Integration of Mental Health & Substance Use Disorder Treatment in Obstetrics Care

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Disclosures

Conflict of Interest

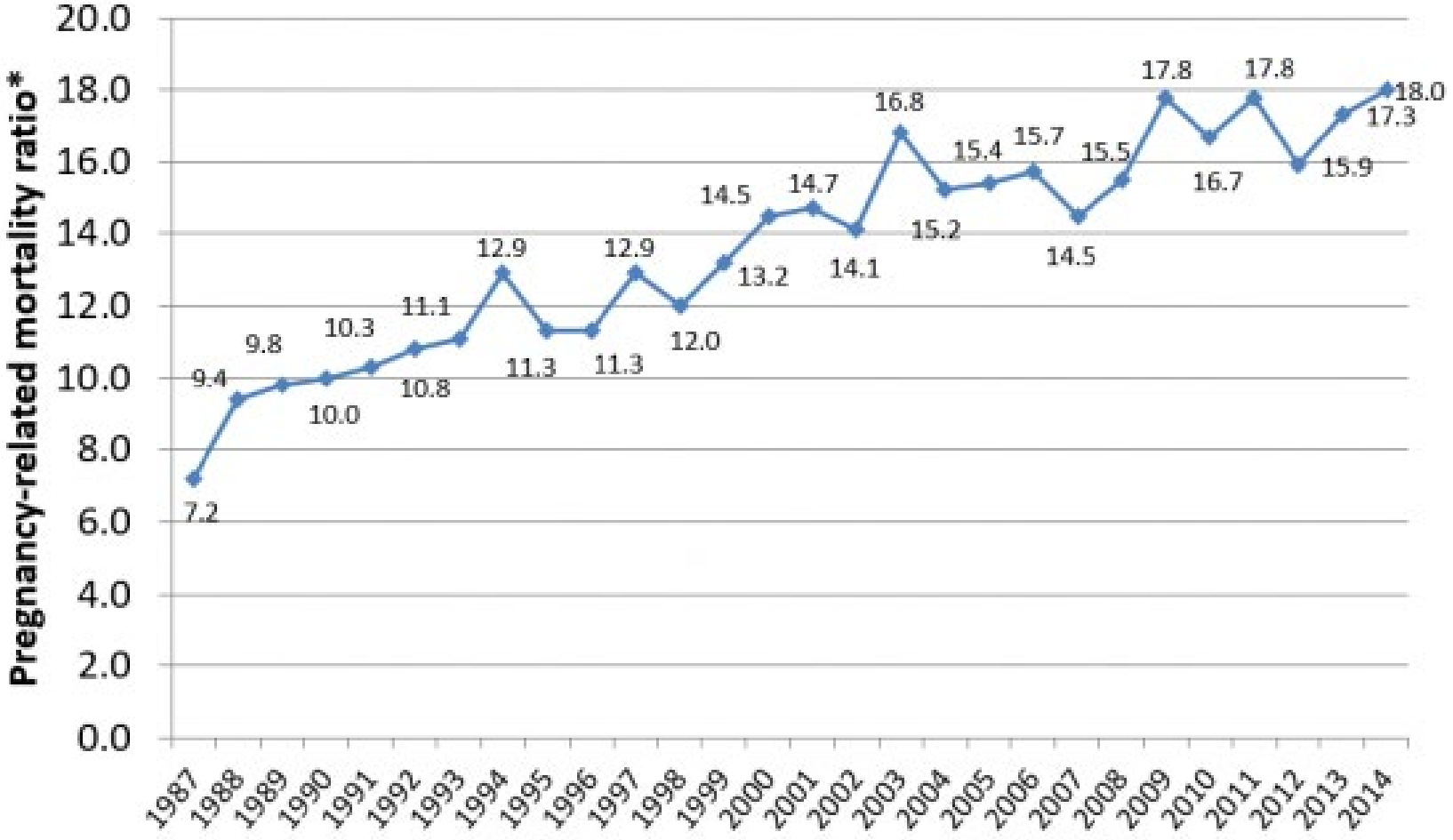
- SAGE Advisory Board
  - Zulresso (Brexanolone) for ppd

- Funding
  - NIH/NIDA: 5UG1DA013727
  - NIH/NIDA: R34 DA046730
  - NIH/NIDA: U54DA016511
  - HRSA: U66 RH31458
  - SAMHSA: TI080221
  - American Foundation of Suicide Prevention 8D477-01
  - Duke Endowment 8868-SP, 8563-SP

Overview

- Integrated Behavioral Health
  - Background
  - Evidence
  - Implementation

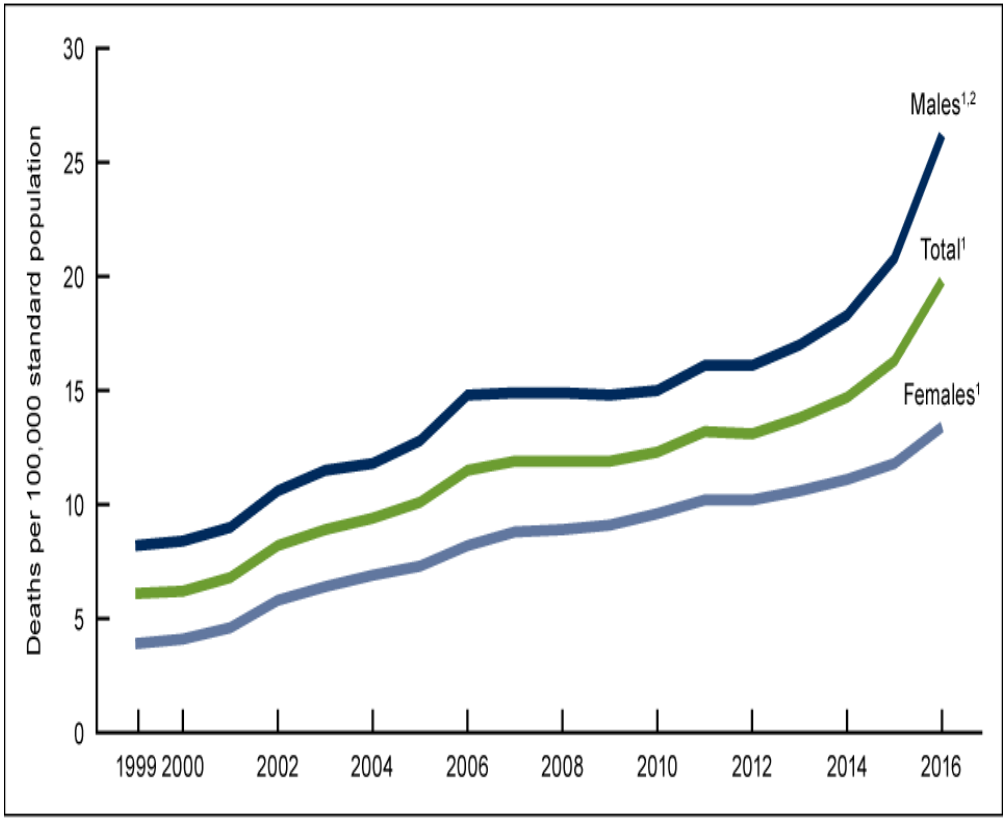
Trends in pregnancy-related mortality in the United States: 1987–2014



**Note:* Number of pregnancy-related deaths per 100,000 live births per year.

Opioid Overdose Deaths

Figure 1. Age-adjusted drug overdose death rates: United States, 1999–2016



[1]Significant increasing trend from 1999 to 2016 with different rates of change over time, $p < 0.001$.
[2]2016 rate for males was significantly higher than for females, $p < 0.001$.
NOTES: Deaths are classified using the *International Classification of Diseases, Tenth Revision*. Drug-poisoning (overdose) deaths are identified using underlying cause-of-death codes X40–X44, X60–X64, X85, and Y10–Y14. The number of drug overdose deaths in 2016 was 63,632. Access data table for Figure 1 at: https://www.cdc.gov/nchs/data/databriefs/db294_table.pdf#1.
SOURCE: NCHS, National Vital Statistics System, Mortality.

1999-2015

Prescription Opioid-Related Deaths

- Increased 471% in women [218% in men]

Synthetic Opioid-Related Deaths

- Increased 850% in women

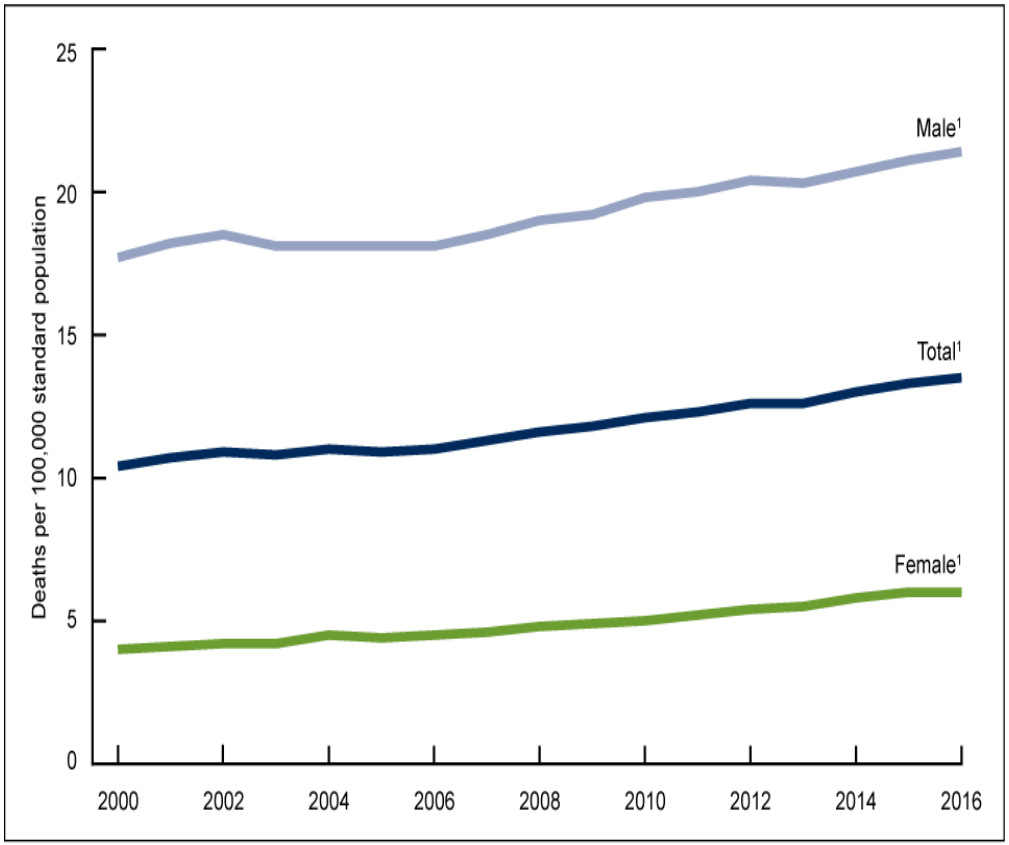
2002-2013

Heroin Use

- Increased 100% in women, [50% in men]

Suicide

Figure 1. Age-adjusted suicide rates, by sex: United States, 2000–2016



[1]Significant increasing trend from 2000 through 2016 with different rates of change over time, $p < 0.001$.
NOTES: Suicides were identified using *International Classification of Diseases, 10th Revision*, underlying cause-of-death codes: U03, X60–X84, and Y87.0.
Age-adjusted death rates were calculated using the direct method and the 2000 standard population.
Access data table for Figure 1 at: https://www.cdc.gov/nchs/data/databriefs/db309_table.pdf#1.
SOURCE: NCHS, National Vital Statistics System, Mortality.

2000-2015

30% increase in suicide overall

2nd leading cause of death age 10-34

4th leading cause of death age 35-54

2000-2016

50% increase in suicide in women

21% increase in suicide in men

Maternal self-harm deaths: an unrecognized and preventable outcome

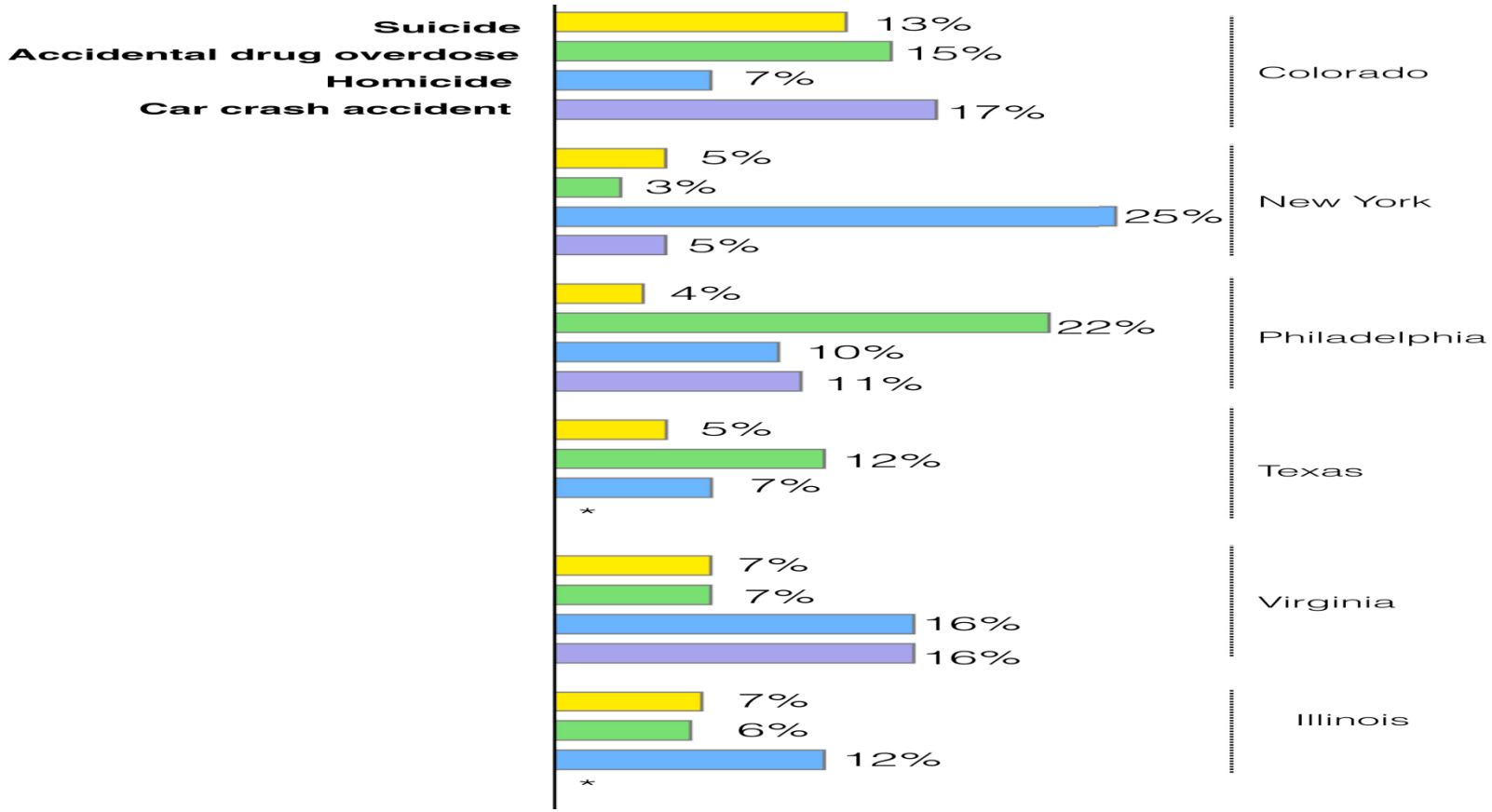
Kimberly Mangla, MD; M. Camille Hoffman, MD, MSCS; Caroline Trumpff, PhD; Sinclaire O'Grady, BA; Catherine Monk, PhD

National Rates of Maternal Deaths due to Suicide or Drug Use:

- Largely Unknown due to lack of or inadequate measurement
  - ~ 14-30%

Maternal self-harm deaths: an unrecognized and preventable outcome

Kimberly Mangla, MD; M. Camille Hoffman, MD, MSCS; Caroline Trumpff, PhD; Sinclaire O'Grady, BA; Catherine Monk, PhD



Screen All Pregnant & Postpartum Women for MH & SUDs

ACOG
The American College of Obstetricians and Gynecologists

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN®

U.S. Preventive Services TASK FORCE

AMERICAN PSYCHIATRIC ASSOCIATION

World Health Organization

AMA

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

NICHQ
National Institute for Children's Health Quality

When to Screen All Pregnant & Postpartum Women for Depression?

ACOG
The American College of Obstetricians and Gynecologists

Screen for depression & anxiety symptoms:
- **at least 1** during the **perinatal period**[1]
- during comprehensive **postpartum visit**[1]

"Clinical staff in obstetrics and gynecology practices should be prepared to initiate medical therapy, refer patients to appropriate behavioral health resources when indicated, or both."

