Psychedelic Use During the Perinatal Period

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Hosted by: Practice Innovation Program
UNIVERSITY OF COLORADO
ANSCHUTZ MEDICAL CAMPUS

INTEGRATED CARE
FOR WOMEN AND BABIES

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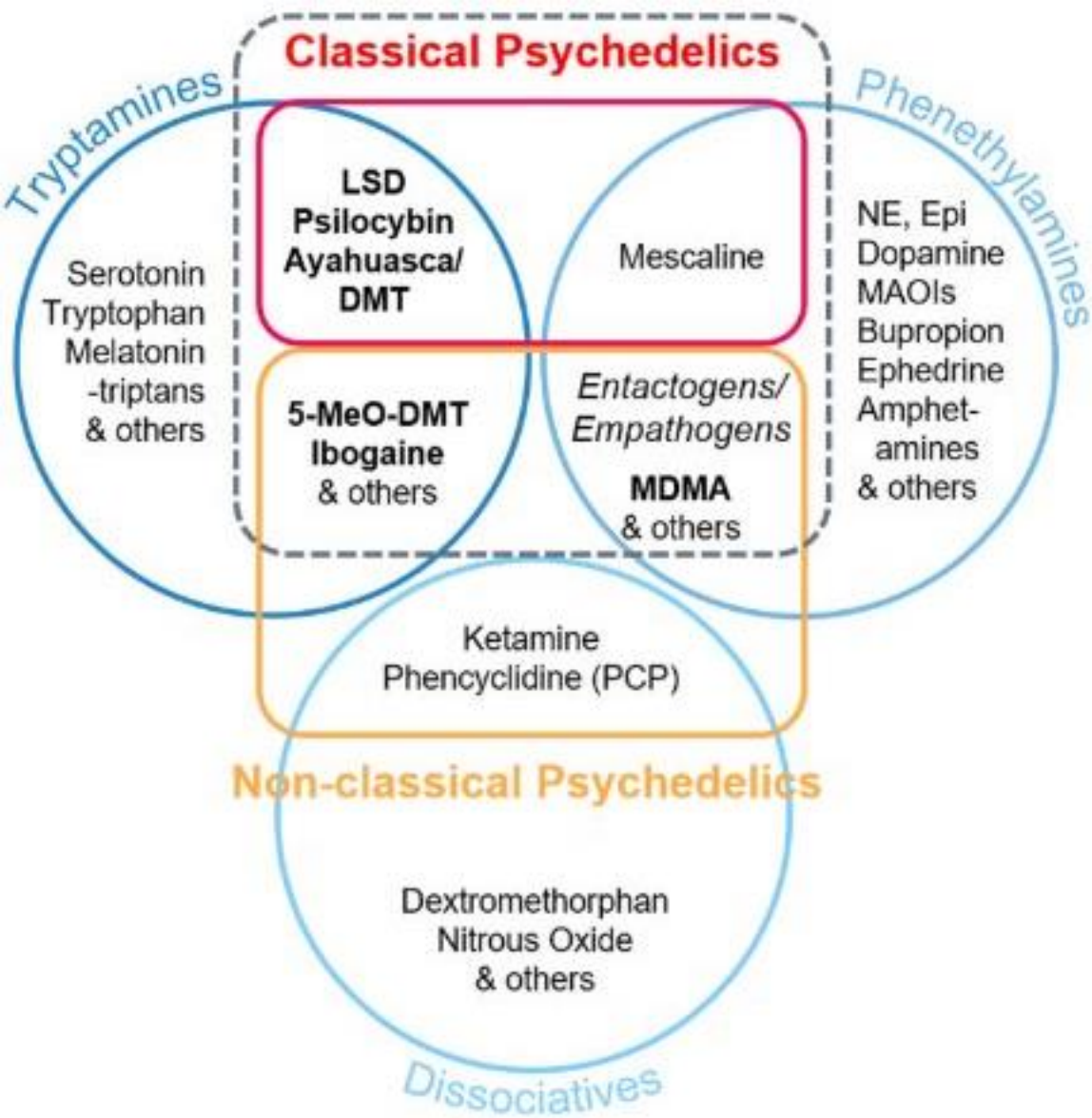
Learning objectives

- Describe the mechanism of action of psychedelics (classical hallucinogens), entactogens (e.g., MDMA) and dissociatives (e.g., ketamine, PCP)
- Appreciate the physiologic differences between pregnant/non-pregnant and lactating/non-lactating states with respect to pharmacokinetic variables
- List three reasons for psychedelic use during the perinatal period
- Summarize knowns and unknowns regarding psychedelic use during pregnancy and lactation
- Appreciate the need for inclusion of pregnant and lactating individuals in medical research

Patient Case: ML

- Pt is 34 yo G5P2113 at approx. 12 weeks gestation by LMP, who presents today for first prenatal visit. She reports recent international travel for an ayahuasca retreat which she describes as powerful and healing. She was unaware of pregnancy at the time of ayahuasca ingestion, which occurred about 4 weeks ago.
- She inquires about risks of ayahuasca during pregnancy, as she had planned to return for another treatment in 2-3 months.
- Now what? ☺



