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ASSESSING THE VALIDITY OF CIGARETTE SMOKING STATUS AMONG MEDICAID MATERNITY CARE PATIENTS

by

TOYA VENICE RUSSELL

A DISSERTATION

Submitted to the graduate faculty of The University of Alabama at Birmingham, in partial fulfillment of the requirements for the degree of Doctor of Philosophy

BIRMINGHAM, ALABAMA

2000

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ABSTRACT OF DISSERTATION GRADUATE SCHOOL, UNIVERSITY OF ALABAMA AT BIRMINGHAM

 Degree
 Ph.D._____
 Program
 Health Education/Health Promotion

 Name of Candidate
 Toya Venice Russell

 Committee Chairs
 Richard A. Windsor and David M. Macrina

The purpose of this study was to document the validity of self-disclosure of smoking status at the onset of care among Medicaid-supported maternity patients. It was a substudy of the Smoking Cessation or Reduction in Pregnancy Trial (SCRIPT). Quantitative and qualitative observational methods were used to measure nondisclosure and to assess whether there was a significant change in SCRIPT deception rates over time. This study was important because truthful disclosure by patients at entry into care has direct implications for prenatal care practice and health education evaluation research. The SCRIPT cohorts were used for the analyses because counties and patients were randomly selected to eliminate selection bias and to assure representativeness.

Analyses revealed a significant difference in the percentage of maternity patients who had cotinine values that did not corroborate their self-reported smoking status for Natural History Study (NHS) 1 (23.8%) and NHS 2 (5.3%). With the exception of cotinine level, the majority of demographic characteristics (mother's age, race, gestational age, passive exposure, number of cigarettes per day) for NHS 1 and NHS 2 suggested that the 2 study samples were comparable. Maternity care professionals believed that social desirability, fear, and denial contribute to patient deception. Deceivers stated that their

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exposure to secondhand smoke explained why they had cotinine values that did not confirm their self-report.

The results of the quantitative analyses and qualitative evaluation supported the conclusion that multiple events contributed to the substantial decrease in the deception rates from NHS 1 to NHS 2, including (a) several site and staff changes or both and (b) an increase in maternity staff skill and comfort level with SCRIPT procedures. Additional knowledge gained from the qualitative evaluations suggested that maternity care providers should be trained to improve their patient assessment and health communication skills to increase patient disclosure of smoking status. The Deception Reduction Model for Providers was developed to identify recent self-initiated quitters and to identify current smokers who do not truthfully disclose.

DEDICATION

My dissertation is dedicated to my brother, Frankye Russell, who died of complications from AIDS in June of 1994. I know that he is my angel because I can feel his presence in everything I do. I see two sets of footprints in the sand, one belongs to Frankye and the other to the Lord.

My dissertation is also dedicated to my family and friends who have supported me and prayed for me since I began pursuing my doctorate degree. I thank God for blessing me with loved ones who believed in me when I did not believe in myself.

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Very special thanks are extended to my friends from Howard University and Meharry Medical College; to the faculty and staff at the University of Alabama at Birmingham (UAB), School of Education; to my Sixteenth Street Church family; and to the Alabama Department of Public Health. In addition, the UAB Minority Health Research Group has provided never-ending words of encouragement, and I thank Dr. B. Lee Green for organizing and mentoring the Group.

In closing, I am a product of my family. This would not have been possible without their love. I am sure that everyone has heard it before, but just in case I have not said it lately–I love you!!

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LIST OF ABBREVIATIONS

ADPH	Alabama Department of Public Health		
AHCPR	Agency for Health Care Policy and Research		
AL PRAMS	Alabama Pregnancy Risk Assessment Monitoring System		
С	Control Group		
<u>C</u>	Comparison Group		
СО	Carbon Monoxide		
СОНЬ	Carboxyhaemoglobin		
СОТ	Cotinine		
E	Experimental Group		
ECO	Expired Air Carbon Monoxide		
EIA	Enzyme-Linked Immunoassay		
ETS	Environmental Tobacco Smoke		
IRB	Institutional Review Board		
LBW	Low Birth Weight		
NCHS	National Center for Health Statistics		
NHS	Natural History Study		
NHSDA	National Households Survey on Drug Abuse		
NIDA	National Institute on Drug Abuse		
NIH	National Institutes of Health		
PP	Postpartum		

LIST OF ABBREVIATIONS (Continued)

SAMHSA	Substance Abuse and Mental Health Services Administration
SCN	Thiocyanate
SCRIPT	Smoking Cessation or Reduction in Pregnancy Trial
SIQ	Self-Initiated Quitter
UAB	University of Alabama at Birmingham
WIC	Women, Infants, and Children

CHAPTER 1

INTRODUCTION

About 25% of American adults continue to smoke cigarettes (United States Department of Health and Human Services [USDHHS], 1999a), despite the fact that smoking has been identified as the single most preventable cause of premature mortality and morbidity in the United States (Centers for Disease Control [CDC], 1993). The smoking prevalence among women of childbearing age (12-44 years old) was 32.6% (USDHHS, 1997b).

There are two forms of exposure to tobacco smoke: active and passive. Active exposure is actually inhaling a cigarette. Numerous studies have demonstrated the increased risk of cancer, heart disease, and stroke from active exposure to tobacco smoke (USDHHS. 1989, 1990). Smokers and nonsmokers are passively exposed when they inhale the exhaled tobacco smoke of others. The adverse health effects attributable to passive or environmental tobacco smoke (ETS) exposure have been confirmed (Environmental Protection Agency [EPA], 1992). It has also been linked to an increased risk of lung cancer in spouses (Sockrider, 1996). Some of these health effects associated with residential ETS exposure include the development or exacerbation of lower respiratory illness and reduction of lung function in children (Spitzer et al., 1990).

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Statement of the Problem

Active and passive tobacco exposure during and after pregnancy causes maternal, fetal, and infant morbidity and mortality (USDHHS, 1980, 1990, 1996). Birth weights are consistently lower for infants born to women who smoke; the risk is increased as the number of cigarettes smoked increases. Among the lightest smokers (1 to 5 cigarettes daily). the low birth weight (LBW) rate was 11%, 61% higher than the nonsmoker rate (USDHHS, 1998). Health risks include miscarriage, preterm births, infant respiratory problems (including asthma), ear aches, learning and behavior problems, and possibly death (DiFranza & Lew, 1995; Horta, Victoria, Menezes, Halpern, & Barros, 1997; Olds. Henderson, & Tatelbaum, 1994; Orlebeke, Knol, & Verhulst, 1997; Wyszynski, Duffy, & Beaty, 1997). Additionally, nicotine is a neurotoxin that destroys fetal brain cells (Slotkin, 1998).

Medical Care Expenditures Attributable to Smoking During Pregnancy

Smoking during pregnancy significantly increases health care expenditures. Infants born to women who smoked during pregnancy are at greater risk of being LBW and being admitted to neonatal intensive care units. The incidence of miscarriage, stillbirth, and health care expenditures for uncomplicated deliveries was similar in both smokers and nonsmokers. But smokers with complicated deliveries used about 66% more health care resources than nonsmokers. Nationally, the estimated costs for medical care for infants born in 1995 to mothers who smoked during their pregnancies ranged from \$1.4 to \$2 billion. These costs are based on extrapolations to costs in 1987 and an estimated 19% to

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20% of pregnant women who smoked in 1995. In addition, both mother and child were more likely to stay in the hospital longer (Adams, Solanki, & Miller, 1997).

United States Smoking Prevalence Rates During Pregnancy

Multiple national data sets, summaries, or both on tobacco exposure during pregnancy are available from three federal agencies: the National Center for Health Statistics (NCHS), the National Institute on Drug Abuse (NIDA), and the Substance Abuse and Mental Health Services Administration (SAMHSA). Results are based on selfreport only and do not include biochemical confirmation.

Inconsistencies in the smoking prevalence rates may be attributed to differences in sampling procedures at each agency. The NCHS includes birth certificate data from all U.S. births for the past 10 years. The SAMHSA data is from the 1979-1995 National Households Surveys on Drug Abuse (NHSDA), an interview survey that included randomly selected households for participation. Furthermore, there are limitations of the data within each agency. For example, NCHS data is extracted from birth certificates. This source is likely to be underreported for reasons including the lack of specific time reference for smoking status, variations in the source of information for each birth, and the growing stigma associated with smoking (Dietz, Adams, Kendrick, & Mathis, 1998; Kharrazi, Epstein, & Hopkins, 1999; Mathews, 1998; Ventura, 1999).

National Center for Health Statistics--Births: Final Data for 1997

Since 1989, 46 states, the District of Columbia, and New York City (80% of U.S. births) have been reporting tobacco use on birth certificates. (Data from California,

Indiana, New York State [except New York City], and South Dakota are not included in these results.) According to birth certificate data, smoking during pregnancy continues to decline. Results indicate that, in 1997, 13.2% of women giving birth were reported to have smoked, down 3% compared with 1996 (13.6%) and 32% since 1989 (19.5%). However, smoking among pregnant teenagers increased in 1997, with the greatest increase among Puerto Rican and Black teenagers. Women in the United States had substantially higher smoking rates (13.2%) compared with women from other countries: Chinese, 1.0%; Japanese, 4.7%; and Filipino, 3.4% (USDHHS, 1999b). Table 1 presents U.S. pregnant smoker prevalence data (percentages) by age and race. White pregnant smokers, between 18 and 19 years, had the highest smoking rate (23%). In 1997, 12.1% of births to smokers compared with 7.1% of births to nonsmokers weighed less than 2.500 g or 5 lb, 8 oz (USDHHS, 1999b).

National Institute on Drug Abuse--National Pregnancy and Health Survey, 1992

The purpose of the National Pregnancy and Health Survey (NPHS) was to determine licit and illicit drug use among women delivering live births. Based on 1992 NIDA statistics, 19.6% of pregnant women used cigarettes during their first trimester. The rate among Blacks (19.1%) is almost equal to the national rate and among White women (23.4%) is even higher than the national rate. Table 2 below shows the agerelated patterns of cigarette use by race. Among women less than 25 years old, Whites have the highest rate; Blacks and Whites have a similar rate for ages 25-29 years. The rate of smoking among Hispanics is highest among women older than 30 years, but it remains lower than the rates of both Blacks and Whites.

Table 1

Age	White	Black
Under 15 years	13.6	2.9
15-17 years	20.7	5.5
18-19 years	23.3	7.4
20-24 years	19.2	8.6
25-29 years	12.4	10.3
30-34 years	10.0	12.7
35-39 years	10.8	15.8
40-49 years	9.8	14.5
Total	14.3	9.7

National Center for Health Statistics (NCHS) 1997 Pregnant Smoking Prevalence by Age and Race (%)

Note. Information compiled from USDHHS, 1999b.

Substance Abuse and Mental Health Services Administration 1995

Survey data from the 1979-1995 NHSDA were analyzed to explore trends in substance use among pregnant women. Among pregnant respondents aged 12-44 years, almost 31% reported cigarette use in the past year and 21.5% in the past month. Approximately 29% of these reported heavy smoking (one or more packs per day) in the past month. The Substance Abuse and Mental Health Services Administration (SAMHSA) estimates that 36.6% of pregnant smokers were covered by public insurance (Medicaid or Medicare). Table 3 presents additional demographic findings of women who smoked cigarettes during pregnancy. The majority of pregnant smokers were White (73.7%), and 46.1% were between the ages of 18 and 25 years. In addition, 76.8% had not taken a college course, and 25.8% had participated in welfare programs (USDHHS, 1997b).

Table 2

Race	<25 years	26-29 years	>30 years	Total
White	30.7%	19.6%	20.0%	23.4%
Black	12.9%	23.0%	31.0%	19.1%
Hispanic	5.3%	3.9%	8.6%	5.7%
Total	21.2%	17.7%	19.3%	19.6%

National Institute on Drug Abuse (NIDA) Age-Related Patterns of Cigarette Use in 1st Trimester by Race (%)

Note. Information compiled from USDHHS, 1996b.

Table 3

Substance Abuse and Mental Health Services Administration (SAMHSA) 1995 Pregnant Smoker Characteristics in the Past Month (%)

Demographic Category	Percentage
Race	
White	73.7
Black	14.0
Hispanic	8.6
Age	
12-17 years	8.2
18-25 years	46.1
26-34 years	38.6
35-44 years	7.1
Education	
> High school	37.4
High school graduate	39.4
Some college	15.6
College graduate	7.5
Welfare	
Yes	25.8
No	74.2

Note. Information compiled from USDHHS, 1999b.

Deception Rate Estimates in Smoking Cessation During Pregnancy Studies

In 1995 it was estimated that the self-reported smoking prevalence among U.S. Medicaid-supported pregnant women (1.52 million) was approximately 29% or 440,000 patients (USDHHS, 1996, 1997b). Windsor et al. (2000) have suggested that the actual smoking prevalence rate among Medicaid maternity patients is much higher than the patient self-reports. Two evaluation research studies that included self-report and cotinine (COT) analysis found overall deception rates from 23.8% (Windsor et al., 1993) to 50% (Kendrick et al., 1995). The authors suggested applying a 20% deception rate to the CDC NCHS data, which results in at least a 17% smoking prevalence rate (660,000+), after entry into care for the U.S. maternity cohort. Of the 660,000 pregnant smokers, 470,000 (31%) are Medicaid recipients. Thus, approximately 70% (470 out of 660) of the pregnant smokers in the United States are Medicaid patients.

Alabama Smoking Prevalence Rates During Pregnancy

The Alabama Pregnancy Risk Assessment Monitoring System (AL PRAMS) began in 1993. The Alabama Pregnancy Risk Assessment Monitoring System is a surveillance system of new Alabama mothers that is supported by the Centers for Disease Control and Prevention. The PRAMS staff at the Alabama Department of Public Health (ADPH) is responsible for collection and analysis of the data. The ADPH Center for Health Statistics is responsible for producing and disseminating yearly reports.

The survey is mailed to a randomly selected sample of new mothers 2 to 4 months after each baby is born. Each mother is sent up to five mailings that include three copies of the questionnaire. If no response has been received after the fifth mailing, up to 15 telephone contact attempts are made to the mothers. In 1996, 1,894 surveys were completed from the sample of 2,513 women, a 75.4% response rate. Pregnancy Risk Assessment Monitoring System researchers oversampled for mothers of LBW babies. A recent study suggests that mothers who had LBW infants were less likely to respond to live-birth and infant-death survey components (USDHHS, 1998). Other characteristics of mothers who are less likely to respond to mailed health surveys are those with four or more children, little prenatal care, and few years of education and who are teenagers, minorities, or both. Because there is a direct strong association between smoking and poor infant health outcome, the smoking rate among nonrespondents may be higher than females who answered the questionnaire.