1. American College of Obstetricians and Gynecologists. Committee opinion: screening for perinatal depression. 2018;757. **2**. Position Statement on Screening and Treatment of Mood and Anxiety Disorders During Pregnancy and Postpartum. American Psychiatric Association. December 2018.

Why Screen All Pregnant & Postpartum Women for Depression?

- **Peripartum Depression is Common**
  - 1 in 7 women experience peripartum depression[1]
    - 1 in 3 low income
  - 1 in 5 women experience peripartum anxiety[2]

1. Gavin NI et al. *Obstet* Gynecol. 2005;106:1071-1083;

2. Ko JY et al. *MMWR Morb Mortal Wkly Rep.* 2017;66:153-158.

Why Screen All Pregnant & Postpartum Women for Depression?

- **Peripartum Depression Persists**
  - 46% of women who screen positive for depression early postpartum, continue to have elevated depressive symptoms at 1- year [1]

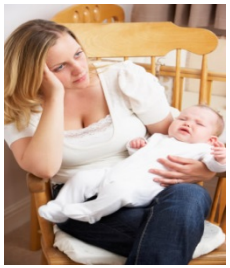
1. Horwitz, S, Briggs-Gowan MJ, Storfer-Isser A, Carter AS revalence, Correlates, and Persistence of Maternal Depression, Journal of Women's Health Vo 15, No.5

Risks of Untreated Peripartum Depression

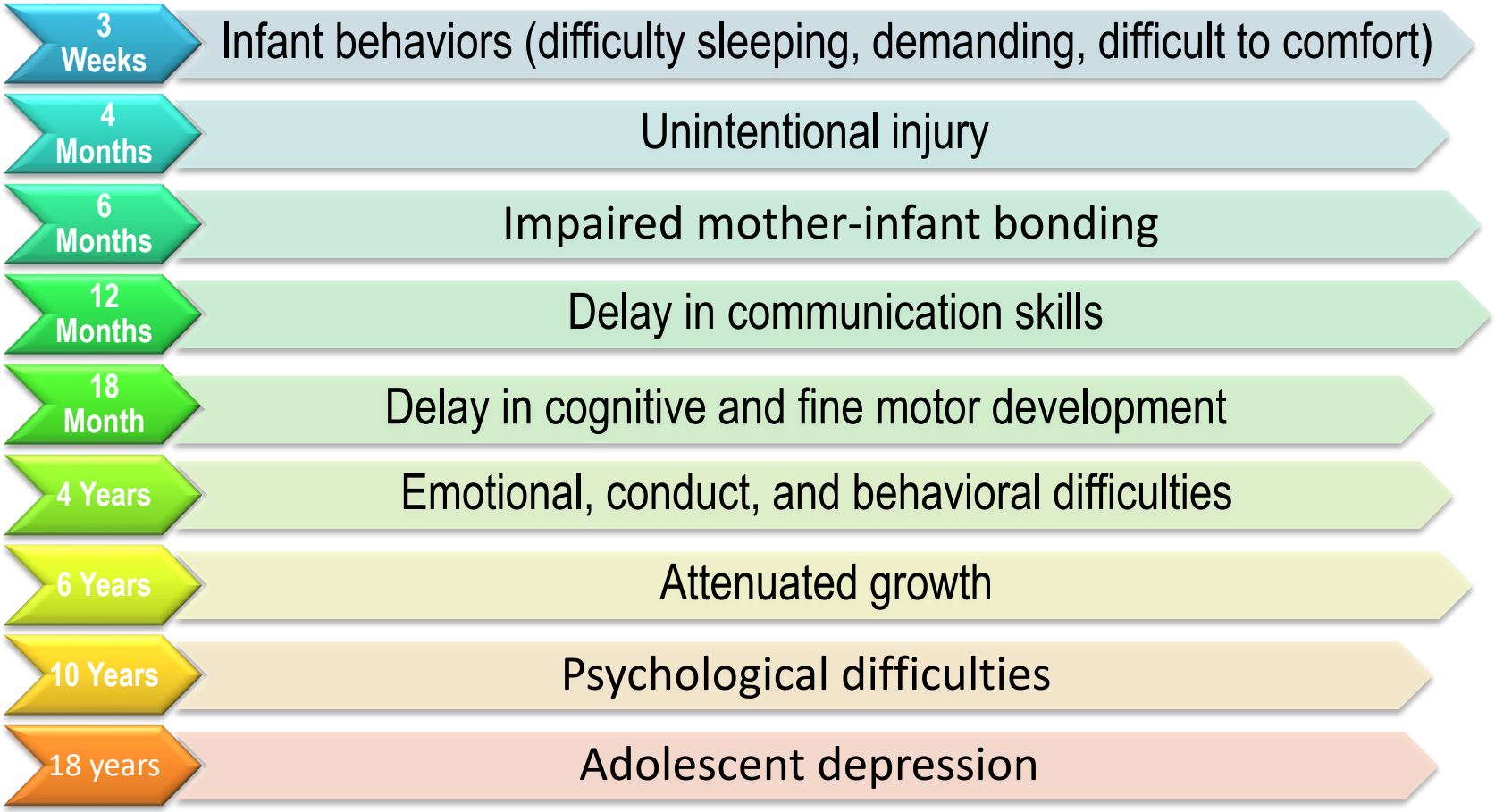
- **Women**
  - Severity of illness/Suicide
  - Poor health habits
  - Relationships


- **Obstetric/Fetal**
  - C-section
  - LBW (OR 1.96)
  - PTB (OR 1.56)


- **Child Development**
  - Less likely to breastfeed
  - Child Development:
    - Sleep, mother-infant bonding, communication, cognition, fine motor, behavioral, academics, psychiatric

In comparison to children of parents without PPD, children of parents with PPD are significantly more likely to:



Of the 30 studies providing data on the impact of PPD on children, 29 reported the long-term negative impact of maternal PPD on the physical and mental development of children.
EPDS=Edinburgh Postnatal Depression Scale.

1. Eastwood JG et al. *BMC Pregnancy Childbirth*. 2012;12:148; 2. Yamaoka Y et al. *Matern Child Health J*. 2016;20:326-336; 3. Kerstis B et al. *Arch Womens Ment Health*. 2016;19:87-94; 4. Valla L et al. *Infant Behav Dev*. 2016;45:83-90; 5. Koutra K et al. *Soc Psychiatry Psychiatr Epidemiol*. 2013;48:1335-1345; 6. Woolhouse H et al. *Arch Womens Ment Health*. 2016;19:141-151; 7. Hanington L et al. *Child Care Health Dev*. 2012;38:520-529; 8. Surkan PJ et al. *BMC Pediatr*. 2014;14:185; 9. Verkuijl NE et al. *Lancet Psychiatry*. 2014;1:454-460; 10. Pearson RM et al. *JAMA Psychiatry*.2013;70:1312-1319.

Peripartum Depression

- Impact on child health and development
- Behavioral problems in kids 3-4 years old
  - 4-fold increased risk
- Poor academic performance-middle school
  - 2-fold increased risk
- Depression in adolescents
  - 7-fold increased risk

Weissman MM. *JAMA Psychiatry.* 2018; 75(3): 227–228.

What is the Cost Peripartum Mood & Anxiety?

- Mathematica Analysis
- Annual Cohort of Mother-Child Dyad
  - followed pregnancy- five years
- Estimated cost 1 year:

  $14.2 Billion

  $ 32,000 per Mother-Child Dyad

The California Health Care Foundation, the Perigee Fund, and the Zoma Foundation
https://www.mathematica.org/news/new-study-uncovers-the-heavy-financial-toll-of-untreated-maternal-mental-health-conditions

Prevention of Postpartum Depression

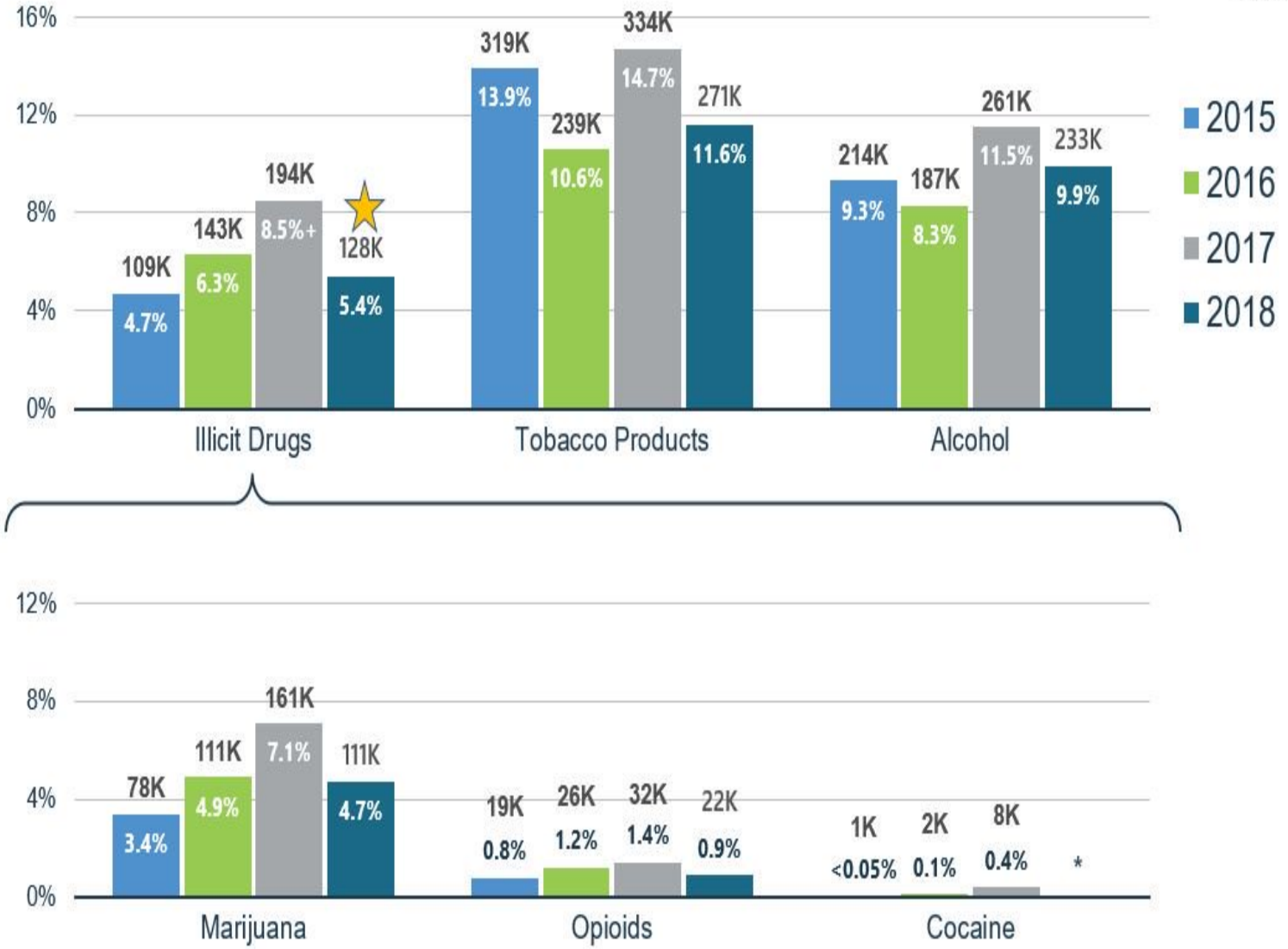
- Grade B Evidence

- Interventions for Prevention of PPD
  - Refer all **at risk** pregnant and postpartum women to **counseling interventions**
- Most Effective Counseling Interventions:
  - Cognitive Behavioral Therapy
  - Interpersonnel Psychotherapy

https://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/perinatal-depression-preventive-interventions?ds=1&s=perinatal

Past Month Substance Use among Pregnant Women

PAST MONTH, 2015-2018 NSDUH, 15-44



* Estimate not shown due to low precision.

\+ Difference between this estimate and the 2018 estimate is statistically significant at the .05 level.

SAMHSA

Tobacco Use in Pregnancy

Obstetric, fetal, and newborn risks

- Ectopic Pregnancy[1]
- Miscarriage[2]
- Placental abruption[3]
- Low birth weight[4-6]
- Prematurity[7,8]
- Stillbirth[9-12]
- Sudden Infant Death Syndrome

Horne et al. 2014[1]; Pineles, Park, and Samet 2014[2]; Salihu and Wilson 2007[3]; Cnattingius 2004; Quesada et al. 2012; Salihu and
Ion and Bernal 2015; Salihu and Wilson 2007[7,8;]; Cnattingius 2004; Forray 2016; Salihu and Wilson 2007; Tikkanen et al. 2006 [9]

Tobacco Use in Pregnancy

- Low birth weight
- Prematurity

- ADHD
- Developmental delays
- Cognitive problems
- Behavioral problems
- School achievement
- Smoking

Conley et al. Am Socio Review 2000; 65 (3), 458-467; Bhutta et. al. JAMA 2002; 288(6), 728-737; Wiebe, 2015; Ncube, 2017

Alcohol Use in Pregnancy

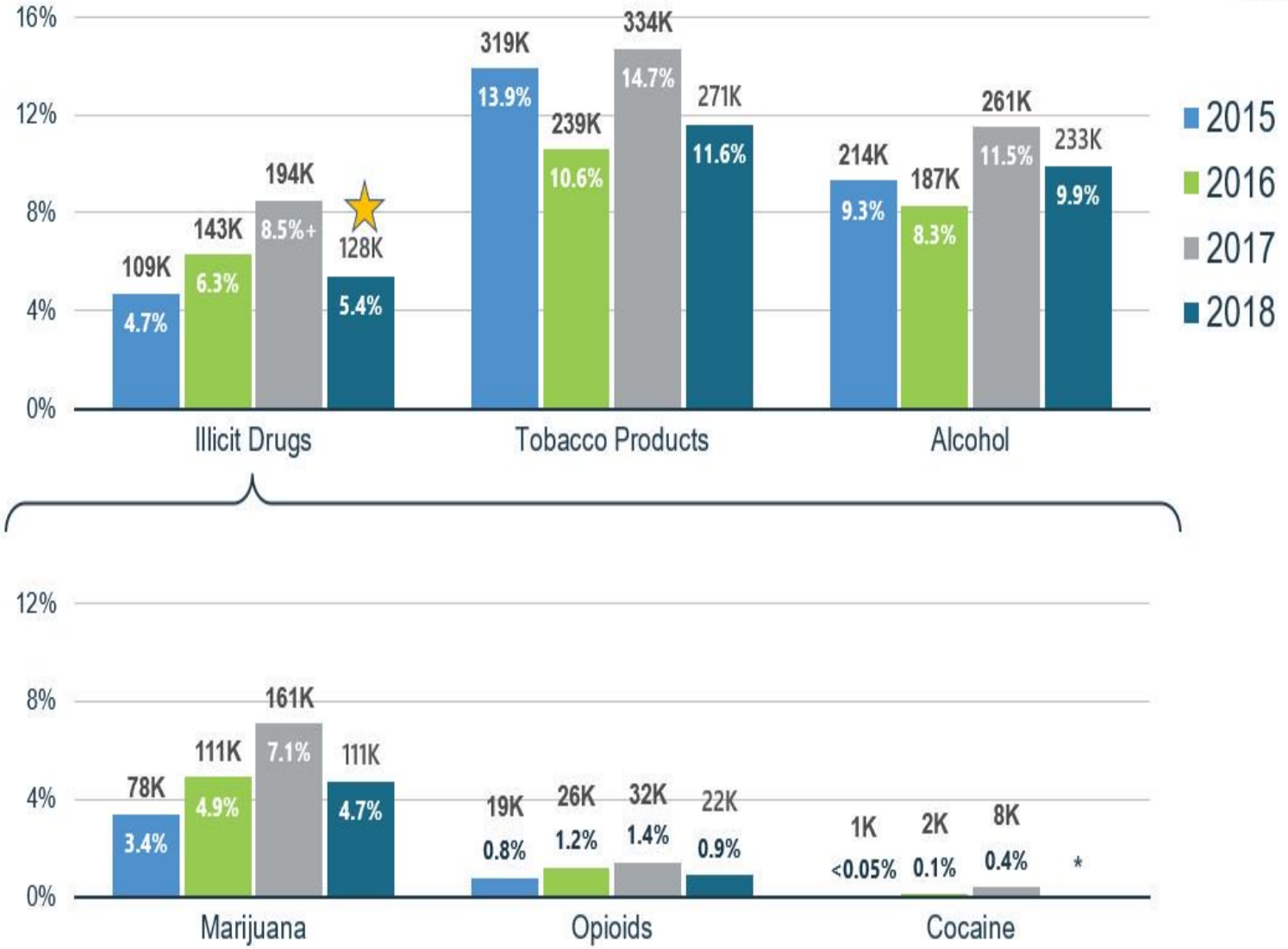
Obstetric, fetal, and newborn risks

- Birth defects
- Preterm birth
- Low birth weight
- Small for gestational age
- Motor dysfunction
- Developmental delay
- Intellectual disability