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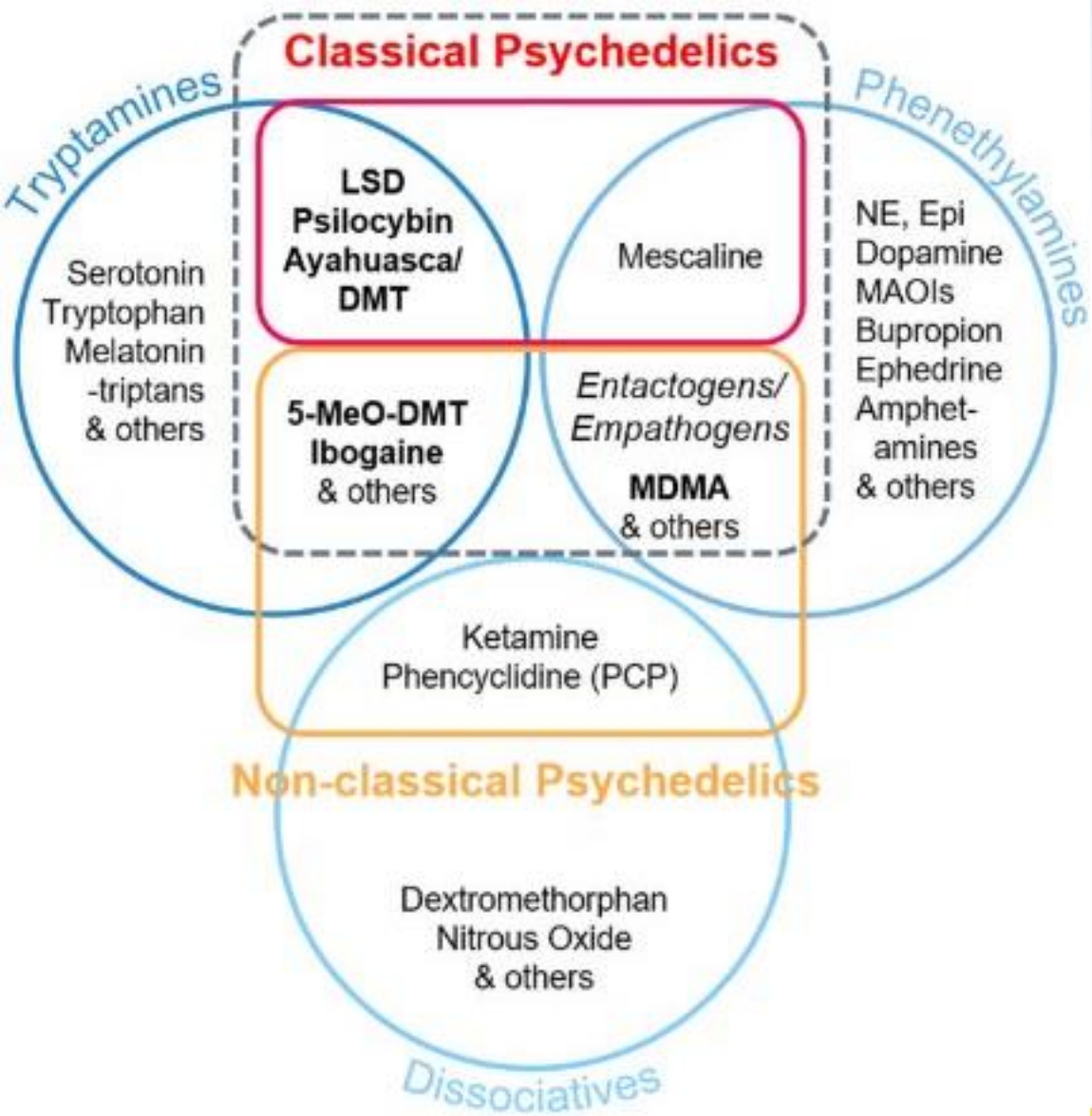

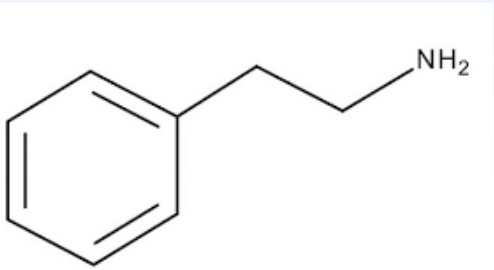

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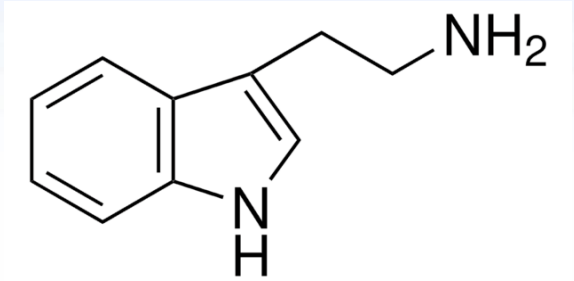