The 1996 AL PRAMS report states that approximately 25% of maternity patients smoked before becoming pregnant, 15.2% smoked during pregnancy, and 21% smoked after pregnancy. Smoking was greater among Medicaid mothers compared with non-Medicaid mothers during (18.7% to 12%) and after (25.8% to 16.6%) pregnancy. The percentage of White mothers who smoked before (35%), during (20.6%), and after (28.3%) pregnancy was more than four times that of the Black mothers (7%, 5%, and 7.3%, respectively). The highest percentage of smokers was for mothers 35 years and older (26.9% before, 18.6% during, and 22.7% after). The percentage of mothers who smoked before (33.8%), during (24%), and after (31.3%) pregnancy was highest among women with less than a high school education. Overall, AL PRAMS data show that pregnant smokers in Alabama are likely to be White. Medicaid-supported women in their mid-30s or older and less educated (ADPH, 1996).

Table 4

Race	1995	1996	1997
White	20.9%	20.6%	16.2%
Medicaid	31.9%	32.0%	31.7%
Non-Medicaid	9.2%	8.6%	8.5%
Black & other	6.0%	5.7%	5.1%
Medicaid	6.9%	6.6%	5.9%
Non-Medicaid	3.7%	3.5%	3.0%
Overall	13.4%	13.0%	12.5%

	Alabama Smokers	During P	regnancy by	Race and	Payment,	1995-1997
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Note. Information compiled from ADPH, 1998.

The Importance of Smoking Cessation Interventions in Maternity Care

Smoking cessation interventions have been recognized as an important strategy for preventing the health risks and related costs of smoking during pregnancy (Adams et al., 1997; Kendrick & Merritt, 1996; Li, Windsor, Lowe, & Goldenberg, 1992). Metaevaluations of randomized prenatal smoking cessation trials have found health education methods to have a behavioral impact (Dolan-Mullen, Ramirez, & Groff, 1994; Windsor, Boyd, & Orleans, 1998; Windsor & Orleans, 1986). In addition, routinely delivering health education smoking cessation methods that are evidence-based offer a cost benefit to public health maternity patients (Li et al., 1992; Windsor et al., 1993; Windsor, Warner, & Cutter, 1988).

The Smoking Cessation or Reduction in Pregnancy Trial

The Smoking Cessation or Reduction in Pregnancy Trial (SCRIPT) is a statewide evaluation research study (1997-2001) jointly conducted by the University of Alabama at Birmingham (UAB) and the ADPH and funded by the National Heart, Lung and Blood Institute of the National Institutes of Health (NIH). Its purpose is to document the effectiveness of tailored smoking cessation patient education methods based on Agency for Health Care Policy and Research (AHCPR) recommended practice routinely delivered by maternity care professionals: nurses, social workers, and nutritionists at each site. SCRIPT consists of three phases: the natural history study--Phase 1, the formative evaluation--Phase 2, and the effectiveness study--Phase 3. The trial is currently in Phase 3 and will continue recruitment through July 2000. SCRIPT Phase 1 and Phase 2 studies provided the data for the proposed deception substudy.

Significance of the Study

Maternity patient nondisclosure of cigarette smoking has been previously noted. Four years ago, the AHCPR released the <u>Smoking Cessation Clinical Practice Guideline</u> which includes recommendations to help pregnant women quit smoking (Fiore, Bailey, & Cohen, 1996). In addition to recommending that clinicians follow the 4 As (ask, advise, assist, and arrange) to help maternity patients quit smoking, AHCPR suggested that health care providers be aware that some pregnant women may try to hide their smoking status.

With the exception of Dolan-Mullen, Carbonari, Tabak, and Glenday (1991), the issue of developing methods to improve truthful disclosure and effectively identify pregnant smokers has received no attention in the literature. A randomized clinical trial was conducted to examine disclosure among a multiethnic (50% White. 33% Black. 15% Hispanic, 3% other) group of adult (\geq 18) maternity patients in Texas during their first prenatal visits. Mullen et al. compared the rates of disclosure with two channels of

questions (written and oral) and two response formats—the usual history question that elicits a "yes" or "no" response and a multiple choice question in which the patient is able to select one of five possible responses that explicitly described smoking status.

The experimental questions were substituted for usual questions concerning smoking, alcohol, and other drugs on the patient history form. Each session lasted 40 min and was conducted by trained nurse educators. Results indicate that, across all races and regardless of channel (oral and written), multiple choice questions improved disclosure by 40%. Urine COT tests biochemically confirmed the results that only 3% of the selfreported nonsmokers were smokers.

High patient deception rates of tobacco use have direct implications for prenatal care practice and health education evaluation research. On a patient level, deception produces underestimates of the prevalence of smoking during pregnancy if the rates are based on nonbiochemically confirmed self-reported data. At a practice level, health care professionals will not be able to provide evidenced-based treatments to patients (e.g., behavioral intervention or drug therapy) if they are not aware of the patients' routine exposure to this risk factor. A thorough review of the smoking cessation and pregnancy literature and contact with ongoing research revealed that no study of this type has been reported. This study is unique because patient deception rates will be documented at entry into maternity care.

Study Objectives and Research Questions

The objective of this study was to assess the validity and reliability of patient selfreports (survey) and biochemical test (saliva COT analyses) data among maternity patients whose care is supported by Medicaid. This research addressed four questions:

 What proportion of a representative sample of obstetrical patients served by the ADPH accurately report smoking status at entry into maternity care? Research Question
 was answered with data from NHS 1 and NHS 2.

2. Does patient response to questions of smoking status vary by ADPH service provider asking the question: social worker, nutritionist, nurse? Research Question 2 was answered with data from NHS 1 and NHS 2 chart reviews.

3. What reasons do the ADPH maternity staff cite for patient nondisclosure of tobacco use? Research Question 3 was answered with data from the formative evaluation focus groups.

4. What reasons do the patients cite for nondisclosure of tobacco use? Research Question 4 was answered with data from NHS 2 patient satisfaction telephone interviews.

Answers from Questions 1 to 4 provided information from which recommendations were made to modify ADPH prenatal care service delivery so that a more accurate disclosure of tobacco use by patients is possible.

CHAPTER 2

REVIEW OF RELEVANT LITERATURE

Multiple evaluation studies of smoking cessation methods during pregnancy have observed high deception rates (Gebauer, Kwo, Haynes, & Wewers, 1998; Gielen et al., 1997; Kendrick et al., 1995; Petersen, Handel, Kotch, Podedworny, & Rosen, 1992; Secker-Walker et al., 1994; Walsh, Redman, Brinsmead, Bryne, & Melmeth, 1997; Windsor et al., 1993). The purpose of this study was to assess nondisclosure rates using both quantitative and qualitative research techniques on entry into maternity care. This insight is important to clinical and health education practice because it will help to clarify how to change current tobacco assessment procedures in clinic settings to more accurately identify pregnant smokers.

This literature review includes a synthesis of studies about nondisclosure of smoking status among nonpregnant populations and a discussion of tobacco use measurements. In addition, this chapter provides a summary of evaluation research smoking cessation during pregnancy studies that have used self-report and biochemical confirmation citing deception rates, if collected.

Deception Studies in Nonpregnant Populations

Since the late 1970s, editorials and articles have been published assessing the validity of self-reported smoking status primarily in adults who suffered from smoking-related illness, such as coronary artery disease or chronic pulmonary disease, and among

nonpregnant adolescents. Self-reports from adult postheart attack patients indicated that 63% quit smoking, but urine COT assays disclosed that 16% to 20% were still smokers (Wilcox, Hughes, & Roland, 1979). Adolescent cigarette smoking self-reports have been found to be both valid (Bauman, Koch, & Bryan, 1982) and invalid (Komro, Kelder, Perry, & Klepp, 1993). In one study of postpartum women, 17% of positive thiocyanate (SCN) tests were accompanied by reports of nonsmoking (Little, Uhl, Labbe, Abkowitz, & Phillips, 1986). Apseloff, Ashton, Friedman, and Gerber (1994) estimated that nearly 16% of people who volunteer for Phase 1 clinical trails and claim to be cigarette nonsmokers are daily smokers. Although investigators used a high urinary COT cutoff of 500 ng/ml because it has a sensitivity of 97% and specificity of 99% (Jarvis, Tunstall-Pedo, Feyerabend, Vesey, & Saloojee, 1987). These and other studies are briefly summarized below in Table 5.

Multiple psychosocial factors influence deception about tobacco use. Feelings of guilt and shame, the fear of being stigmatized, and simply being deceptive are suggested reasons why smokers increasingly choose not to reveal their smoking status to physicians (Squire, 1991). It has been almost 20 years since smoking was officially accepted as an addiction (USDHHS, 1980). Reidenberg (1994) has questioned why standard medical practice is not followed with nicotine addiction (i.e., routinely confirm the patient's claim of cessation with a urine test). Nondisclosure of smoking status became so common in smoking treatment clinics that many researchers began using biological markers to confirm their patients' claims to cessation (Kozlowski, Herman, & Frecker, 1980).

Table 5

Study	Sample description	Test	Cutoff	Deception rate
Ohlin et al., 1976	Illness	COblood	0.8%	19%
Sillett et al., 1978	Heart	COblood	<u>≥</u> 1.6%	Trial 1 = 22%
				Trial 2 = 40%
Wilcox et al., 1979	Heart	COT—urine	10 ng/ml	16% - 20%
Kirk et al., 1980	Heart	SCN-blood		42.9%
Ronan et al., 1981	Heart	CO-blood	<u>≥</u> 1.6%	8.8%
Little et al., 1986	PP women	SCNurine	> 0.8 umol/l	17%
Wagenknecht et al., 1992	Young adults, heart	COT-blood	≥ 14 ng/mL	4.4%
Klesges et al., 1992	Adults	COblood	<u>≥</u> 2%	4.2%
Apseloff et al., 1994	Nonsmokers	COT—urine	≥ 500 ng/mi	27%
Pokorski et al., 1994	Navy recruits	COT—urine	≥ 50 ng/ml	_1%
Note. $NA = not applicable; E = experimental; C = control; CO = carbon monoxide; COT$				

Deception Studies of Tobacco Use Among Adult Nonpregnant Populations

<u>Note.</u> NA = not applicable; E = experimental; C = control; CO = carbon monoxide; COT = cotinine; SCN = thiocyanate, PP = postpartum.

Truthful Disclosure Studies in Pregnant Populations

Klebanoff, Levine, Clemens, DerSimonian, and Wilkins. (1998) assessed the accuracy of self-reported smoking during pregnancy using serum COT assays for biochemical confirmation. A cutoff of 10 ng/ml identified as active smoker among the 448 participants. Results indicated that 95% of women who denied smoking and 87% of selfreported smokers reported their status correctly. Therefore, it was concluded that pregnant women provide accurate self-reports of cigarette use. Previous studies in the scientific literature provide additional evidence of the validity of self-reported smoking habits during pregnancy (English, Eskenazi, & Christianson, 1994; Pacifici et al., 1993; Parazzini et al., 1996).

Walsh, Redman, and Adamson (1996) also examined the accuracy of selfreported smoking status in pregnant women. The purpose of their study was to estimate the proportion of pregnant women misclassified as nonsmokers by usual-care midwives and to compare self-reported data with a biochemical measure. During their first visit, women attending a prenatal clinic in New South Wales were questioned about their smoking habits. Nonsmokers were approached by a midwife during their second visit to respond to questions regarding their smoking behavior during the first visit and within the last week. Patients provided a urine sample for COT analysis after completing the questionnaire. Of the 166 women who were classified as self-reported nonsmokers, 9 (5%) had urinary COT levels greater than 500 nmol/l. Based on the survey and the biochemical test, the estimated proportion of midwife-identified nonsmokers who could be reclassified as smokers was 7.4%.

Measurements of Tobacco Use

Self-Reported Data

Self-reported data refer to information derived from written or oral questionnaires of patient's tobacco exposure. Studies that use one or more of these methods are able to immediately review and assess subject responses for the purpose of preliminary analysis. It is the least expensive of the types of measurement (Aday, 1991; Windsor, Baranowski, Clark, & Cutter, 1994). The validity of self-report of patient smoking status has been questioned by numerous researchers (Patrick et al., 1994; Walsh et al., 1996). Major disadvantages to self-report include the inability to accurately recall exposure (recall bias) and the subject may purposely be dishonest (deception bias) about exposure or may not be willing to disclose the desired information (Haley & Hoffman, 1985; Luepker, Pallonen, Murray, & Pirie, 1989; Murray. O'Connel, Schmidt, & Perry, 1987; Solberg, 1997). Table 6 highlights published smoking cessation studies for pregnant women that used selfreport only to measure tobacco exposure at the onset and during care (Dolan-Mullen et

al., 1994; Windsor, Boyd, & Orleans, 1998; Windsor & Orleans, 1986).

Table 6

ŝ	Smoking	Cessation	Studies for	r Pregnant	Women: Self-Report	Measurement Only
-						

Study	Sample size	Quit Rates
Donovan et al., 1972-73	E = 263; C = 289	Not Reported
Baric et al., 1975	E = 63; C = 47	E = 14%; C = 4%
Loeb et al., 1983	E = 500; C = 500	E = 15%; C= 14%
Lilley & Forester., 1986	$E = 74^{a}; C = 73^{a}$	$E = 5.4\%^{a}$; $C = 1.4\%$
MacArthur et al., 1987	E = 493; C = 489	E = 9%; C = 6%
Madeley et al., 1989	E = 450; C = 390	E = 7.4%; C = 3.4%
Messimer et al., 1989	$E = 57^{a}; C = 60$	$E = 26.3\%^{a}; C = 13.3\%^{a}$
King et al., 1992	E = 951; C = 211	$E = 5\%^{a}; C = 5\%^{a}$
Lillington et al., 1995	E = 79; C = 146	$E = 12\%^{a}; C = 12\%^{a}$

<u>Note.</u> E = experimental group, C = control group, <u>C</u> = comparison group. Information compiled from Windsor and Orleans, 1986 and Windsor, Boyd, and Orleans, 1998.^a = Recalculated

Significant Other Reports

Significant other reports have been used to verify self-report in several smoking cessation studies among nonpregnant subjects (Cummings, Emont, Jaen, & Sciandra, 1988; Marlett, Curry, & Gordon, 1988; McLaughlin, Dietz, Mehl, & Blot, 1987). Often, the smoker provides the name and contact information of the spouse or partner, friend. family member, or coworker that he or she identifies as being able to corroborate the selfreported smoking status. This method of corroboration is advantageous because it is less expensive than biochemical validation. A disadvantage is that the significant other may have limited exposure to the smoker. However, if the significant other lives with the
subject, the smoking status may be known. It is possible that he or she will inadvertently provide a false report of smoking status (Emont, Collins, & Zywiak, 1991).

There is one study in the smoking cessation in pregnancy literature that used key informants to validate self-reported smoking status. A randomized controlled trial conducted at The University National Hospital in Norway used significant other reports to corroborate self-reported smoking status. The significant others were partners or close family members who accompanied the women to their ultrasound examination (at the 32nd week visit) and witnessed the patient's response to smoking. One hundred and four (experimental = 54 and control = 50) heavy smoking women (> 20 cigarettes per day) participated in this study. Twenty percent of the experimental group and 4% of the usual care (control group) quit smoking (Valbo & Nylander, 1994). No independent testing of patients was performed, so the accuracy of the significant other report is not known. This was a follow-up to a previous study that was conducted at Buskerud Central Hospital in Norway (Valbo & Schioldborg, 1994) and is presented later in this chapter.