(CDC, 2011; APA, 2013)

Past Month Substance Use among Pregnant Women

PAST MONTH, 2015-2018 NSDUH, 15-44



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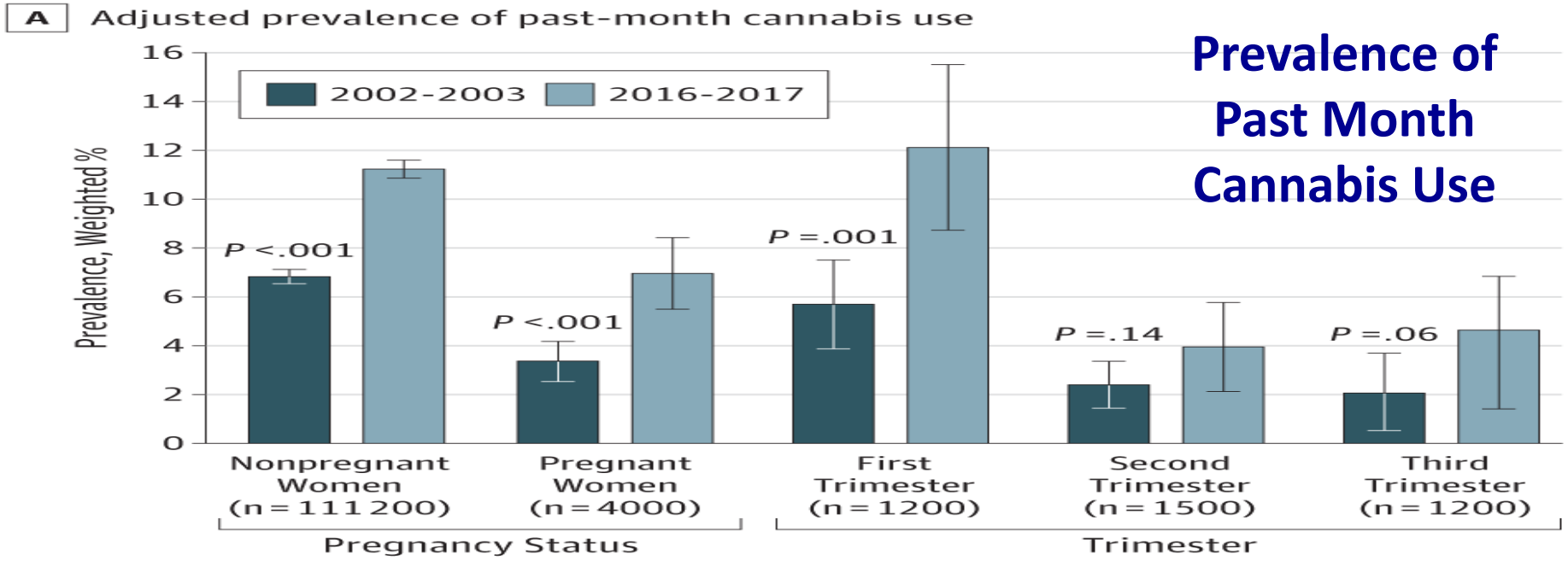
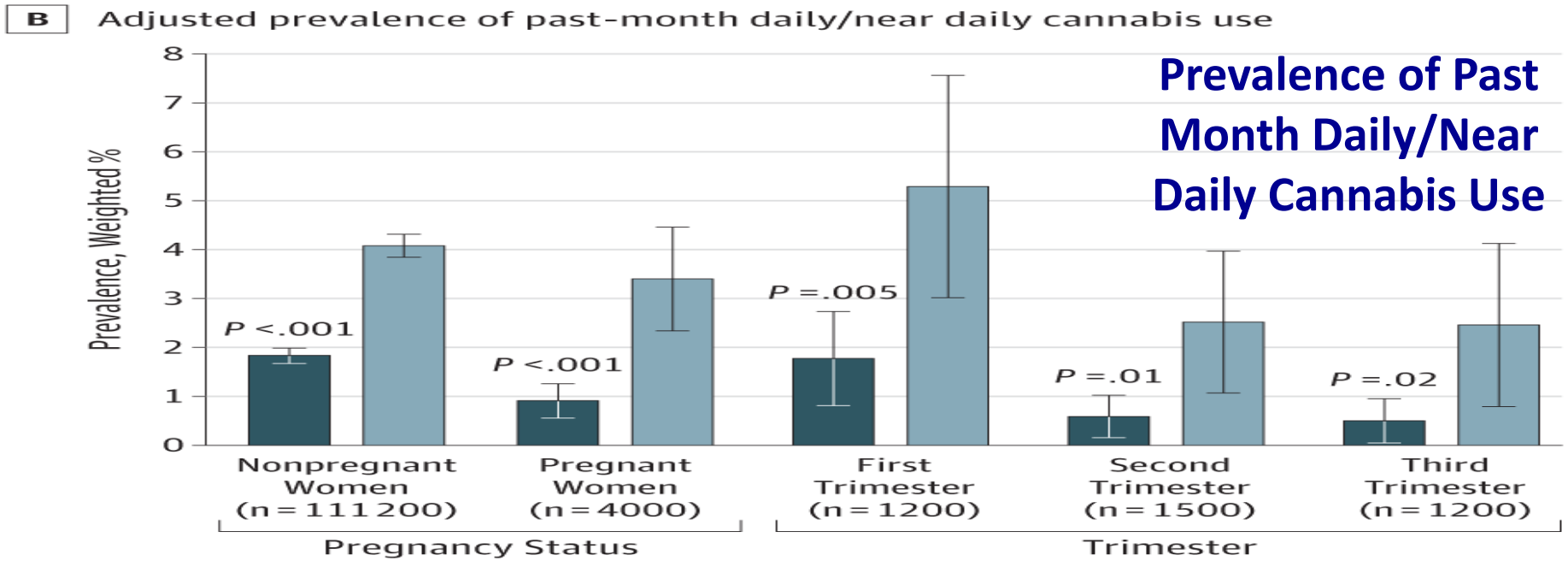
SAMHSA



Prevalence of Past Month Cannabis Use

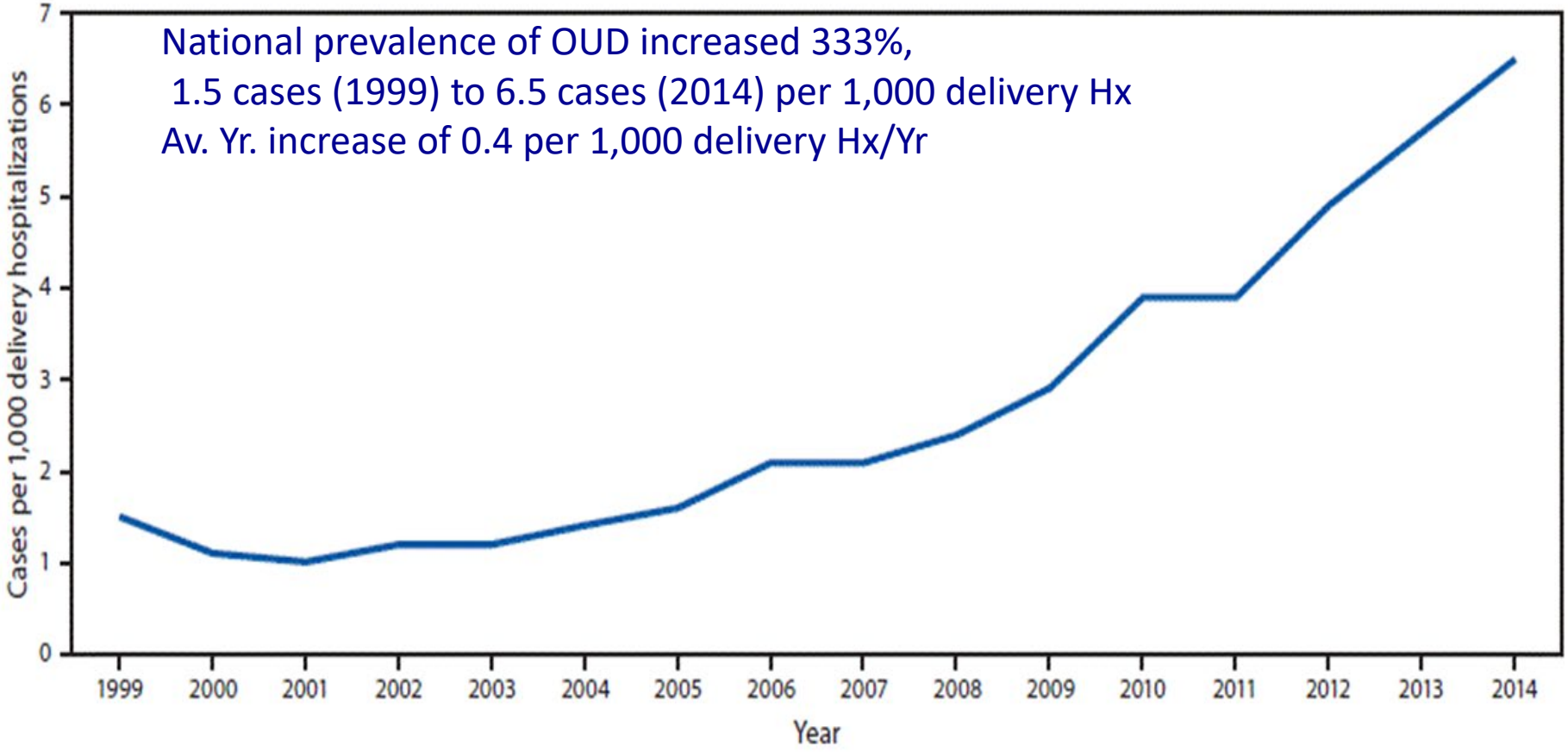


Prevalence of Past Month Daily/Near Daily Cannabis Use

Volkow N et al., *JAMA.* 2019;322(2):167–169.

Prevalence of Perinatal Opioid Use Disorder

Per 1,000 Delivery Hospitalizations in US 1999-2014



Haight SC, et al.,. MMWR Morb Mortal Wkly Rep 2018;67:845–849.

Table 2. Associations between Opioid Abuse or Dependence during Pregnancy and Obstetrical Outcomes: United States, 2007–2011

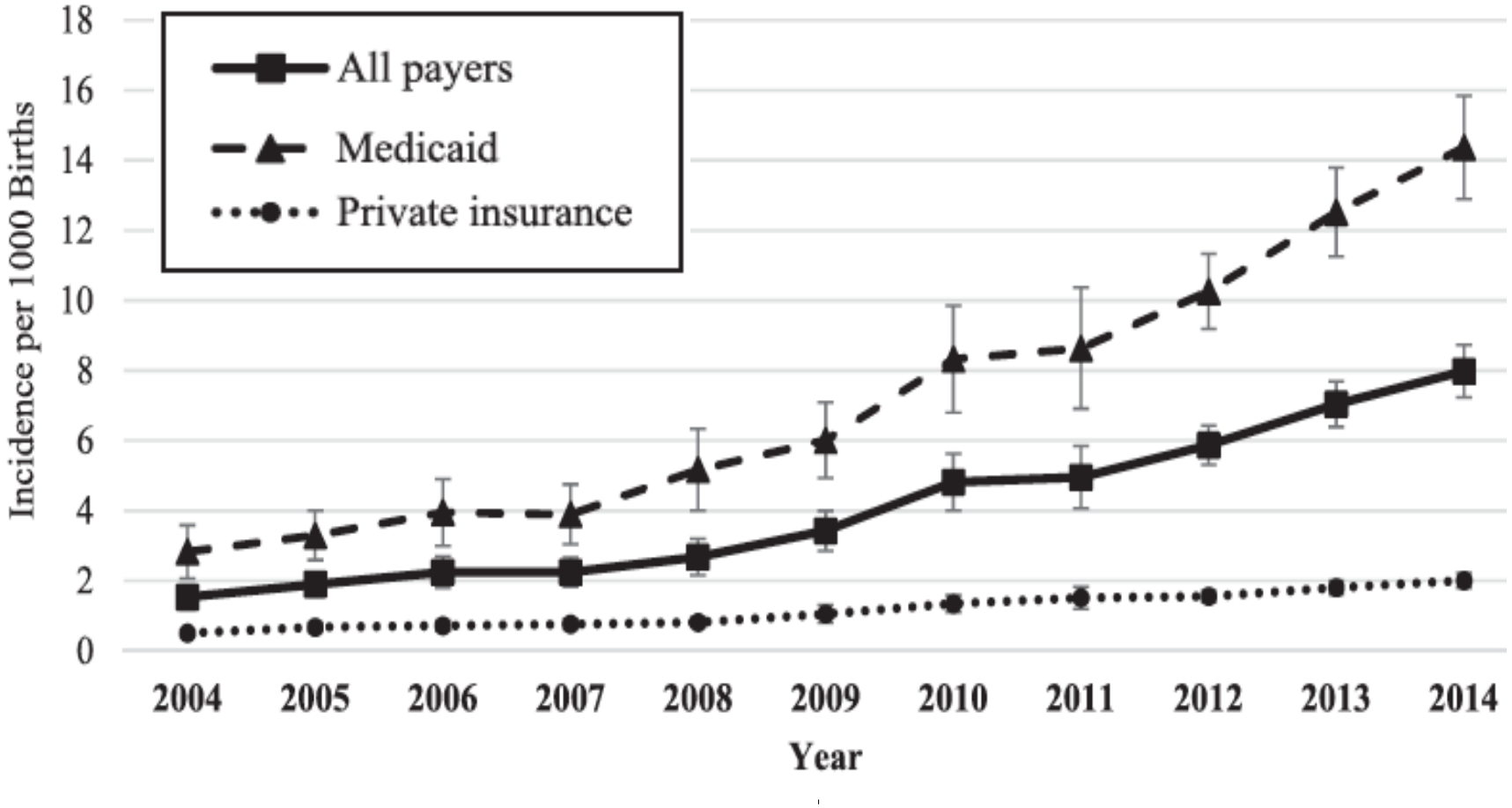
	Delivery Hospitalizations with Opioid Abuse or Dependence	Delivery Hospitalizations without Opioid Abuse or Dependence	Multivariable Odds Ratio* (95% CI)
	n (%)	n (%)	
Total	60,994	20,456,485	
Died during hospitalization	20 (0.03)	1,311 (0.006)	**4.6 (1.8–12.1)**
Cardiac arrest	24 (0.04)	1,873 (0.01)	**3.6 (1.4–9.1)**
Intrauterine growth restriction	4,157 (6.8)	431,032 (2.1)	**2.7 (2.4–2.9)**
Placental abruption	2,315 (3.8)	215,057 (1.1)	**2.4 (2.1–2.6)**
Length of stay >7 days	1,837 (3.0)	235,738 (1.2)	**2.2 (2.0–2.5)**
Preterm	10,538 (17.3)	1,506,941 (7.4)	**2.1 (2.0–2.3)**
Oligohydramnios	2,736 (4.5)	564,410 (2.8)	**1.7 (1.6–1.9)**
Transfusion	1,205 (2.0)	208,073 (1.0)	**1.7 (1.5–1.9)**
Stillbirth	727 (1.2)	124,607 (0.6)	**1.5 (1.3–1.8)**
Premature rupture of membranes	3,499 (5.7)	778,157 (3.8)	**1.4 (1.3–1.6)**
Cesarean delivery	22,130 (36.3)	6,768,679 (33.1)	**1.2 (1.1–1.3)**
Severe preeclampsia or eclampsia	722 (1.2)	289,668 (1.4)	**0.8 (0.7–0.9)**
Anesthesia complications	20 (0.03)	3,123 (0.02)	2.1 (0.8–5.3)
Cerebrovascular complications	37 (0.06)	5,079 (0.02)	2.0 (0.9–4.4)
Sepsis	273 (0.4)	79,169 (0.4)	1.3 (1.0–1.7)
Postpartum hemorrhage	1,866 (3.1)	589,811 (2.9)	1.1 (0.9–1.2)

Statistically significant values are indicated in bold.

* Adjusted for age group, race, primary payer, previous cesarean section, multiple gestation, and maternal preexisting conditions shown in table 1.

(Maeda, 2014)

Neonatal Abstinence Syndrome (NAS)



Winkelman et al. Pediatrics. 2018 Apr;141(4).

