. This 4-6 week interval between the death and the interview

was not problematic in terms of recall, for previous studies have shown that women have accurate recall of significant life events such as childbirth as long as 5-7 years after the event (Githens, Glass, Sloan & Entman, 1993). Interviews of the infant mortality mothers and the mothers who had healthy babies were conducted in their homes.

Data collection procedure and recording

All of the data analyzed in this study was obtained in the primary infant mortality study. Demographic data was collected on the mothers by chart review. Since all of the data needed for the study could not be collected by chart review alone, a structured interview was also necessary. In particular, the data regarding exposure to passive smoke was not reported on the chart, so it was obtained from the interview only. All of the interviews were done by a public health nurse experienced in maternal-child nursing. Every interview was conducted by the same nurse, who was trained by the study's principal investigator. A copy of the interview questions used in the secondary data analysis can be found in Appendix A.

Procedures for protection of human subjects and approval of UCRIHS

The proposal for the secondary study was reviewed by the Michigan State University Committee on Research

involving Human Subjects (UCRIHS) and approved December 14, 1996 (Appendix B).

Several strategies were utilized in the primary study to protect the rights of the women who agreed to participate in this study. First, written consent (see Appendix C) was obtained prior to the interview. The women were informed of the purpose of the study, that participation was voluntary, and that they had the right to refuse to participate. Additionally, the women were told that they could refrain from answering any questions and could end the interview at any time. Anonymity of the women was maintained at all times. Participants also received financial compensation of twenty dollars at the completion of the interview.

In the secondary data analysis, the data provided was coded so that the participants would remain anonymous. The researcher had no access to the identity of the participants.

Operational definitions

Within the interview, maternal passive smoke exposure was measured by specific survey questions related to the smoking habits of other members of the pregnant woman's household or workplace. If the mother responded affirmatively to any of the questions regarding passive smoke exposure (questions 1-4 on page 10 of the interview),

or indicated that a spouse, lover or boyfriend smoked around her while pregnant on a daily basis (question 12, page 9 of the interview) she was considered to have been passively exposed to cigarette smoke during her pregnancy. The interviewer was trained by the primary investigator to ask the questions so that the contact with the passive smoke was evaluated, as opposed to the contact with the smoker. A negative response to question 12 on page 9 of the interview (Smoked around me while pregnant on a daily basis: Spouse Lover Boyfriend) or to questions 1-4 on page 10 of the interview (related to other household member smoking behaviors) indicated that no passive smoke exposure occurred. Passive smoke exposure was only assessed in the pregnant woman's household or workplace. Other possible sources of passive smoke exposure (i.e. restaurants, bars, or Bingo halls) were not included in the primary study and, therefore, were not assessed in this study. Active smokers (defined as any admission to active smoking during pregnancy and assessed by question 4 on page 11 of the interview) were excluded from the study.

The nature of the passive smoke exposure is recorded as daily (5 points), weekly (3 points), or infrequent (1 point, and defined as any exposure occurring less than weekly). Workplace and household passive smoke exposure were added

together and evaluated on a continuum from 0 (no passive smoke exposure) to the highest score obtained (16). Higher scores reflected more exposure.

Neonatal mortality is defined as death before age twenty-eight days. The neonatal mortality group already exists, since it is derived from the sample selection criteria of the primary study. Fetal deaths and deaths during the birth process are not included in the definition of neonatal mortality, however deaths occurring shortly after birth (i.e., minutes to hours) are included.

Instrumentation

The interview questions related to passive smoke exposure during pregnancy were developed specifically for the primary study. Test-retest measures of reliability were not done. Tests of inter-rater reliability were not applicable since the same person conducted all of the interviews. However, the tools used are similar to those used in other studies measuring passive smoke exposure (interview, self-report format, etc.) (Lazzaroni et al., 1991; Martin & Bracken, 1986; Ogawa et al., 1991).

