Perinatal Services BC

BRITISH COLUMBIA CENTRE ON SUBSTANCE USE

Networking researchers, educators & care providers

Treatment of Opioid Use Disorder During Pregnancy

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Disclosure

- No conflict of interest

Outline

- Review opioid use during pregnancy
- Overview guideline supplement development process
- Review guideline recommendations
- Perinatal Services BC forthcoming tools and activities

Opioid Use in Pregnancy

- Non-medical opioid use during pregnancy is associated with:
  - Fetal growth restriction
  - Fetal demise
  - Neonatal opioid withdrawal (aka NAS)
  - If injecting drugs, going harms related to injection drug use (overdose, HIV, Hep C, infection etc.)

1. Lund IO, Fitzsimons H, Tuten M, Chisolm MS, O'Grady KE, Jones HE. Comparing methadone and buprenorphine maintenance with methadone-assisted withdrawal for the treatment of opioid dependence during pregnancy: maternal and neonatal outcomes. *Substance abuse and rehabilitation.* 2012;3:17-25.
2. McCarthy JJ, Leamon MH, Finnegan LP, Fassbender C. Opioid Dependence and Pregnancy: Minimizing Stress on the Fetal Brain. *American journal of obstetrics and gynecology.* 2016.

Engaging in Care

- Opportunity!
- OUD care during pregnancy, intrapartum and post partum:
  - Eliminate or reduce non-medical opioid use
  - Significantly improve pregnancy outcomes
- Benefits of OAT (opioid agonist treatment)

3. WHO Guidelines Approved by the Guidelines Review Committee. *Guidelines for the Identification and Management of Substance Use and Substance Use Disorders in Pregnancy*. Geneva: World Health Organization Copyright (c) World Health Organization 2014.; 2014.
4. Lind JN, Interrante JD, Ailes EC, et al. Maternal Use of Opioids During Pregnancy and Congenital Malformations: A Systematic Review. *Pediatrics.* 2017.
5. Zedler BK, Mann AL, Kim MM, et al. Buprenorphine compared with methadone to treat pregnant women with opioid use disorder: a systematic review and meta-analysis of safety in the mother, fetus and child. *Addiction (Abingdon).*2016.

Perinatal Services BC

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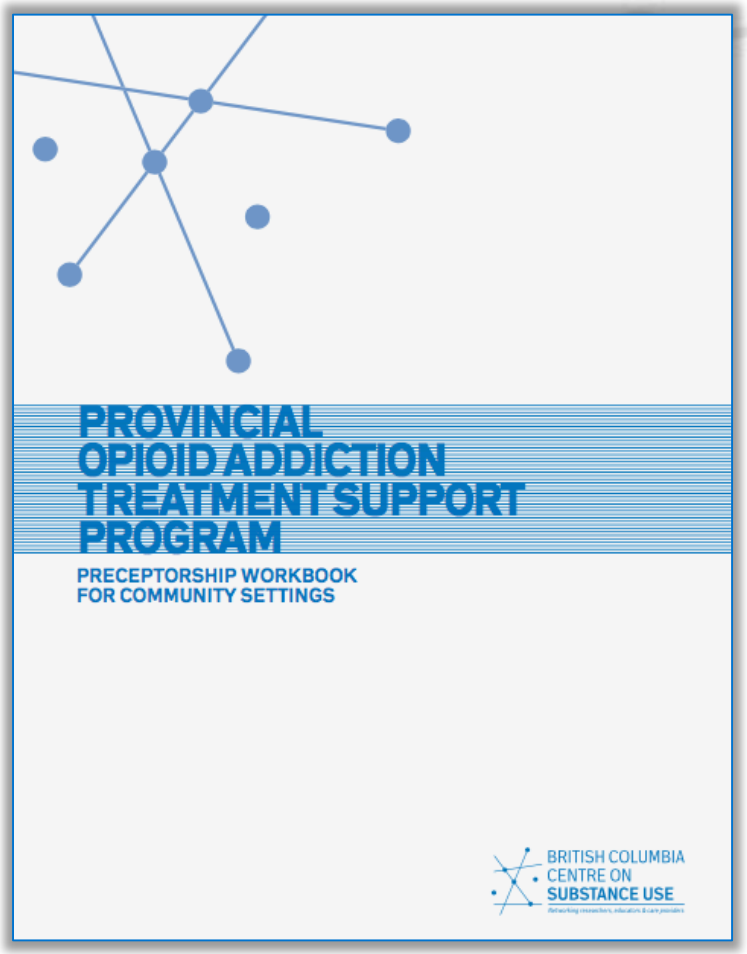
Notification of Bylaw Amendment – Methadone Maintenance Program