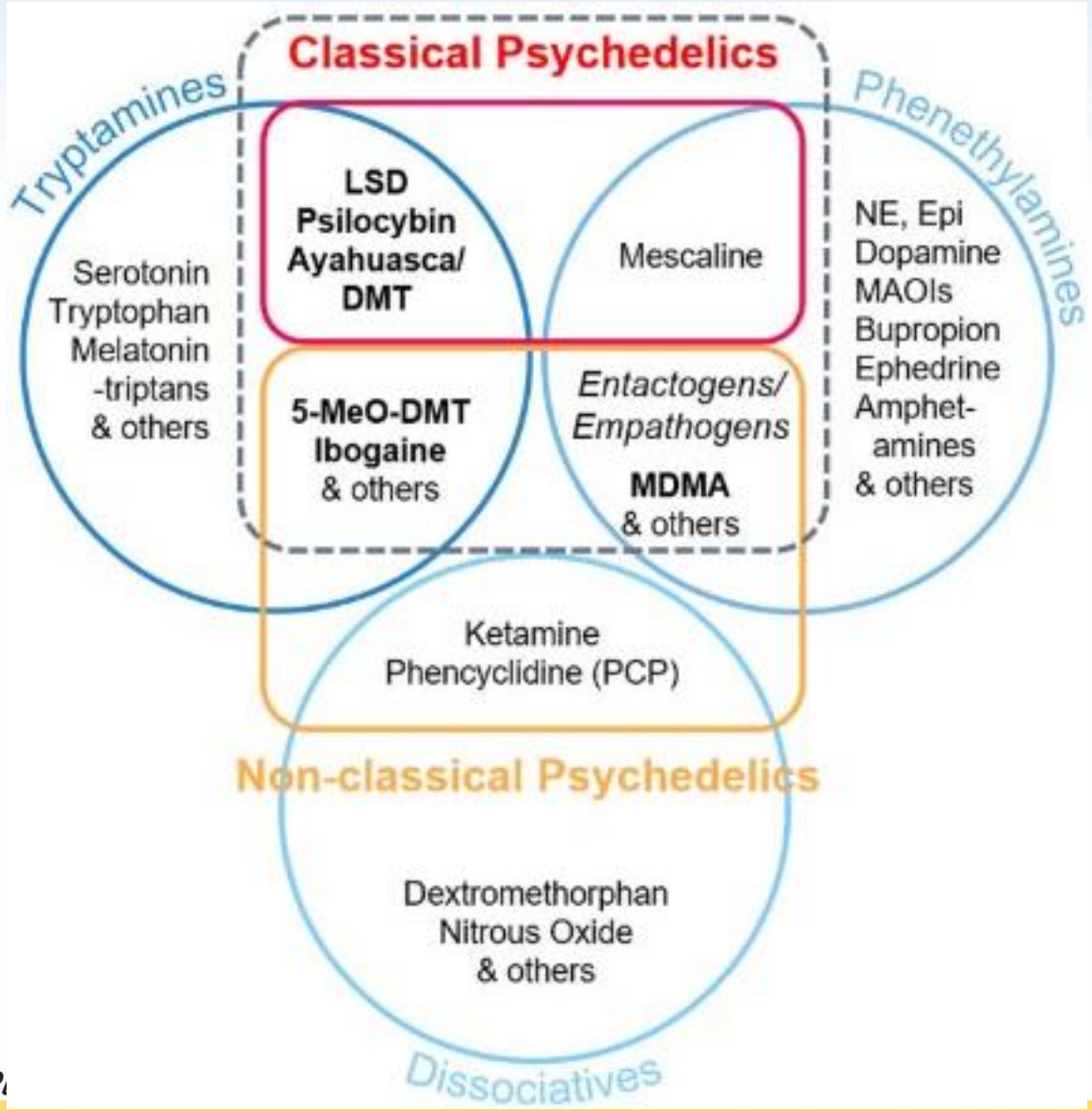

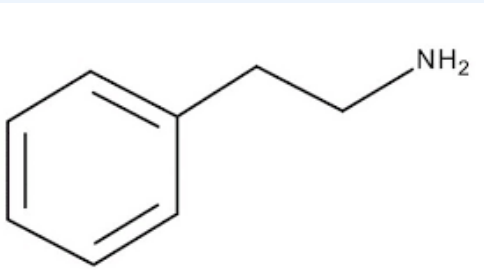

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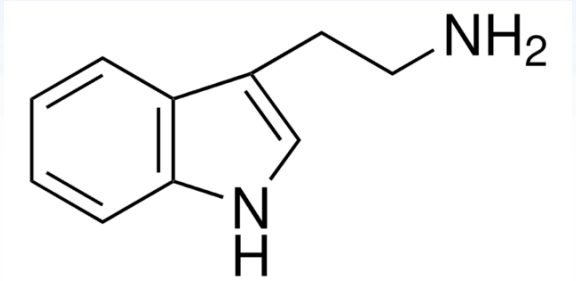

