

# Infants Born to Opioid-Dependent Women in Ontario, 2002–2014

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## Abstract

**Background:** There is a paucity of data characterizing mother-infant pairs with prenatal opioid dependence in Canada. We therefore conducted a study of relevant births in Ontario from 2002 to 2014.

**Methods:** We used data from the Institute for Clinical Evaluative Sciences, the linked databases of coded population-based Ontario health services records. Differences in characteristics of opioid-dependent mother-neonate pairs and infant hospital costs by year were assessed using linear regression, and we calculated rates of preterm birth, low birth weight, birth defects, mortality, and neonatal abstinence syndrome.

**Results:** The number of infants born to opioid-dependent women in Ontario rose from 46 in 2002 to almost 800 in 2014. Methadone was most frequently used for prenatal opioid dependence; there was little buprenorphine or buprenorphine + naloxone use. Rates of preterm birth and low birth weight were high. The proportion of neonates with neonatal abstinence syndrome (58%) was stable over the study period. The mean length of neonatal hospital stay was 13.96 days. Infant hospital costs increased from \$724 774 in 2003 to \$10 539 988 in 2013, and the mean cost per infant grew from \$9928 to \$12 917. Birth defect prevalence was 75.84/1000 live births (95% CI 68.12/1000 to 84.10/1000). The stillbirth rate was 11.39/1000 births (95% CI 8.47/1000 to 14.99/1000), and the infant mortality rate was 12.21/1000 live births (95% CI 9.16/1000 to 15.95/1000).

**Conclusion:** We observed a 16-fold increase in the number of mother-infant pairs affected by opioid dependence in Ontario over the past decade. Adverse birth outcome rates were high. Expanded services for opioid-dependent women and their children are needed.

**Key Words:** Buprenorphine, methadone, pregnancy, neonatal abstinence syndrome

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Competing interests: None declared.

Received on August 25, 2016

Accepted on November 7, 2016

## Résumé

**Contexte :** Vu le manque de données caractérisant les couples mère-enfant avec une dépendance prénatale aux opioïdes au Canada, nous avons mené une étude sur les naissances pertinentes en Ontario de 2002 à 2014.

**Méthodologie :** Nous avons utilisé des données de l'Institut de recherche en services de santé, plus précisément des bases de données liées de dossiers de services de santé codés représentatifs de la population de l'Ontario. Nous avons évalué les différences dans les caractéristiques des couples mère-nouveau-né dépendants aux opioïdes et les coûts hospitaliers annuels pour les bébés à l'aide d'une analyse de régression linéaire, et nous avons calculé les taux de naissance prématurée, de poids insuffisant à la naissance, d'anomalie congénitale, de mortalité et de syndrome de sevrage néonatal.

**Résultats :** Le nombre de bébés nés de femmes dépendantes aux opioïdes en Ontario a augmenté, passant de 46 en 2002 à près de 800 en 2014. Le traitement le plus courant pour la dépendance prénatale aux opioïdes était la méthadone; l'utilisation de buprénorphine ou de buprénorphine et de naloxone était faible. Les taux de naissance prématurée et de poids insuffisant à la naissance étaient élevés. La proportion de nouveau-nés atteints du syndrome de sevrage néonatal (58 %) était stable tout au long de la période à l'étude. La durée moyenne des hospitalisations en néonatalogie était de 13,96 jours. Les coûts hospitaliers pour les bébés sont passés de 724 774 \$ en 2003 à 10 539 988 \$ en 2013, et le coût moyen par bébé est passé de 9 928 \$ à 12 917 \$. La prévalence des anomalies congénitales était de 75,84/1000 naissances vivantes (IC à 95 % : 68,12/1000 à 84,10/1000). Le taux de mortalité était de 11,39/1000 naissances (IC à 95 % : 8,47/1000 à 14,99/1000) et le taux de mortalité infantile était de 12,21/1000 naissances vivantes (IC à 95 % : 9,16/1000 à 15,95/1000).

**Conclusion :** D'après nos observations, le nombre de couples mère-enfant touchés par la dépendance aux opioïdes en Ontario s'est multiplié par 16 au cours de la dernière décennie. Les taux d'issue négative de la grossesse étaient élevés. Il faudrait donc élargir la gamme de services offerts aux femmes dépendantes aux opioïdes et à leurs enfants.