The questions related to passive smoke exposure have face validity, and content validity was established through a review of the literature and review by content experts. The questions related to amount and frequency of passive

smoke exposure in non-smokers are asked because there is a possibility that the effect of passive smoke exposure in pregnancy is dose-dependent (Ahlborg & Bodin, 1991; Lazzaroni, et al. 1990). Although urinary cotinine levels are not measured in this study, there is support for the use of an interview, self-report format to establish the amount of passive smoke exposure in pregnant women. A strong relationship has been found between self-reported exposure to cigarette smoke and urinary cotinine (a metabolic derivative of nicotine) levels (Haddow, et al. 1988). This supports self-reported data as valid. An additional strength of this study is that the same nurse, trained by the study principal investigator, gathered all of the data for the study.

Scoring and data summarizing procedures

Interview questions related to smoke exposure are scored according to the relationship of the person exposing the mother to passive smoke in the household or at work, and whether contact with the pregnant woman was daily (5 points), weekly (3 points), or infrequent (1 point). Household and workplace scores were summed and ranked on a continuum from 0 to the highest score obtained (16). Higher scores indicate more exposure to passive smoke.

Pilot studies and pretest

Pilot studies and pretests were not done. Again, this should not be problematic because the instruments used in this study are similar to those used in other studies of passive smoke exposure (Ahlborg & Bodin, 1991; Lazzaroni et al., 1990; Martin & Bracken, 1986; Ogawa et al., 1991).

Research design

A non-experimental, retrospective, correlational design was used to study the relationship between the two variables: maternal passive smoke exposure during pregnancy and healthy babies/babies who died.

Data analysis

A t-test was utilized to answer the question. To do this, the data was separated into two groups (mortality and healthy), and the amount of passive smoke exposure was summed for a total score. The mean total score for each group was then compared using a t-test. This strategy was expected to best answer the question of the relationship of neonatal mortality and passive smoke exposure.

Results/Findings

Description of sample

A sample of 27 mothers (10 mothers who had a neonatal death and 17 matched mothers who had a healthy infant) was available from the primary study. However, the operational

definition of maternal passive smoke exposure used for this study required that only non-smokers exposed to passive smoke were included in the sample. On that basis, a total of 9 active smokers (defined as any admission to active smoking during pregnancy and assessed by question 4 on page 11 of the interview) were excluded from the sample, thereby reducing the sample size to 18. Of this sample, 5 of the mothers had a neonatal death, and 13 matched mothers had a healthy infant.

Sample Demographics

In the secondary study, the average age of the women in the sample was 26.5. In the mortality group, 40% of the women were never married, 20% were now married, 20% were cohabitating, and 20% were divorced. In the healthy infant group, 31% were never married, 61% were now married, none were cohabitating, and 8% were divorced. Sixty percent of the mortality group was Caucasian, in contrast to 77% of the healthy infant group. The remainder of the women in the mortality group were African-American (20%) and Latino (20%). In the healthy infant group, there were 15% African-Americans and 8% Hispanics. With the exception of one mother in the mortality group with a tenth grade education, the remainder of the mothers in the sample had completed twelfth grade (40% mortality group, 38% healthy infant

group). The two groups were similar with respect to years of college completed, with at least some college completed by 40% of the mortality group and 46% of the healthy infant group. Additionally, 15% of the healthy infant group had some graduate level education. The majority of the mothers in both groups worked outside the home during their pregnancy (80% in the mortality group, 70% in the healthy infant group). Clearly, the women in the study were more alike than different in relation to the demographic data that was gathered. This finding helps to reduce the effect of variables other than passive smoke exposure on the study results.

Findings

For a descriptive summary of passive smoke exposure, see Table 1. Fourteen of the eighteen women in the sample denied having a spouse who smoked (score = 0). The remainder of the women stated that their spouse smoked around them while they were pregnant (n = 4), and categorized their contact with the smoker as infrequent(score = 1).

Although none of the women responded affirmatively to having a lover who smoked during their pregnancy, four of

Table 1

Summary of Passive Smoke Exposure Scoring

Category/Response	Value	Frequency
Smoker Spouse		
no	.00	14
yes	5.00	4
Smoker Lover		
no	.00	18
Smoker Boyfriend		
no	.00	14
yes	5.00	4
First Household Member		
mother		1
sibling		1
other sig. family member		1
other close friends		1
Contact With First Household Member		
infrequent	1.00	1
daily	5.00	3
Second Household Member (identified as sibling)		1
Contact With Second Household Member		
weekly	3.00	1
Contact with first workplace member		
infrequent	1.00	2
daily	5.00	3
Contact with second workplace member		
weekly	3.00	1

the fourteen women in the sample had a boyfriend who smoked during their pregnancy. All four of these women rated their contact with the smoker as daily (score = 5).