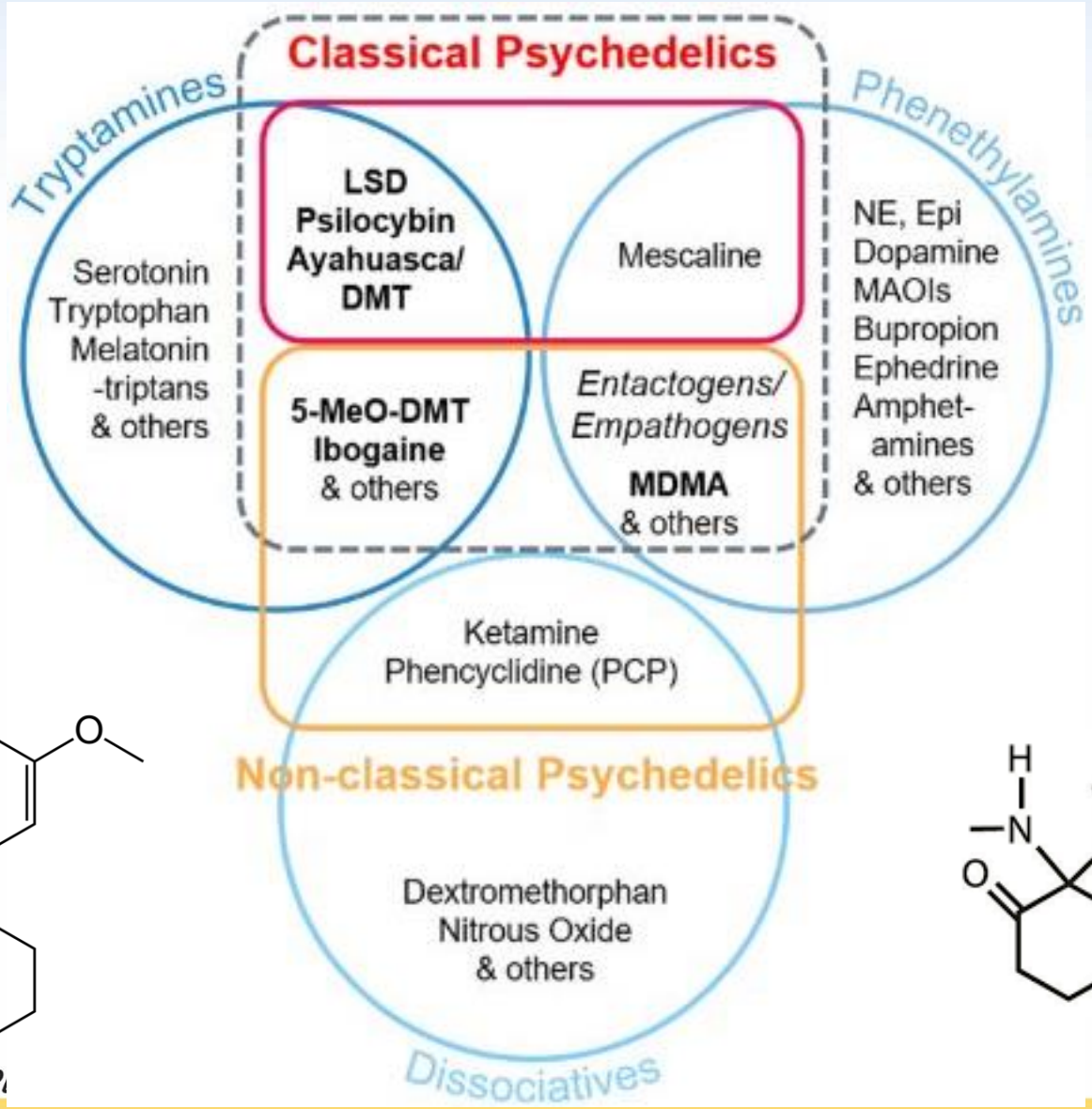

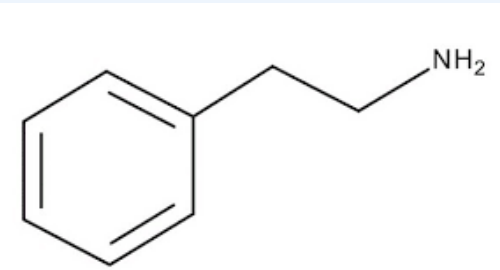

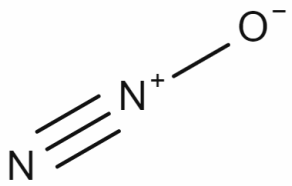

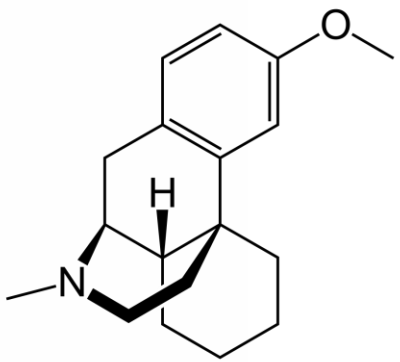

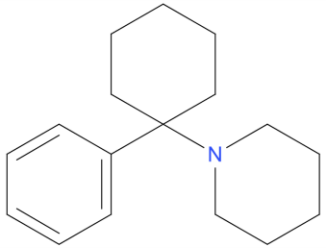