Research

JAMA | Original Investigation

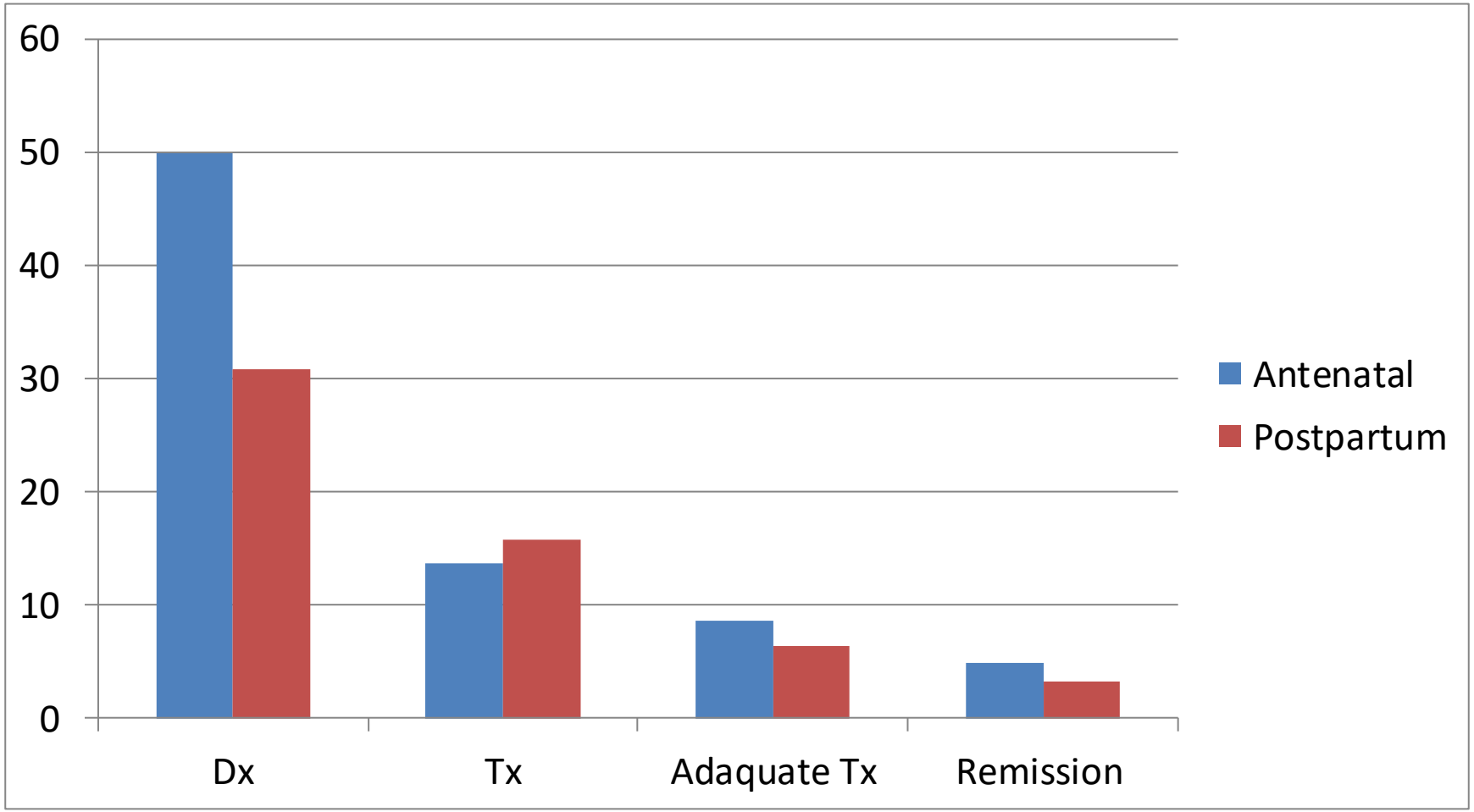
Association Among County-Level Economic Factors, Clinician Supply, Metropolitan or Rural Location, and Neonatal Abstinence Syndrome

Stephen W. Patrick, MD, MPH, MS; Laura J. Faherty, MD, MPH, MS; Andrew W. Dick, PhD; Theresa A. Scott, MS; Judith Dudley, BS; Bradley D. Stein, MD, PhD

- Median rate NAS
  - Overall
    - 7.1 per 1,000 births
  - Mental health shortage areas:
    - 14.0 per 1,000
  - Highest 10 year unemployment rate:
    - 20.1 per 1,000

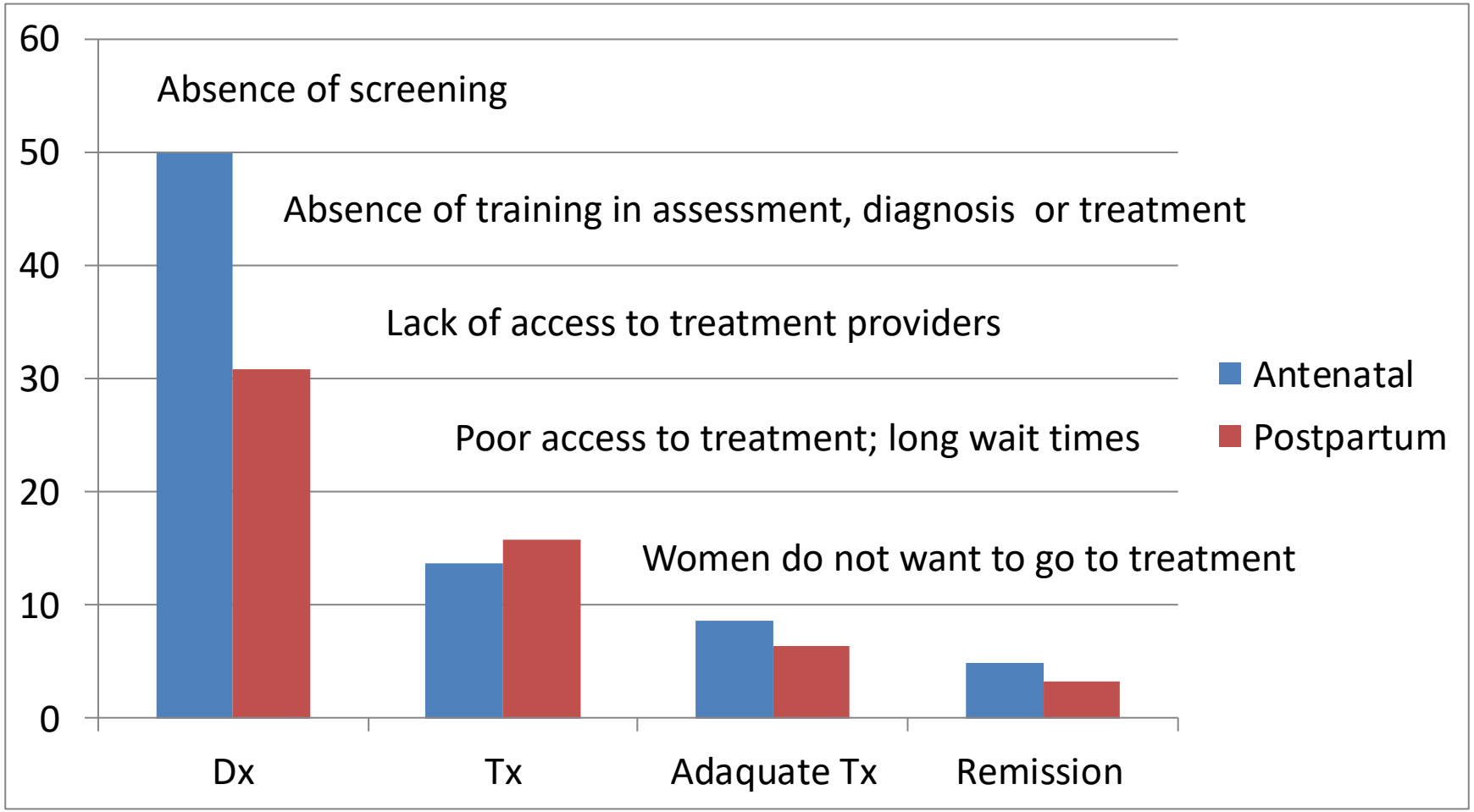
Patrick, 2019

Peripartum Treatment "Cascade"



Cox et al., 2016; *J Clin Psych*

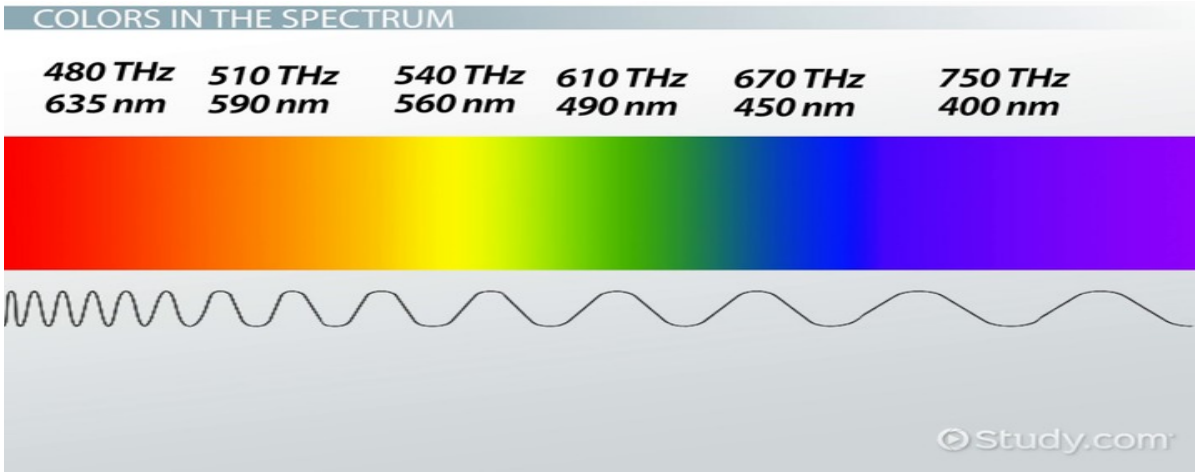
Peripartum Treatment "Cascade"



Cox et al., 2016; *J Clin Psych*

Integrated Care

- Systematic coordination of general, behavioral, mental health and addiction care with the goal of improving clinical outcomes and patient experience, and reducing costs.
- Large spectrum of integration
  - Coordinated
  - Co-Located
  - Integrated

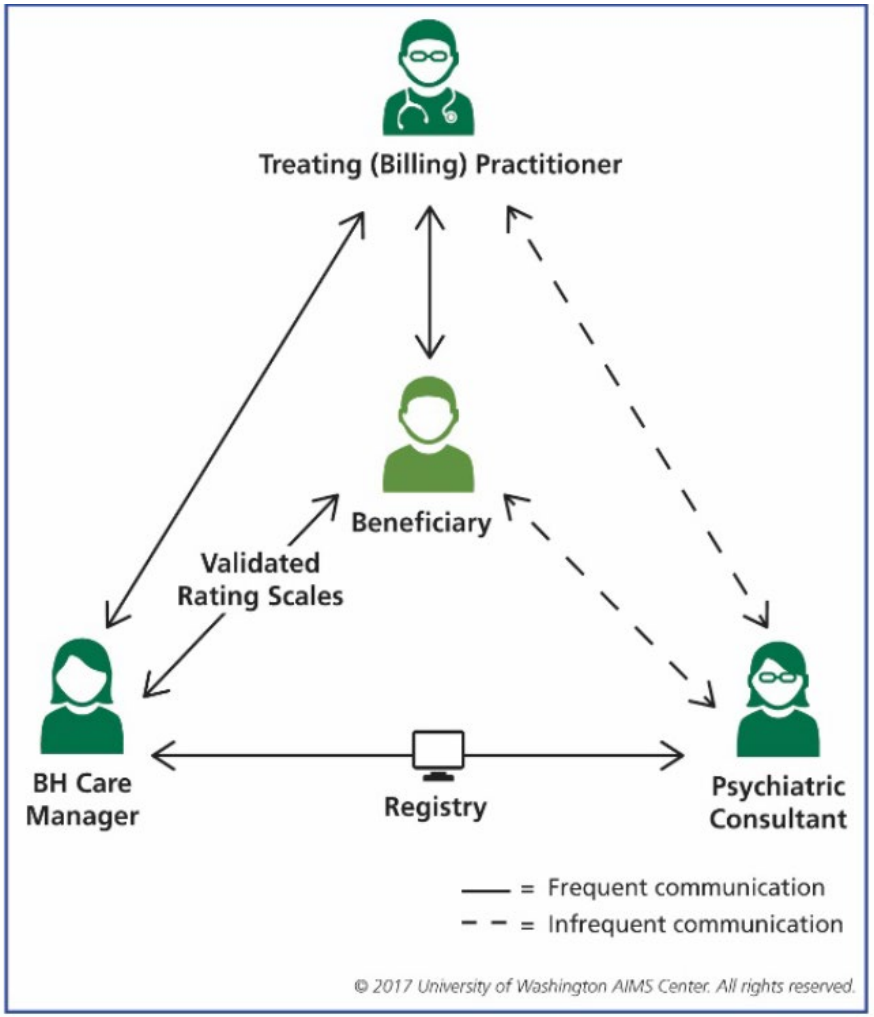


SAMHSA 6 Levels of Integrated Care

COORDINATED KEY ELEMENT: COMMUNICATION		CO LOCATED KEY ELEMENT: PHYSICAL PROXIMITY		INTEGRATED KEY ELEMENT: PRACTICE CHANGE	
LEVEL 1 Minimal Collaboration	LEVEL 2 Basic Collaboration at a Distance	LEVEL 3 Basic Collaboration Onsite	LEVEL 4 Close Collaboration Onsite with Some System Integration	LEVEL 5 Close Collaboration Approaching an Integrated Practice	LEVEL 6 Full Collaboration in a Transformed/ Merged Integrated Practice
Behavioral health, primary care and other healthcare providers work:					
In separate facilities, where they:	In separate facilities, where they:	In same facility not necessarily same offices, where they:	In same space within the same facility, where they:	In same space within the same facility (some shared space), where they:	In same space within the same facility, sharing all practice space, where they:
▸▸ Have separate systems ▸▸ Communicate about cases only rarely and under compelling circumstances ▸▸ Communicate, driven by provider need ▸▸ May never meet in person ▸▸ Have limited understanding of each other's roles	▸▸ Have separate systems ▸▸ Communicate periodically about shared patients ▸▸ Communicate, driven by specific patient issues ▸▸ May meet as part of larger community ▸▸ Appreciate each other's roles as resources	▸▸ Have separate systems ▸▸ Communicate regularly about shared patients, by phone or e-mail ▸▸ Collaborate, driven by need for each other's services and more reliable referral ▸▸ Meet occasionally to discuss cases due to close proximity ▸▸ Feel part of a larger yet non-formal team	▸▸ Share some systems, like scheduling or medical records ▸▸ Communicate in person as needed ▸▸ Collaborate, driven by need for consultation and coordinated plans for difficult patients ▸▸ Have regular face-to-face interactions about some patients ▸▸ Have a basic understanding of roles and culture	▸▸ Actively seek system solutions together or develop work-a-rounds ▸▸ Communicate frequently in person ▸▸ Collaborate, driven by desire to be a member of the care team ▸▸ Have regular team meetings to discuss overall patient care and specific patient issues ▸▸ Have an in-depth understanding of roles and culture	▸▸ Have resolved most or all system issues, functioning as one integrated system ▸▸ Communicate consistently at the system, team and individual levels ▸▸ Collaborate, driven by shared concept of team care ▸▸ Have formal and informal meetings to support integrated model of care ▸▸ Have roles and cultures that blur or blend

Collaborative Care- Primary Care

- 1990s; 80 RCTs
- Reduce MDD Sx
- Decreases Stigma
- Increase provider & patient satisfaction
- Improves clinical workflow/efficiency
- Reduces costs
- CMS/Billing Codes