The women's exposure to other household members who smoked was assessed as well. Fourteen of the women denied passive smoke exposure from other household members. The remaining four had contact with at least one household member who smoked: a smoking mother (n=1), a smoking sibling (n=1), a significant family member (n=1), or a close friend (n=1). One of the exposed women identified the contact with the smoker as infrequent (score = 1), and the rest stated that the contact was daily (score = 5).

Only one member of the sample had passive smoke exposure from a second household member. In this case, additional passive smoke exposure was obtained through contact with a sibling. The smoke exposure was identified as weekly (score = 3). None of the sample identified passive smoke exposure from a third household member.

Passive smoke exposure also occurred in the workplace. Two women had infrequent contact with a co-worker who smoked (score = 1), and three reported the contact as daily (score = 5). One additional woman reported passive smoke exposure at work from a second co-worker, and stated that the contact was weekly (score = 3). None of the women had passive smoke

exposure at work from more than two people.

When the women's scores for passive smoke exposure were summed for total passive smoke exposure, it was found that 38.9% (n=7) had reported that they had no passive smoke exposure during their pregnancy. The remaining 61.1% (n=11) had passive smoke exposure scores from 2 to 16, with a mean score of 4.389. The results of summarizing the total passive smoke exposure scores for the sample are presented in Table 2.

Table 2

Summary of Passive Smoke Exposure Scores

Score	Frequency	Percent
.00	7	38.9
2.00	1	5.6
5.00	6	33.3
6.00	1	5.6
10.00	1	5.6
15.00	1	5.6
16.00	1	5.6
Total	18	100.00

Passive smoke exposure scores were also analyzed separately for the mortality and the healthy infant groups, and an exposure index from 0 (no passive smoke exposure) to 16 (the highest amount of passive smoke exposure reported) was developed (refer to Figure 3). There were two mothers

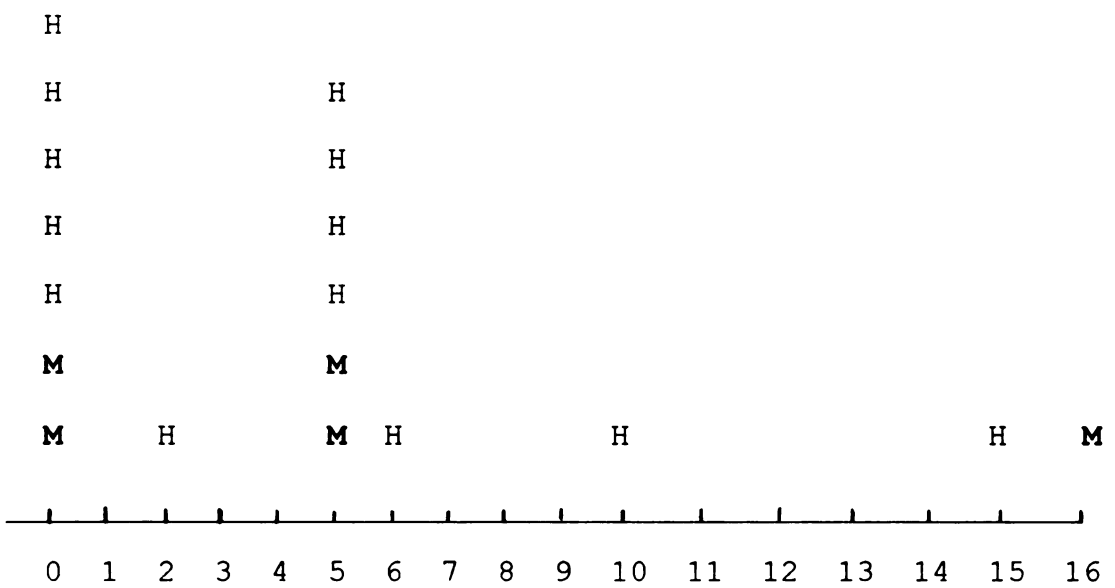

Figure 3. Passive Smoke Exposure Scores Separated by Healthy (H) and Mortality (M) Groups.

in the mortality group with no passive smoke exposure (score = 0), two with a total passive smoke exposure score of 5, and one with a total passive smoke exposure score of 16. The mothers of healthy infants had passive smoke exposure scores ranging from 0 to 15.