Re: Methadone Maintenance Program – sections 1-19 and 9-3 of the Bylaws made under the *Health Professions Act*, RSBC 1996, c.183 – seeking to repeal

Dear registrant,

As was announced by Minister Terry Lake last September, the Ministry of Health has established a new BC Centre for Substance Use (BCCSU) to link provincial opioid substitution treatment educational efforts to academia and clinical research, and to leverage networks of regional health authority practitioners, family physicians, and recovery service providers to address the current opioid crisis. Today, Minister Lake announced $5 million of additional funding for the BCCSU, as well as new clinical guidelines that will come into effect on June 5, 2017, replacing the College's existing *Methadone and Buprenorphine: Clinical Practice Guideline for Opioid Use Disorder*.

Provincial Opioid Addiction Treatment Support Program (POATSP)



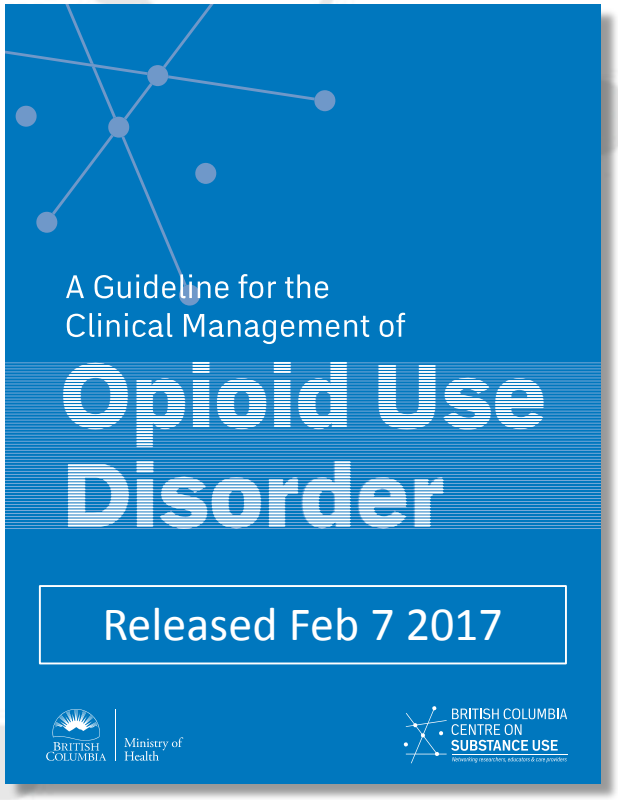
71

New Full Exemptions Issued
(since June 2017)

CPSBC 2016/2017 – 45 new exemptions
CPSBC 2015/2016 – 43 new exemptions

Guideline Supplements

- Two forthcoming
  - **Pregnancy** and Youth
- Supplement to the main provincial OUD guideline



www.bccsu.ca

Supplement Development Process

Guideline Development Committee

- **Ronald Abrahams**, MD, CCFP, FCFP, M.S.C. (Committee Co-chair)
- **Andrea Ryan**, MD, CCFP, Dip. ISAM (Committee Co-chair)
- **Jola Berkman**, RN, BScN, BSc(med)Hons
- **Eric Cattoni**, MD, CCFP
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- **Janine Hardial**, MD, CCFP
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- **Cheyenne Johnson**, RN, MPH, CCRP
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- **Christy Sutherland**, MD, CCFP, Dip. ABAM
- **Meaghan Thumath**, RN, BSN, MScPH
- **Lani Wittmann**, RN, MN, IBCLC, PNC©