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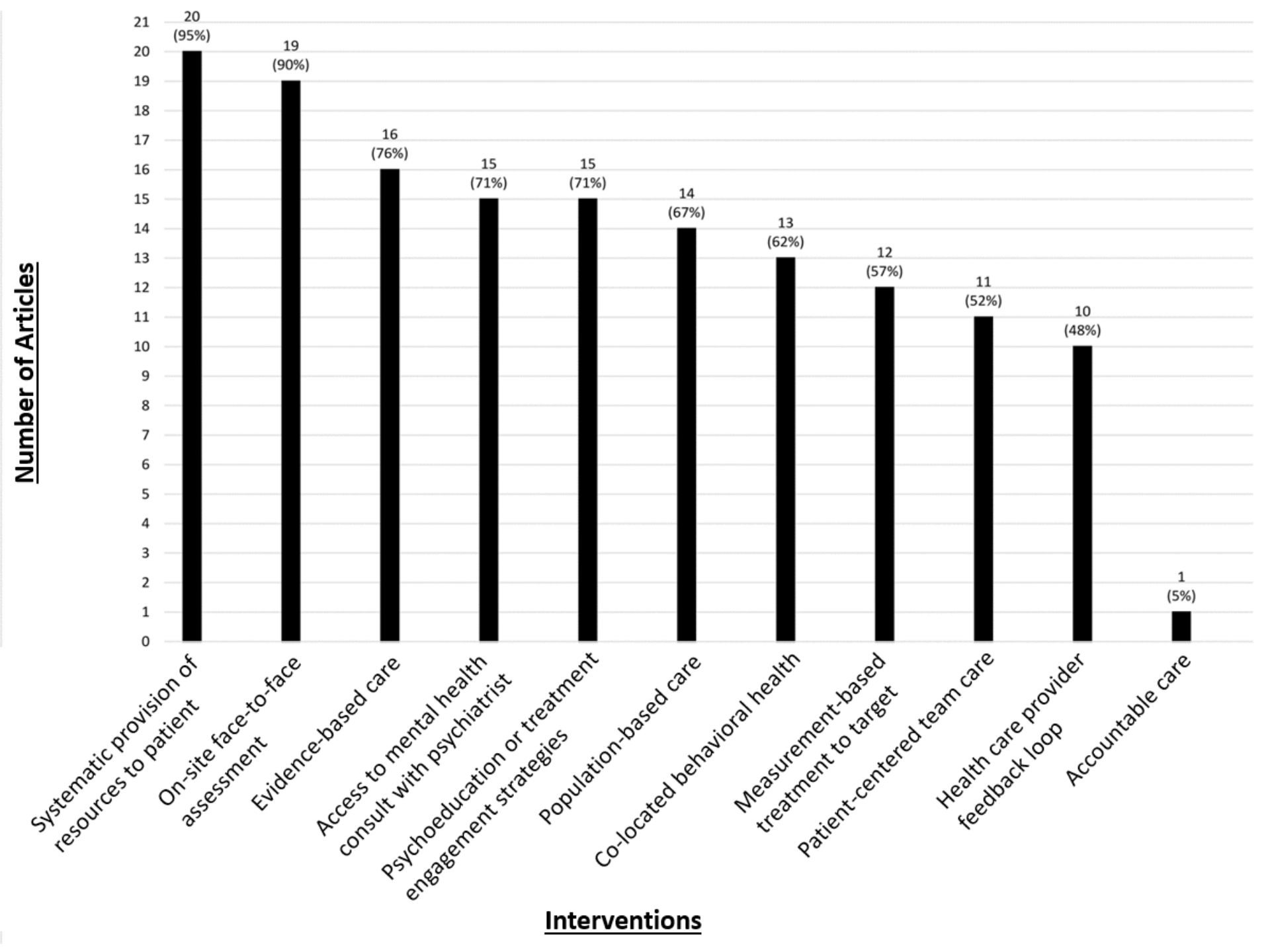
A Systematic Review of Integrated Care Interventions Addressing Perinatal Depression Care in Ambulatory Obstetric Care Settings

Tiffany A. Moore Simas, MD, MPH, MEd[1,a,b,c,2,a], **Michael P. Flynn, MD**[1,a], **Aimee R. Kroll-Desrosiers, MS**[1,d], **Stephanie M. Carvalho, BA**[1], **Leonard L. Levin, MS LIS, MA**[1,e,3], **Kathleen Biebel, PhD**[1,b], and **Nancy Byatt, DO, MS, MBA**[1,a,b,2,b]

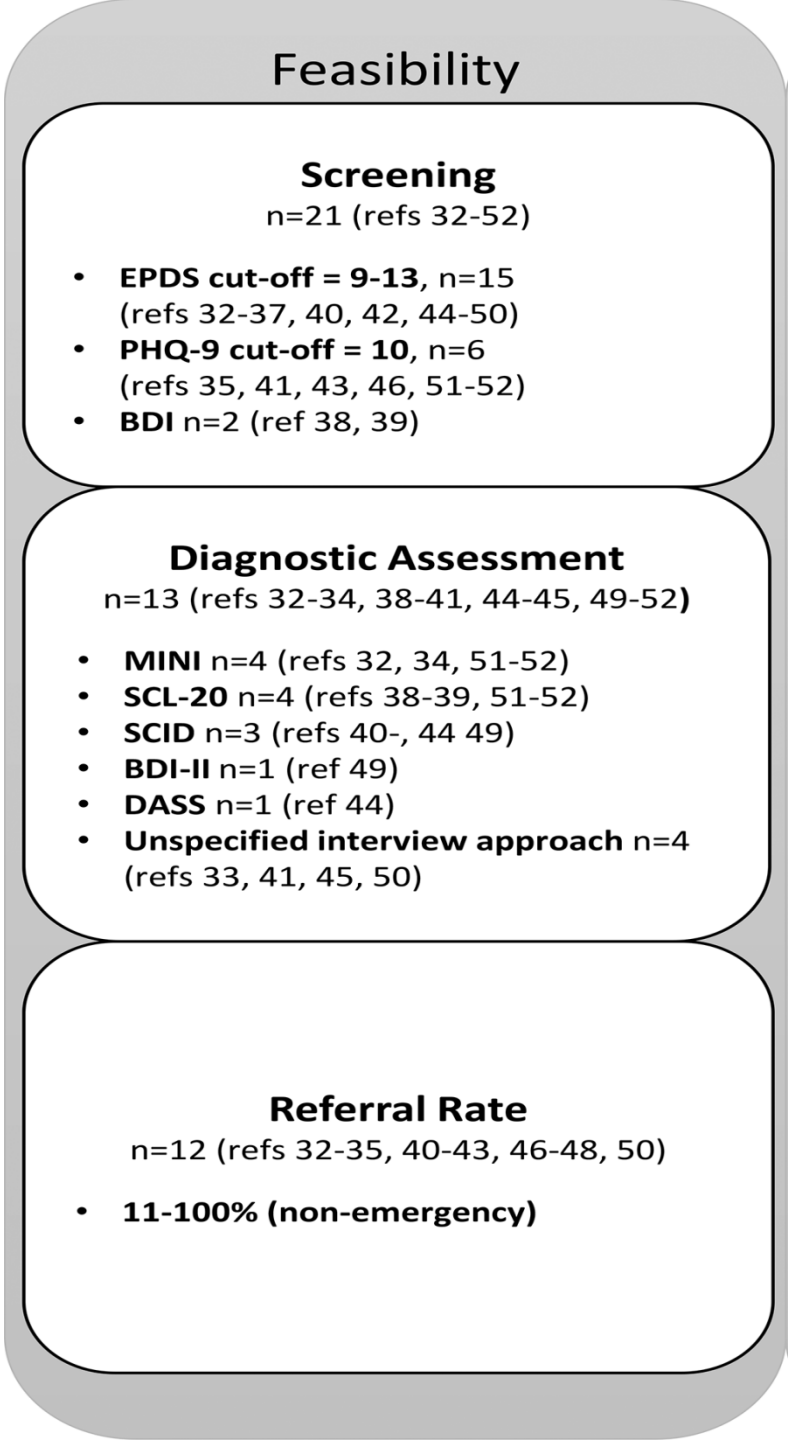
- Integrated Care - Ob/Gyn
- Systematic review 21 articles
  - At least 1 of 11 components of integrated behavioral health


Number of Articles
21
20
19
18
17
16
15
14
13
12
11
10
9
8
7
6
5
4
3
2
1
0
20 (95%)
19 (90%)
16 (76%)
15 (71%)
15 (71%)
14 (67%)
13 (62%)
12 (57%)
11 (52%)
10 (48%)
1 (5%)
Systematic provision of resources to patient
On-site face-to-face assessment
Evidence-based care
Access to mental health consult with psychiatrist
Psychoeducation or treatment engagement strategies
Population-based care
Co-located behavioral health
Measurement-based treatment to target
Patient-centered team care
Health care provider feedback loop
Accountable care
Interventions

Integrated Behavioral Health

Feasible

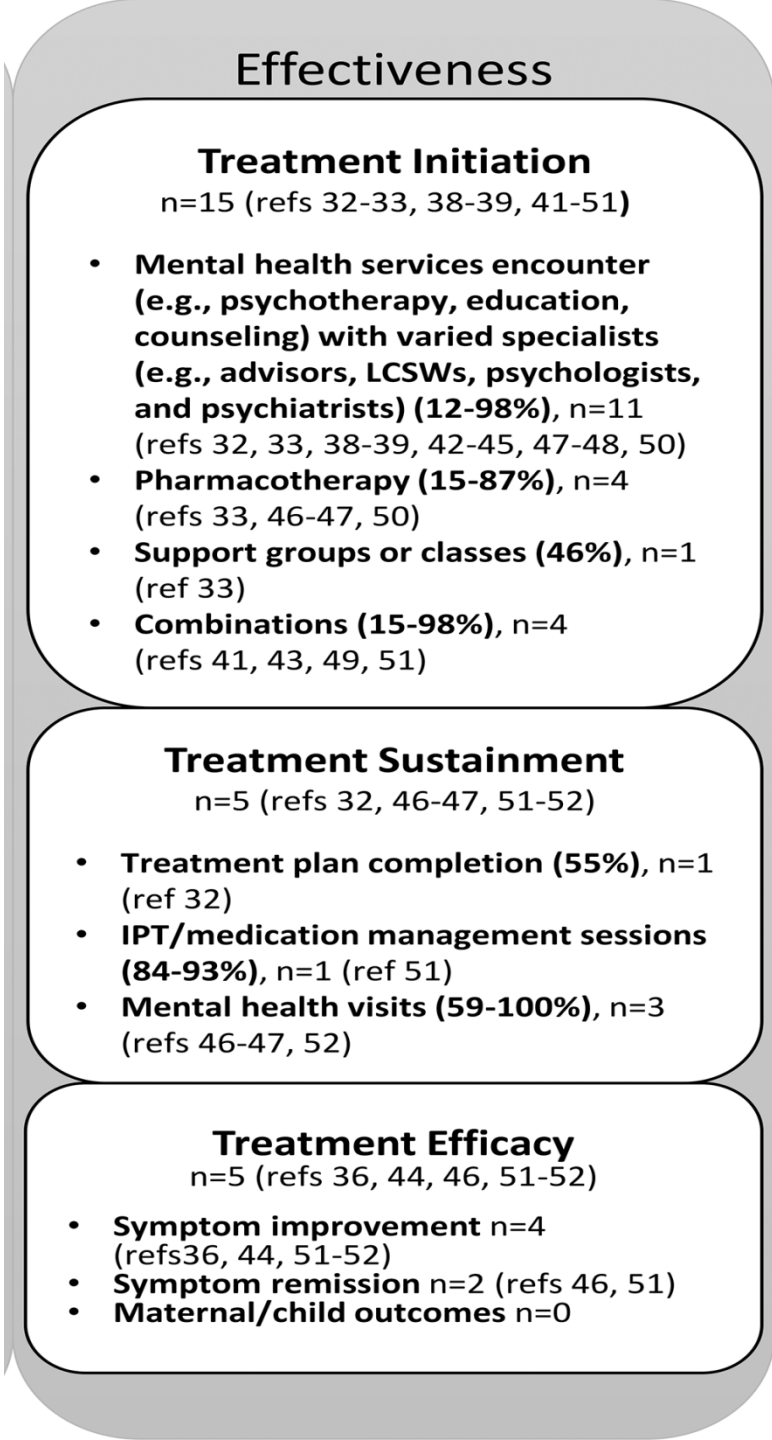
- Screen
- Diagnosis
- Refer



Integrated Behavioral Health

Effective Tx

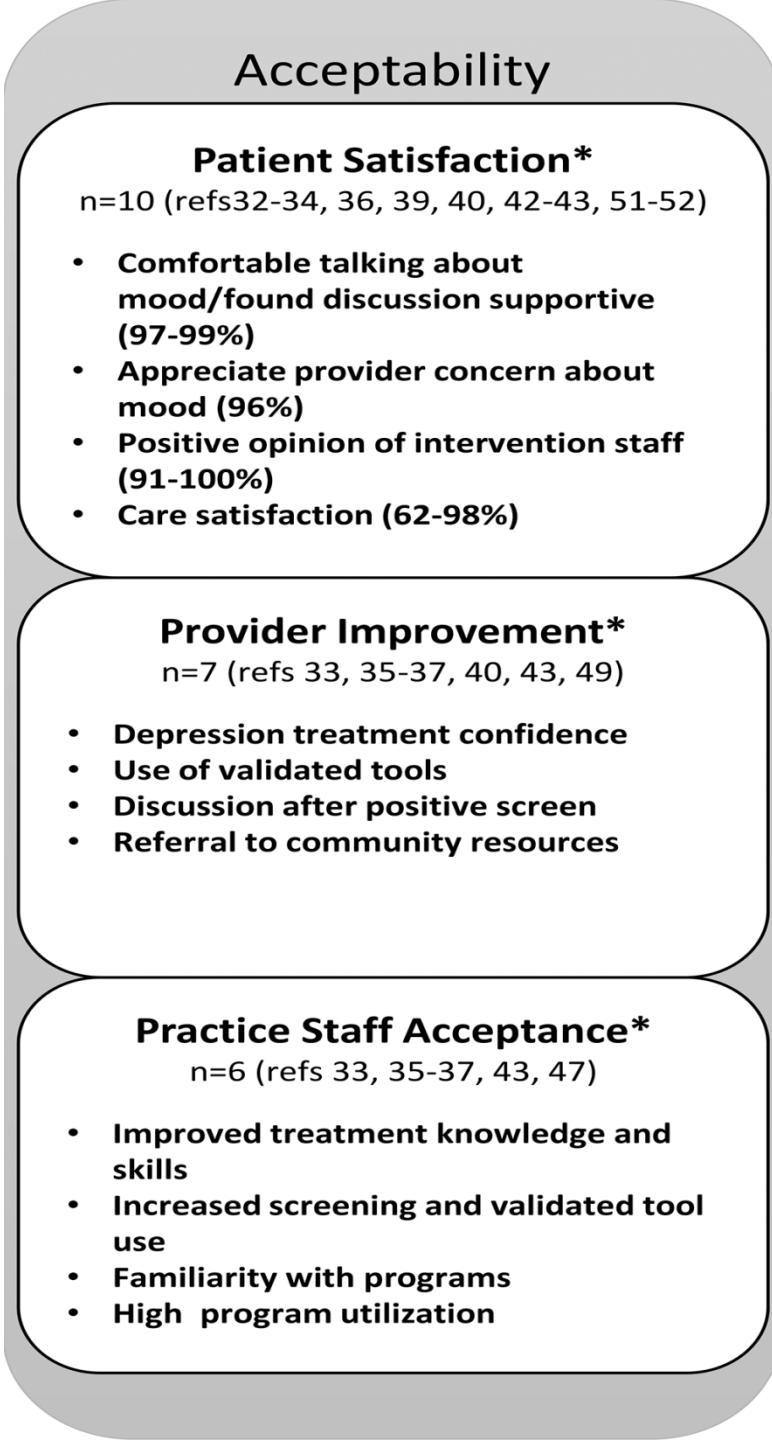
- Started
- Sustained
- Effective



Integrated Behavioral Health

Acceptable

- Patients
- Providers
- Staff



Integrated Behavioral Health

Sustainable

- Start-up expense
- 1.4 FTE NP
- 0.6 FTE Admin

Sustainability

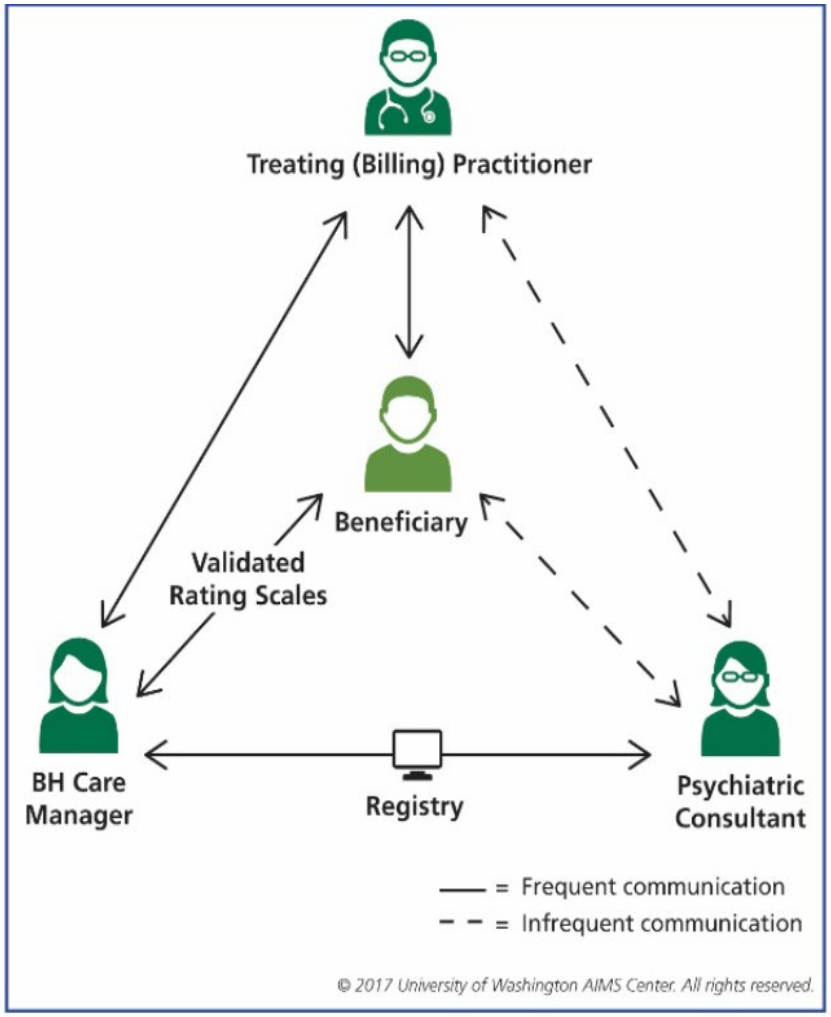
Intervention Costs/Resources

n=3 (refs 35, 44, 51)