A t-test was used to compare the mean passive smoke exposure score for the healthy infant group to the mean passive smoke exposure score of the mortality group. The mean passive smoke exposure score for the healthy infant group was 3.9231 (*SD* = 4.663), and the mean score for the mortality group was 5.6000 (*SD* = 6.1189). This difference was not significant (*t* = -.63, df = 16, *p* = .54), at a confidence interval of 95%, but the trend was in the expected direction - that is, the mortality group, on average, reported more passive smoke exposure. It is acknowledged that, for both groups, the passive smoke exposure was low on the 0-16 scale.

Discussion

Interpretation of findings with respect to theoretical model

The theoretical model hypothesized for this study was the *Effects of Maternal Passive Exposure to Cigarette Smoke on Neonatal Mortality* (Figure 1). It was hypothesized that the results of this secondary analysis of data would support the relationships between factors postulated in the

model. This did not occur. This finding is not surprising given the extremely small sample size and other limitations of the study. It must also be remembered that neonatal mortality is a multifaceted concept, and passive smoke exposure is only a small piece of a multifactorial causative model.

Interpretation of findings with respect to literature

The results of this study do not contradict the findings identified in the literature, for there were no studies reviewed that specifically addressed a potential link between maternal passive cigarette smoke exposure in pregnancy and neonatal mortality. One study did report an increased risk of fetal death (spontaneous abortion or stillbirth) for nonsmoking women exposed to passive smoke at work (Ahlborg & Bodin, 1991). Two other studies addressed passive smoke exposure in pregnancy in terms of birthweight outcomes (Lazzaroni et al., 1990; Martin & Bracken, 1986), and described a relationship between birthweight reduction and passive smoke exposure during pregnancy. Low birthweight has also been implicated in neonatal mortality outcomes (IOM, 1985). However, since neither fetal death outcomes nor low birthweight outcomes were evaluated in the secondary analysis under discussion, it is not possible to compare the results of this study with the results discussed

in the existing literature. In general, the results of this study do support a trend which links passive smoking and negative pregnancy outcomes.

Interpretation of findings with respect to methods employed in the study

The methods used to evaluate maternal passive cigarette smoke exposure in this study (interview, self-report format, etc.) were similar to those used in other studies where significant relationships between passive smoke exposure and other variables were found (Lazzaroni et al., 1991; Martin & Bracken, 1986; Ogawa et al., 1991). However, neonatal mortality was not a variable in any of the aforementioned studies. Additionally, sample sizes were much larger in the studies described in the literature review. This may help to explain the non-significant results.

Limitations

The major problem encountered in the data analysis was that in order to confine the analysis to non-smokers passively exposed to cigarette smoke during pregnancy, nine members of an already-small sample had to be eliminated as members of the study group. This created two very small groups for comparison and reduced the neonatal mortality sample by 50%.

There are several limitations of the research design itself. Because the population under study was limited to those neonatal deaths occurring at just one hospital in Ingham County for 1994, the sample size was small. Also, not all of the potential members of the sample agreed to participate in the primary study, resulting in a possible reduction in the sample of women who had passive smoke exposure during their pregnancy. One potential reason for women refusing to participate in the study is that data gathering about pregnancy behavior from a mother who has had a neonatal death is difficult. Additionally, with an interview design, it is possible that participants underestimated their passive smoke exposure because of a desire to "look good" to the interviewer. Chart data on passive smoke exposure in pregnancy is generally not available, and chart data on active smoking is notoriously unreliable.

Another limitation of the research design was that matching was not done on gravidity, educational level, and infant gender. All of these variables are suspected to affect birthweight, and thus pregnancy outcomes such as neonatal mortality (Ahlborg & Bodin, 1991; Eskenazi et al., 1995; Haddow et al., 1988). It is acknowledged, however, that inclusion of these criteria, although valid

for this secondary analysis, would have only served to further decrease the sample size.