Supplement Review Process

External Reviewers

- **Kate Bodkin**, BA, MD, CCFP
- **Andrew Gaddis**, Fulbright Scholar
- **Hendrée Jones**, PhD
- **Lorena Marcellus**, RN, BSN, MN, PhD
- **Alice Ordean**, MD, CCFP, MHSc, FCFP, FASAM
- **Launette Rieb**, MD, MSc, CCFP, FCFP, Dip. ABAM, CCSAM

Summary Table of (Draft) Recommendations

Care Principles
1. Clinicians caring for pregnant individuals with opioid use disorder should apply the principles of trauma-informed and culturally safe practice.
2. Clinicians should assess each patient's basic medical and psychosocial needs (e.g., mental wellness, security, stable housing) and make necessary referrals to secure social determinants of health.
3. Integrated and individualized care programs are essential to fostering stability and improving treatment and pregnancy outcomes.
4. All pregnant people with opioid use disorder should have access to the full scope of harm reduction supplies and services available to the general patient population.
Prenatal Screening and Assessment
5. All individuals who are or may become pregnant should be offered regular screening for alcohol, tobacco, and non-medical drug use, and informed of the risks and risk reduction strategies. Screenings should be accompanied by brief support.
Pharmacological Treatment
6. Withdrawal management alone is not recommended due to high rates of relapse and subsequently elevated risk of fatal and nonfatal overdose, infections, and negative pregnancy outcomes.
7. All pregnant individuals with opioid use disorder should be offered opioid agonist treatment (OAT). OAT has been shown to eliminate or substantially reduce non-medical opioid use, leading to improved maternal and neonatal outcomes in comparison to untreated opioid use disorder and/or withdrawal management strategies.
8. The type of OAT to be initiated should be selected based on patients' individual circumstances and with consideration of access and availability. i. **Methadone** is traditionally recognized the first-line option for OAT during pregnancy. ii. **Buprenorphine/naloxone** is an alternative first-line medication for this population. Recent studies have found this medication to be as safe and effective as methadone and buprenorphine monotherapy during pregnancy. iii. **Slow-release oral morphine** may be considered for patients who are not successfully retained in treatment with buprenorphine/naloxone or methadone. iv. **Injectable opioid agonist treatment (iOAT)** has not been studied in the context of pregnancy. Caution should be exercised when prescribing iOAT for individuals who are pregnant or may become pregnant. This caution should be exercised with consideration of the potential harms of denying access to iOAT for a pregnant person who otherwise meets eligibility criteria.
9. Unless clinically indicated, transitioning between methadone, buprenorphine/naloxone, and slow-release oral morphine during pregnancy and postpartum periods is not recommended for patients who are stable on one of these medications prior to becoming pregnant.
10. For patients stable on buprenorphine/naloxone prior to becoming pregnant, transition to buprenorphine monotherapy during pregnancy is not necessary.
Postpartum Considerations
11. Rooming-in is recommended as the standard of care for opioid exposed infants as it facilitates care for the mother-child dyad as one unit while alleviating neonatal opioid withdrawal symptoms. Assessment and treatment of neonatal opioid withdrawal symptoms should be conducted in rooming-in settings.
12. Breastfeeding should be encouraged in mothers who are stable on OAT.

