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# Smoking in Pregnant Women Screened for an Opioid Agonist Medication Study Compared to Related Pregnant and Non-Pregnant Patient Samples

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# Abstract

**Background**—Little is known about the prevalence and severity of smoking in pregnant opioid dependent patients.

**Objectives**—To first characterize the prevalence and severity of smoking in pregnant patients screened for a randomized controlled trial, MOTHER (Maternal Opioid Treatment: Human Experimental Research), comparing two agonist medications; and second, to compare the MOTHER screening sample to published samples of other pregnant and/or substance use disordered patients.

**Methods**—Pregnant women (N=108) screened for entry into an agonist medication comparison study were retrospectively compared on smoking variables to samples of pregnant methadone-maintained patients (N=50), pregnant opioid or cocaine dependent patients (N=240), non-pregnant methadone-maintained women (N=75), and pregnant non-drug-addicted patients (N=1,516).

**Results**—Of screened patients, 88% (n = 95) smoked for a mean of 140 months (*SD*=79.0) starting at a mean age of 14 (*SD*=3.5). This rate was similar to substance use disordered patients and significantly higher compared to general pregnant patients (88% v. 22%, p < .001).

**Conclusion and Scientific Significance**—Aggressive efforts are needed to reduce/eliminate smoking in substance-abusing pregnant women.

### Keywords

pregnancy; substance abuse; pharmacologic treatment; opioid dependence; methadone; buprenorphine

# Introduction

In response to public education, smoking during pregnancy in the United States has declined over recent decades, nevertheless, 22% of pregnant women report current smoking (1).

Smoking while pregnant is a critical modifiable risk factor for pregnancy-related morbidity and mortality (2). Smoking tobacco during pregnancy increases the risks for adverse pregnancy outcomes and neonatal morbidity and mortality (3,4). Quitting smoking before or during pregnancy can substantially reduce or eliminate risks to women and their infants, yet only 18–25% of women quit smoking during pregnancy (5).

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In contrast to pregnant women in general, little is known about smoking and smoking cessation behaviors of pregnant women dependent on substances other than nicotine. Smoking rates among methadone maintained patients, are known to be exceptionally high (e.g., rates well over 90%) (6). In non-pregnant patients, peak smoking occurs after methadone administration (7) and methadone has been associated with dose-related increases in smoking (8). Because continued smoking is associated with adverse health effects (*for review* see 9), there is a need to address smoking cessation in substance-dependent populations (10). Opioid-dependent pregnant women who smoke are a group at especially high risk for medical complications and psychosocial problems (11). Despite data (e.g., 12) suggesting that smoking may be more harmful to the developing fetus than use of illicit drugs, and that the combination of smoking and illicit drug use is associated with worse birth outcomes than illicit drug use alone (e.g., 13), the additional health burden of cigarette smoking during pregnancy is often underestimated by health-care providers (14).

The two primary objectives of the present study were: first, to characterize the prevalence and severity of smoking in pregnant patients screened for a randomized controlled trial, MOTHER (Maternal Opioid Treatment: Human Experimental Research), comparing two agonist medications; and second, to compare the MOTHER screening sample to published samples of other pregnant and/or substance use disordered patients. To address the second objective, comparison samples were identified in the published literature. MedLine searches were conducted using key words such as "nicotine dependence", "smoking", "pregnancy", "substance abuse" and "United States". Search results were reviewed to identify reports with variables comparable in content and format to those in the MOTHER screened sample. Four samples were identified that had a target comparison sample and at least one variable of interest in common with the screened MOTHER sample: 1) pregnant methadone-maintained women (11); 2) pregnant opioid or cocaine dependent women (15); 3) non-pregnant methadone-maintained men and women (6); and 4) a nationally representative sample of pregnant women (1).

#### Methods

#### Sites

The parent of this secondary data analysis project is the multi-site MOTHER study examining the comparative safety and efficacy of methadone and buprenorphine in the treatment of opioid-dependence among pregnant women and their neonates (see 16). All study sites provide comprehensive care including addiction treatment.

#### **Participants**

Data were obtained from *N*=108 opioid-using pregnant women who completed the initial screening battery for potential admission to the MOTHER study between July 2005 and October 2007.

#### Procedures

All participants signed local IRB-approved informed consent for study participation. They subsequently completed a screening assessment battery, which included the Addiction Severity Index (17), Structured Clinical Interview for the Diagnostic and Statistical Manual Drug section (SCID-E; 18), and a Tobacco Dependence Screener (19).