A final limitation was that passive smoke exposure was only assessed in the pregnant woman's household or workplace. Other possible sources of passive smoke exposure (i.e. restaurants, bars, or Bingo halls) were not included in the primary study and therefore could not be evaluated in the secondary analysis.

Implications of results for existing literature

The study results do not necessarily contradict the existing literature. Although this study did not show that the mortality mothers had a significantly higher amount of passive smoke exposure than the mothers of the healthy infants, the trend was in the expected direction: there was more passive smoke exposure during pregnancy in the mortality group. There is still reason to believe that maternal passive smoke exposure during pregnancy may have an influence on neonatal mortality outcomes. More research is necessary.

Implications for advanced nursing practice and primary care

Although the results of this study were not statistically significant, one can still make a case for the avoidance of maternal passive cigarette smoke exposure during pregnancy, based on trends in these data and in the

literature review. There is clearly a relationship between passive cigarette exposure in pregnancy and negative pregnancy outcomes, and this knowledge should be shared by all primary care providers and incorporated into their health promotion efforts for women. Since advanced practice nurses are present in a variety of health care settings in which health promotion, prevention and intervention services are provided for women, they are in an ideal position to use any contact with women of childbearing age to discuss the risks associated with passive exposure to cigarette smoke during pregnancy. Anticipatory guidance could also occur. Advanced practice nurses could use this information to enhance positive pregnancy behaviors, for instance, praising a woman for having a low amount of passive smoke exposure, or, if the father of the baby is present at a visit, encouraging him to help keep his partner's passive smoke exposure low.

It is difficult for women to avoid passive smoke exposure when members of their household or workplace smoke. Advanced practice nurses can address this concern through community education. Some examples of how this might be accomplished are participating in public service announcements requesting that household members and co-workers refrain from smoking around pregnant women, or

creating posters or brochures describing the risks to the fetus exposed to passive smoke. It is acknowledged that a much more difficult issue is when the pregnant woman works in a place that is typically smoke-filled - for example, a bar. Some of the women in this category may simply not consider it an option to change jobs to avoid passive smoke exposure during pregnancy. In this instance, careful education is necessary, and the APN can support the woman as she examines her choices and develops strategies to reduce her passive smoke exposure. Finally, the APN can help develop legislation that would require mandatory smoke filtration devices in places that pregnant women may be employed - for example, bars and restaurants.

Recommendations for further research

Further research is necessary to establish a relationship between maternal passive cigarette smoke exposure during pregnancy and neonatal mortality. Future studies should be designed in a manner in which a larger sample size can be obtained. Steps should also be taken to control for the large number of biological and social factors that may affect birthweight, and thus neonatal mortality - such as fetal gender and mother's education (Lazzaroni et al., 1990). Consideration should also be given to such factors as the type of cigarette smoke (filter

or nonfilter, low tar or nicotine, etc.), smoking rate, room size, and ventilation. Perhaps an analysis could be done in a fashion that does not exclude active smokers from the sample, but instead categorizes the smoke exposure to assess cumulative effects. Finally, an effort should be to create a standardized tool for measurement of maternal passive smoke exposure in pregnancy, so that comparisons between studies could be simplified.

Summary

No single approach will answer all of the questions about neonatal mortality, or produce information that will solve the neonatal mortality problem. The aim of this study was to develop knowledge, that when combined with the knowledge generated from studies examining other variables, could lead to the development of interventions to reduce the incidence of neonatal mortality. Despite the non-significant results of this study, there exists a convincing trend that indicates that there may indeed be a relationship between passive smoke and untoward outcomes for neonates. More research is necessary.