## INTRODUCTION

The problem of opioid use and addiction during pregnancy has become prominent in recent years.<sup>1,2</sup> Compared with the outcomes in unexposed infants, prenatal opioid exposure is associated with adverse perinatal outcomes and increased health care costs.<sup>3</sup> Placental transmission of illicit opioids and opioid agonist therapies such as methadone and buprenorphine leads to fetal dependence and neonatal withdrawal (neonatal abstinence syndrome).<sup>4</sup> NAS affects neonatal adaptation in critical areas of sleep, feeding, and autonomic function.<sup>5,6</sup> Neonates with severe NAS require prolonged hospitalization and pharmacotherapy with unknown long-term effects.<sup>7</sup>

The incidence of NAS rose in Canada from 0.28/1000 live births in 1992 to 4.29/1000 in 2011.<sup>2</sup> Rates of NAS also increased in the United States, with annual hospital charges for NAS rising from \$190 million to \$720 million.<sup>8</sup> Canadian hospital costs have not been reported, and Canadian data on NAS are limited.<sup>2</sup> The largest Canadian study to date compared how opioid use for pain and prescription opioid misuse contributed to NAS but was not specific to mother-infant pairs with opioid dependence.<sup>1</sup>

Characterizing opioid-dependent mother-infant pairs in the Canadian context is important because of differences in population characteristics, insurance for health care, and available treatments compared with other settings. Prenatal buprenorphine (Subutex; Indivior Inc.,

Richmond, VA) is widely used in Europe and the United States<sup>9–12</sup> but is available only under exceptional access in Canada. Buprenorphine + naloxone (Suboxone; Indivior UK Ltd., Slough, United Kingdom), the formulation of buprenorphine for non-pregnant patients, has been listed on the Ontario drug formulary with a limited use code since 2013 and has been available under exceptional access since 2011. Early studies suggested potential for fetal harm from buprenorphine + naloxone exposure,<sup>13–15</sup> although data are emerging to support buprenorphine + naloxone use in pregnancy.<sup>16</sup> Methadone treatment, historically the gold standard for opioid dependence in pregnancy, is available in Canada.

The aim of this study was to characterize the prenatal management and outcomes of opioid-dependent women and their infants in Ontario. Available population-based data permitted systematic study of NAS in a large number of mother-infant pairs.

## METHODS

Data from the Institute for Clinical Evaluative Sciences were used to study births to opioid-dependent pregnant women in Ontario. The ICES data comprise the linked databases of coded universal coverage health service records for Ontario residents who are members of the Ontario Health Insurance Program. Opioid-dependent women and their infants delivered between April 1, 2002, and December 31, 2014, were included in the study. Maternal opioid dependence in pregnancy was defined by a diagnosis of opioid dependence in the two years before delivery. Codes specific for opioid dependence were ICD-10: F11.0 to F11.9 and ICD-9: 30401, 30403, 30471, 30473, 30400, 30402, 30470, 30472. Women with codes for multiple substance use (ICD-10: F19.0 to F19.9) and unspecified drug dependence (ICD-9: 2920, 30481, 30483, 30480, 30482, 64833; OHIP: 304) were included if they had a prescription for opioid agonist therapy during pregnancy.

The study population was further restricted to mother-infant pairs for which there was at least one Ontario Drug Benefit program prescription record during the three years prior to delivery. The ODB is Ontario's publicly funded prescription program for those aged over 65 and for low-income individuals of any age. The ICES data include information on ODB prescriptions, but there is no indicator for ODB coverage; membership is identified through prescription records. Mother-infant pair linkage was achieved using the ICES MomBaby dataset,<sup>17</sup> which includes

## ABBREVIATIONS

ADGs	ambulatory diagnostic groups
CIHI	Canadian Institute for Health Information
GA	gestational age
ICES	Institute for Clinical Evaluative Sciences
NAS	neonatal abstinence syndrome
NIHB	Non-Insured Health Benefits
ODB	Ontario Drug Benefit
OHIP	Ontario Health Insurance Program
SES	socioeconomic status
SSRI	selective serotonin reuptake inhibitors

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