Biological Sample Testing

It is of fundamental importance that public health research of tobacco exposure accurately monitor and measure personal levels. Four biochemical tests of body fluids, saliva, urine, blood, or expired air have been used to measure active and passive tobacco exposure among pregnant women by detecting the presence of SCN. COT, or CO. These biochemical markers have been compared to determine which test best distinguishes smokers from nonsmokers (Jarvis et al., 1987). Table 7 is provided to demonstrate that there are clear differences in the biochemical test values according to exposure level. Following Table 7 is a brief discussion of each test, including the costs, and a section on sensitivity and specificity.

Table 7

Biochemical markers	No exposure	Passive exposure	Active exposure
SCN			
Serum (µmol/1)	49.9	a a	123.9
Saliva (mmol/1)	1.3	a	2.5
Urine (µmol/1)	75.2		153.2
COT (ng/ml)			
Saliva	1.7	8	330
Serum	1.5	7.3	294
Urine	4.8	12.9	1448
СО			
ECO (ppm)	5.6	10.6	21.3
COHb (%)	0.9	3	4.1

Mean Values of Biochemical Markers by Exposure

<u>Note.</u> SCN = thiocyanate, COT = cotinine, CO = carbon monoxide, ECO = air expired carbon monoxide, COHb = carboxyhaemoglobin. Information compiled from Jarvis et al., 1987.

^a = Missing values

Sensitivity and Specificity

Self-Report

Patrick et al. (1994) conducted a meta-analysis of the validity of self-report of 26 studies. Using Medline, they found 26 studies containing comparisons between self-reported smoking and biochemical assessments (51 comparison studies were identified earlier). Studies restricted to pregnant women were excluded. A total of 36,830 subjects were included in the 26 studies and 51 comparisons. The sensitivity and specificity of self-reports were calculated for each study as measures of accuracy. Sensitivity is defined as

the ability of the test to correctly identify those who have the disease. Specificity is defined as the ability of the test to correctly identify those who do not have the disease (Gordis, 1996). Across all studies, the sensitivity of self-report was 87% and specificity was 89%, indicating that self-report of smoking status was accurate in many studies. Because COT-plasma had the highest specificity, it was recommended for use in community clinic-based intervention studies and with student populations to corroborate self-report.

Biochemical Tests

Jarvis et al. (1987) examined the sensitivity and specificity of COT, CO, and SCN (see Table 8). Air expired carbon and carboxyhaemoglobin have about the same specificity, but carboxyhaemo-globin was more sensitive. Serum SCN tests are most often used because they are more sensitive and specific than urine and saliva SCN. Saliva COT was the most sensitive and specific of the three COT tests. It was concluded that, although COT is the measure of choice, expired air-carbon monoxide is considerably cheaper and simpler to use in most clinical settings.

Table 8

Sensitivity and Specificity of Each Biochemical Marker

Biochemical marker	Cutoff value	Sensitivity % cigarette smokers	Specificity % nonsmokers
SCN	70	07	70
Serum (µmol/l)	/8	80	/9
Saliva (mmol/l)	1.64	86	63
Urine (µmol/l)	118	63	63

Table 8 (Continued)

Biochemical marker	Cutoff value	Sensitivity % cigarette smokers	Specificity % nonsmokers
COT (ng/ml)			
Saliva	14.2	99	82
Serum	13.7	97	81
Urine	49.7	98	83
СО			
ECO (ppm)	10	88	84
COHb (%)	1.7	92	82

<u>Note.</u> The cut-off value was chosen to minimize the number of misclassifications. SCN = thiocyanate, COT = totinine, CO = carbon monoxide, ECO = air expired carbon monoxide; COHb = carboxyhaemoglobin. Information compiled from Jarvis et al., 1987.

<u>CO</u>

Carbon monoxide is a poisonous gas that replaces oxygen in blood and reduces the flow of oxygen to the fetus. There are two methods to measure CO levels: air expired carbon monoxide (ECO) and carboxyhaemoglobin (COHb). Several factors can influence the amount of CO absorbed, including the type of cigarette consumed, the depth of inhalation, the frequency, and the amount. It may also be influenced by environmental exposures like marijuana or secondhand smoke or both. Carbon monoxide has a half-life of 3 to 5 hr and cannot detect active tobacco exposure from the previous day. A portable CO analyzer with additional supplies (t-valves and mouthpieces) and maintenance (calibration kits) can cost up to \$1,500 and provides an instant CO value that is measured in parts per million (ppm; Windsor, 1990). Although the common cutoff for a maternity patient to be considered a smoker is \geq 10 ppm (Jarvis et al., 1987; Vitalograph, 1998), Hartmann, Thorp, Pahel-Short, and Koch (1996) used \geq 5 ppm. Table 9 illustrates the cutoff values and sensitivity and specificity of both ECO and COHb.

Study	Sample size	Quit rates	Deception rates
Bauman et al., 1981	E = 36; C = 43	E = 6%; C = 3%	Not Reported
Burling et al., 1983	E = 105 (65);	$E = 10\%^{a}; C = 3\%^{a}$	Not Reported
	C = 104 (74)		
Price et al., 1991	$E_1 = 71; E_2 = 52;$	$E_1 = 5.6\%; E_2 = 3.8\%;$	7%
	C = 70	C = 1.4%	
Rush et al., 1992	E = 175; <u>C</u> = 144	E = 10.4%; <u>C</u> = 5.2 %	Not Reported
Hartmann et al., 1996	E = 107; C = 100	E = 20%; C = 10%	11%

Smoking Cessation Studies for Pregnant Women: Self-Report and Carbon Monoxide Measurement

<u>Note.</u> E = experimental group, $E_1 =$ Experimental group 1, C = control group, <u>C</u> = comparison group. Information compiled from Windsor and Orleans, 1986 and Windsor, Boyd, and Orleans, 1998.

a = Recalculated.

<u>SCN</u>

Thiocyanate testing for tobacco exposure is measured from traces of hydrogen cyanide in tobacco inhaled when a cigarette is smoked. Cyanide is metabolized in the liver and eliminated through the kidneys. Thiocyanate is in all body fluids--blood, urine, and saliva--and is measured by mass spectrophotometry analysis in micrograms per milliliter. In addition to tobacco, however, SCN is influenced by consumption of certain foods, such as nuts, beer, and green leafy vegetables. Despite these influences, SCN is a reliable test to confirm smoking status because of its long life in body fluids: 10 to 14 days without fluctuation. Therefore, active exposure (cutoff ≥ 100 ug/ml) can be detected even if a smoker quits 1 week prior to testing.

Windsor et al. (1989) examined the accuracy of SCN among pregnant women enrolled in a smoking cessation intervention study. Patients provided written self-reports and a saliva sample at the first prenatal visit, at a midpoint visit, and within 2 to 4 weeks of the due date. All participants were told that the saliva sample would validate their selfreport. Deception was only 6% (Windsor et al., 1989). It was concluded that saliva SCN is a particularly good measure because of the ease of saliva collection, its long half-life, and its cost effectiveness over COT. Currently, SCN costs about \$6 per test for lab analysis (Windsor, 1990).

Table 10

Smoking Cessation Studies for Pregnant Women: Self-Report and Thiocyanate Measurement

Study	Sample size	Body fluid	Ouit rates	Deception rates
Ershoff et al., 1983 Sexton & Hebel, 1984	E = 57; C = 72 E = 388; C = 395	Urine (E only) Saliva	$E = 28\%; C = 14\%^{a}$ E = 27%; C = 3%	Not reported Not reported
Windsor et al., 1982-84	$E_1 = 103; E_2 = 102;$ C = 104	Saliva	$E_1 = 14\%; E_2 = 6\%;$ C = 2%	6%
Mayer et al., 1990	E ₁ = 72; E ₂ = 70; C = 77	1/3 saliva at PP	$E_1 = 11\%; E_2 = 7\%;$ C = 2.6%	Not reported
Valbo & Schioldborg, 1991	$E_1 = 50; E_2 = 50;$ $E_3 = 50; C = 50$	Saliva	$E_1 = 16\%; E_2 = 6\%;$ $E_3 = 8\%; C = 6\%$	Not reported
Hjalmarson et al., 1991	E = 492: C = 231	Saliva at 34 weeks and PP	E = 12.6%; C = 8.6%; PP = 15.8%	Not reported

<u>Note.</u> $E = experimental group, E_1 = Experimental group 1, E_2 = Experimental group 2, E_3 = Experimental group 3, C = control group, <u>C</u> = comparison group, PP = Postpartum.$ Information compiled from Windsor and Orleans, 1986 and Windsor, Boyd, and Orleans, 1998.

^a = Self-report only.

<u>COT</u>

Cotinine is a metabolite of nicotine that can also be measured in serum, saliva, and

urine. Saliva COT is the most sensitive and specific of the three. Cotinine is not

influenced by environmental exposures other than tobacco and has a half-life of 12 to 18 hr. It is measured in nanograms per milliliter, with a normal cutoff value of \geq 20 ng/ml for smokers (SCRIPT uses a cutoff of \geq 30 ng/ml for smokers). Cotinine testing can be expensive and requires special lab techniques, immunoassay (\$25) or gas chromatography (\$35), and refrigeration storage (Windsor, 1990). New technology has been recently made available for assessment of COT in clinical settings. Serex, Inc. markets two NicoMeters, one to detect the presence of COT in urine and one to detect the presence of COT in saliva. Both NicoMeters are LabTab immunoassays that utilize gold particles coated with monoclonal antibodies and a series of avidity "traps" that allow for quantitative measurement. A positive result indicates the presence of COT in the saliva or urine. NicoMeter strips cost \$3.50 per strip. Cotinine is considered the measure of choice to estimate daily nicotine consumption (Curmings & Richard, 1988; Jarvis et al., 1987).

In 1991, Haddow, Knight, Kloza, Palomaki, and Wald used serum COT without self-report to assess smoking status in pregnancy among heavy smokers. This experimental physician-delivered trial used personalized patient COT level feedback as an intervention component; 2,700 (experimental = 1343 and control = 1357) patients participated in the study. The experimental group had a quit rate of 7.9%. The quit rate for control group and the overall deception rate were not reported.

Etzel (1990) conducted a review of the literature to evaluate the relationship between saliva concentration and self-reported tobacco smoke exposure in both active and passive smokers. Twenty-two articles were included in the final analysis. Specific information regarding population studied, reported tobacco smoke exposure, method of measurement, and COT concentrations was assessed. Results indicated that the saliva COT test provides a clear distinction between passive (5 to 10 ng/ml) and active (>10 ng/ml) levels of tobacco exposure. In addition, Etzel suggested that, based on saliva COT concentrations, the four categories of tobacco smoke exposure are A (COT = 0, no active, no passive); B (COT = < 10, no active, some passive); C (COT = 10-100, infrequent active, some passive); and D (COT = > 100, regular active, some passive). Tables 11 and 12 illustrate the smoking cessation studies for pregnant women that used saliva and urine COT.

Table 11

Smoking Cessation Studies for Pregnant Women: Self-Report and Saliva Cotinine

Sample size	Quit rates	Deception rates
E = 400; C = 414;	E = 14.3%;	Overall = 28%;
<u>C</u> = 100	C = 8.5%; <u>C</u> = 3%	E = 32%; C = 17%
\overline{E} = 125; C = 121	E = 6.2%; C = 5.6%	E = 32%; C = 48%
E = 84; C = 94	E = 15.5%; C = 0%	E = 19%
	Sample size E = 400; C = 414; C = 100 E = 125; C = 121 E = 84; C = 94	Sample sizeQuit rates $E = 400; C = 414;$ $E = 14.3\%;$ $\underline{C} = 100$ $C = 8.5\%; \underline{C} = 3\%$ $E = 125; C = 121$ $E = 6.2\%; C = 5.6\%$ $E = 84; C = 94$ $E = 15.5\%; C = 0\%$

<u>Note.</u> E = experimental group, C = control group, <u>C</u> = comparison group. Information compiled from Windsor, Boyd, and Orleans, 1998.

Table 12

Smoking Cessation Studies for Pregnant Women: Self-Report and Urine Cotinine

Study	Sample size	Quit rates	Deception rates	
Ershoff et al., 1989	E = 126; C = 116	E = 22.2%; C = 8.6%	4%	
O'Connor et al., 1992	E = 100; C = 109	$E = 12\%^{a}; C = 5\%^{a}$	16.7%	
Petersen et al., 1992	$E^{1} = 71; C = 78$	$E_1 = 19\%^a; C = 18\%^a$	25%	
Secker-Walker et al., 1994	E = 188; C = 226	E = 14%; C = 11%	25.6%	
Kendrick, 1995	E = 1467; C = 1767	$E = 3\%^{a}; C = 3\%^{a}$	E = 49%; C = 32%	

Study	Sample size	Quit rates	Deception rates
Walsh, 1997	E = 127; C = 125	E = 12%; C = 0%	E = 12%; C = 52%
Lowe, 1998	E = 44; C = 34	E = 9%; C = 0%	

<u>Note</u>. E = experimental group, C = control group, <u>C</u> = comparison group. Information compiled from Windsor, Boyd, and Orleans, 1998.

a = Recalculated.

A thorough review of the smoking cessation for pregnant women literature revealed that, since 1972. 9 out of 30 used only self-report to assess cigarette smoking status. The remaining 21 used either significant other reports (2 studies) or at least one type of biochemical test (19 studies) to confirm self-report. Of these 19 studies, 12 reported deception rates at follow-up. The estimated average deception at follow-up from all 12 studies is 34% for experimentals and 27% for controls (see Table 13). This summary confirms the critical need to document deception for all evaluation studies and at entry into care.