- Byatt et al.: **$8.38/woman/year** plus start-up administrative expenses and community capacity building (ref 35)
- Grote et al.: **$1,117/woman** (ref 51)
- Harvey et al.: 1.4 FTE senior-level mental health nurse and 0.6 FTE administrative staff (ref 44)

Integrated or Collaborative Care- Ob Care

- Limited Ob data
- CMS/Billing Codes
  - SC Medicaid does not support
- Leverage existing resources

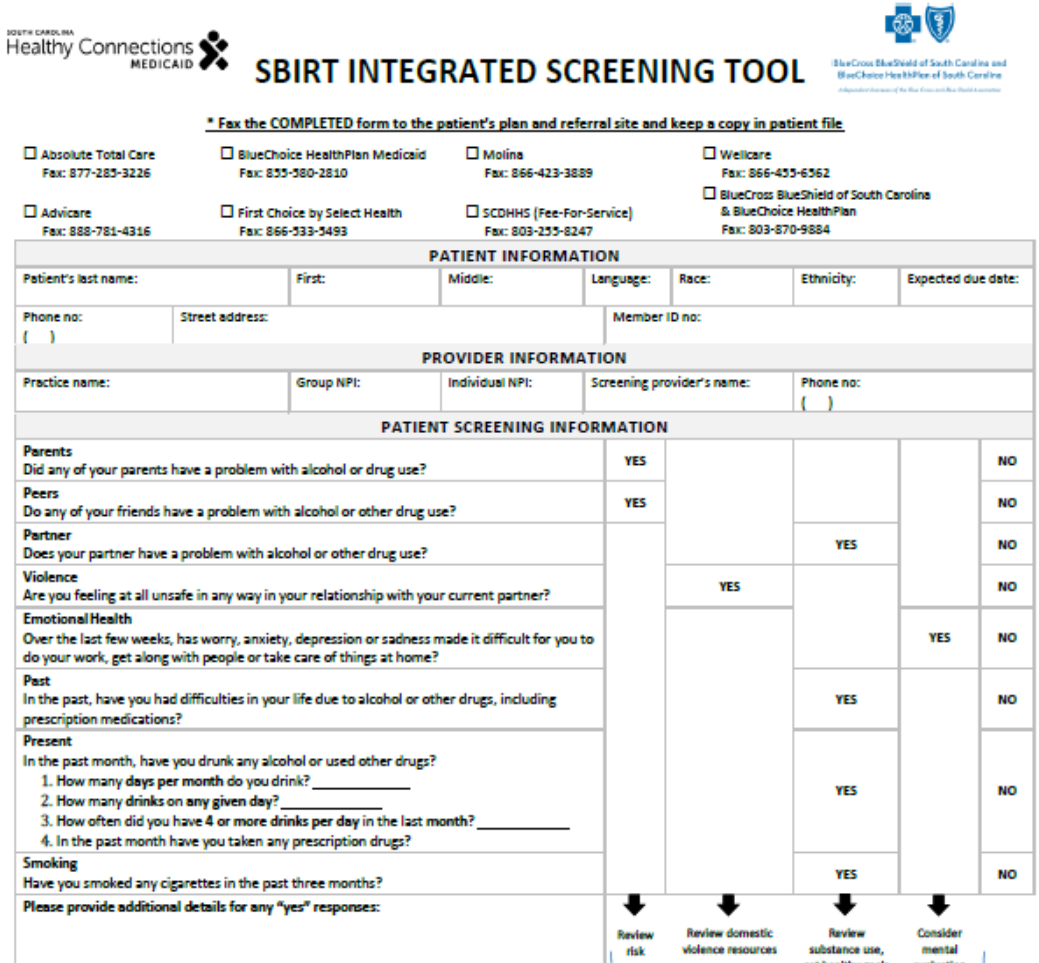


Birth Outcomes Initiative

Mental Health and Substance Use Screening- SBIRT

- **SCREENING** quickly assesses the frequency and severity of substance use, identify the appropriate level of treatment.
- **BRIEF INTERVENTION** focuses on increasing insight and awareness regarding substance use and motivation toward behavioral change.
- **REFERRAL TO TREATMENT** provides those identified as needing more extensive treatment with access to specialty care.

Substance Abuse and Mental Health Services Administration. Clinical Guidance for Treating Pregnant and Parenting Women With Opioid Use Disorder and Their Infants. HHS Publication No. (SMA) 18-5054. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2018.; Wright, Tricia E. et al. The Role of Screening, Brief Intervention, and Referral to Treatment in the Perinatal Period. 2016;215(5):539-547



SOUTH CAROLINA Healthy Connections MEDICAID

SBIRT INTEGRATED SCREENING TOOL

BlueCross BlueShield of South Carolina and BlueChoice HealthPlan of South Carolina

*** Fax the COMPLETED form to the patient's plan and referral site and keep a copy in patient file**

- ☐ Absolute Total Care — Fax: 877-285-3226
- ☐ BlueChoice HealthPlan Medicaid — Fax: 855-580-2810
- ☐ Molina — Fax: 866-423-3889
- ☐ Wellcare — Fax: 866-455-6562
- ☐ Advicare — Fax: 888-781-4316
- ☐ First Choice by Select Health — Fax: 866-533-5493
- ☐ SCDHHS (Fee-For-Service) — Fax: 803-255-8247
- ☐ BlueCross BlueShield of South Carolina & BlueChoice HealthPlan — Fax: 803-870-9884

PATIENT INFORMATION

Patient's last name:	First:	Middle:	Language:	Race:	Ethnicity:	Expected due date:
Phone no: ( )	Street address:		Member ID no:			

PROVIDER INFORMATION

Practice name:	Group NPI:	Individual NPI:	Screening provider's name:	Phone no: ( )

PATIENT SCREENING INFORMATION

Parents Did any of your parents have a problem with alcohol or drug use?	YES				NO
Peers Do any of your friends have a problem with alcohol or other drug use?	YES				NO
Partner Does your partner have a problem with alcohol or other drug use?			YES		NO
Violence Are you feeling at all unsafe in any way in your relationship with your current partner?		YES			NO
Emotional Health Over the last few weeks, has worry, anxiety, depression or sadness made it difficult for you to do your work, get along with people or take care of things at home?				YES	NO
Past In the past, have you had difficulties in your life due to alcohol or other drugs, including prescription medications?			YES		NO
Present In the past month, have you drunk any alcohol or used other drugs? 1. How many **days per month** do you drink? _____ 2. How many **drinks on any given day**? _____ 3. How often did you have **4 or more drinks per day** in the last month? _____ 4. In the past month have you taken any prescription drugs?			YES		NO
Smoking Have you smoked any cigarettes in the past three months?			YES		NO
Please provide additional details for any "yes" responses:	↓ Review risk	↓ Review domestic violence resources	↓ Review substance use, set healthy goals	↓ Consider mental evaluation	

ADVICE FOR BRIEF INTERVENTION

	Y	N	N/A
Did you State your medical concern?			
Did you Advise to abstain or reduce use?			
Did you Check patient's reaction?			
Did you Refer for future assessment?			

At Risk Drinking	
Non-Pregnant	**Pregnant/Planning Pregnancy**
7+ drinks/week 3+ drinks/day	**Any Use is Risky Drinking**

CONFIDENTIAL SBIRT REFERRAL INFORMATION

Patient referred to: (Check all that apply)	☐ DMH	☐ DAODAS	☐ DHEC Quitline Fax: 800-483-3114	☐ Private provider (Name & NPI)	☐ Domestic violence 803-256-2900
Date of referral appointment (DD/MM/YY):	Date screened:	☐ Patient refused referral	☐ Referral not warranted:	☐ Patient requested assistance	

Women's health can be affected by emotional problems, alcohol, tobacco, other drug use and domestic violence. Women's health is also affected when those same problems are presented in people close to us. By "alcohol," we mean beer, wine, wine coolers or liquor.

Physician's Signature: _____

**Adapted from Institute for Health & Recovery, (2015)*

Screening:

Substance Use

Domestic Violence

Mental Health (Past, Present)

↓

Brief Intervention:

Assessment

Motivational Interviewing

[increase likelihood of accessing tx]

↓

Referral to Treatment:

Follow up

[ensure accessed treatment]

South Carolina Healthy Connections Medicaid

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Past In the past, have you had difficulties in your life due to alcohol or other drugs, including prescription medications?			YES		NO
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**Adapted from Institute for Health & Recovery, (2015)*

Text Based Screening in Ob Office

⬇

Brief Intervention
Remote Care Coordinator

⬇

Referral to Treatment
Telemedicine/ Office or Home
Follow up

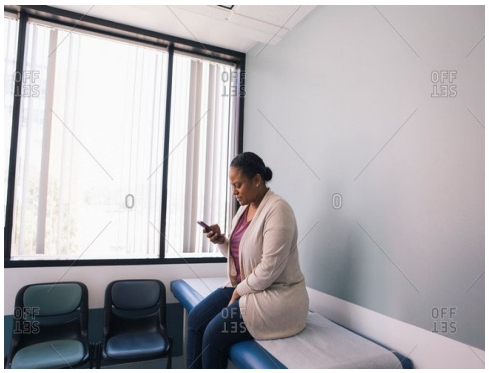
⬇

Communicate with Ob Team
Screening information
Referral and Tx Progress

Screening

Text Based Screening in Ob Office

- Program is briefly introduced [brochure provided]
- Women provide verbal consent & cell phone number
- Cell phone number entered in web-based system
- Patient receives text immediately and survey to be completed in office while waiting



Screening

Text Based Screening in Ob Office

- Self-report, as opposed to in-person interviews yield higher rates of reporting substance use & depression.
- + Screens = EDPS, NIDA, AA

  - Increase specificity of screens
- Categorize patients according to needs to optimize time and workflow

Gryczynski, J et al. (2017). Validation of the TAPS-1: A four-item screening tool to identify unhealthy substance use in primary care. *Journal of General Internal Medicine, 32*(9), 990-996.

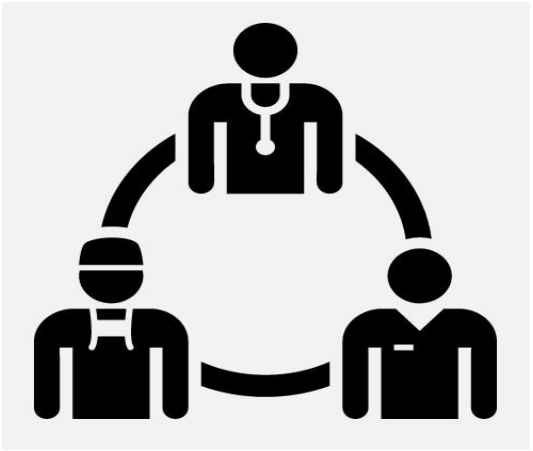
Screening

Text Based Screening in Ob Office

- Algorithm classifies women into clinical categories and priority for assessment and intervention:
  - Low Risk
  - Risk Factors for Depression
  - Positive Depression Screen
  - Substance Abuse High/Low Risk
  - Domestic Violence Risk

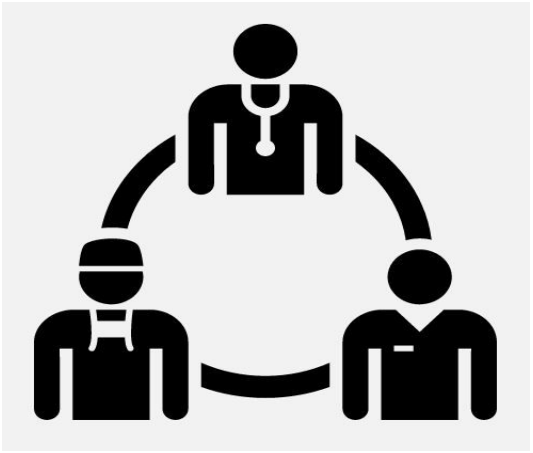
Brief Intervention & Referral to Treatment

- Care Coordinator Contacts Patient
- Assessment
- Creates Care Plan
- Motivational Interview/Referral Services
- Follow-Up with Patient
- Care Coordinator provides summary of screen, assessment and plan to provider via EHR.

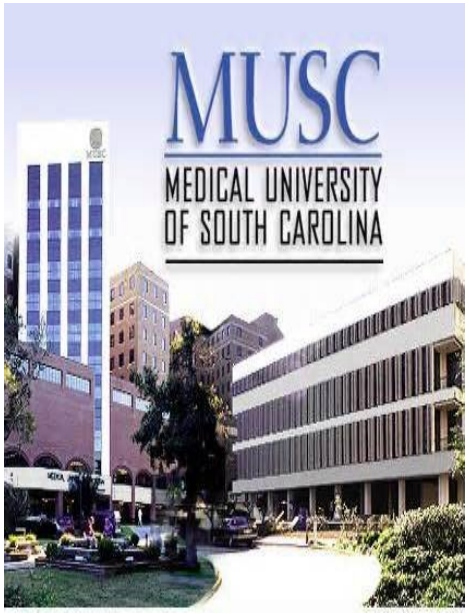


Brief Intervention & Referral to Treatment

- Reduce the need for training and re-training
- Increase the reach of experts in MI, care coordination & mental health
- Patient connects with one care coordinator



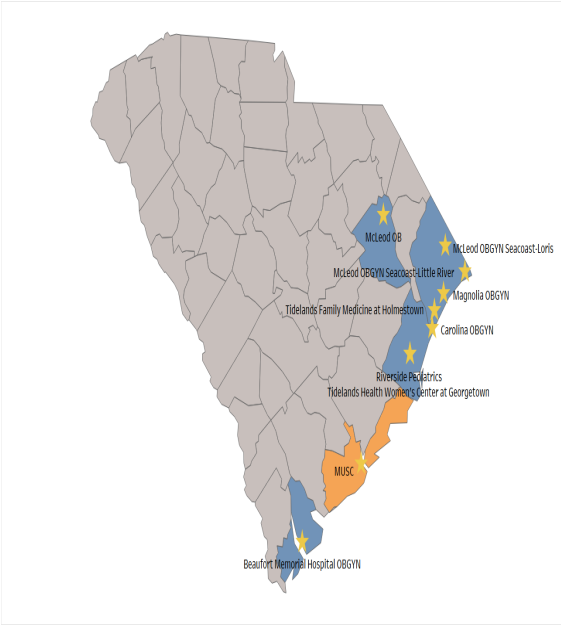
Referral to Treatment



NIH National Institute on Drug Abuse
The Science of Drug Abuse & Addiction

LLR sc.gov
Making South Carolina a Safe Place to Work and Live

DORIS DUKE CHARITABLE FOUNDATION



Program Enrollment

Where a women enters care:

- Prenatal care at obstetricians office
- Delivery at hospital
- Postnatal care at obstetricians office
- Well-child visits at pediatricians office

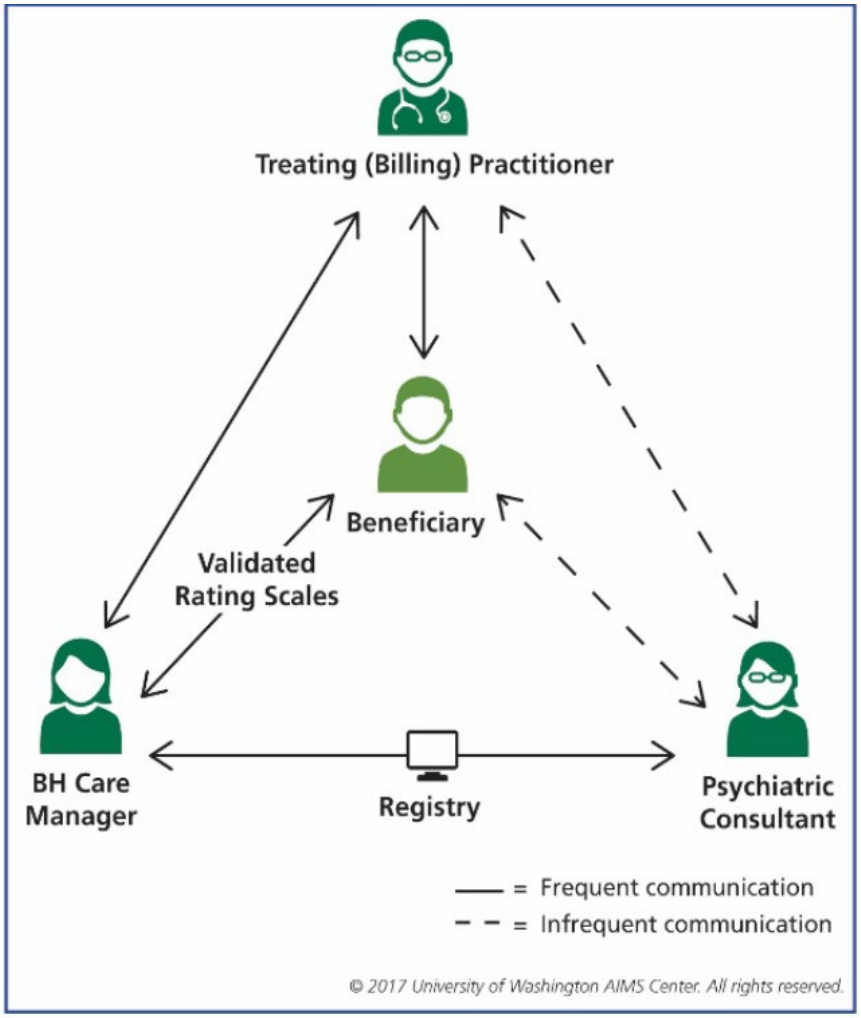
Follow-up Screenings

- Enroll anytime
- Each trimester of pregnancy
- Months 1, 3, 6, 9, 12, 15, 18 postpartum