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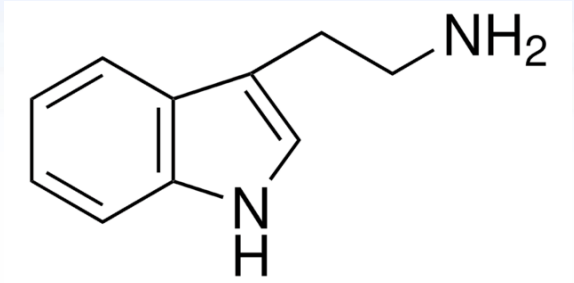
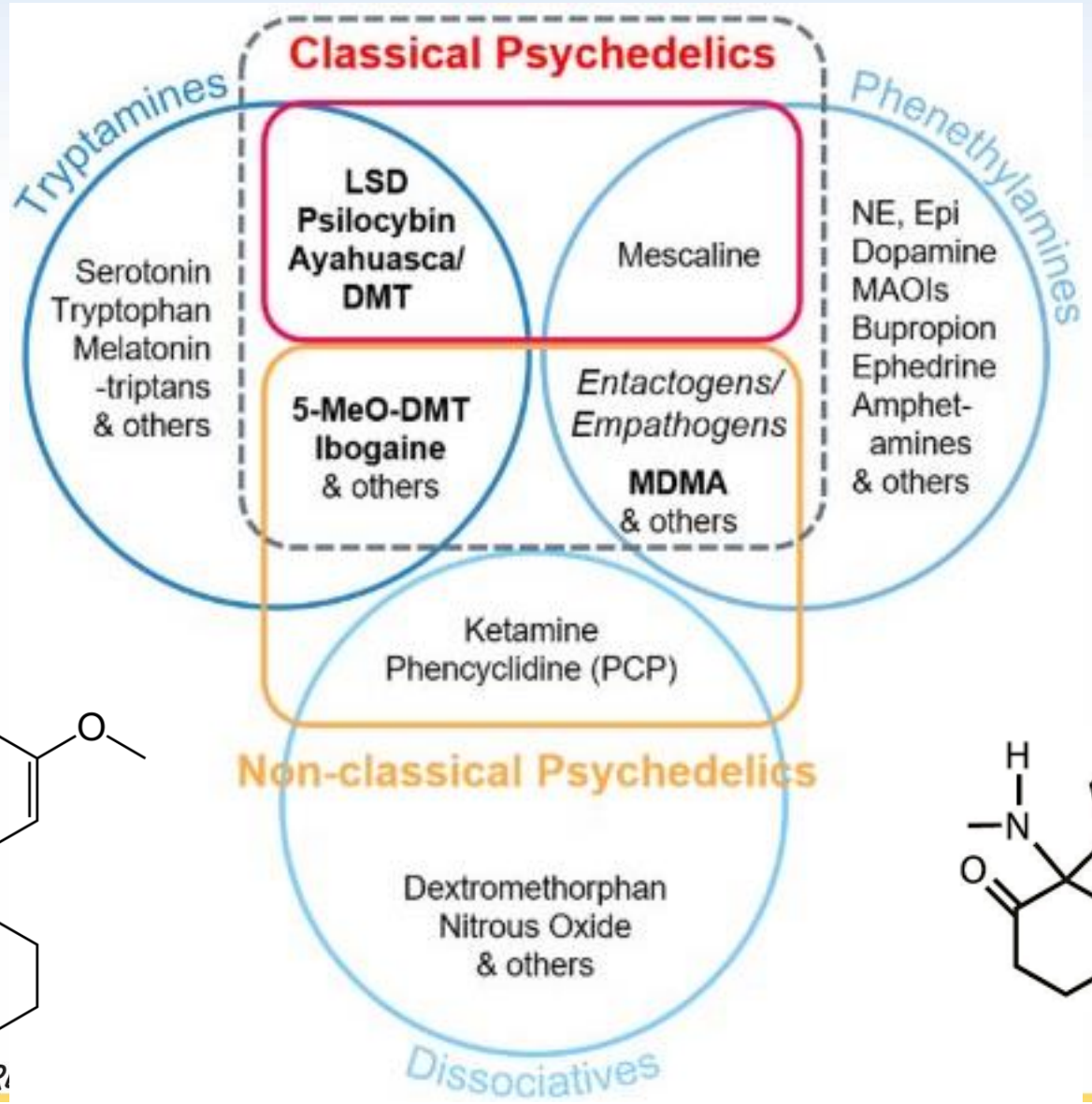
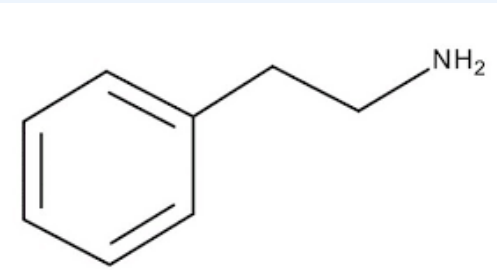
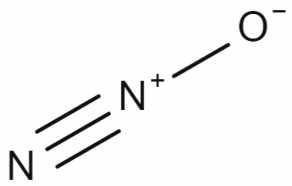