Table 13

Deception Rates for Evaluation Research in Pregnancy

Study	Sample size	Measurement	Deception rates
Price et al., 1991	$E_1 = 71; E_2 = 52; C = 70$	СО	$E_1 = 7\%; E_2 = 8\%; C =$
			7%
Hartmann et al., 1996	E = 107; C = 100	CO	E = 11%; C = 11%
Ershoff et al., 1989	E = 126; C = 116	Urine COT	E = 4%; C = 4%
O'Connor et al., 1992	E = 100; C = 109	Urine COT	E = 17%; C = 17%
Petersen et al., 1992	E = 71; C = 78	Urine COT	E = 25%; C = 26%
Secker-Walker et al.,	E = 188; C = 226	Urine COT	E = 26%; C = 26%
1994			
Kendrick et al., 1995	E = 1467; C = 1767	Urine COT	E = 49%; C = 32%

Study	Sample size	Measurement	Deception rates
Walsh et al., 1997	E = 127; C = 125	Urine COT	E = 12%; C = 52%
Windsor et al., 1993	E = 400; C = 414;	Saliva COT	E = 32%; C = 17%
Gielen et al., 1997	E = 125; C = 121	Saliva COT	E = 32%; C = 48%
Gebauer et al., 1998	E = 84; C = 94	Saliva COT	E = 19%; C = 19%
Windsor et al., 2000	E = 139; C = 126	Saliva COT	E = 10%; C = 10%
Windsor et al., 1985	$E_1 = 102, E2 = 103$	Saliva SCN	$E_1 = 6\%, E_2 = 6\%,$
	C = 104		C = 6%
Total = 13	E = 3262; C = 3450	Combined	E = 32%; C = 26%

Note. $E = experimental group, E_1 = Experimental group 1, E_2 = Experimental group 2, C = control group.$

CHAPTER 3

RESEARCH METHODS

The purpose of this study was to document the validity of disclosure of smoking habits among Medicaid-supported maternity patients at the onset of care. Quantitative and qualitative observational measures were applied to understand nondisclosure and to assess whether there was a significant change in SCRIPT deception rates over time (Gordis, 1996; Rothman, 1986). This study was important because patient truthful disclosure at entry into care has direct implications for prenatal care practice and health education evaluation research. SCRIPT was the appropriate data set to use for the analyses because counties and patients were randomly selected to eliminate selection bias and to assure representativeness.

Selection of Public Health Maternity Clinics and Obstetrical Patients

A representative sample of Alabama public health maternity care clinics and Medicaid-supported obstetrical care patients was randomly selected to reflect a census and racial variation. In 1994, ADPH maintained 86 clinics in 67 counties within 11 public health areas. A county had to have at least one or more pregnant smokers per week to be eligible. The 16 eligible counties were grouped into seven clusters based on the percentage of Black patients: Cluster 1--79% to 84%, Cluster 2--55% to 66%, Cluster 3--52% to 61%, Cluster 4--24% to 38%, Cluster 5--12% to 15%, Cluster 6--12% to 17%, and Cluster 7--30% to 31% (see Table 14). One county from each cluster was randomly

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selected to create a 20% representative sample of Alabama Medicaid maternity patients (see Table 15).

Based on a 1997 estimated smoking prevalence of 18% to 20%, investigators determined that approximately 1,400 to 1,600 (32,000 x .18 to .20 prevalence x .25 census) smokers will present for maternity care at the eight SCRIPT counties per year.

Table 14

_	% Black	County	<u>n</u> new	<u>n</u> Black	% 1st trimester	Estimated smokers*	Cluster
1A.	84%	Dallas	536	450	69%	9	1
1 B .	84%	Montgomery	1,303	1,095	68%	144	
2.	79%	Jefferson	3,902	3,083	61%	478	
3.	66%	Mobile	637	420	61%	108	2
4.	55%	Lee	626	344	59%	114	
5.	61%	Tuscaloosa	1,100	617	63%	184	3
6.	52%	Houston	812	422	57%	163	
7.	38%	Calhoun	962	366	64%	230	4
8.	24%	Shelby	506	121	65%	140	
9.	12%	Marshall	812	97	64%	236	5
10A.	4%	Cullman	547	22	70%	170	
10B.	15%	Walker	415	62	70%	117	
10.	12%	Dekalb	474	57	70%	137	6
11.	17%	St. Clair	403	69	70%	119	
12.	30%	Baldwin	402	121	73%	99	7
13.	31%	Covington	355	110	71%	86	
Total		-	13,792	7,510		2,585	
				(54%)		(18.7%)	

SCRIPT Eligible Counties: New Maternity Patients and Estimated Smokers, 1996

Note. Information compiled from ADPH, 1998.

⁴ = assumes a 32% White prevalence and a 7% Black prevalence for Medicaid patients.

Table 15

	%				% lst	Estimated	Public health
	Black	County	<u>N</u> new	<u>n</u> Black	trimester	smokers+	area
1.	79%	Jefferson	3,902	3,083	61	478	4
2.	55%	Lee	626	344	59	114	8
3.	52%	Houston	812	422	57	163	10
4.	38%	Calhoun	962	366	64	230	6
5.	4%	Cullman	547	22	70	170	2
б.	15%	Walker	415	62	70	117	l
7.	17%	St. Clair	403	69	70	119	5
8.	30%	Baldwin	402	121	73%	99	9
Total			13,792	7.510		2,585	
			_	(54%)		(18.7%)	

Original Eight Randomly Selected SCRIPT Counties: New Maternity Patients and Estimated Smokers, 1996

Note. Information compiled from ADPH, 1998.

* = assumes a 32% White prevalence and a 7% Black prevalence for Medicaid patients.

Natural History Study 1 (NHS 1) and Natural History Study 2 (NHS 2) Methods Research Question 1: What proportion of a representative sample of obstetrical patients served by the ADPH accurately report smoking status at entry into care?

The data source for Research Question 1 consisted of NHS 1 and NHS 2. The SCRIPT NHS 1 was conducted during the summer of 1997 (a) to document smoking rates among Medicaid-supported obstetrical patients at the onset of and during pregnancy, (b) to biochemically confirm the self-reported smoking rates, (c) to confirm normal patient quit rates during pregnancy, and (d) to document relapse rates during pregnancy of selfinitiated quitters (SIQs).

All patients who presented over a 4-week period at 1 of 11 SCRIPT sites (Baldwin [2], Calhoun [1], Cullman [1], Houston [1], Jefferson [4], Lee [1], St. Clair [1], and Walker [1]) for their intial prenatal care visit were asked by ADPH staff (nurses, social

workers, and nutritionists) to complete a baseline assessment form and to give a saliva sample (see Appendix A). Patients were told at the time of collection that the sample would be tested to confirm their self-reported smoking status by examining the COT levels in their saliva, and written informed consent was obtained (see Appendix A). Four hundred and forty-six new maternity intakes were screened at baseline (entry into care), and 431 agreed to participate in NHS 1 (97% participation rate, 14 refusals). Twenty-five percent of the patients self-reported current cigarette use.

The baseline assessment consisted of 13 questions related to demographics. smoking status, and other behavior risk factors related to smoking and pregnancy (see Appendix A). Question 5 on the NHS screening assessment elicited one of five possible responses on smoking status: (a) I smoke regularly now; (b) I smoke some now, but have cut down since I became pregnant; (c) I stopped smoking, after I found out I was pregnant; (d) I stopped smoking, before I found out that I was pregnant; and (e) I never smoked (Windsor, Woodby, & Russell, 1998).

The Dissertation Research

The high deception rates documented during the NHS 1 (see Table 23) served as the impetus for this dissertation. Because of the high deception rates, it was determined that a second NHS would be implemented as a comparison. This dissertation research was an observational study (Gordis, 1996; Rothman, 1986) that examined SCRIPT deception rates at two observation points over time. The difference in rates of the two natural history studies prompted further investigation to attempt an explanation of the documented differences. The methods for NHS 2 are described in the following sections and were comparable to the first NHS (see Appendix B).

Natural History Study 2 (NHS 2) Patient Sample

One county collected NHS data for 4 weeks from February-March 1998, and seven counties participated from November-December 1998. All patients were screened to confirm the prevalence, passive exposure, and smoking behavior rates among maternity patients upon entry into care for the NHS 2. The eligibility criteria for inclusion in this study were that each woman was pregnant and received prenatal care at a SCRIPT site for her initial visit for this pregnancy. The sample size for this research was unique because there was not one number that would appropriately represent the size needed for the analyses of each question. Therefore, each question had a separate sample size, based on the data previously gathered and the statistical needs of that particular question. The sample size in NHS 2 (N = 339) was roughly comparable to the observed NHS 1 (N = 431) at entry into care. The combined sample size (NHS 1 and NHS 2) was 770 patients.

Natural History Study Measurement and Instrumentation

The NHS protocol stated that, after signing the informed consent, patients were to provide saliva samples and complete brief one-page, self-administered baseline forms to document their smoking statuses, commitments to quit, health beliefs, and passive exposure. Patients were told during the informed consent review that their saliva was going to be tested. Maternity staff shipped the saliva-filled vials to UAB for storage. Samples were tested at Dartmouth Hitchcock Medical Center Laboratories using enzymelinked immunoassay (EIA) procedures for COT analysis. Enzyme-linked immunoassay relies upon the competition between free COT in the sample and COT bound to enzyme for antibody fixed to a polystyrene plate. Excess enzyme is washed away, substrate is added, and the measured absorbance in a microplate reader is inversely proportional to the amount of COT in the sample (D. Hougman, personal communication, October 15, 1998). A cutoff of \leq 30 ng/mL was used to identify a quitter or never smoker (Windsor et al., 1993). Patients were told during the informed consent review that their saliva was going to be tested.

Treatment of the Data

Patient demographic variables, such as county, age, race, fetal gestational age, passive smoke exposure in the home, smoking status, and number of cigarettes smoked, were examined using descriptive statistics. Demographic comparisons, including the number of cigarettes smoked and COT values, were made between NHS 1 and NHS 2. In addition, the samples were combined to provide an overall deception rate for both studies. Reliability or stability refers to the reproducibility of the results. Reliability was assessed by calculating a Pearson correlation coefficient for COT level and number of cigarettes smoked at baseline and follow-up. Only NHS 1 smokers were included because some NHS 2 smokers received the SCRIPT intervention baseline and follow-up. The quantitative data were analyzed using Statistical Package for the Social Sciences (1999).

Statistical hypothesis testing was conducted to determine whether the proportion of deceivers at entry into care from the NHS 1 was equal to the proportion of deceivers at entry into care from NHS 2. Given that the standard error was known, the most appropriate test for this question was to calculate a \underline{Z} score ($\alpha = 0.05$) and to determine

whether the probability of obtaining a value of \underline{Z} that was as extreme or more extreme than that observed (Fleiss, 1973). Then, $\underline{Z} = ((p_1-p_2) / {}^{\diamond}p(1-p)(1/n_1 + n_2))$ because the two samples were drawn from the comparable populations at the same sites.

Chart Review Methods

Research Question 2: Does the obstetrical patient's response to the question of smoking status vary by health professional posing the question (i.e., social worker, nutritionist, nurse)?

The data source for Research Question 2 consisted of chart reviews of two groups of patients--those who truthfully disclosed their smoking statuses and those who did not truthfully disclose (deceivers) their smoking statuses at entry into care. A deceiver was defined as a patient who self-identified as an exsmoker or never smoker and had a COT value (\geq 31) that was inconsistent with her self-report.

Chart Review Sample Selection

At baseline. 52 patients from NHS 1 and 10 patients from NHS 2 were identified as deceivers (23.8% and 5.3%, respectively). The two studies had significantly different deception rates, therefore suggesting that two different populations were represented. Charts were reviewed in the sites where deception was documented. At an 80% power, a total of 114 (52 deceivers plus 62 nondeceivers) charts were reviewed for NHS 1 and 99 (10 deceivers plus 89 nondeceivers) were reviewed for NHS 2. A total of 213 charts were reviewed for Research Question 2. Data were extracted from the nurse, social worker, and nutritionist assessment forms. A copy of these forms, as well as the form used to abstract the data from the patient charts, can be found in Appendix C.

Chart Review Analysis Plan

Permission was obtained from the ADPH to review charts from both studies. This subsample consisted of patients who truthfully disclosed their smoking statuses combined with those who did not truthfully disclose (deceivers) their smoking statuses at baseline. Information extracted from the charts included each patient's self-identified smoking status to the nurse, nutritionist, and social worker and the number of cigarettes smoked.

A one-way within subjects design (Figure 1) was arranged to determine whether the chart reviews suggest varying patient smoking status responses to the different professionals.

Response to smoking status question (R)			
Subject (S)	Nurse	Social worker	Nutritionist
1			
2			

Figure 1. Assignment of subjects in a one-way within subjects design.

Repeated measures (or a one-way analysis of variance) was selected because each patient was asked about her smoking status by the nurse, the social worker, and the nutritionist at different times during her initial prenatal care visit. Computation of the sum of squares (<u>SS</u>) and the mean square (<u>MS</u>) is needed for repeated measures analysis (Tabachnick & Fidell, 1996). Given the response is R and the subject is S, then the interaction of individual differences when responding the $F = MS_R/MS_R$ degrees of freedom = (r - 1), (r - 1)(s - 1).

SCRIPT Formative Evaluation

Qualitative Evaluation

Qualitative research is increasingly being used to gain insight about the human behavior. Open-ended questions are used so participants may express themselves without having to select a response from a provided list. An underlying assumption is that people who share common experiences also share psychosocial processes. These processes form core constructs that support, or inhibit, social processes as they are repeated over time (Creswell, 1998; Glaser, 1978; Glaser & Strauss, 1967; Strauss & Corbin, 1997). Qualitative inquiry was appropriate for this study because patient deception as it relates to smoking behavior among pregnant women has not been explained thoroughly in the literature. Based on the deception rate findings from NHS 1, there was a need for indepth research to explain why patients choose not to truthfully disclose and to discover whether patients are more likely to deceive a particular health care practitioner.

Maternity Staff Focus Group Methods

Research Question 3: What reasons do the ADPH maternity staff cite for patient nondisclosure of tobacco use? Research Question 3 was answered with data from the formative evaluation focus groups.

Maternity staff focus groups were conducted by SCRIPT investigators (Dr. Crawford and Dr. Woodby) as a part of the SCRIPT Formative Evaluation during the winter of 1998. Although the groups primarily focused on intervention strengths and weaknesses, there was also a discussion about overall program improvement that included an attempt to further understand deception.

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Staff Focus Group Sample

Research Questions 3 and 4 required qualitative analyses, and, unlike quantitative analyses, there are no formulae for sample size estimation in qualitative inquiry. The sample size depends on the purpose of the study, what is known, what will be useful information, what will have credibility, and what can be done within the available time and resources (Patton, 1990). Maternity staff including nurses, social workers, and nutritionists participated in the focus groups. One focus group (8 total) was conducted at each SCRIPT site with the maternity staff (23 participants) for approximately 1 hr.

Focus Group Field Guide Development

Grounded theory methodology has been used in qualitative research to generate or discover a theory (Strauss & Corbin 1997). Grounded theory research typically includes repeated 20- to 30-min interviews with open-ended questions. The purpose of the interviews is to further understand previous findings and to identify information that continues to offer an understanding of the findings until no more information can be found (Creswell, 1998). The staff focus group field guide questions were designed using the grounded theory approach in an effort to generate an explanation or theory for patient deception. The specific focus group question (see Appendix D) pertaining to deception was stated as follows: "Some women in the program reported that they quit smoking. and, yet, the COT levels in their saliva indicate that they are still smoking. What do you think might have been happening with those women?"

Focus Group Summarization Techniques

Cross-case analysis is a qualitative summarization technique that involves establishing a pattern by grouping together common answers from different people (Patton, 1990). Cross-case analysis was used to organize focus group responses into three general themes--fear, social desirability, and denial. These themes were generated or discovered after reviewing staff responses and were not predetermined. A summary of maternity staff interpretation of patient deception as it relates to cigarette smoking and suggestions for approaching the deceivers is presented in Chapter 4 (Table 33).