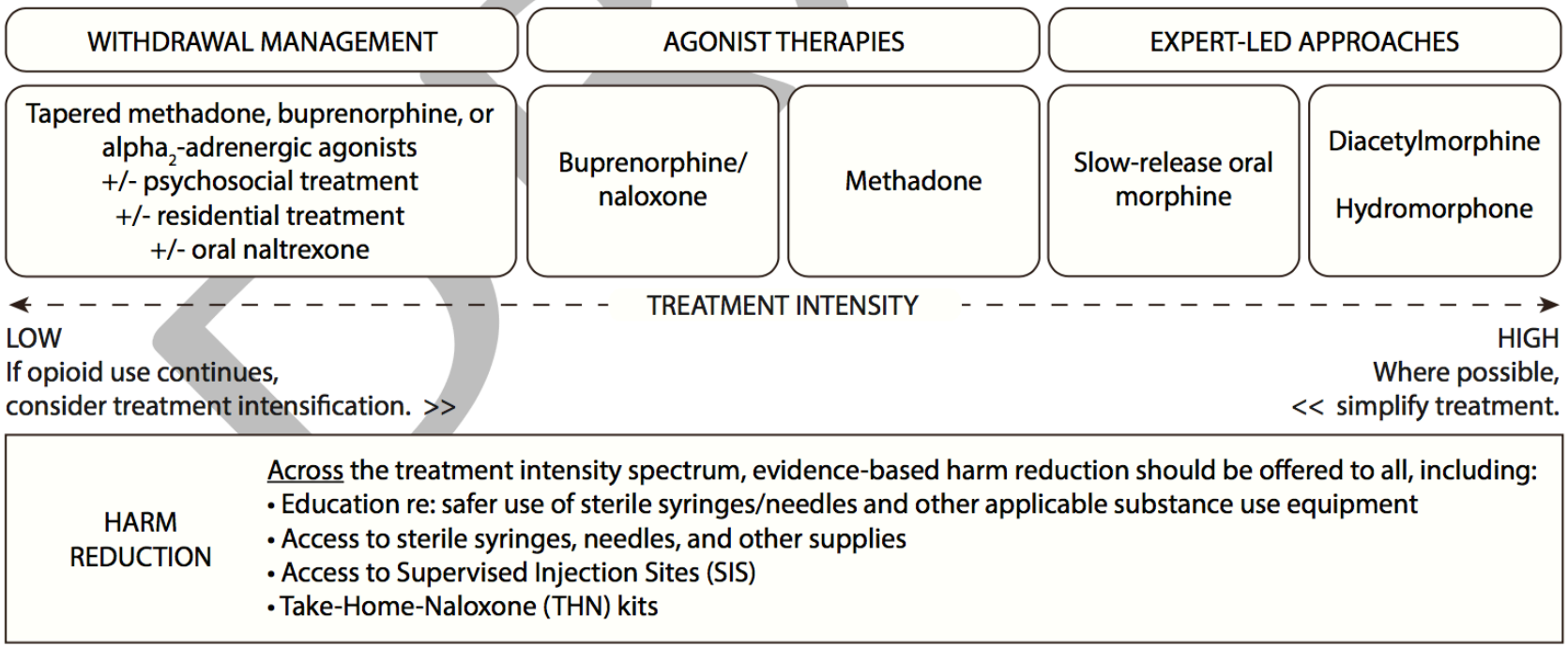
Care Principles (Recommendations #1-4)

- Clinicians caring for pregnant individuals with opioid use disorder should:
  - apply the principles of **trauma-informed** and **culturally safe** practice
  - assess each patient's basic medical and psychosocial needs (e.g., mental wellness, security, stable housing) and make necessary referrals to secure **social determinants of health**
  - Offer **integrated and individualized** care programs which are essential to fostering stability and improving treatment and pregnancy outcomes
  - Provide/facilities access to the full scope of **harm reduction** supplies and services available to the general patient population.

Prenatal Screening and Assessment (Recommendation #5)

- All individuals who are or may become pregnant should be offered **regular screening for alcohol, tobacco, and non-medical drug use**, and informed of the risks and risk reduction strategies. Screenings should be accompanied by **brief support.**

Overview of the continuum of care for OUD



CLINICAL GUIDANCE FOR TREATING PREGNANT AND PARENTING WOMEN WITH OPIOID USE DISORDER AND THEIR INFANTS

SAMHSA

Canadian Paediatric Society

PRACTICE POINT

Management of Infants born to Mothers who have used Opioids during Pregnancy

Posted: Jan 11 2018

Show right menu

Principal author(s)