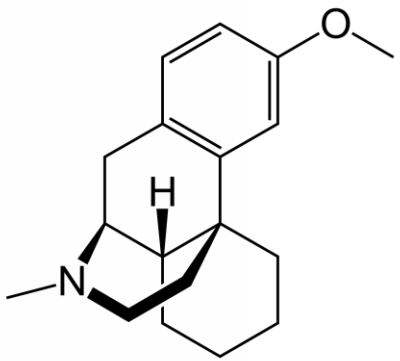
Act as serotonin agonists at 5HT2A receptors

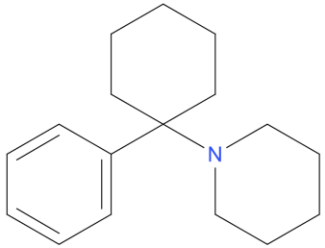




Increase norepinephrine and dopamine in synapses







NMDA receptor antagonists, plus a mishmash of other stuff

PMID 37682446


Spoiler alert:
THERE IS NO DATA
makeameme.org

A brief timeline

- 1974: Congress asks the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research for recommendations re: research involving pregnant women and fetuses -> 45 CFR 46 Subpart B
- 1977: Women of childbearing age excluded from phase I and early phase II clinical trials
- 1993: “The FDA…acknowledged the need for clinical data regarding the use of drugs in women” (Illamola et al 2018)
- 1993: NIH recommends inclusion of women, including pregnant women, in clinical trials
- 2001: Subpart B re-written to be less prescriptive and more inclusive

45 CFR 46 Subpart B

Pregnant women or fetuses may be involved in research if all of the following conditions are met:

(a) Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on nonpregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses;

(b) The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or, if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means;

(c) Any risk is the least possible for achieving the objectives of the research;

(d) If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means, her consent is obtained in accord with the informed consent provisions of subpart A of this part;

(e) If the research holds out the prospect of direct benefit solely to the fetus then the consent of the pregnant woman and the father is obtained in accord with the informed consent provisions of subpart A of this part, except that the father's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.

(f) Each individual providing consent under paragraph (d) or (e) of this section is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;

(g) For children as defined in §46.402(a) who are pregnant, assent and permission are obtained in accord with the provisions of subpart D of this part;

(h) No inducements, monetary or otherwise, will be offered to terminate a pregnancy;

(i) Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and

(j) Individuals engaged in the research will have no part in determining the viability of a neonate.

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Pregnant women or fetuses may be involved in research if all of the following conditions are met:

(a) Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on nonpregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses;

(b) The risk to the [redacted] that hold out the prospect of direct benefit for the woman or the fetus; or, if there is no such prospec[redacted]imal and the purpose of the research is the development of important biomedical knowledge which[redacted]

(c) Any risk is the[redacted]arch;

(d) If the researc[redacted]nt woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prosp[redacted]he research is the development of i[redacted] with the informed consent provisions of sub[redacted]

(e) If the researc[redacted]ner is obtained in accord with the informe[redacted]e to consent because of unavailability, inc[redacted]

(f) Each individual providing consent under paragraph (d) or (e) of this section is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;

(g) For children as defined in §46.402(a) who are pregnant, assent and permission are obtained in accord with the provisions of subpart D of this part;

(h) No inducements, monetary or otherwise, will be offered to terminate a pregnancy;

(i) Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and

(j) Individuals engaged in the research will have no part in determining the viability of a neonate.