Patient Satisfaction Telephone Interview Methods

Research Question 4: What reasons do the obstetrical patients cite for nondisclosure of tobacco use? Research Question 4 was answered with data from NHS 2 patient satisfaction telephone interviews.

The telephone interviews were conducted by the investigator in November 1999 to further understand each deceiver's recollected experiences about completing the survey and providing the saliva sample. Based on advice from staff and previous telephone interviewing experience, it was determined the best approach to asking about deception would be to address the issue in the context of a health professional and clinic satisfaction survey. This approach allowed the investigator to utilize essential interviewing skills--gain trust, appear nonjudgemental, and appear neutral and unbiased (Ovretveit, 1998). The interviews lasted approximately 15 min, and patients were informed that the interviews were recorded for quality assurance purposes.

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Patient Telephone Interview Sample

All patients who did not truthfully disclose their smoking habits from NHS 2 (N = 10) were given the opportunity to respond to a telephone interview. Patton (1990) refers to this sampling procedure as criterion sampling because all of the patients met some criteria (deception) for inclusion. It was determined that NHS 1 deceivers would not be included in the telephone interviews because 2 years had passed since NHS 1 was conducted. Previous experience with attempts to contact patients by telephone confirmed a 47% contact rate (Russell, Woodby, Windsor, Crawford, Chisolm, Hardin, & DiClemente, manuscript in preparation). The contact rate of the telephone interviews for this study was 30%.

Telephone Interview Field Guide Development

Patient telephone interview field guide questions were also designed using the grounded theory approach. The field guide consisted of open-ended questions and elaboration probes that were designed to be conversational and interactive. Patients were asked 15 questions to assess patient-provider relationships. More specifically, they were asked about their comfort level with and trust in the nurse, social worker, nutritionist, and doctor; their self-efficacy to quit; and their current smoking status. In addition, patients were asked to offer an explanation as to why their COT level was higher than the \leq 30 level for quitters, nonsmokers, or both (see Appendix E).

Telephone Interview Summarization Techniques

The original analysis strategy was to analyze the interviews with case analysis by writing a case study for each patient and then to generate a theory for explaining nondisclosure of tobacco use during pregnancy based on the response to the deception question. Because only 3 out of 10 patients were contacted, the findings presented in Chapter 4 were not considered contributions to a possible theory and are presented in summary form as anecdotal findings.

CHAPTER 4

RESULTS

This study assessed the validity and reliability of patient self-reports (survey) and biochemical test (saliva COT) data among ADPH maternity care patients at entry into care. Data were obtained from multiple sources: two NHSs, patient chart reviews, staff focus groups, and patient telephone interviews. The results of the analysis are presented by research question.

Research Question 1: What proportion of a representative sample of obstetrical patients served by the ADPH accurately report smoking status at entry into care? Research Question 1 was answered with data from NHS 1 and NHS 2.

Descriptive Statistics

For NHS 1, 431 new maternity intakes were recruited from 11 sites, and 339 patients were recruited from 8 sites for NHS 2. Table 16 highlights patient recruitment distribution by site for both NHS 1 and NHS 2. Recruitment in NHS 2 decreased at all sites except Calhoun, Lee, and Jefferson County–Western. Although there was a site change because of Medicaid maternity care contract renegotiations, Calhoun County recruited the greatest number of patients for both studies (Health Department = 64 and Regional Medical Center = 82).

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Table 16

Natural History Study (NHS) Recruitment by Site	

County	NHS 1 (<u>n</u>)	NHS 2 (<u>n</u>)
1. Calhoun (HD)	64	a
2. Calhoun (RMC)	2	82
2. Houston	47	33
3. Lee	39	60
4. St.Clair	25	21
5. Walker	45	34
6. Cullman	55	28
7. Jefferson County-Western	40	59
8. Jefferson County-Bessemer	40	a
9. Jefferson County-Eastern	32	a
10. Jefferson County-Leeds	8	a
11. Baldwin	35	a
12. Covington	a	22
Total	431	339

<u>Note.</u> HD = health department, RMC = regional medical center.

a = site did not participate.

Natural History Study 1 and NHS 2 participants were comparable on the majority of demographics (see Table 17). A two-sided Wilcoxon test was used to determine statistical significance or nonsignificance for mean age, mean months pregnant. mean number of cigarettes per day, and mean COT. A binomial test for two proportions was used for percent Black and percent ETS. The racial distribution was primarily White and Black, with at least 55% of the smokers from both studies being White. In addition, the mother's average age was approximately 22 years old, and fetal gestational age was approximately 3 months for NHS 1 and NHS 2. Passive exposure was measured based on the number of smokers who live with the patient. The percentage of ETS exposure was very similar, NHS 1 = 58% and NHS 2 = 56% lived with one or more smokers. Active exposure was measured by determining the mean value of COT in the saliva and the mean number of cigarettes smoked daily. Only a 40% subsample of saliva was tested for COT in NHS 1 among patients who self-identified as never smokers. All saliva samples from NHS 2 were biochemically tested. Although the average number of cigarettes smoked per day is almost equal, the mean COT levels in NHS 1 (103.4 ng/ml) and NHS 2 (60.1 ng/ml) were statistically significant (p = 0.001).

Table 17

Natural History Study (NHS) Demographic Comparability

	NHS 1 <u>n</u> = 431	NHS 2 <u>n</u> = 339	p value*
Mean age	21.7 (<u>n</u> = 430)	21.5 (<u>n</u> = 339)	0.62
% Black	42.7(n = 431)	36.9 (n = 314)	0.09
Mean months pregnant	2.9 (<u>n</u> = 402)	2.8(n = 320)	0.77
% ETS in Home	58.3 (<u>n</u> = 426)	55.5 (<u>n</u> = 338)	0.30
Mean number of cigarettes per day (A+B)	9.3 (<u>n</u> = 106)	9.0 (<u>n</u> = 87)	0.69
Mean COT	103.4 (<u>n</u> = 261)	60.1 (<u>n</u> = 275)	0.00*

<u>Note.</u> ETS = environmental tobacco smoke, A + B = I smoke regularly now + I smoke some now, but have cut back since I became pregnant.

* = <u>p</u> < 0.001.

Table 18 further confirms the comparability of the two natural history studies. A

logistic regression analysis was performed on five of the six covariables--age, race, months

pregnant, COT, and home ETS exposure. The number of cigarettes smoked was rejected

by SPSS 9.0 because of the large number of missing cases within this co-variable.

Table 18

Logistic Regression Analysis Predictors of Study Participation

Covariable	Beta weight	Standard error	p value ^a
Age	-0.02	0.02	.43

Table 18 (Continued)

Covariable	Beta weight	Standard error	p value ^a
Race	0.30	0.20	0.14
Months pregnant	0.00	0.06	0.99
СОТ	0.00	0.00	0.00*
Home ETS	0.12	0.10	0.22

<u>Note.</u> ETS = environmental tobacco smoke.

a = Wald test statistic.

* = <u>p</u> < 0.01.

Additional Quantitative Analysis

Smoking Prevalence Comparisons

Smoking prevalence was measured by patient self-report of smoking status on the baseline surveys (Appendices A and B). The NHS screening assessments elicited one of five possible responses on smoking status: (a) I smoke regularly now; (b) I smoke some now, but have cut back since I became pregnant; (c) I stopped smoking after I found out I was pregnant; (d) I stopped smoking before I found out I was pregnant; and (e) I never smoked.

The differences in the self-reported smoking prevalence rates for NHS 1 and NHS 2 are presented in Table 19. Natural History Study 1 had a sample size of nearly 100 more patients than NHS 2. Both studies had at least 100 self-reported current smokers (A or B respondents), with the overwhelming majority of smokers being White (NHS 1 = 85%; NHS 2 = 84%). There was little to no difference between NHS 1 and NHS 2 in the percentage of SIQs (1% difference), exsmokers (5% difference), and never smokers (no difference). Patient self-reported smoking status was not statistically significantly different between the studies (p = 0.41).

Table 19

Smoking status	NHS 1	NHS 2	Total
Current smokers (A + B)	25%	30%	27%
White	85%	84%	85%
Black	13%	11%	12%
SIQs (C)	15%	16%	5%
White	52%	62%	57%
Black	48%	30%	40%
Exsmokers (D)	11%	6%	9%
White	80%	68%	76%
Black	18%	32%	22%
Never smokers (E)	49%	49%	49%
White	34%	35%	34%
Black	61%	56%	59%

Natural History Study Self-Reported Smoking Prevalence Results by Race

<u>Note.</u> Ten patients did not self-identify as White or Black for NHS 1, and 25 patients did not report smoking status for NHS 2. A + B = I smoke regularly now + I smoke some now, but have cut back since I became pregnant, SIQ = self-initiated quitters, NHS = Natural History Study.

The current smokers from both studies were comparable on all demographic variables (see Table 20). There was no significant difference between the two study cohorts on any of the variables.

Table 20

Demographic Comparability of Natural History Study 1 and Natural History Study 2 Current Smokers

Variable	Natural History Study 1 (<u>n</u> = 109)	Natural History Study 2 (n = 100)	p value
Mean age	22.8 (<u>n</u> = 109)	22.6 (<u>n</u> = 100)	0.94
Percentage Black	14.7% (<u>n</u> = 109)	11.0% (<u>n</u> = 93)	0.52

Table 20 (Continued)

Variable	Natural History Study 1 (<u>n</u> = 109)	Natural History Study 2 (n = 100)	p value
Mean months pregnant	2.7 (<u>n</u> = 99)	2.8 (<u>n</u> = 93)	0.34
Percentage environmental tobacco smoke (ETS) in home	71.6% (<u>n</u> = 109)	74% (<u>n</u> = 100)	0.86
Mean number of cigarettes per day	9.3 (<u>n</u> = 106)	8.9 (<u>n</u> = 86)	0.76
Mean COT	210.3 (<u>n</u> = 88)	185.0 (<u>n</u> = 82)	0.10

Deceiver Demographics, Deception Rate Comparisons, and Regression Analysis

Although the mean COT value for the combined NHS 1 and NHS 2 deceivers (151 ng/ml) was much higher than that observed in NHS 1 (103 ng/ml) or NHS 2 (60 ng/ml), other demographic characteristics (i.e., mean age, mean months pregnant, % ETS) in this subgroup were similar to those in the sample. Table 21 presents demographic comparison data for the combined NHS 1 and NHS 2 deceivers and nondeceivers, providing insight on how deceptive smokers are different from nondeceptive smokers. There was a statistically significant difference in the mean age (p = <0.05) and in the percentage of Blacks (p = < 0.05) between the deceivers and the nondeceivers. All other demographic variables were similar.

Table 21

Demographic Comparability of	of Deceivers and	1 Nondeceivers	for Natural	History	Study 1
and Natural History Study 2				-	

	Deceivers ($\underline{n} = 62$)	Nondeceivers ($\underline{n} = 209$)	p value ^a
Mean age	20.9	22.7	0.01*
Percentage Black	22.6	12.9	0.02*

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Table 21 (Continued)

	Deceivers ($\underline{n} = 62$)	Nondeceivers ($\underline{n} = 209$)	p value ^a
Mean months pregnant	2.5	2.8	0.19
Percentage environmental tobacco smoke (ETS) in home	56.5	72.7	0.19
Mean COT	151.2	198.11	0.10
a = Wald test statistic.			

Fifty-two participants from NHS 1 and 10 from NHS 2 who reported as SIQs or exsmokers or never smokers had COT levels greater than or equal to 31 ng/ml (Table 22). The two counties from NHS 1 with the most deceivers had no deceivers in NHS 2. As noted in Table 23, White women were more likely not to truthfully disclose their smoking statuses.

Table 22

Natural History Study 1 and Natural History Study 2 Deceivers by Self-Report

Study	Self-initiated quitters (C)	Exsmokers (D)	Never smokers (E)	Total
Natural History Study 1 ($\underline{n} = 52$)	21	20	11	52
Natural History Study 2 ($\underline{n} = 10$)	9	1	0	10
Total	30	21	11	62

Table 23

Natural History Study 1 and Natural History 2 Deceivers by Race

Study	White	Black	Total
Natural History Study 1	36.6%	12.8%	23.8%
Natural History Study 2	10.4%	0.7%	5.3%

Deception rates were calculated using the following formula:

$$\frac{\Sigma C + D + E \text{ with } > 30 \text{ COT level}}{\Sigma C + D + E}.$$

The overall deception rates were 23.8% (69 out of 290) for NHS 1 and 5.3% (10 out of 188) for NHS 2. These deception rates were significantly different. An unusually high \underline{z} score = 17 ($\underline{p} < 0.001$) was calculated, further supporting the idea that something occurred between NHS 1 and NHS 2 that substantially increased maternity patient disclosure of cigarette smoking. The total combined (NHS 1 and NHS 2) deception rate was 18.6% (79 out of 478). Insufficient samples were not included in the analysis (NHS 1 = 39.4% and NHS 2 = 18.9%).

Table 24 presents the demographic comparability of the deceivers from NHS 1 and NHS 2. There was no significant difference between the deceivers from NHS 1 and NHS 2.

Logistic regression analysis was executed to determine to what extent the covariables age, race, months pregnant, and COT level would predict deception. The number of cigarettes smoked was rejected by SPSS 9.0 because of the large number of missing cases within this variable. Table 25 shows the beta weight, standard error, and Wald statistic for each of these variables. Cotinine level was the only statistically significant variable in predicting deception. further confirming previously mentioned findings. In addition, the logistic regression results support the idea that some of the covariables that could predict deception may not have been measured (i.e., the patient's morals/values, the patient's comfort level, the history of the patient-provider relationship), and therefore could not be included in the analysis (J. M. Hardin, personal communication. October 19, 1999).

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Table 24

Variable	Natural History Study 1 (<u>n</u> = 52)	Natural History Study 2 (<u>n</u> = 10)	p value ^a
Mean age	21.0 (<u>n</u> = 52)	20.3 (<u>n</u> = 10)	0.56
Percentage Black	25.0 (<u>n</u> = 52	10.0 (<u>n</u> = 10)	0.21
Means months pregnant	2.6 (<u>n</u> = 48)	2.2 (<u>n</u> = 9)	0.79
Percentage environmental tobacco smoke	65.4 (<u>n</u> = 45)	80.0 (<u>n</u> = 10)	0.31
Mean number of cigarettes per day	^b ($\underline{\mathbf{n}} = 0$)	$b(\underline{\mathbf{n}}=0)$	0
Mean COT	156.5 (n = 52)	123.4 (<u>n</u> = 10)	0.19

Demographic Comparability of Natural History Study 1 and Natural History Study 2 Deceivers

^a = Wald test statistic, ^b = missing data, no valid cases to perform test.