Thierry Lacaze, Pat O'Flaherty; Canadian Paediatric Society, Fetus and Newborn Committee

Abstract

The incidence of infant opioid withdrawal has grown rapidly in many countries, including Canada, in the last decade, presenting significant health and early brain development concerns. Increased prenatal exposure to opioids reflects rising prescription opioid use as well as the presence of both illegal opiates and opioid-substitution therapies. Infants are at high risk for experiencing symptoms of abstinence or withdrawal that may require assessment and treatment. This practice point focuses specifically on the effect(s) of opioid withdrawal and current management strategies in the care of infants born to mothers with opioid dependency.

Pharmacological Treatment (Recommendations 6-10)

#6: **Withdrawal management alone is not recommended** due to high rates of relapse and subsequently elevated risk of fatal and nonfatal overdose, infections, and negative pregnancy outcomes.

Safety Considerations
Withdrawal Management Alone

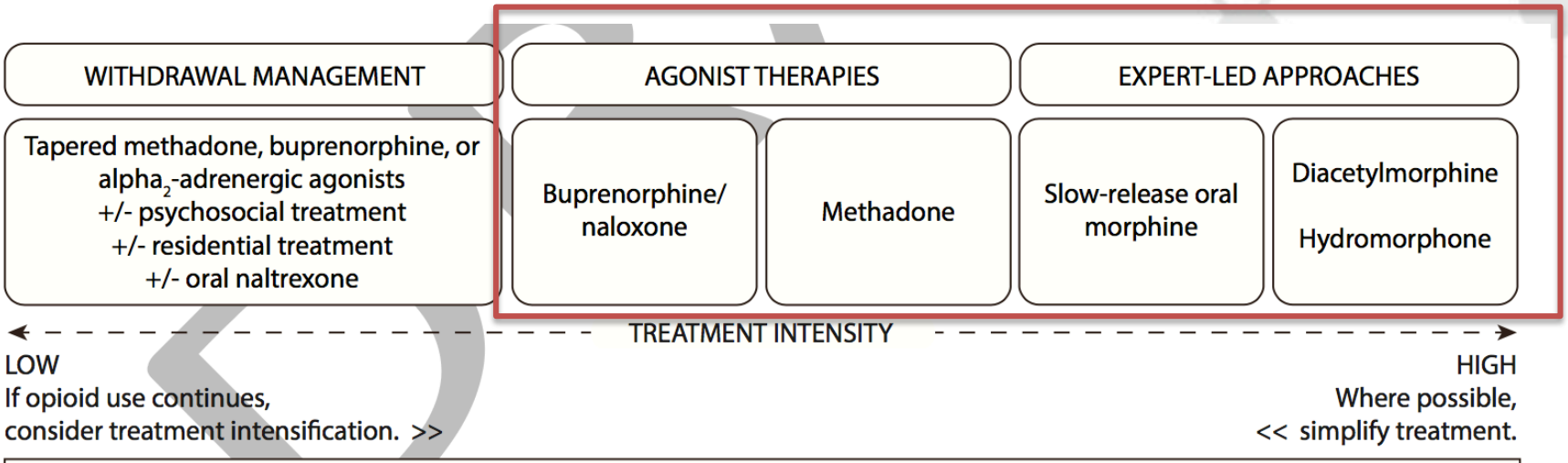
- Detox can potentially be an important first point of contact and a bridge to other treatment options
- **However**, detox as a standalone intervention associated with:
  - High rates of relapse (Strang et al., 2003)
    - 90% relapse – most within 7 days
  - HIV-transmission (MacArthur et al., 2012)
  - Morbidity and Mortality (Luty 2003, Simpson and Friend, 1988)

Pharmacological Treatment (Recommendations 6-10)

#7 All pregnant individuals with opioid use disorder should be **offered opioid agonist treatment (OAT)**

OAT has been shown to eliminate or substantially reduce non-medical opioid use, leading to improved maternal and neonatal outcomes in comparison to untreated opioid use disorder and/or withdrawal management strategies.

