



## Brief communication

## Accuracy of prenatal smoking data from Washington State birth certificates in a population-based sample with cotinine measurements

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## ABSTRACT

**Purpose:** To assess the accuracy of smoking data in contemporary U.S. birth certificates.**Methods:** We compared data on prenatal smoking as reported on Washington State birth certificates to cotinine measured in archived newborn screening dried blood spots for 200 infants born in 2007 (100 randomly selected from births to self-reported nonsmokers and 100 born to self-reported smokers). We estimated the sensitivity of the birth certificate data to identify prenatal smokers and the precision with which self-identified third trimester smokers report smoking levels.**Results:** Infants born to two (2%) mothers who reported they did not smoke during the pregnancy had whole blood cotinine concentrations consistent with active smoking by the mother (sensitivity 85%). Sensitivity of the birth certificate to identify reported smokers who continued to smoke throughout pregnancy was similar (89%). Among self-identified third trimester smokers whose infants' specimens were collected shortly after delivery, Spearman rho between infant cotinine and maternal-reported cigarettes/day in the third trimester was 0.54.**Conclusions:** Birth certificates may represent a viable option for assessing prenatal smoking status, and possibly smoking cessation and level among smokers, in epidemiologic studies sufficiently powered to overcome a moderate amount of exposure measurement error.

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## Introduction

Prenatal smoking is associated with several adverse infant outcomes [1], but it remains unclear whether it increases the risk of longer term outcomes, such as childhood cancer [2,3]. For uncommon outcomes that typically necessitate a retrospective study, public knowledge of smoking's adverse effects may exacerbate the potential for selection bias [4] and differential reporting [5] of prenatal smoking in epidemiologic studies. Birth certificate prenatal smoking data may circumvent these biases. Although generally obtained before disease onset or identification (e.g., in studies with linked death or cancer registry data), smoking is still self-reported and is generally underreported [6–18]. This too may bias results [19,20], but generally in a predictable, conservative manner.

To ascertain the magnitude of such bias, we compared birth certificate smoking data for 200 infants born in Washington State in 2007 to cotinine levels in their newborn screening dried blood

spots (DBS). Neonatal and maternal plasma cotinine are almost perfectly correlated [21] and techniques for assessing cotinine in DBS have been validated [22,23]. To date, relatively few studies [6,15,16] have attempted to validate the data collected since the U.S. National Standard for birth records was revised to include smoking level by trimester [24], and only a clinic-based study [17] used a biologic measure of smoking to validate (older) birth certificate data. Therefore, we conducted a population-based study to examine the accuracy of contemporary U.S. birth certificate data using a biologic measure of maternal prenatal smoking. Specifically, we assessed the nicotine metabolite cotinine in blood collected from these mothers' infants shortly after birth.

## Methods

## Identification of participants

All participants were live-born singleton infants with complete birth certificate smoking data and who provided blood for universal neonatal screening after a hospital delivery in 2007 in Washington State. Typically, six 14 mm DBS are collected on a single card before discharge, and the card is archived at the Washington State

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Department of Health after partial use for newborn screening. We required that at least two unused, fully saturated DBS be available: one to remain in the archives and one to assess cotinine. To ensure the quality of this gold standard, we applied the following inclusion criteria: (1) absence of maternal/child blood transfusion during the hospitalization; (2) delivery on the day of admission (to exclude mothers unable to smoke shortly before delivery, as the half-life of cotinine is as low as 8.8 hours among pregnant women [25]); and (3) initial blood collection within 48 hours of birth (the half-life of cotinine is 16.3 hours in newborns [26]). From birth records with complete data on smoking, we randomly selected 100 infants whose birth certificate indicated no maternal prenatal smoking and 25 infants from each of four maternal smoking groups: low (<10), medium (10 to <20), high (20 to <30), and very high ( $\geq 30$ ) mean cigarettes/day across each of the three trimesters.

#### Assessment of cotinine in DBS

We punched two 6.35 mm circles from the most saturated areas of each DBS, methanol-rinsing the punch between specimens. The Environmental Health Laboratory and Trace Organics Analysis Center at the University of Washington (Seattle, WA) assessed cotinine levels blinded to maternal-reported smoking. Assays were conducted in six batches, with three negative controls and two positive controls in each batch. Twenty-three (12%) of samples were split and assayed in duplicate (intraclass correlation = 0.9999). Cotinine levels were corrected for reagent blank values and spike recovery efficiency (92.5%–101.2%). Samples below the reporting limit (0.009–0.02 ng cotinine) were assigned half the limit for that batch. We reassayed one batch (18% specimens) using two less saturated punches from the same DBS; agreement was very good (Spearman  $\rho = 0.93$ ; 100% concordance when classifying mothers as smokers/nonsmokers).