Table 25

Logistic Regression Analysis Predictors of Deception

	Beta weight	Standard error	p value ^a
Age	-0.07	0.04	0.06
Race	-0.08	0.34	0.81
Months pregnant	-0.09	0.10	0.37
COT	0.00	0.00	0.00*
Home environmental tobacco smoke	0.08	0.15	0.62

^a = Wald test statistic.

* = <u>p</u> < 0.0001.

Six sites participated in both NHS 1 and NHS 2. Linked site analysis was performed for three of the six sites that had deception in both natural history studies. A comparison of deceiver mean COT levels by site is shown in Table 26. Each county had the same number of deceivers for both NHS 1 and NHS 2. The mean COT level was greater in each site for NHS 2.

Table 26

<u>Comparison of Deceiver Mean Cotinine Levels by Sites Participating in Both Natural</u> <u>History Study 1 and Natural History Study 2</u>

Study	St. Clair	Houston	Walker
Natural History Study 1	100 ng/ml (<u>n</u> = 1)	$110 \text{ ng/ml} (\underline{n} = 2)$	189 ng/ml (<u>n</u> = 3
Natural History Study 2	$124 \text{ ng/ml} (\underline{n} = 1)$	138 ng/ml (<u>n</u> = 2)	198 ng/ml (<u>n</u> = 3)

The results of a regression analysis of the deceivers for the three sites is in Table

27. There was no significant difference in the extent to which the covariables would

predict deception at these three sites.

Table 27

Logistic Regression Analysis of Deceivers for Three Sites Participating in Both Natural History Study 1 and Natural History Study 2

	Beta weight	Standard error	p value ^a
Age	-0.50	0.45	0.26
Race	12.84	60.70	0.83
Months pregnant	-0.41	1.10	0.71
COT	0.01	0.02	0.68
Home environmental tobacco smoke	0.01	1.18	0.99

a = Wald test statistic.

Test-Retest Reliability Results

Reliability means stability of the extent to which the same results will be produced if two observations are taken from the same participant at two different points in time (Windsor et al., 1994). Baseline and follow-up COT levels and number of cigarettes smoked data from NHS 1 self-identified smokers were used to determine the reliability of these measures. Table 28 shows the Pearson correlation coefficients that were calculated to determine the test-retest reproducibility for baseline and follow-up COT levels ($\mathbf{r} =$ 0.59), as well as baseline and follow-up number of cigarettes smoked ($\mathbf{r} = 0.56$). Both of the measures were significant ($\mathbf{p} < 0.01$) and, therefore, were observed to be reliability.

Research Question 2: Does the obstetrical patient's response to the question of smoking status vary by health professional posing the question (i.e., social worker, nutritionist, nurse)? Research Question 2 was answered with data from NHS 1 and NHS 2 chart reviews.

Table 28

Reliability of Cotinine Levels and Number of Cigarettes Smoked

	СОТ	No. of cigarettes
Pearson correlation coefficient	0.578	0.559
p value	0.000*	0.000*

Chart reviews from 11 sites within 9 SCRIPT counties were conducted during November 1999. Self-reported smoking status data were extracted from 213 charts, 54%

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from NHS 1 and 46% from NHS 2. Sixty-six percent of the charts were from White maternity patients, and 33% of the charts were from Black maternity patients. Table 29 presents the number of charts reviewed from each site by study.

Table 29

County	Natural History Study 1	Natural History Study 2	Total
Cullman	33	0	33
Houston	9	20	29
St. Clair	9	20	29
Walker	7	15	22
Lee	0	22	22
Covington	2	22	22
Calhoun	20	0	20
Baldwin	11	a	11
Jefferson County-Bessemer	9	a	9
Jefferson County-Western	9	0	9
Jefferson County-Eastern	7	a	7
Total	114	99	213

Number of Charts Reviewed at Each Site by Study

a =Site did not participate.

Table 30 presents the self-reported smoking status for each study by maternity care provider. Of the charts reviewed, a total of 60 patients self-reported as smokers for NHS 1, and 89 patients self-reported for NHS 2.

Overall, approximately 10% (21/213) of the patients' responses to nurse, social worker, and nutritionist were observed to be inconsistent or unreliable. As shown in Table 31, the rate varied by site, ranging from 0% to 18% unreliable responses.

Table 30

	Natural History Study 1		Natural History Study 2	
Maternity care provider	Smoker	Nonsmoker	Smoker	Nonsmoker
Nurse	21	77	26	61
Social Worker	19	89	31	66
Nutritionist	20	80	32	54
Total	6 0	246	89	181

Patient Self-Reported Smoking Status to Maternity Care Provider by Study

Table 31

Percentage of Patients With Unreliable Responses by Site

County	Number of unreliable responses	Total number of responses	Percentage
Cullman	2	33	6.1
Houston	1	29	3.4
St. Clair	4	29	13.8
Walker	4	22	18.2
Lee	0	22	0.0
Covington	4	22	18.2
Calhoun	2	20	10.0
Baldwin	2	11	18.2
Jefferson County-Bessemer	1	9	11.1
County	Number of unreliable responses	Total number of responses	Percentage
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Jefferson County-Western	0	9	0.0
Jefferson County-Eastern	1	7	14.3
Total	21	213	9.9

Table 32 shows the univariate repeated measures results for the chart review data. The Fisher's <u>F</u> ratio statistic for the provider effects was 0.74, and the Fisher <u>F</u> ratio statistic for the provider study was 1.80. Therefore, there was not a significant difference in patient's response to the question of smoking status whether the nurse, social worker, or nutritionist asked the question. In addition, there was no significant difference in patient responses to health care providers between NHS 1 and NHS 2 (<u>F</u> = 4.63).

Table 32

Univariate Repeated Measures Analysis for Chart Reviews

Source	Degrees of freedom	<u>F</u> statistic	p value
Provider	2	0.739	0.478
Provider by study	2	1.797	0.167
Study	1	4.631	0.033

Qualitative Evaluation

Research Question 3: What reasons do the ADPH maternity staff cite for patient nondisclosure of tobacco use? Research Question 3 was answered with data from formative evaluation focus groups.

Although there were eight separate focus groups at eight different sites, several common themes were offered as reasons or explanations for patient deception by maternity staff. Upon review of the focus group responses, specific staff comments were arranged by three general themes--social desirability, fear, and denial (Table 33). The overall consensus was that patients are not telling the truth because they want to avoid being reprimanded at that visit. Staff also suggested that patients are more likely to truthfully disclose to nurses than to social workers because of the social workers' perceived reputation of removing children from their homes.

Table 33

Maternity Staff Focus Group Responses

Theme	Staff response
Social desirability	"They know they shouldn't be smoking; they are telling you what you want to hear. They don't want a lecture."
	"Guilt they think they will be judged that they will be looked down on."
	"I feel they felt the pressure of someone in the medical field asking about their smoking and they thought they would be criticized. Everybody knows they shouldn't smoke when they are pregnant."

Table 33 (Continued)

Theme	Staff response
Fear	[They think] "Maybe I shouldn't say I do smoke because they might take my baby."
	"They may have thought they were going to be tested for marijuana."
	"They are afraid. This is a religious town a dry county. They've been in church and told not to smoke and have sex."
	"They are lying. They feel like they are going to get into trouble."
Denial	"My husband's first cousin has smoked as long as we've been together. She has never bought a pack of cigarettes in her life. She doesn't consider herself a smoker."
	"Some women are nonchalant about telling us, they don't think it's a big deal."
	"Maybe they think it [their exposure] isn't going to show up."

Note. From "A qualitative evaluation of intervention materials and methods for a smoking cessation program for pregnant women in Medicaid maternity care," by M. A. Crawford, L. L. Woodby, R. A. Windsor, and T. V. Russell. (Manuscript in preparation.)

Research Question 4: What reasons do the obstetrical patients cite for

nondisclosure of tobacco use? Research Question 4 was answered with data from NHS 2

patient satisfaction telephone interviews)

Although 10 deceivers from NHS 2 were eligible to participate in the telephone

interviews, the investigator was only able to interview three patients because of

disconnected telephones ($\underline{n} = 3$), unavailable ($\underline{n} = 2$), no phone ($\underline{n} = 1$), and relocation ($\underline{n} = 1$)

1). Because of the small number of respondents, the results of the patient telephone

interviews presented here are merely anecdotal and cannot be generalized to study

population.

Each of the contacted patients began her prenatal care during the first trimester.

Family planning and Women, Infant, and Children (WIC) supplemental nutrition program

are the services most often used. There was no difference among the patients in response to their comfort level with the maternity staff. All three stated that the health care providers (nurse, social worker, nutritionist, and doctor) were easy to talk to and that they explained things in an understandable manner. The patients also expressed that they believed the health care providers spend enough time with them. When asked about their comfort level when talking about personal things like cigarette, drugs, or alcohol use, all the patients stated that they felt comfortable discussing these things because of their longtime established relationships with the maternity staff. One patient responded, "Very comfortable because I know that those things are bad for the baby." Only two patients could decide which provider they were most comfortable speaking to: one said the social worker because she gave her a lot of good information, and the other said the doctor because she knew him from a previous pregnancy. In addition, all believed that they were treated well and that all patients are treated the same at the individual county health departments. Overall, the patients felt that the maternity staff were "good," "nice," and "helpful."

Three patients quit smoking during their pregnancy, and two have remained exsmokers since they gave birth. The patient who relapsed has a 7-week-old son and stated that she "only smokes a half a pack per day." All completed the baseline assessment and provided the saliva sample at the same time. They also understood that the sample was going to test for cigarette smoking and felt comfortable providing their saliva so that it could be tested. Two patients had COT levels equal to 151 ng/mL and 152 ng/mL, and one patient had a level of 31 ng/mL. When asked for an explanation of why the COT values did not suggest that they were exsmokers, one patient explained that she had "only quit a day or two earlier. So I guess that it was able to pick it up since it hadn't been long since I quit." The other two patients suggested their values must have been high because they live with smokers.

CHAPTER 5

SUMMARY, DISCUSSION, CONCLUSIONS, AND RECOMMENDATIONS

Because of the well-documented health risks associated with smoking cigarettes and the observation that smoking cessation interventions, especially during the first trimester, have been shown to reduce the risk (Fiore et al., 1996; Windsor, 1990), it is imperative that maternity patients truthfully disclose their smoking statuses to their health care providers during their initial maternity care visits. Patients who disclose their smoking statuses can receive the appropriate prenatal care and treatment. The purpose of this study was to assess the validity and reliability of patient self-report and biochemical test data among ADPH maternity care patients at entry into care. A summary, discussion and conclusions based on these results, and recommendations are presented in this chapter.

Summary

The following research questions were developed to assess the nondisclosure problem:

1. What proportion of a representative sample of obstetrical patients served by the ADPH accurately report smoking status at entry into maternity care?

2. Does the patient's response to the question of smoking status vary by health professional asking the question: social worker, nutritionist, nurse?

3. What reasons do the ADPH maternity staff cite for patient nondisclosure of tobacco use and how do staff suggest approaching patient deception?

4. What reasons do the obstetrical patients cite for nondisclosure of tobacco use?

Data from SCRIPT, a statewide evaluation research study conducted in Alabama, were analyzed to answer these questions. The SCRIPT was designed to document the effectiveness of tailored, smoking cessation patient education methods routinely delivered by maternity care professionals at each site: nurses, social workers, and nutritionists. Participants for this deception study were 770 new maternity care patients (Q1 and Q2), 23 public heath maternity care professionals (Q3), and 3 deceivers from NHS 2 (Q4).

All SCRIPT participants were asked to complete a smoking behavior survey and provide a saliva sample for COT analysis to confirm their self-report. Chart reviews were conducted on all patients who had COT levels that did not corroborate their smoking status, as well as on a number of patients who truthfully disclosed their smoking statuses. We determined how often patients provide inconsistent responses to the different health professionals within the same clinic. Maternity staff focus groups and patient telephone interviews provided qualitative insight about why maternity patients do not truthfully disclose their smoking status.

Data were analyzed using SPSS Version 9.0 software (1999). Analyses included descriptive statistics and cross-tabulations of demographic characteristics of the study population. Hypotheses testing procedures were applied (a) to determine whether the proportion of deceivers at entry into care from the NHS 1 was equal to the proportion of deceivers at entry into care from NHS 2 (\underline{z} score) and (b) to determine the relationship between patients response to smoking status and the health professional posing the

question (chi-square). Pearson correlation coefficients were calculated to determine the reliability of COT level and the number of cigarettes smoked. Summarization techniques were used to interpret qualitative findings.

Demographic characteristics, mother's age, race, gestational age, passive exposure, number of cigarettes per day for NHS 1 and NHS 2 suggested that the two study samples were comparable. Analyses revealed a significant difference ($\mathbf{p} = 0.001$) in the number of maternity patients who had COT values that did not corroborate their self-reported smoking status for NHS 1 ($\mathbf{n} = 52$) and NHS 2 ($\mathbf{n} = 10$). Both COT level and number of cigarettes smoked were found to be reliable measures among NHS 1 smokers. Patient chart reviews revealed no significant difference in the patients' responses to the question of smoking status when posed by various health professionals. In general, maternity care professionals believed that social desirability, fear, and denial contribute to patient deception. Deceivers stated that their exposure to secondhand smoke explained why they had COT values that did not confirm their self-report.

Discussion

Explanations for Differences in Deception

The high deception rate from NHS 1 (24%) was alarming and, thus, was the basis for conducting NHS 2 (5%). According to Windsor et al. (1994), three primary threats or biases to the validity of evaluation results must be ruled out: selection, measurement, and history. The following is a discussion of how each bias may or may not have contributed to the observed differences in the deception rate of NHS 1 and NHS 2.

Selection Bias

Selection bias refers to the representativeness of a sample or the extent to which the results can be applied to the defined population. Selection bias is comprised of four dimensions that include eligibility for an evaluation study, study refusals, study dropouts, and study lost to follow-up or attrition. A number of efforts were made to eliminate selection bias in SCRIPT. The eligibility criteria were the same for both natural history studies. Sites were randomly selected based on the number of new maternity intakes, estimated number of new smokers, and percentage racial distribution. All pregnant English-speaking prenatal care patients were eligible to participate. A demographic comparison of patients who refused to participate may show a difference in the characteristics of maternity patients who agreed to participate in NHS 1 (refusal rate = 3.4%) versus NHS 2 (refusal rate = 0.6%). Overall, the refusal rate was small and from both studies were White women in their early 20s. No follow-up data were measured and discussed in this research; therefore, participant dropout and attrition were not issues.

Measurement Bias

Measurement bias refers to the data collection process as well as the instrumentation used to assess a study sample. With the exception of one site (research assistant collected data at Western Jefferson) during NHS 2, ADPH maternity staff were responsible for informed consent and patient assessments (data collection). During the year and a half between the NHS studies, four original sites were excluded, two new sites were added, and some of the original maternity staff no longer worked at the SCRIPT sites. As a result, in three counties the maternity staff member who collected data for NHS 1 was not necessarily the same person(s) who collected for NHS 2.