APPENDIX A

Interview Questions Related to Active and Passive Smoking

Question 12, page 9

12. Smoked around me while pregnant on a daily basis.

Spouse Lover Boyfriend

Questions 1-4, page 10

Other Household Member Behaviors

I now want you to think back during your pregnancy. Please think about other household members (other than the men just mentioned). If you lived with more than three people think about the three with whom you had the most frequent contact. Please indicate if these other household members:

1.	Smoked yes ___ no ___	Relationship	Contact with you a. daily contact b. weekly contact c. infrequent contact
2.	Smoked yes ___ no ___	Relationship	Contact with you a. daily contact b. weekly contact c. infrequent contact
3.	Smoked yes ___ no ___	Relationship	Contact with you a. daily contact b. weekly contact c. infrequent contact
4.	Workplace (where did they work?) 1. 2. 3.	Relationship 1. 2. 3.	Contact w/you for each a. daily contact b. weekly contact c. infrequent contact

Question 4, page 11

4. Cigarettes: How often during the (1st, 2nd, 3rd trimester) did you smoke?

	1st	2nd	3rd
Amount	___	___	___
Daily	___	___	___
Several times/week	___	___	___
Never	___	___	___

APPENDIX B

MICHIGAN STATE
UNIVERSITY

December 16, 1996

TO: Linda Beth Tiedje
A-230 Life Sciences Building

RE: IRB#: **96-783**
TITLE: MATERNAL PASSIVE SMOKE EXPOSURE IN PREGNANCY AND NEONATAL MORTALITY
REVISION REQUESTED: N/A
CATEGORY: 1-E
APPROVAL DATE: 12/14/96

The University Committee on Research Involving Human Subjects' (UCRIHS) review of this project is complete. I am pleased to advise that the rights and welfare of the human subjects appear to be adequately protected and methods to obtain informed consent are appropriate. Therefore, the UCRIHS approved this project and any revisions listed above.

RENEWAL: UCRIHS approval is valid for one calendar year, beginning with the approval date shown above. Investigators planning to continue a project beyond one year must use the green renewal form (enclosed with the original approval letter or when a project is renewed) to seek updated certification. There is a maximum of four such expedited renewals possible. Investigators wishing to continue a project beyond that time need to submit it again for complete review.

REVISIONS: UCRIHS must review any changes in procedures involving human subjects, prior to initiation of the change. If this is done at the time of renewal, please use the green renewal form. To revise an approved protocol at any other time during the year, send your written request to the UCRIHS Chair, requesting revised approval and referencing the project's IRB # and title. Include in your request a description of the change and any revised instruments, consent forms or advertisements that are applicable.

PROBLEMS/ CHANGES: Should either of the following arise during the course of the work, investigators must notify UCRIHS promptly: (1) problems (unexpected side effects, complaints, etc.) involving human subjects or (2) changes in the research environment or new information indicating greater risk to the human subjects than existed when the protocol was previously reviewed and approved.

If we can be of any future help, please do not hesitate to contact us at (517)355-2180 or FAX (517)432-1171.

Sincerely,

David E. Wright, Ph.D.
UCRIHS Chair

DEW:bed

cc: Kathy Walker Mathis

OFFICE OF
RESEARCH AND GRADUATE STUDIES

University Committee on Research Involving Human Subjects (UCRIHS)
Michigan State University
232 Administration Building
East Lansing, Michigan
48824-1046

517/355-2180
FAX: 517/432-1171

APPENDIX C

Informed Consent Form

Respondent No.: _____

I am being asked to participate in a research study conducted by Dr. Linda Beth Tiedje, PhD, RN, Professor in the College of Nursing at Michigan State University. The study will explore several factors related to smoking, drinking, and drug use in pregnancy. If I agree to participate, a research assistant will be asking me questions about my health, social support, family, and my pregnancy behaviors. The entire interview will take about one hour, at the end of which I will be given $20.00.

No risks or discomforts are expected to result from this study although it is possible that some of the questions might make me feel uncomfortable. If this happens and I wish to talk to a specialist in this area, I can let the research assistant know and she will put me in contact with Dr. Tiedje who will talk to me.

Although I may not benefit directly from this study, my participation will assist health care professionals in understanding the needs of women like myself. All information collected will be identified by a code number only. After all the information has been collected for this study, any information identifying names with code number will be destroyed.

Participation in this study is voluntary and refusal to participate will not affect my future care. I understand that I can stop participating at any time during the interviews; all I have to say is "I want to stop". Additionally, I am free to answer only those questions that I wish.

If I should have any questions regarding this study, or wish to withdraw from the study, I may contact Elaine Berry at 339-9534.

Signing this consent indicates that I understand and am willing to participate in this study.

Study Participant _____

Parent (in participants under age 18) _____
Research Assistant _____

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