#### Measures

**Demographic**—Age, ethnicity, marital status, current employment status and estimated gestational age at treatment entry were determined for the MOTHER screening sample from

the initial screening forms that were completed by all potential participants. This same information was extracted from each of the four articles, if available. To compare the MOTHER screening sample to the published samples, ethnicity, marital status, and current employment status were recoded into binary categories. Ethnicity was defined as: Black v. White/Other; Marital status was defined as: Currently married v. Never married, Widowed, Divorced or Separated; Current employment status was defined as: Employed (full or part-time) v. Non-employed.

**Tobacco Dependence Screener (TDS)**—All participants were administered the *TDS* (19) which assesses 10 symptoms of nicotine dependence. The TDS has good reliability and validity and better tobacco dependence screening ability (19) than the Fagerstrom Tolerance Questionnaire (20). Two additional items asked about time spent on activities needed to obtain cigarettes; and tolerance to nicotine's effects.

**Addiction Severity Index (ASI)**—All participants completed a modified ASI 5.0 (17), a semi-structured interview assessing lifetime and pre-treatment psychosocial functioning. For this study, individual items regarding cigarette smoking were compared between groups in order to examine participants' pre-treatment smoking characteristics.

Structured Clinical Interview for the Diagnostic and Statistical Manual Drug section (SCID-E)—Participants completed the SCID-E (18), a semi-structured interview assessing current and lifetime abuse and dependence on either drugs and/or alcohol diagnoses. For this study, current diagnoses were examined.

**Statistical Analyses**—Two different types of summary data were collected from the comparison articles (1,6,11,15): frequencies of categorical variables (e.g., gender) and means and standard deviations of continuous variables (e.g., age). Pairwise inferential comparisons between the MOTHER screening sample and a sample from one of the four articles were then conducted using the  $\chi^2$  goodness-of-fit test for categorical variables, and the independent-samples *t* test for continuous variables. [Single-sample *t* tests were used to compare the age of the MOTHER screening sample to the age of the pregnant drug-dependent (15) and non-pregnant methadone-maintained (6) samples, because standard deviations for these variables were not available in the respective articles.] The overall MOTHER screening sample (*N*=108) was used for comparisons with (15) and (1). The MOTHER screened smoking sub-sample (*n*=95) was used for comparisons with (11) and (6), which were publications where data were reported for current smokers only and not the sample as a whole.

## Results

#### Demographic and pre-treatment characteristics

The overall MOTHER sample characteristics are shown in Table 1. On average, they entered addiction treatment when 17.8 weeks pregnant (SD=6.3). Based on 105 [three participants did not complete the SCID assessment] participants, 98 (93%) of the MOTHER screening were opioid dependent, 27 (26%) were cocaine dependent, 7 (7%) were marijuana-dependent, and none were alcohol or benzodiazepine dependent. The characteristics of the sub-group of current smokers (n=95) are also shown in Table 1 (values in brackets). Their average gestational age at entry and their current drug dependence was similar to the total sample described above.

Compared to the methadone-maintained pregnant sample of which only current smokers characteristics were reported (11), the MOTHER screened smoking sub-sample had a

significantly lower proportion of Blacks and Unemployed. The MOTHER screening sample also had a significantly lower proportion of Blacks and unemployed than the pregnant drugdependent sample (15). The MOTHER screening sample did not differ on marital status compared to the other samples examined. Finally, the MOTHER screening smoking subsample was significantly younger compared to a methadone-maintained non-pregnant sample for which only current smokers data were reported (6). Interpretation of this finding is difficult as the pregnant sample included only child bearing age women and would of course be younger than the non-pregnant sample that comprises those who are past childbearing age. The categorical data presented in Goodwin et al. (1), prevented statistical comparison.

#### **Cigarette smoking**

Individual items on the TDS were examined for the 95 women in the MOTHER sample who indicated current smoking in the past 30 days before treatment entry on the ASI. Three smoking participants had incomplete TDS symptom data. [The number of symptoms for which there are available data are indicated by the denominator in the fractions that follow.] The symptoms endorsed were: 95/95 (100%) one or more withdrawal symptoms, 91/95 (96%) smoking more than intended, 84/95 (88%) felt dependent on cigarettes, 74/95 (78%) can't quit smoking, 73/95 (77%) craved cigarettes, 64/94 (68%) smoking despite health problems, 62/94 (66%) resumed smoking to avoid withdrawal symptoms, 50/95 (53%) indicated smoking tolerance, 50/95 (53%) time spent on activities needed to obtain cigarettes, 49/93 (53%) smoking despite having a serious illness made worse by smoking, 48/92 (52%) smoking despite psychological problems and 19/94 (20%) gave up work or social obligations to smoke.