Data collection measurement protocol for both studies included obtaining informed consent, assisting the participants with survey completion, and collecting a saliva sample from the participant for COT analysis. Although the biochemical test and the consent process did not change from NHS 1 to NHS 2, the survey instrument did change slightly. In addition, the survey instrument was reduced from two pages with 13 questions for NHS 1 (Appendix A) to a one page, 8-item survey for NHS 2 (Appendix B). The use of standard collection procedures and similar measurements decreased the potential for measurement bias as an explanation for the differences in the deception rates.

Historical Effects

Historical effects are the most plausible explanation for the observed differences in deception. Historical bias refers to the unplanned exposure to program methods and materials. There are three dimensions of this type of bias: external history, internal historical events, and treatment effects. The lines of communication between the SCRIPT staff and the ADPH site staff were established prior to implementing NHS 1. From the beginning, site staff have assisted in editing materials, including protocols, surveys, and consent forms. During the summer of 1997, maternity care staff were trained in patient data collection protocol, but they may not have been completely comfortable with the procedures (internal history). NHS 2 was implemented during the winter of 1998, almost a year and a half after NHS 1. By this time, staff had received additional formal (SCRIPT Pilot Study) and informal (SCRIPT retreats) training that increased their self-efficacy and

comfort levels with the data collection procedures. It also may have enhanced their patient communication skills and improved recruitment and disclosure rates. It is plausible that training and experience in implementation, plus the process of involving the staff in all major program decisions, was an "intervention." It may be the primary explanation for the significant differences in deception rates over time.

Lessons Learned From the Patient Chart Reviews, Staff Focus Groups, and Patient Telephone Interviews

Chart reviews determined whether prenatal care patients vary their responses to the question of smoking status depending on the health professional asking the question. Our results indicated that approximately 90% of patients provided consistent responses to maternity care providers. Of the 10% who did not, many patients were SIQs for 1 or 2 days prior to their initial visits. If they were heavy smokers, this may explain in part why some of their COT levels were equal to a smokers. In addition, it was not observed that these patients truthfully disclosed their smoking statuses to the maternity nurses more than to the social workers or the nutritionists. This finding supports the anecdotal comments from deceivers who stated that they felt comfortable talking to each of their providers about sensitive issues, such as alcohol, drug, and cigarette use. Deceivers stated that they were SIQs and exposure to secondhand smoke in their home was their explanation for their high COT levels. In contrast, this observation does not support the belief of several maternity care professionals who stated that patients may feel more comfortable disclosing to a nurse because she is perceived as genuinely concerned and responsible for helping the patient achieve and maintain a healthy lifestyle. Providers have suggested that health department social workers were more often perceived as Human Resource social workers

and that patients may have feared losing their baby or their Medicaid (Crawford, Woodby, Windsor, & Russell, in preparation).

The chart reviews also provided valuable insight about the functional value of smoking for Medicaid maternity patients. In this case, the functional value of tobacco use is defined as the physiological benefits, psychological benefits, or both derived from tobacco use as defined by the smoker (i.e., the reasons that a person gives for smoking). Chart progress notes told a reoccurring story of low income, uneducated, unemployed, often abused women who often live with at least four other family members in poor housing conditions. As previously observed, these patients were under a tremendous amount of stress and anxiety (Russell et al., 1998). Cigarette smoking may serve as a major source of stress relief for these patients and may represent one of the few things that they can control.

Conclusions

The importance of conducting NHSs was documented in this report. It allowed SCRIPT researchers to determine patient nondisclosure of smoking status at entry into care and to determine the effect of changes in patient assessment methods and materials. Significant differences in deception rates were observed between the studies in the percentage of patients with COT values that did not corroborate their self-report.

Focus groups to assess maternity staff beliefs were very useful. They provided valuable insight from the providers' perspectives about why patients do not disclose their smoking statuses--fear, social desirability, and denial. The telephone interviews with the deceivers from NHS 2 were designed to further understand the patient provider

relationship and the reasons why patients deceive. These responses, although only anecdotal, were not as useful because of the low contact rate, 3 out of 10 patients.

Our quantitative analyses and qualitative evaluation suggested that multiple historical events, planned and unplanned, contributed to the substantial decrease in the deception rate from NHS 1 to NHS 2. These events included several site or staff changes, or both, an increase in maternity staff skill and comfort level with SCRIPT procedures, and improved patient provider communication.

Recommendations

This section is divided into three parts: (a) recommendations for health education evaluation research, (b) recommendations for prenatal care practice, and (c) recommendations for future research in this area.

Recommendations for Health Education Evaluation Research

Based on the findings of this study, the following recommendations are offered for health education evaluation research:

1. Because the deception rates for NHS 1 and NHS 2 were significantly different, an NHS 3 should be conducted in 2000 to confirm the NHS 2 deception rate.

2. Patient focus groups should be conducted to assess patient(s) understanding of

the assessment questions and responses. For example, when a patient states that she quit smoking after finding out that she was pregnant, consider asking when she found out she was pregnant and how many days since she quit. This information may be useful in determining whether the patient is truly deceiving the provider. 3. Because of the small number of women who participated in the patient interviews, a study should be conducted to further examine the patient/provider relationship among Medicaid-supported maternity patients.

4. A study should be conducted to assess patient beliefs as they relate to the seriousness of smoking while pregnant and susceptibility of the potential health risks using the Health Belief Model (Becker, 1974; Rosenstock, 1990).

The Health Belief Model is suggested because it posits that maternal disclosure of smoking status is determined by the patient's assessment of perceived benefits of cessation and risk of illness versus the costs of cessation.

5. Future evaluation research studies should conduct natural history studies as the first phase of all studies.

Recommendations for Prenatal Care Practice

The following recommendations are suggested for prenatal care practice:

1. Prenatal care professionals should understand the risks associated with smoking during pregnancy and should be able to effectively communicate these risks to the mother.

2. Prenatal care professionals should be trained to improve patient communication skills which may decrease potential barriers to truthful disclosure.

3. Prenatal care professionals should conduct on-site biochemical screening as a routine part of the initial visit.

Recommendations for Future Research in This Area

The Deception Reduction Model for Providers was developed as a result of this dissertation research. The purpose of the model is to identify recent SIQs and to identify current smokers who do not initially truthfully disclose. Prior to implementing the model, providers should establish a positive, helping relationship with patients by discussing the need and importance of truth disclosure. Health care providers must then use their ears, eyes, and noses to determine whether a patient is deceiving. Does the patient sound unsure of her response to smoking? Does any part of her body (teeth, lips, finger nails) resemble that of a smoker? Does her breath or her clothes smell like cigarette smoke? The model should be tested for its efficacy to increase disclosure of cigarette smoking among maternity patients.

The ideal approach to reduce deception would be to use the Serex NicoMeter Strips described in Chapter 2. This has implications for reducing deception by providing immediate feedback and by providing quantitative documentation of smoking as a vital sign in patient charts. It is further recommended that NicoMeter strips be used either alone or in conjunction with the Deception Reduction Model for Providers (Figure 2) to assist maternity care providers in identifying pregnant smokers.



Figure 2. Deception reduction model for providers.

Note. AHCPR = Agency for Health Care Policy and Research, DRMP = Deception Reduction Model for Providers.

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APPENDIX A

SCRIPT IRB APPROVAL LETTER, SCRIPT NATURAL HISTORY STUDY 1 PROTOCOL, AND NHS 1 CIGARETTE SCREENING FORM

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Protection of Human Subjects

Assurance Identification/Certification/Declaration

(Common Federal Rule)

POLICY: Research activities involving human subjects may not be conducted or supported by the Departments and Agencies adopting the Common Rule (56FR28003, June 16, 1991) unless the activities are exempt from or approved in accordance with the common rule. See Section 101(b) the common rule for exemptions, institutions submitting applications of proposals for support must submit certification of appropriate institutional Review Board (IRB) review and approval to the Department or Agency in accordance with the common rule institutions with an assurance of compliance that: covers the research to be conducted on file with the Department, Agency, or the Department of Health and Human Services (INHS) should submit certification of IRB review and approval with each appleation or proposal unless otherwas advised by the Department of Agency, institutions with an assurance must submit an assurance and certification of IRB review and approval within 30 days of a writen request from the Department of Agency.

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4. Title of Applica	uon or Activity	5. Name of Principal Investigator, Program Director, Fellow, or Other	
Smoking C (SCRIPT)	essation Reduction in Pregnancy Trial	Richard Windsor, Ph.D.	
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S. The official signing be in certified that the information provided above is correct and that, as required induce reviews will be performed and certification will be previded (205)934–3789 (205)975–5977 (205)975–5977 (205)975–5977		The University of Alabama at Sirmingham					
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Authorized for local repression on		OFTIONAL FORM SIC (552) Sconsored by HHS/FHS/1-					

SCRIPT NATURAL HISTORY STUDY Patient Survey and Saliva Collection Methods

The following is a description of the methods to collect patient data and saliva samples on all new maternity intakes. Health department staff will:

- Verify that the County ID numbers on the vial and survey form are the same.
- Give the patient the vial with the cotton roll and the survey form to fill out.
- Ask the patient to read and initial the informed consent statement and to answer all the survey questions.
- Instruct the patient to remove the cotton roll from the vial and place it in her mouth between her cheek and gums. Ask her to get the cotton roll soggy. Do not bite or chew it. Ask her to do this while she completes the survey.
- After 3 to 4 minutes, ask the patient to put the soggy cotton roll into the vial and to cap the vial tightly.
- Review survey for completeness and to check that all responses are marked within the boxes.
- Initial the informed consent statement and write the patient's chart number on both pages of the survey.
- For all patients who respond to question #5 A. B, or C place the Cigarette Smoking Follow-Up Form Reminder in their cliant. A follow-up survey and saliva sample will be completed at their next prenatal visit (> 30 days from today's date).
- The saliva sample should immediately be placed in the refrigerator in the SCRIPT rack. UAE staff will arrange pick-up biweekly.
- The patient survey should be faxed to the UAE SCRIPT office before 5:00 p.m. each day. Fax number (205) 975-9811. The hardcopy should then be placed in the yellow SCRIPT file folder. Hardcopies will be collected at the end of the Natural History Study.

Methods for Patient Follow-up Visit

All patients who responded on the initial survey that they currently smoked or had quit after they found out they were pregnant will complete a follow-up survey and provide a saliva sample. This will be collected at the patient's next scheduled prenatal visit (\geq 30 days after initial visit). Health department staff will be alerted by chart reminder forms and by lists provided by the UAB SCRIPT staff as to patients requiring follow-up.

- Locate patient follow-up surveys and saliva collection vials in SCRIPT box. Patient's name and ID number will be on the individual envelopes.
- Please repeat the patient survey and saliva collection methods as previously described. Remove chart reminder from patient's chart.

6/11/97

Chart #	County ID	*	7
l agree to complete this am exposed to smoke. T	s survey about cigarette smoking. I This information is confidential.	will give a saliva sample to show h	ow mu
Patient Initials	Staff Initials	Date	
•	••Please mark X by only one respo	nse or fill in the box***	
1 147			
1. What is your age:			
2. Which group best des	cribes your race?		
_ Black Whit	e UHispanic UOthe	r	
3. How many months pr	regnant are you ?	Number of Months	
. Have you smoked a ci	garette, even one puff & thin the	last 30 days? Yes	
. Which statement best	asscribes your cigarette smoking r	low?	
a. I smoke regular	y now – about the same number a	s BEFORE I became pregnant.	
Number of cigar	ettes I smolle EACH DAY.		
) b. I smoke some no	ow, but I cut down on the number (of cigarettes Ismoke AFTER	
I became pregna Number of cigar	nt. ettes I smoke EACH DAY.		
c. I stopped emoki	ng AFTER I found out I was pregna	int - I am not smoking.	
] d. I stopped smoki	ng BEFORE I found out I was preg	nant - I am not smoking.	
e. I have NEVER su	ooked cigarettes. (Mark here if you	have only tried smoking)	
How many cigarette so DO NOT COUNT YOL	nokers live in the same house with IRSELF)	you?	

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	7. How is cigarette smoking handled where you live?
	No one smokes where I live - they smoke outside.
	Only special guests may smoke where I live.
	People may only smoke in certain rooms where I live.
	People may smoke anywhere where I live.
	8. How many of your family members and friends whom you see regularly are cigarette smokers?
	None A Few Some Most
	9. Do people you work with smoke around you?
	Yes
	No
	 I i den't work
	10. How sure are you that you could/can ston smoking for 24 hours?
	Not at all Very sure
	A little Very, very sure
	Joznewkat I do not smoke
	11. Do you use chewing/smokeless tobacco? Yes No
	12. In the last 7 days, how many days did you have an alcoholic drink (beer, wine, liquor)?
	Number of days
	13. Which best describes you?
	I do not drink alcohol (bu: not because of this pregnancy).
	I stopped drinking alcohol (beer, wine, liquor) because of this pregnancy.
	I drink alcohol (beer, wine, liquor).
	Chart # County ID#
5	MOKING CESSATION-REDUCTION IN PREGNANCY TRIAL (SCRIPT)
8	Fax Number (205) 975-9811
1	

85

APPENDIX B

SCRIPT NATURAL HISTORY STUDY 2 PROTOCOL AND NHS 2 CIGARETTE SCREENING FORM

SCRIPT NATURAL HISTORY STUDY II

Patient Survey and Saliva Collection Methods

- For <u>all new maternity intakes</u> attach their ALACLAS lab label to the CIGARETTE SMOKING SCREENING FORM.
- . Give patient the vial with the cotton roll and the survey form to fill out.
- Ask patient to read and initial the informed consent statement and to answer all the survey questions.
- Instruct patient to remove the cotton roll from the vial and place it in her mouth between her cheek and gums. Ask her to get the cotton roll soggy. Do not bite or chew it. Ask her to do this while she completes the survey.
- After 3 to 4 minutes, ask her to put the soggy cotton roll into the vial. Cap the vial tightly.
- Review survey for completeness and check that all responses are marked.
- · Initial the informed consent statement .
- For all patients who respond to question #1 YES recruit for SCRIPT. If the
 patient agrees to participate do not collect a second saliva sample.
- The salive same should immediately be placed in the refrigerator in the SCRIPT rack. Shipment COAS will occur on the 1st and 3st Monday of every month.
- The patient survey should be faxed to the UAE SCRIFT office. Fax number (205) 975-9811.
- The hardcopy should then be placed in the yellow SCRIPT file folder. Hardcopies will be shipped with saliva samples.

Patients Who Refuse to Participate

- If the patient refuses to participate in the Natural History Study please write "refused" on the survey form.
- Fax the survey to the UAB SCRIPT office at (205) 975-9811. This information will allow comparison with study participants.
- Place the hardcopy in the yellow SCRIPT file folder along with other surveys and ship with saliva samples.



CIGARETTE SMOKING SCREENING FORM

NHS2

HDATT4	PATIENT	LABEL	HERE
--------	---------	-------	------

I agree to complete this survey about digarefte smoking. I will give a saliva sample to show how much I am exposed to smoke. This information is confidential.