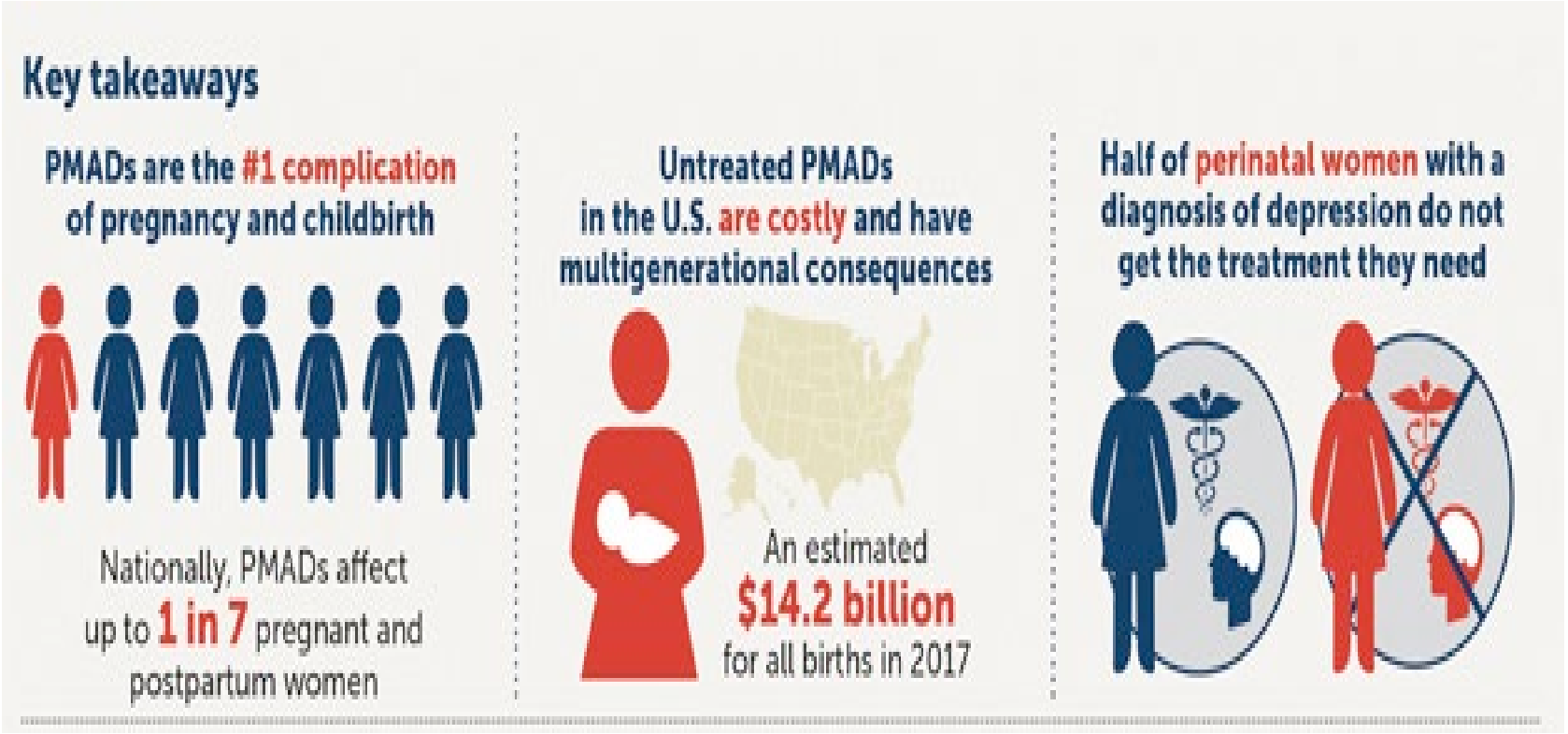
Virtual Collaborative Ob Care

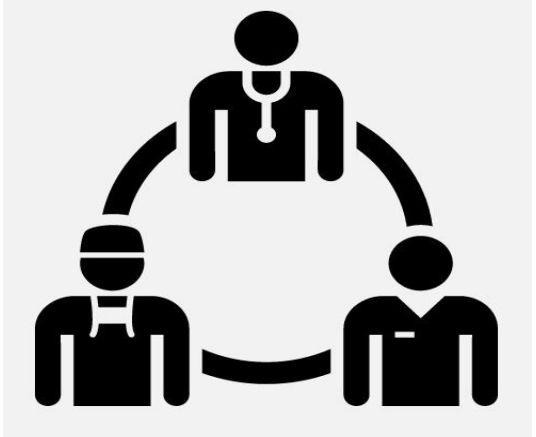
Evaluation

- Improve detection
- Reduce sx
- Decreases Stigma
- Increase provider & patient satisfaction
- Improve clinical workflow/efficiency
- Reduces costs
- CMS/Billing Codes



Summary


Key takeaways
PMADs are the #1 complication of pregnancy and childbirth
Nationally, PMADs affect up to 1 in 7 pregnant and postpartum women
Untreated PMADs in the U.S. are costly and have multigenerational consequences
An estimated $14.2 billion for all births in 2017
Half of perinatal women with a diagnosis of depression do not get the treatment they need



Acknowledgements

- Collaborators
  - Katie Cristaldi, MD
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  - Donna Johnson, MD
  - Kathleen Brady, MD, PhD
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  - Jimmy McElligott, MD
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  - Claire Smith, MD
  - Edie Douglas, MPH
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- Funding
  - NIH/NIDA/ORWH
  - HRSA
  - SAMHSA
  - American Foundation of Suicide Prevention
  - Duke Endowment

Thank you

Connie Guille
Email: guille@musc.edu

Summary

Text Based Screening in Ob Office

Brief Intervention
Remote Care Coordinator

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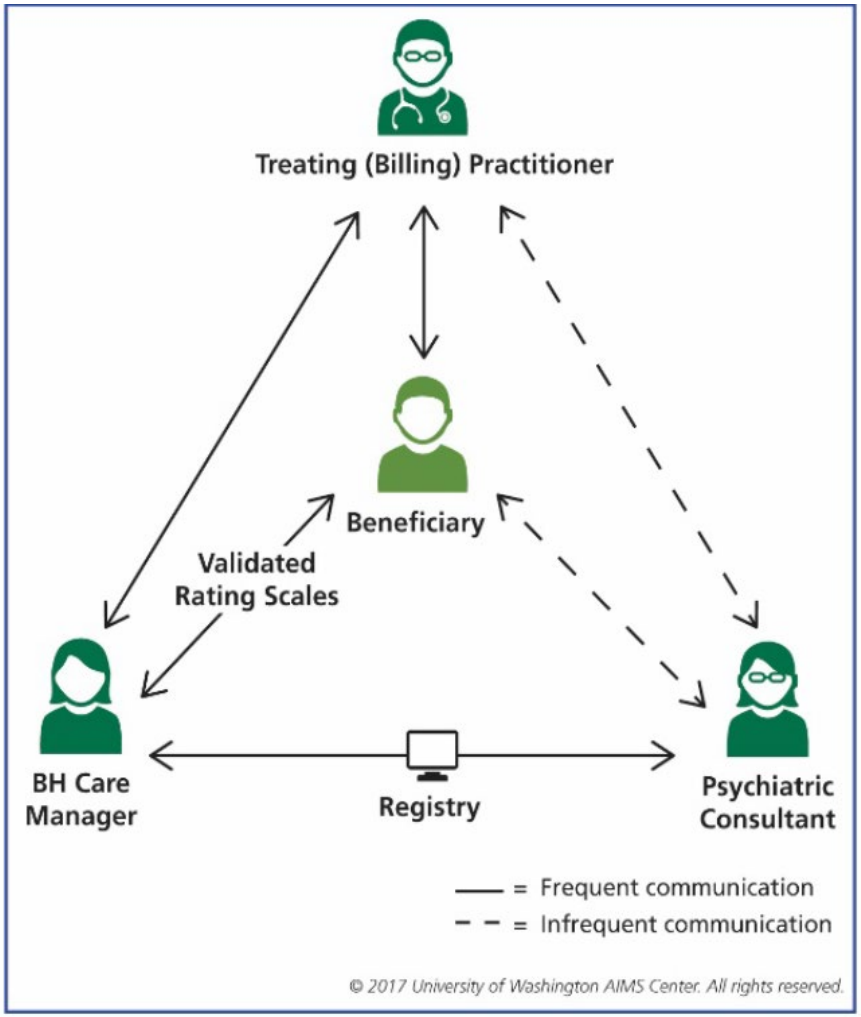


The Washington Post

Health

First drug specifically for postpartum depression is approved

The new medication must be taken intravenously over 60 hours.

McGinley & Bernstein, 2019

Brexanolone

- Beta-cyclodetrin, IV formulation of allopregnanolone[1,2]
  - Symptom improvement: 24 hours; remission: 3 days
- Mechanism[1,2]
  - Modulation of GABA-A receptors
- Logistics[1,2]
  - 60 – hour IV infusion in healthcare facility
  - Continuous pulse ox, q2 hour mentation checks
- Side Effects[1]
  - Blackbox warning: sedation, loss of consciousness
- Cost[1]
  - $34,000 per patient

1. "Brexanolone (Zulresso) for Postpartum Depression," 2019, 73-74
2. Meltzer-Brody, Colquhoun & Riesenberg, et. al., 2018, 1058-1070

Brexanolone

How does it work?

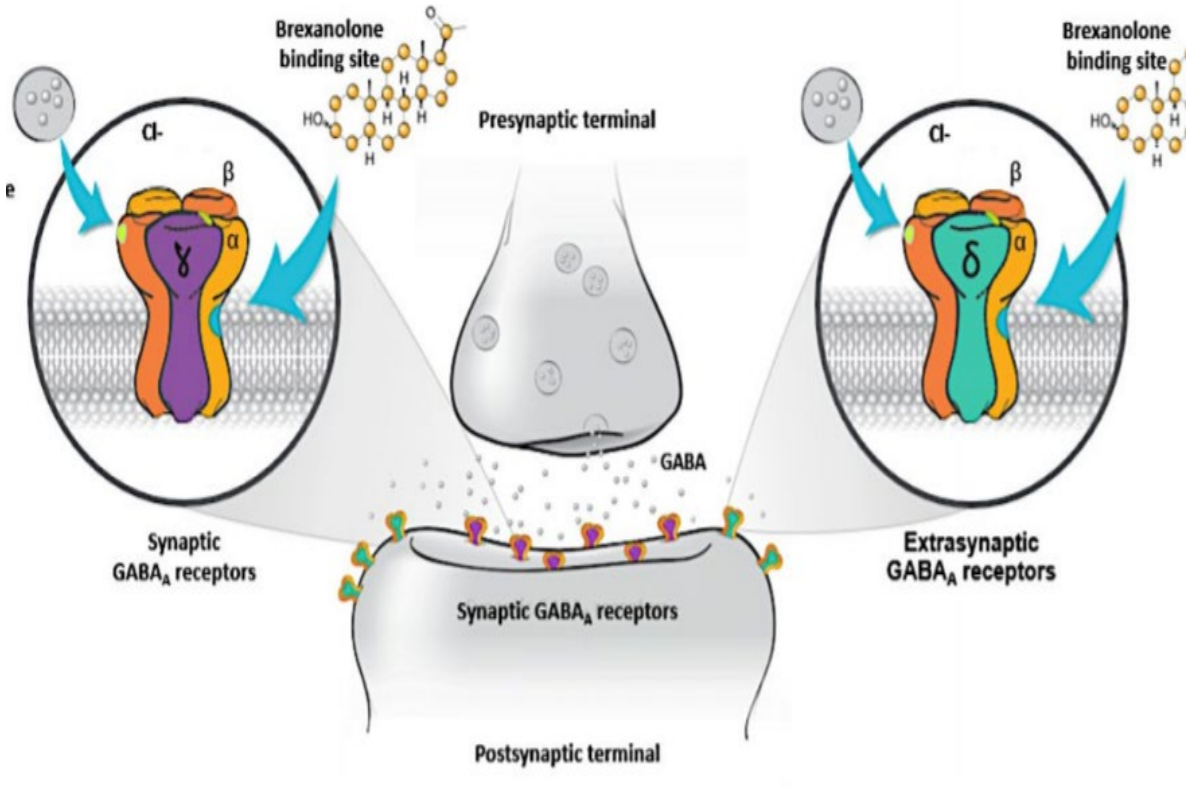


Figure 2. Bhati, (n.d)

Stanford MEDICINE | Department of Psych and Behavioral Scien

Efficacy of brexanolone injection in post-partum depression: Two multicentre, double-blind, randomized, placebo-controlled, phase 3 trials

Purpose

- Objective
  - To assess the efficacy and safety of Brexanolone in the treatment of postpartum depression
- Endpoints
  - Primary – change from baseline in the mean 17-item Hamilton Rating Scale for Depression (HAM-D) total score at 60 hr post-infusion
  - Secondary – mean HAM-D score change from baseline at 30 days after infusion
  - Secondary – comparison of adverse effects among treatment and placebo groups

METHODS

Study Design

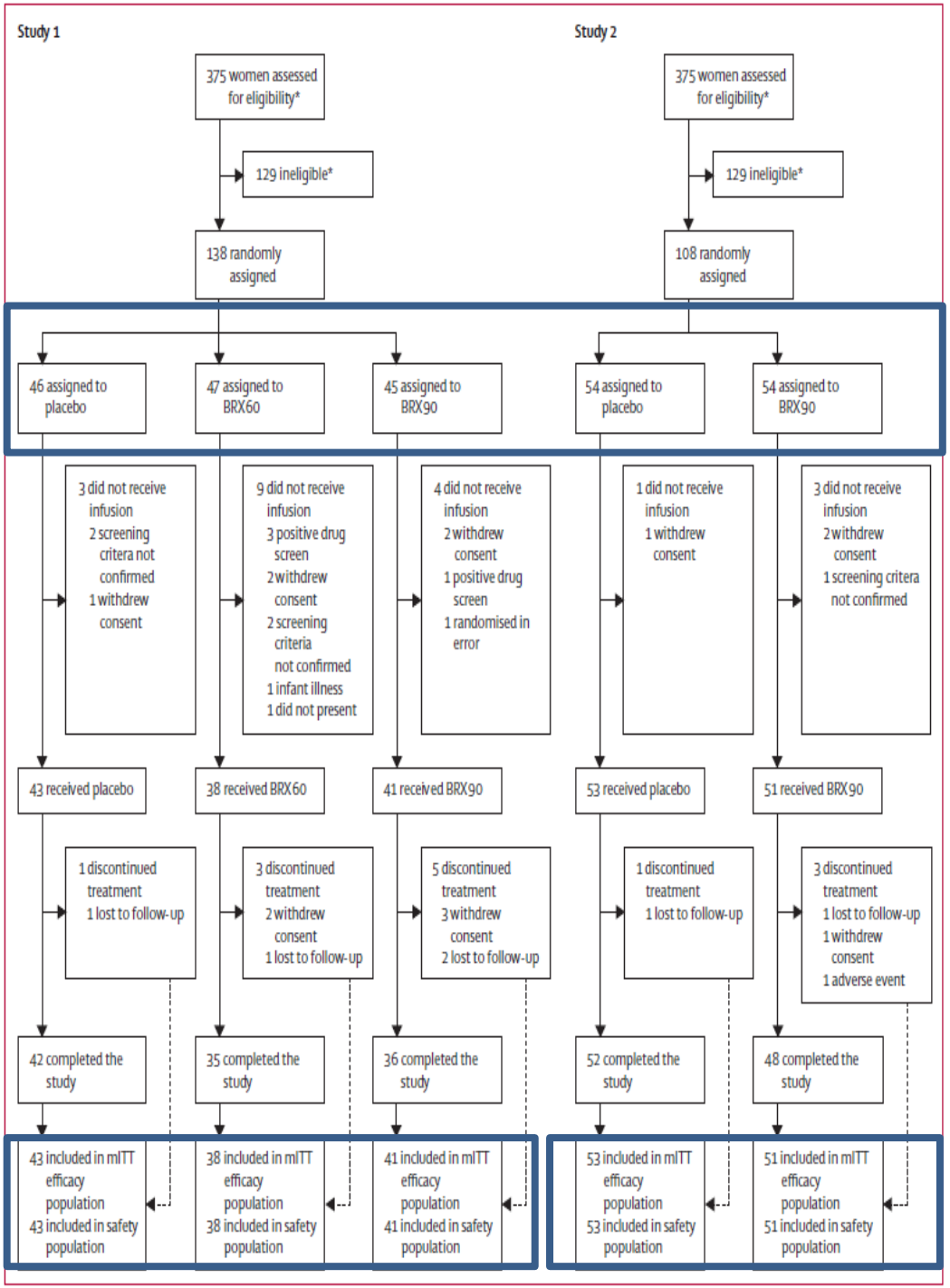
- Randomized, double-blind, placebo-controlled
  - 30 clinical research centers
  - Randomization:
    - Study 1 (Mean HAM-D $\geq$ 26)