Table 2 shows the ASI-derived cigarette smoking characteristics of the MOTHER screening sample compared to the other samples. The MOTHER screened smoking sub-sample, on average, did not differ on examined variables of age of smoking initiation, months of regular smoking or current smoking status from the methadone-maintained pregnant sample (11). The MOTHER screening sample, on average, did not differ from a drug-dependent pregnant sample (15) on examined smoking characteristics. In contrast, the MOTHER screened smoking sub-sample reported significantly fewer months of regular cigarette use compared to the non-pregnant methadone-maintained sample (6). This finding is likely related to the average age differences between the two samples.

Finally, the MOTHER screening sample reported a significantly higher rate of current smoking compared to the general obstetrical population (1); comparable data from (1) on additional variables of cigarette smoking were not available.

## Discussion

The percentage of pregnant participants screened for the MOTHER study who reported current cigarette smoking is more than four times higher than in the general pregnant population (1). The high rate of cigarette smoking is alarming because continued smoking during pregnancy is associated with diverse adverse health effects (4). The fact that this high rate of cigarette smoking did not differ compared to the other drug-dependent or methadone-maintained samples regardless of pregnancy status further illustrates the critical imperative to address cigarette smoking cessation in pregnant and non-pregnant substance-dependent populations (10), especially for those individuals who are opioid-dependent. Interestingly, comparing the MOTHER screening sample to any of the samples showed similarities in the average age [14 or 15 years] at which smoking was initiated and duration of continued smoking. These ages meet the definition of "young initiators." Those individuals who initiate smoking by age 15 compared to those who start smoking after this age, were less

likely to cease cigarette smoking and reported higher levels of nicotine dependence than the older initiators (21). The high rates of cigarette smoking at a young age in all samples emphasize the urgent need to focus smoking prevention messages toward youths. Specialized information and intervention for youth at risk for or already engaging in other substance use behavior may also be needed (22).

The MOTHER screening sample demonstrated both risk and protective factors for smoking during pregnancy. More women in the MOTHER screening sample were White and married compared to pregnant drug-dependent samples (15,23). Being White can predict smoking during pregnancy (24). Being unmarried has been among five independent factors related to cigarette smoking (25).

There are several limitations of this study. First, data were collected as part of a larger ongoing randomized double-blind study and previously-published data were used for comparative purposes. As a result, equivalent measures were not available across all the comparison samples. Like previous studies, this study relies on commonly used broadlydefined measures of smoking. A prospective trial examining smoking history and current smoking could include more comprehensive and sensitive measures and yield results supporting stronger conclusions. However, the present data are an important first step in the development of direct comparisons between smoking treatments for this patient population. Second, the sample sizes of the examined groups are variable and may limit the power to detect differences in some instances. However, this limitation is tempered by the fact that differences in the expected direction were observed on most measures of interest. A larger sample size would have allowed for participants to be further categorized according to smoking severity and perhaps yielded additional interesting outcomes.

Despite these limitations, the present study provides some of the first data examining the prevalence of smoking in pregnant women seeking opioid–agonist treatment. While the health risks of smoking during pregnancy are well known, future research must focus on several important issues. First, characterizing how these risks are exacerbated or mitigated in pregnant drug-dependent women. Second, how the addictive disorder that is the focus of treatment and smoking together fuel negative bio-behavioral outcomes in these women and their offspring. Third, developing and implementing effective behavioral and medication treatments to reduce and eliminate smoking over the course of pregnancy to improve maternal and child health is imperative.