To estimate the cotinine concentration, we assumed that each pair of punches contained 12.32  $\mu\text{L}$  of serum [27] and 28  $\mu\text{L}$  (0.028 mL) of whole blood (12.32  $\mu\text{L}/(1-0.56)$ , where 0.56 is the portion estimated for hematocrit [28] and clotting factors in capillary blood from a term neonate aged 1–3 days). The latter is similar to that used previously on adult DBS (12  $\mu\text{L}$  for one 6.35 mm punch [22]). We present cotinine concentrations as ng/mL whole blood for comparability to prior studies measuring cotinine in neonatal DBS [23,29].

#### Statistical analysis

We classified a mother as a true smoker if she reported having smoked any number of cigarettes in any trimester or if her infant's DBS contained cotinine greater than 5 ng/mL. We used this cut point because in adult DBS, cotinine 1–5 ng/mL can indicate high exposure to environmental tobacco smoke [22] and is nearly identical to the optimum cut point of 6 ng/mL determined in a recent study assessing cotinine in neonatal DBS [29]. We then identified how many of the 100 self-reported nonsmokers were true smokers and estimated the sensitivity of the birth certificate to identify true smokers. We estimated sensitivity as  $11/(11 + \text{number of self-reported nonsmokers who were true smokers})$ . In the present context, sensitivity is defined as the number of smoking mothers who reported that they smoked divided by the total number of smokers. Here we estimate the numerator as 11 because in 2007, 10% of Washington State birth certificates indicated prenatal smoking and therefore, given 100 self-reported nonsmokers (as included here), there would be approximately 11 self-reported smokers ( $11/111 = 10\%$ ).

Among reported smokers, we identified those who reportedly quit by the third trimester but continued to smoke. Finally, among

mothers who reported still smoking in the third trimester, we estimated the precision with which they reported smoking level by calculating Spearman rho [30] between cotinine (continuous) and reported third trimester cigarettes/day (continuous).

#### Protection of human subjects

Work was conducted after receipt of approvals from the Washington State and Fred Hutchinson Cancer Research Center Institutional Review Boards. Before release, specimens were anonymized by archive staff using a previously described protocol [31].

## Results

#### Characteristics of participants

Approximately half (48%) of the reported nonsmokers were non-Hispanic Caucasian; 30% were Hispanic (Table 1). The majority (82%) of reported smokers were non-Hispanic Caucasian. The mean elapsed time between infant birth and blood collection was less than 24 hours. Among self-reported smokers, mean cigarettes/day declined as the pregnancy progressed, but 76% said they still smoked during the third trimester. They consumed a mean of 14.7 cigarettes/day (standard deviation 10.9, Table 1; median 10, range 2–40 cigarettes/day, data not shown).

#### Cotinine and reported smoking status

Cotinine ranged from below the reporting limit to 169 ng/mL (Table 2). Mean, median, interquartile range, and maximum cotinine levels were markedly greater in infants whose mothers reported smoking during the third trimester (median 36.6, mean 45.7 ng/mL) than in infants whose mothers reported smoking only

**Table 1**  
Maternal and infant characteristics and smoking, by maternal prenatal smoking status on the birth certificate, Washington State 2007

Characteristics	Did not smoke during pregnancy	Smoked during pregnancy <sup>a</sup>
	<i>N</i> = 100 <sup>b</sup>	<i>N</i> = 100 <sup>b</sup>
	<i>n</i> (%)	<i>n</i> (%)
Mother's race/ethnicity		
Caucasian	46 (48)	81 (82)
Hispanic	29 (30)	7 (7)
Asian/Pacific Islander	13 (14)	3 (3)
African American	5 (5)	3 (3)
Native American	3 (3)	5 (5)
Male infant	53 (53)	56 (56)
Preterm (<37 wk)	3 (3)	5 (5)
Low birth weight (<2500 g)	1 (1)	3 (3)
	Mean (SD)	Mean (SD)
Birth to blood collection (h)	23.2 (8.8)	23.4 (8.3)
Cigarettes smoked/d <sup>†</sup>		
Before pregnancy <sup>‡</sup>	12.0 (11.3)	21.3 (14.6)
1st trimester	n/a	20.5 (14.9)
2nd trimester	n/a	17.9 (14.6)
3rd trimester	n/a	14.7 (10.9)

n/a = not applicable; SD = standard deviation.

<sup>a</sup> Twenty-five infants from each of the four maternal smoking levels (low (<10), medium (10 to <20), high (20 to <30), very high ( $\geq 30$ ) cigarettes/day).

<sup>b</sup> May not add to totals due to missing data; percent among those with complete data.

<sup>c</sup> Among those smoking during the specified period: two prenatal nonsmokers and 97 prenatal smokers who smoked before pregnancy; and 98 prenatal smokers who smoked during the first trimester, 82 during the second trimester and 76 during the third trimester.

<sup>d</sup> Three months before conception.

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