Overview of the continuum of care



Pharmacological Treatment (Recommendations 6-10)

#8: The type of OAT to be initiated should be selected based on patients' individual circumstances and with consideration of access and availability.

- **Methadone** is traditionally recognized the first-line option for OAT during pregnancy.
- **Buprenorphine/naloxone** is an alternative first-line medication for this population. Recent studies have found this medication to be as safe and effective as methadone and buprenorphine monotherapy during pregnancy.
- **Slow-release oral morphine** may be considered for patients who are not successfully retained in treatment with buprenorphine/naloxone or methadone.
- **Injectable opioid agonist treatment (iOAT)**. Caution should be exercised when prescribing iOAT for individuals who are pregnant or may become pregnant. This caution should be exercised with consideration of the potential harms of denying access to iOAT for a pregnant person who otherwise meets eligibility criteria.

Methadone in pregnancy

- Most frequently prescribed OAT during pregnancy
- For the mother
  - Prevents relapse, minimizes fluctuations in serum opioid levels (eliminates fetal stress)
- For the neonate:
  - Longer gestation, higher live birth rates, greater birth rates, early discharger from hospital
- Methadone prescribing information in the main guideline www.bccsu.ca

Buprenorphine (+ buprenorphine/naloxone)

- Growing evidence supports equal efficacy & potential superiority of buprenorphine in pregnancy
- Neonatal outcomes similar to methadone
  - However, NOWS may be less severe

ADDICTION

SSA SOCIETY FOR THE STUDY OF ADDICTION

REVIEW

doi:10.1111/add.13462

Buprenorphine compared with methadone to treat pregnant women with opioid use disorder: a systematic review and meta-analysis of safety in the mother, fetus and child

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Venebio Group, LLC, Richmond, Virginia, USA,[1] Center for Biobehavioral Health Disparities Research, Division of Community Health, Duke University, Durham, NC, USA,[2] UNC Horizons, Department of Obstetrics and Gynecology, School of Medicine, University of North Carolina at Chapel Hil, Chapel Hill, NC, USA[3] and Departments of Psychiatry and Behavioral Sciences and Obstetrics and Gynecology, School of Medicine, Johns Hopkins University, Baltimore, MD, USA[4]

ABSTRACT

Aims To assess the safety of buprenorphine compared with methadone to treat pregnant women with opioid use disorder. **Methods** We searched PubMed, Embase and the Cochrane Library from inception to February 2015 for randomized controlled trials (RCT) and observational cohort studies (OBS) that compared buprenorphine with methadone for treating opioid-dependent pregnant women. Two reviewers assessed independently the titles and abstracts of all search results and full texts of potentially eligible studies reporting original data for maternal/fetal/infant death, preterm birth, fetal growth outcomes, fetal/congenital anomalies, fetal/child neurodevelopment and/or maternal adverse events. We ascertained each study's risk of bias using validated instruments and assessed the strength of evidence for each outcome using established methods. We computed effect sizes using random-effects models for each outcome with two or more studies. **Results** Three RCTs ($n = 223$) and 15 cohort OBSs ($n = 1923$) met inclusion criteria. In meta-analyses using unadjusted data and methadone as comparator, buprenorphine was associated with lower risk of preterm birth [RCT risk ratio (RR)

Rural, Pregnant, and Opioid Dependent: A Systematic Review

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[1]Assistant Professor, Northern Ontario School of Medicine, Thunder Bay, ON, Canada. [2]Adjunct Lecturer, University of Toronto, Toronto, ON, Canada.