F	Patient initials Staff initials Date
	and and a second se The second sec The second se
1	. Have you smoked a cigarette, even one puff, within the last 30 days? Cites O No
2	. Which statement best describes your cigarette smoking new?
	O z. I smoke regularly now-about the same number as BEFORE I became pregnant Number of cigarettes I smoke EACH DAY
	G b. I smoke some now, but I cut down on the number of cligarettes I smore AFTER I became pregnant. Number of cligarettes I smore EACH DAY
	C c. I stopped smc+ing AFTER I found out I wills pregnant + I cm not smoking
	$C_{\rm c}$, is stopped smooting EEFORE Found out I was pregnant. Families motioning,
	\mathbb{C}^{-1} e. I have never smoked digarettes. (Mark here if you have only thed smoking)
:	How many cligarette smokers live in the same house with you? (20 NOT COLNT YOURSELF)
	04 01 02 03 04 crimere
4	How is digarette smoking handled where you live?
	C No one smokes where I live - they smoke outside.
	C Only special guests may smoke where t live.
	O People may only smoke in certain rooms where I live.
	O People may smoke anywhere i live.
5.	How many of your family members and friends whom you see regularly are cigarette smokers?
	O None O A few O Some O Most
٤.	Do people you work with smake around you? Oiyes OiNo Oil don't work.
7.	How sure are you that you could/can stop smoking for 24 hours?
	O Not at all O A little O Somewhat O Very sure O Very, very sure O I do not smoke
٤	How many months pregnant are you? Number of months
-	
No.	

1.1

APPENDIX C

CHART REVIEW ABSTRACT FORM, NURSE HEALTH ASSESSMENT, NUTRITIONIST HEALTH ASSESSMENT, AND SOCIAL WORKER HEALTH ASSESSMENT

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County

SCRIPT Smoking Status Chart Review Form

Please review the chart of each maternity patient listed below. Turn to the provided review date and fill-in "S" for smoker or "NS" for nonsmo: based on the patient's response to that particular health care provider. If the patient is a smoker, record the number of cigarettes smoked.

Patient Name	Chart	Date to	Social V	Vorker	Nu	'SC	Nutriti	ionist
	Number	Review	S or NS	// Cigs	S or NS	# Cigs	S or NS	# Cigs
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INITIAL EDC:			I MP Norma	lin: 🗆 T	imina Ci	Amount []	Duratio
	WKS=EDC /						00:0:10
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Name NUTRITION ASSESSMENT Date of Service WIC prenatal/Diabetes CHR # ANSWER ALL THE FOLLOWING QUESTIONS (May be completed by patient). CIRCLE Is your appetite for food (circle one): Good Fair Poor Na Yesi 2. Are you now or have you ever been on a special diet? Yes. Do you ever eat dirt, clay, cornstarch, ice, or other non-food items? No 3 . . . Does anyone besides yourself cook and grocery shop at your house? No Yes 2 Is your stove or refrigerator broken? Na 5 Yes -Are you away from home for meals? No Yes 6

7	Is diarrhea, constipation, nausea, or vomiting ever a problem?	No	Yes
8.	Are you taking any medicine that you bought at the store without a doctor ordering it?	No	NØ5-
9	Are you taking any medicine other than vitamins ordered by a doctor?	No	Yes
10.	Have you ever smoked cigarettes or used smokeless tobacco?	No	Yes:
11	If yes, are you an ex-smoker?; or smoking now?; #/24 hours Do you drink beer, wine, wine coolers, liquor, or mixed drinks? If yes, how often? (Circle one) Never, 1-2 Times a Year, 1-2 Times a Month.	Na	192
12	t or more Times a Wesk? When was your last drink? Have you ever used marijuana, cocaine, crack, or other street drugs? If yes, when was the last time?	No	Nes.
13.	Do you take vitamins?	No	Yes
14	Does your household use food stamps?	No	Yes

FOR WIC PRENATAL ONLY TO BE COMPLETED BY NURSE/NUTRITIONIST:



ALACLAS LABEL

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		ALACLAS LABEL
FOR DIAE	ETES ONLY TED BY NURSE/NUTRITIONIST ONLY.	Name
Type of Diabet Year diagnose Diabetic medic Personal and fi	er Mellitus Type I Type II Gestational d ations (name and dosage) amily histon; (circle all that apply): heart disease high blo	od pressure stroke high chalesteral diabetes
Other health p	reblems or medical complications?	
Does patient:	3. do foot care? When? b. cut toenails? Kow?	How?
	c. complain of any of the following in FEET or HANDS?	Circle all that apply) tingling burning numbress
	d. monitar blood glucose? If no, why not? It yes, haw?	
	e. test unne för ketones?	
	f. keep a written record of blood glucose results and take it to	the doctor?

FOOD INTAKE/FREQUENCY

Date	Milk/ Cheese 3-4 c	Meit & Substitutes 23	Fruits 2-4	Vegetables 3-5	Breads/ Cereals 9.11	Desserts/ Candy/Chips	Sodas/ Koolade	Colles Tea	Water	Alcohoi

ASSESSMENT/COMMENTS

		· · · ·					. .
		· _					·
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PLAN/INTERVENTION/EDUCATION

	· -	· -

• •

WIC Only: Breastleading

encourágeo?

Reinforcement

Referrals made (circle all that app'y) (mmunizations Food Stamps Medicaid Substance Abute Health Care

Substance Abuse Pamphlet given? Yes No.

counseling given? Yes _ No _

-

WIC CERTIFICATION DOCUMENTATION

Yes _ 32 _	Date			i
Yes	Nutritional Risk			
	Priority/Waiting List			
Yes _ Au _	Certified?			
	Ineligible/Termination Reason			
•,	Ineligible/Termination Notice Given			
	Food Package Code			
	Status Code	W/B	W/B	W/B
•	Required Education Topics			

ALACLAS LABEL

PSYCHOSOCIAL ASSESSMENT/CASE PLAN

Date of	Service	
CHR #	<u> </u>	

Explained and offered case management services. Patient accepted Yes / No. Date Accepted ______

Name

Include identifying information incorporating strengths and weaknesses. List problems/needs.

____ ____ -----..... (Continue on Progress Notes) CASE PLAN Develop plan of care to correspond with and address identified problems/needs. (Cantinue on Progress Notes) Title Signature ____ Date of Completion

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PSYCHOSOCIAL ASSESSMENT WORKSHEET

Name	<u> </u>	
Date of Service		
CHR #		

ALACLAS LABEL

EDC (if indicated): _____

		PSYCHOSOCIAL ASSESSMENT	NOTES
_		Circle "Y" es or "N" o as appropriate.	Description of lindings, assessment, etc.
		SOCIAL SUPPORTS	
N	Y	Good Relationship with Partner	
Y	N	Family Violence	
N	Y	Good Support System	
N	Y	Good Relationship with Relatives	
		COMMUNITY SUPPORTS	
N	Y	Transportation Adequate	
Y	N	Legal Assistance Needed	
N	v	Allends Blember of Church	
		Needs Referent for Community Services	
	N.	SHELLERVINO I NITION	
т 		Purelless or Soon to be Evicted	
v.	v	Litulities Connected	
,	Ň	Lives Alone	
	- 14 - V	Adenuate Food	
v	ý	Home Talenhone Massing Telenhone	
-	····		
	•	ECONOMIC STATUS	
¥	¥	Employed	
¥.	Y	Adequate Income	
v	Ŷ	Adequate Budgeting	
'	Ν	Public Benefits Needez	
		EDUCATIONAL NEEDS	
	Ν	Limited incomplete Education	
	N	Lance or Literacy Earriers	
	N	History of Special Education	
:	¥	Schoul Age Children Attending School	
-		EMOTIONAL/PHYSICAL HEALTH	
,	N	Mental Health Problems	
	N	Drug, Alcohol Use/Ab_ae	
ı	Y	Good Physical Health	
	Ν.	Topace: Use	
-			
	11	Cuttent Prennance Freits Answer	
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	N.	Cutsidentities Albert 11 - 25 https://www.hone	
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	P1	Protitions wereases - Franciscos	
	N	Ale Registration of the	
	N	Addescent Mother	
-			· · · · · · · · · · · · · · · · · · ·
	N	Needs Referral to Domar/Clinic	
	N	HIV Symptoms	
	N	Other HIV + Family 'Members/Partner	
	Y	Understands/Practices Safer Sex	
	۲	Medicaid/Health Insurance/VA Benefits	
	Y	Physical/Emotional Support Available	
	N	Needs Financial Assistance v/Medications	
	A 1	CHILD HEALTH ISSUES	
	11	Needs Referral to Domor/Specialty Clinic	
	Y .	Age-appropriate Dese opment	
	N U	Medical Symptoms of Ses	
	, T	Good Understanding Medical Condition	
	IN .	iveeus Financial Assistance with Medications/formula	

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APPENDIX D

MATERNITY STAFF FOCUS GROUP FIELD GUIDE DECEPTION QUESTION 6

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SCRIPT POST PILOT QUALITATIVE STUDY QUESTIONS FOR FOCUS GROUP DISCUSSION WITH SITE STAFF

1. Some women in the program report that they quit smoking and, yet, the cotinine levels in their saliva indicate that they are still smoking. What do you think might have been happening with those women?

November 4, 1997

APPENDIX E

PATIENT TELEPHONE INTERVIEW FIELD GUIDE

NHS 2 Patient Telephone Interview Field Guide Operations

- 1. How many months did you go to the _____ county health department for prenatal services?
- 2. What services do you use when you go to the _____ county health department?
 - a. I would like to ask you some questions about your most recent pregnancy. Tell me about your first prenatal care visit at the _____ county health department. You know, the visit when you saw all of the health care providers (nurse, social worker, and nutritionist) on the same day.
- 3. Tell me about your visit with the nurse.

How easy is it to talk to her about your health and health problems?

- a. Does she explain things in a way that you can understand? {Language, educational barriers}. (If no) What does she need to do differently?
- b. Does she spend enough time with you?

(If yes or no) Why do you feel that way?

How comfortable are you talking to her about personal things like cigarette, drug, or alcohol use? Why do you say that? {cultural barriers, communication problems could be due to patient or provider}

- a. What is it about her that makes you feel that way?
- b. Do you feel like she really listens to you and understands what your life is like?
- c. What could she do to make you more comfortable?

How much would you say you trust her with personal information about your life or lifestyle? Why do you feel that way?

- a. Have you ever held something back from her because you were afraid she might tell somebody? *{gossip, tell police, social services}*
- b. Have you ever held something back from her because you were afraid she might think badly of you?
- 4. Tell me about your visit with the social worker.

How easy is it to talk to her about your health and health problems?

- a. Does she explain things in a way that you can understand? *{language, educational barriers}* (If no) What does she need to do differently?
- b. Does she spend enough time with you?

(If yes or no) Why do you feel that way?

How comfortable are you talking to her about personal things like cigarette, drug, or alcohol use? Why do you say that? {cultural barriers, communication problems could be due to patient or provider}

- a. What is it about her that makes you feel that way?
- b. Do you feel like she really listens to you and understands what your life is like?
- c. What could she do to make you more comfortable?

How much would you say you trust her with personal information about your life or lifestyle? Why do you feel that way?

- a. Have you ever held something back from her because you were afraid she might tell somebody? {gossip, tell police, social services}
- b. Have you ever held something back from her because you were afraid she might think badly of you?
- 5. Tell me about your visit with the nutritionist.

How easy is it to talk to her about your health and health problems?

- a. Does she explain things in a way that you can understand? *{language, educational barriers}* (If no) What does she need to do differently?
- b. Does she spend enough time with you?

(If yes or no) Why do you feel that way?

How comfortable are you talking to her about personal things like cigarette, drug, or alcohol use? Why do you say that? {cultural barriers, communication problems could be due to patient or provider}

- a. What is it about her that makes you feel that way?
- b. Do you feel like she really listens to you and understands what your life is like?
- c. What could she do to make you more comfortable?

How much would you say you trust her with personal information about your life or lifestyle? Why do you feel that way?

- a. Have you ever held something back from her because you were afraid she might tell somebody? *{gossip, tell police, social services}*
- b. Have you ever held something back from her because you were afraid she might think badly of you?
- 6. Tell me about your visit with the doctor.

How easy is it to talk to him/her about your health and health problems?

- a. Does he/she explain things in a way that you can understand? {language, educational barriers} (If no) What does she need to do differently?
- b. Does he/she spend enough time with you?

(If yes or no) Why do you feel that way?

How comfortable are you talking to him/her about personal things like cigarette, drug, or alcohol use? Why do you say that? {cultural barriers, communication problems could be due to patient or provider}

- a. What is it about him/her that makes you feel that way?
- b. Do you feel like he/she really listens to you and understands what your life is like?
- c. What could he/she do to make you more comfortable?

How much would you say you trust him/her with personal information about your life or lifestyle? Why do you feel that way?

- a. Have you ever held something back from him/her because you were afraid he/she might tell somebody? *{gossip, tell police, social services}*
- b. Have you ever held something back from him/her because you were afraid he/she might think badly of you?
- 7. Of the providers you saw, who did you feel most comfortable speaking to? Why?

- 8. What words would you use to describe how you were treated at the _____ county health department?
- 9. Do you think that everyone is treated the same at the _____ county health department?
- 10. Did you want to quit smoking when you found out that you were pregnant? If yes, how sure were you that you could quit smoking cigarettes?

Not at all A little Some A lot

- Are you now a smoker?
 If yes, how many cigarettes do you smoke per day? _____
- 12. Do you remember holding a dental roll in your mouth and completing a creamcolored form that asked you about your cigarette smoking? Did you complete the form while you had the dental roll in your mouth or did you complete the form at a different time than when you held the dental roll in your mouth?
- 13. Tell me how you felt about holding the dental roll in your mouth.
 - a. What were you told about the dental roll?
 - b. (If she mentions the test) How comfortable did you feel with the fact that it would be tested for nicotine?
- 14. Tell me about completing the form that asked you about your cigarette smoking. [Wait.] You stated that you were not smoking cigarettes at that time, but your dental roll test value was _____. The normal test value for a smoker is >30. Why do you think your value was _____ if you were not smoking?
- 15. Is there anything else that I should have asked you about your maternity care or clinic experience?

GRADUATE SCHOOL UNIVERSITY OF ALABAMA AT BIRMINGHAM DISSERTATION APPROVAL FORM DOCTOR OF PHILOSOPHY

Name of Candidate	Toya Venice Russell
Graduate Program	Health Education/Health Promotion
Title of Dissertation	Assessing the Validity of Cigarette Smoking Status Among
	Medicaid Maternity Care Patients
<u></u>	

I certify that I have read this document and examined the student regarding its content. In my opinion, this dissertation conforms to acceptable standards of scholarly presentation and is adequate in scope and quality, and the attainments of this student are such that she may be recommended for the degree of Doctor of Philosophy.

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