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# Table 1

Demographic Characteristics of Samples Varying by Pregnancy and Drug-Dependence Status

|                            |   |   |  |   | Pregnant<br>General      |
|----------------------------|---|---|--|---|--------------------------|
| Variable Mean $(SD)$ or %  | MOTHER <i>N</i> =108 [ <i>n</i> =95<br>current smokers] | Pregnant Methadone-<br>Maintained (11) <i>N</i> =50 | Pregnant Drug- Dependent(15)<br>N=240  | Non-Pregnant Methadone-<br>Maintained(6) <i>N=</i> 75 women | Population(1)<br>N=1,516 |
| Age <sup>a</sup>           | 27.6 (6.2) [27.8 (6.3)]                                 | 29.5 (4.1)  | 28.0 ( <i>nr</i> )                     | 36 (nr)   |                          |
|                            |   | t(155) = -1.72<br>p = .087                          | t(106) = -0.67<br>p = .506             | t(94) = -12.69<br>p < 0.001                                 |                          |
| % Black <sup>a</sup>       | 20 [20]   | 80  | 98                                     | 40  |                          |
|                            |   | $\chi^2(1) = 50.14$<br><b>p&lt;.001</b>             | $\chi^2(1) = 144.42$<br><i>p</i> <.001 | $\chi^2(1) = 7.93$<br><i>p</i> <.005                        |                          |
| % Not Married <sup>a</sup> | 86 [85]   | 80  | 85                                     |   |                          |
|                            |   | $\chi^{2}(1)=.61$<br>p=.433                         | $\chi^{2}(1) = .04$<br>p = .837        |   |                          |
| % Unemployed <sup>a</sup>  | 86 [85]   | 98  | 88                                     |   |                          |
|                            |   | $\chi^2(1)=5.81$<br><i>p</i> =.016                  | $\chi^2(1) = 28.22$<br><i>p</i> <.001  |   |                          |
| Notes:                     |   |   |  |   |                          |

a'The results of the inferential tests reported directly below each line of descriptive statistics (either *t*, *df*, *p*, or  $\chi^2$ , *df*, *p*, respectively) is the test of difference between the MOTHER screening sample and the respective sample.

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The MOTHER screening sample used for the comparisons with (11) and (6) current smoking samples is N=95 as these are the participants who reported currently smoking. Values for this sub-sample are indicated in brackets; *nr*=not reported.

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# Table 2

Smoking Characteristics of Samples Varying by Pregnancy and Drug-Dependence Status

| Pregnant General<br>Population (1)<br>N=1,516                | 22                                      | $\chi^2(1) = 242.86$<br><i>p</i> <.001                                    |  |                        |  |                            |                          |                        |
|--|---|---|--|------------------------|--|----------------------------|--------------------------|------------------------|
| Non-Pregnant Methadone-<br>Maintained (6) <i>N=</i> 75 women | 100                                     | Not compared statistically as<br>only smokers were selected<br>for sample |  |                        | 240  | t(93) = -12.22<br>p < .001 |                          |                        |
| Pregnant Drug-Dependent<br>(15) N=240                        | 83                                      | $\chi^{2}(1) = 1.24$<br><i>p</i> =.266                                    | 15   | t(318)=-1.58<br>p=.114 | 136  | t(312)=0.20<br>p=.652      | 13                       | t(319)=0.52<br>p=.605  |
| Pregnant Methadone-<br>Maintained (11) <i>N</i> =50          | 88 (N=57)                               | $\chi^2(1)$ = .002<br>p=.964  | 14   | t(143)=0.00<br>p=1     | 151  | t(142)=.87<br>p=.385       | 17                       | n(143)=-0.68<br>p=.496 |
| MOTHER <i>N</i> =108 [ <i>n</i> =95 current<br>smokers]      | 88 [100]                                |   | 15 (3.2) [14 (3.5)]                                  |                        | 127 (84.1) [140 (79.0)]                      |                            | 14 (9.3) [18 (9.3)]      |                        |
| Mean (SD) or %   | % Reported current smoking <sup>a</sup> |   | Age at first cigarette use <sup><math>a</math></sup> |                        | Months of regular cigarette use <sup>a</sup> |                            | Cigarettes per $day^{a}$ |                        |

Note:

<sup>*a*</sup>The results of the inferential tests reported directly below each line of descriptive statistics (either *t*, *df*, *p* or  $\chi^2$ , *df*, *p*, respectively) is the test of difference between the MOTHER screening sample and the respective sample. The MOTHER screening sample used for the comparisons with (11) and (6) current smoking samples is N=95 as these are the participants who reported currently smoking. It should be noted that for (11), there were a total of N=57 participants that were examined for smoking status and all other data reported in (11) were based upon the N=50 smokers. Values for this sub-sample are indicated in brackets; nr=not reported. Page 8