F*** this just exclude them

3.6 million

Pregnancies in the US, 2022

3 million

Breastfeeding people in the US each year

90%

Pregnant people taking at least one medication

~100%

Lactating people taking at least one medication

1.29%

Proportion of PK studies 1968-2013 including pregnant people

2.8%

Proportion of new drugs approved by the FDA from 2010-2019 with labels containing human data re: lactation

Changes during pregnancy

Pharmacokinetic process	Physiological changes during pregnancy	Pharmacokinetic modifications
Absorption	↓ Gastric acidity	Altered absorption
	↓ Gastric emptying	Delayed absorption
	↓ Gastrointestinal motility	↓ C_{max}
	↑ Blood flow in skin, mucous membranes and muscles	↑ Bioavailability IM and external administration
Distribution	↑ Total body water	↑ Vd of hydrophilic and lipophilic drugs
	↓ Protein concentration	↑ Free fraction of drugs
Metabolism	↑ or ↓ enzymatic activity	Altered hepatic clearance
	Cholestasis	↓ Biliary elimination
Renal excretion	↑ Renal blood flow and GFR ↓ Tubular reabsorption	↑ Renal clearance

Illamola SM et al. Inclusion of pregnant and breastfeeding women in research – efforts and initiatives. Br J Clin Pharmacol. 2018 Feb;84(2):215–222.

Changes during lactation

- ~500kcal/day dedicated to making milk
- Significant hormonal shifts (prolactin, estrogen, progesterone, oxytocin, glucocorticoids, insulin, PTHrP, serotonin, etc)
- Active transport of essential metals (iron, copper, zinc)
- Drop in bone mineral density up to 10%
- Up and downregulation of expression of drug transporters

A literature review of drug transport mechanisms during lactation

CPT Pharmacometrics Syst Pharmacol. 2024;00:1–11.

Christine Gong[1] | Lynn N. Bertagnolli[2] | David W. Boulton[2] | Paola Coppola[3]

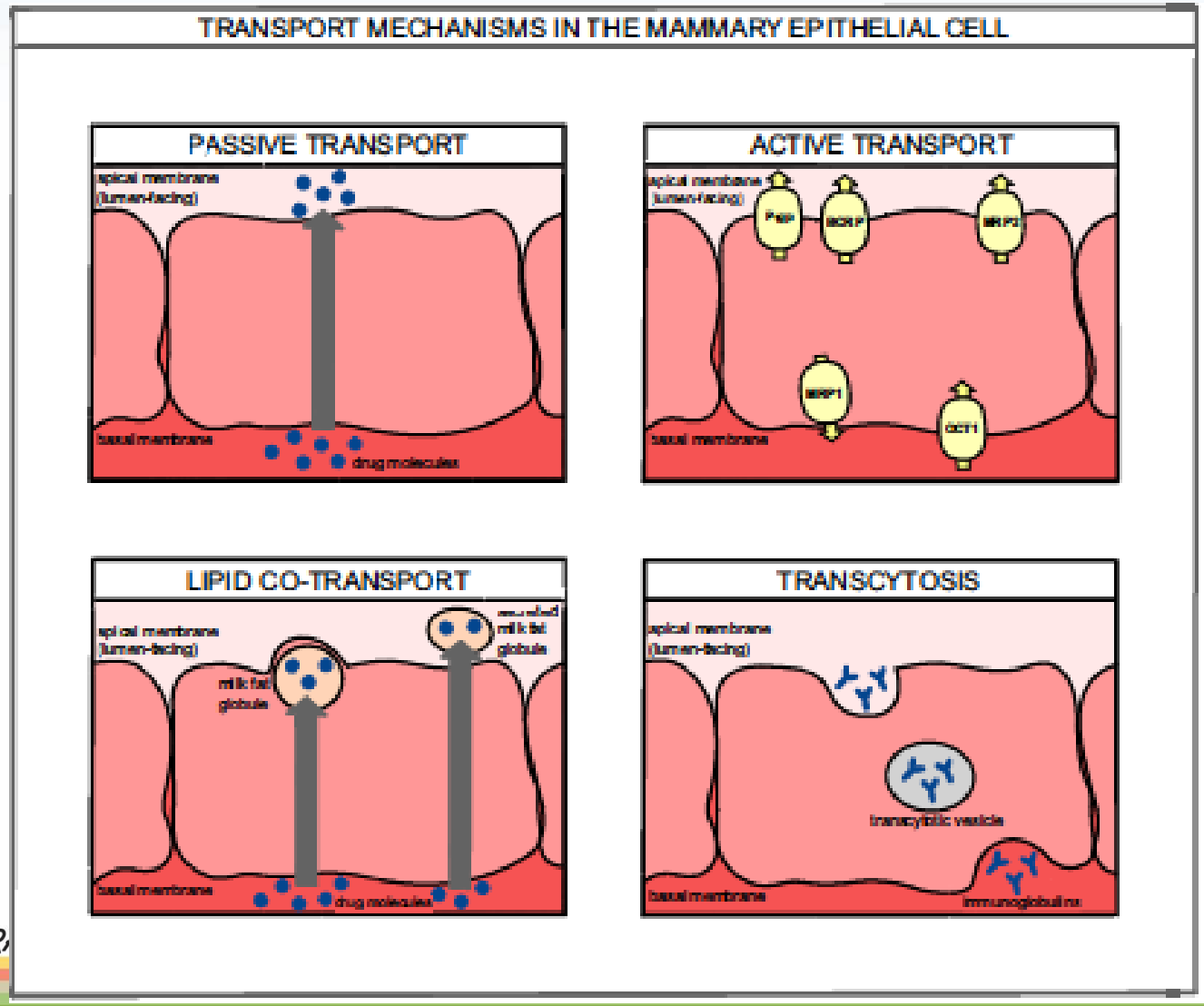
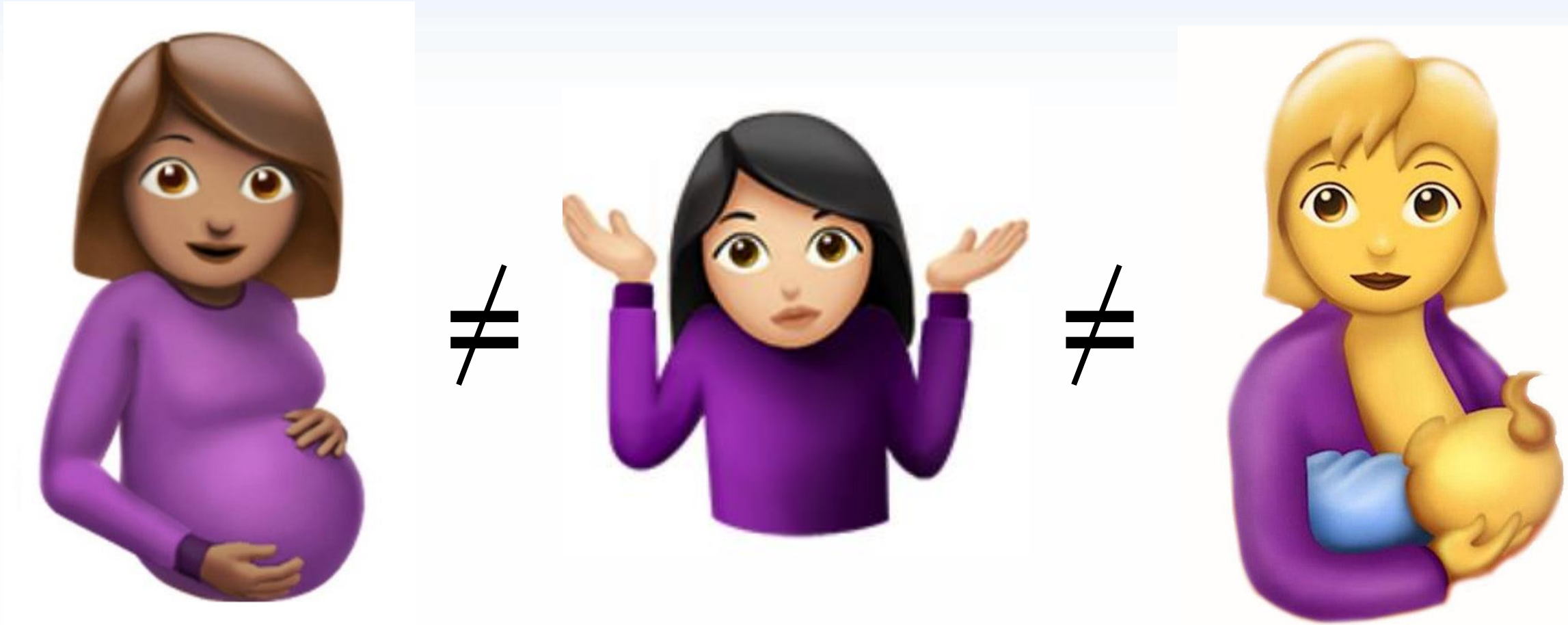