      Brexanolone 90 ug/kg vs. Brexanolone 60 ug/kg vs. placebo
    - Study 2 (Mean HAM-D 20-25)

      Brexanolone 90 ug/kg vs. placebo
- Each patient received 60 hrs continuous infusions
- Repeated assessments of HAM-D
- Adverse effects recorded

Study 1

Needed 40 patients/group up to achieve 90% power to detect a difference of 9



Study 2

Needed 50 patients/group to achieve 90% power to detect a difference of 8

Population

- **Inclusion Criteria**
  - Females aged 18-45 yo
  - Negative UPT & reliable contraception
  - ≤6mo postpartum
  - Onset of PPD in the third trimester to 4 weeks postpartum
  - Good health
  - Discontinued breastfeeding
  - If on antidepressant, must be stable dose

- **Exclusion Criteria**
  - ESRD on dialysis
  - Allergy to pregnanolone or progesterone
  - Hgb <10
  - PMH schizophrenia, schizoaffective, attempted suicide
  - Drug or alcohol abuse
  - Recent ECT

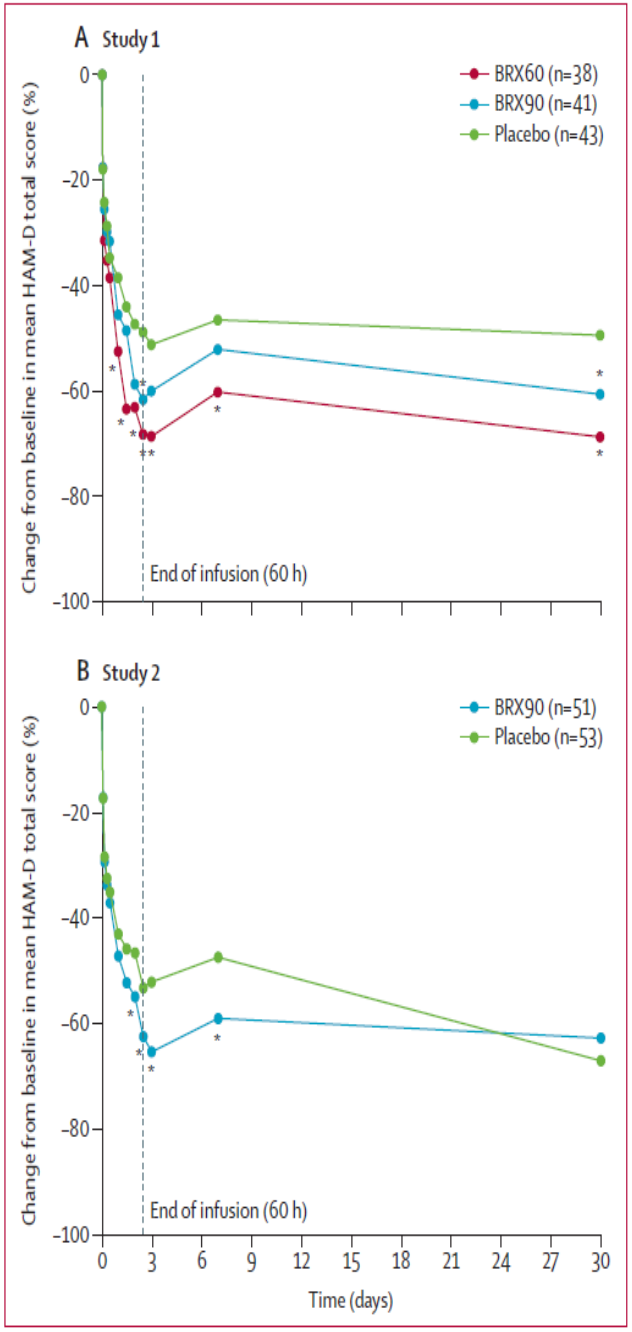
RESULTS

Results – Demographics

- Well-balanced baseline characteristics
  - Mean age: 27-28 yo
  - Race: white (62%), African American (35%), Hispanic (17%)
  - Onset of depression: Similar across all groups, generally within 4 weeks PP
  - Antidepressants at baseline: 22% across both studies

Results

- Primary Endpoint: 60 hrs
  - Significant reduction in HAM-D scores at the end of 60 hours among both studies
- Secondary Endpoint: 30 d
  - Study 1 - Significant reduction in HAM-D scores at 30 days among both treatment groups



Study 1

BRX60 (M [SE])

-19.5 [1.2]

Mean change [95% CI]

-5.5 [-8.8,-2.2]

BRX90 (M [SE])

17.7 (1.2)

Mean change [95% CI]

-3.7 [-6.9,-0.5]

Placebo (M [SE])

14.0 [1.1]

Study 2

BRX90 **(M [SE])**

14.0 [0.8]

Mean change [95% CI]

-2.5 [-4.5,0.5]

Placebo (M [SE])

-12.1 [0.8]

	Study 1			Study 2	
	Placebo (n=43)	BRX60 (n=38)	BRX90 (n=41)	Placebo (n=53)	BRX90 (n=51)
Overall					
Any adverse event	22 (51%)	19 (50%)	22 (54%)	24 (45%)	25 (49%)
Severe adverse event	0	1 (3%)	0	1 (2%)	2 (4%)
Serious adverse event	0	1 (3%)	0	0	1 (2%)
Adverse event leading to discontinuation of study treatment	1 (2%)	1 (3%)	0	0	2 (4%)
Deaths	0	0	0	0	0
Adverse events in three or more patients					
Headache	7 (16%)	7 (18%)	6 (15%)	6 (11%)	9 (18%)
Dizziness	1 (2%)	6 (16%)	6 (15%)	4 (8%)	5 (10%)
Somnolence	3 (7%)	7 (18%)	2 (5%)	2 (4%)	4 (8%)
Infusion site pain	1 (2%)	1 (3%)	4 (10%)	2 (4%)	5 (10%)
Nausea	3 (7%)	1 (3%)	0	2 (4%)	5 (10%)
Dry mouth	0	4 (11%)	0	1 (2%)	2 (4%)
Fatigue	0	1 (3%)	1 (2%)	2 (4%)	3 (6%)

Data are n (%). Treatment-emergent adverse events were defined as an adverse event with onset after the start of study drug, or any worsening of a pre-existing medical condition or adverse event with onset after the start of study drug. Treatment-emergent adverse events were coded according to the Medical Dictionary for Regulatory Activities version 19.1 or later. BRX60=brexanolone injection 60 μg/kg per h. BRX90=brexanolone injection 90 μg/kg per h.

Table 3: **Treatment-emergent adverse events**

Results

- **Secondary Endpoint: Adverse effects**
  - Similar across all groups

Blackbox Warning

- **Loss of consciousness**
  - Study 1
    - BRX60 – 1 of 38 (3%)
  - Study 2
    - BRX90 – 1 of 51 (2%)
  - Across both studies
    - 5 total patients with excessive sedation

DISCUSSION

Discussion

- PPD is common
- High morbidity & mortality
- Brexanolone shows efficacy in the treatment of moderate-severe depression
  - Quick onset and response
    - 3 days vs 6-8 weeks with SSRIs
  - Some durability at 30 days

2. Meltzer-Brody, Colquhoun & Riesenberg, et. al., 2018, 1058-1070

5. Stewart & Vigod, 2016, 2177-2186
6. Brummelte & Galea, 2016, 153-166

Limitations

- **Large placebo response**
  - Consistent with most other MDD studies
- **Mean change in HAM-D Score 2.5-5.5 points**
  - Consistent with most other MDD studies
- **Access**
  - Healthcare facility
  - Social support
  - 60 hour monitoring
  - Cost/Insurance coverage

Conclusions

- Brexanolone: novel MOA
- Safety and efficacy moderate-severe postpartum depression
- Quick response

But,

- Access/Insurance coverage
- Longitudinal studies are needed

References

1. Brexanolone (Zulresso) for Postpartum Depression. *Jama*. 2019;322(1):73. doi:10.1001/jama.2019.6622.

2. Meltzer-Brody S, Colquhoun H, Riesenberg R, et al. Brexanolone injection in post-partum depression: two multicentre, double-blind, randomised, placebo-controlled, phase 3 trials. *The Lancet.* 2018;392(10152):1058-1070. doi:10.1016/s0140-6736(18)31551

3. American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Disorders (5th Ed.)*. Arlington, VA: American Psychiatric Publishing; 2013.

4. ACOG Practice Bulletin No. 92: Use of Psychiatric Medications During Pregnancy and Lactation. *Obstetrics & Gynecology.* 2008;111(4):1001-1020. doi:10.1097/aog.0b013e31816fd910.

5. Stewart, D. and Vigod, S. (2016). Postpartum Depression. *New England Journal of Medicine*, 375(22), pp.2177-2186.

6. Brummelte S, Galea LA. Postpartum depression: Etiology, treatment and consequences for maternal care. *Hormones and Behavior*. 2016;77:153-166. doi:10.1016/j.yhbeh.2015.08.008.

7. Bhati, M. Psychopharmacology of Depression: Beyond Monoamines. *Stanford Medicine Department of Psychiatry and Behavioral Sciences.* Accessed from https://ncps.org/sites/ncps.org/files/Saturday%207_%20Bhati%20FINAL.pdf

ADDICTION

SSA SOCIETY FOR THE STUDY OF ADDICTION

METHODS AND TECHNIQUES

doi:10.1111/add.14651

Accuracy of five self-report screening instruments for substance use in pregnancy

Steven J. Ondersma[1], Grace Chang[2], Tiffany Blake-Lamb[3], Kathryn Gilstad-Hayden[4], John Orav[5], Jessica R. Beatty[1], Gregory L. Goyert[6] & Kimberly A. Yonkers[4,7]

- 315 of 1220 participants (26.3%) met reference standard criteria for positivity.
- The single-item screening questions from the NIDA Quick Screen showed high specificity (0.99) for all substances, but very poor sensitivity (0.10-0.27).
- The 5Ps showed high sensitivity (0.80-0.88) but low specificity (0.35-0.37).
- The CRAFFT, SURP-P and 5Ps had the highest area under the curve (AUC) for alcohol (0.67, 0.66 and 0.62, respectively)
- The WIDUS had the highest AUC for illicit drugs and opioids (0.70 and 0.69, respectively).

Ondersma SJ et al., Addiction. 2019 Sep;114(9):1683-1693.

Screening: Which Measure to Use?

- Universal Screening: ACOG, AAP, AMA, CDC
- N=1220 racially, ethnically and socio-economically diverse pregnant women
  - Substance Use Risk Profile-Pregnancy (SURP-P)
  - CRAFFT (acronym for five-item screener with items related to car, relax, alone, forget, friends and trouble), 5Ps (parents, peers, partner, pregnancy, past)
  - Wayne Indirect Drug Use Screener (WIDUS)
  - National Institute on Drug Abuse (NIDA) Quick Screen.
  - Participants later provided a urine sample and completed a calendar recall-based interview regarding substance use

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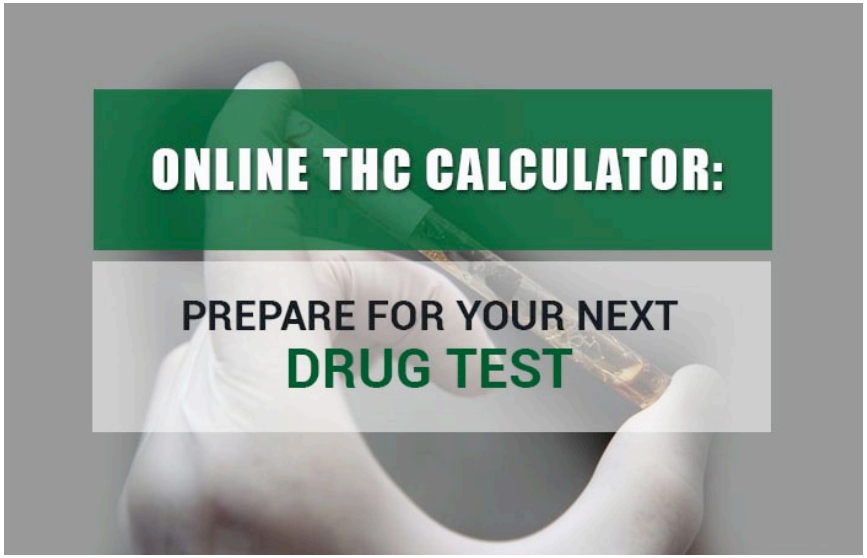
- The 5Ps showed high sensitivity (0.80-0.88) but low specificity (0.35-0.37).
- The CRAFFT, SURP-P and 5Ps had the highest area under the curve (AUC) for alcohol (0.67, 0.66 and 0.62, respectively)
- The WIDUS had the highest AUC for illicit drugs and opioids (0.70 and 0.69, respectively).

Ondersma SJ et al., Addiction. 2019 Sep;114(9):1683-1693.

Screening

Drug toxicology is **NOT** recommended for **universal** screening because it has limitations and should only be considered if there is a clinical indication and with consent.



Edinburgh Postnatal Depression Scale

- Review Item 10
- Total Score w/ Reverse Scoring
- High Probability of Peripartum Depression

Diagnosis

- EDPS score of >13

  Sensitivity: 0.80

  Specificity: 0.90
- If borderline, repeat in 2 weeks
- EDPS score of >10
  - 20% will have suicidal ideation

Patient Health Questionnaire (PHQ-9)

For each statement, please mark the response which best represents how often have you been bothered by any of the following problems over the **PAST 2 WEEKS**?

	Not at all	Less than half the days	More than half the days	Nearly everyday
Little interest or pleasure in doing things.	○	○	○	○
Feeling down depressed or hopeless.	○	○	○	○
Trouble falling asleep, staying asleep or sleeping too much.	○	○	○	○
Feeling tired or having little energy.	○	○	○	○
Poor appetite or overeating.	○	○	○	○
Feeling badly about yourself- or that you are a failure or that you have let yourself or your family down.	○	○	○	○
Trouble concentrating on things such as reading the newspaper or watching TV.	○	○	○	○
Moving or speaking so slow that others could have noticed. Or the opposite, being so fidgety or restless that you have been moving around a lot more than usual.	○	○	○	○
Thoughts that you would be better off dead or hurting yourself in some way.	○	○	○	○

	Not difficult at all	Somewhat difficult	Very difficult	Extremely difficult
If you have experienced any of these problems, how difficult have they made it for you to do your work, take care of things at home, or get along with other people?	○	○	○	○

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If you have comments or questions regarding this survey please email us at intern.health@yale.edu

Patient Health Questionnaire (PHQ-9)

- High probability DSM-5 Depression Diagnosis:
  - Add up all items
  - Cut off score: PHQ > 10
  - 88% sensitivity and 88% specificity

- Severity of Symptoms:
  - Add up all items (including outside shaded area)
  - 5-9 = Mild Depression
  - 10-14 = Moderate Depression
  - 15-19 = Moderate Severe Depression
  - 20 + = Severe Depression

(Kroenke et al., 2001)

Patient Health Questionnaire (PHQ-9)

- Severity of Symptoms:

PHQ-9 Score	Depression Severity	Proposed Treatment Action
0-4	None-Minimal	None
5-9	Mild	Monitor, repeat at follow-up
10-14	Moderate	Psychotherapy and Pharmacotherapy
15-19	Moderate-Severe	Psychotherapy and Pharmacotherapy
20+	Severe	Pharmacotherapy, Psychotherapy and Referral to Psychiatrist

(Kroenke et al., 2001)

Peripartum Depression

- Completed Screen
  EDPS: review item 10; Score 10/13 +
  PHQ-9: review item 9; Score 10 +
- Assessment & Diagnosis