Supplementary Issue: Substance Use in Pregnancy

ABSTRACT: The nature, impact, and treatment of substance use during pregnancy are well described for women living in urban settings. Less is known about pregnant substance-using women living in rural communities. The objective of this review is to describe the existing evidence for the management of substance use in pregnant women living in rural areas. A systematic review of the literature was conducted using PubMed, Embase, and the Cochrane Database of Systematic Reviews, and the quality of the evidence was assessed using the GRADE system. Twenty-two articles that met the inclusion criteria were identified. Descriptive studies document high rates of smoking, marijuana, and polysubstance use among rural, substance-using pregnant women compared to their urban counterparts. Management of substance use disorders is limited by access to and acceptability of treatment modalities. Several innovative, integrated addiction and prenatal care programs have been developed, which may serve as models for management of substance use during pregnancy in rural settings.

KEYWORDS: opioids, pregnancy, rural and remote, addiction

SUPPLEMENT: Substance Use in Pregnancy

CITATION: Jumah. Rural, Pregnant, and Opioid Dependent: A Systematic Review. *Substance Abuse: Research and Treatment* 2016:10(S1) 35–41 doi: 10.4137/SART.S34547.

TYPE: Review

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CORRESPONDENCE: njumah@nosm.ca

Pharmacological Treatment (Recommendations 6-10)

#9 Unless clinically indicated, **transitioning between methadone, buprenorphine/naloxone, and slow-release oral morphine during** pregnancy and postpartum periods is **not recommended** for patients who are stable on one of these medications prior to becoming pregnant.

Pharmacological Treatment

#10: For patients stable on buprenorphine/naloxone prior to becoming pregnant, transition to **buprenorphine monotherapy during pregnancy is not necessary.**

What about the naloxone (in buprenorphine)?

- Naloxone: *theoretical* risk that naloxone may pose to the fetus by elevating maternofetal cortisol levels
- Several recent studies have found **no statistically significant** differences between the two formulations in terms of pregnancy and treatment outcomes

6. Debelak K, Morrone WR, O'Grady KE, Jones HE. Buprenorphine + naloxone in the treatment of opioid dependence during pregnancy-initial patient care and outcome data. *The American journal on addictions / American Academy of Psychiatrists in Alcoholism and Addictions.* 2013;22(3):252-254.
7. Wiegand S, Stringer E, Seashore C, et al. *750: Buprenorphine/naloxone (B/N) and methadone (M) maintenance during pregnancy: a chart review and comparison of maternal and neonatal outcomes.* Vol 2102014.
8. Lund IO, Fischer G, Welle-Strand GK, et al. A Comparison of Buprenorphine + Naloxone to Buprenorphine and Methadone in the Treatment of Opioid Dependence during Pregnancy: Maternal and Neonatal Outcomes. *Substance Abuse: Research and Treatment.* 2013;7:61-74

What about the naloxone (in buprenorphine)?

- In Canada available as buprenorphine/naloxone (Suboxone®)
  - Recently remove pregnancy as contraindication in product monograph
- Buprenorphine mono-produce available via Special Access Programme (SAP)

Post partum recommendations

- #11 **Rooming-in is recommended** as the standard of care for opioid exposed infants as it facilitates care for the mother-child dyad as one unit while alleviating neonatal opioid withdrawal symptoms. Assessment and treatment of neonatal opioid withdrawal symptoms should be conducted in rooming-in settings.
- #12 **Breastfeeding should be encouraged** in mothers who are stable on OAT.

Summary

- Release date: Spring 2018
- NEW! Perinatal RACE Line April 1st
  - www.raceconnect.ca
- Stay tuned for more practice support and educational

RACE

RAPID ACCESS TO CONSULTATIVE EXPERTISE

Educational

- Online addiction medicine diploma program
  - Nursing modules coming Summer 2018!
- Interdisciplinary fellowship program
  - Nursing
  - Social Work
  - Physicians
- Provincial opioid addiction training support program

Visit www.bccsu.ca under the 'Training'

Summary

- Guideline recommendations highlights:
  - Withdrawal management alone is dangerous
  - OAT should be offered for all pregnant individuals
    - Methadone (1st line)
    - Buprenorphine/naloxone (alternative 1st line)
    - Slow release oral morphine (SROM) (2nd/3rd line)
    - Injectable OAT (caution)
  - Transitioning OAT is not recommended including transition to buprenorphine mono-therapy

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