TABLE 4 Downregulated or upregulated expression of mammary drug transporters during lactation.

Drug transporter	Expression during lactation	Citation
P-gp	Downregulation	[19]
MRP1	Downregulation	[19]
MRP2	Downregulation	[19]
MRP5	Upregulation	[19]
BCRP	Upregulation	[12,25]
OATP1A2	Upregulation	[19]
OATP2B1	Upregulation	[19]
OATP3A1	Downregulation	[19]
OATP4A1	Downregulation	[19]
OCT1	Upregulation	[19,35]
OCT3	Downregulation	[19,35]
OCTN1	Upregulation	[19]
OCTN2	Downregulation	[19]
SVCT1	Upregulation	[19]
CNT1	Upregulation	[19]
CNT3	Upregulation	[19]
ENT1	Downregulation	[19]
ENT3	Upregulation	[19]
PEPT1	Downregulation	[19]
PEPT2	Upregulation	[19]

Abbreviations: BCRP, breast cancer resistance protein; CNT, concentrative nucleoside transporter; ENT, equilibrative nucleoside transporter; MRP, multidrug resistance-associated protein; OATP, organic anion transporting polypeptide; OCT, organic cation transporter; OCTN, novel organic cation transporter; PEPT, peptide transporter; P-gp, P-glycoprotein; SVCT, sodium-dependent nucleobase-ascorbic acid transporter.

2025 COLOR

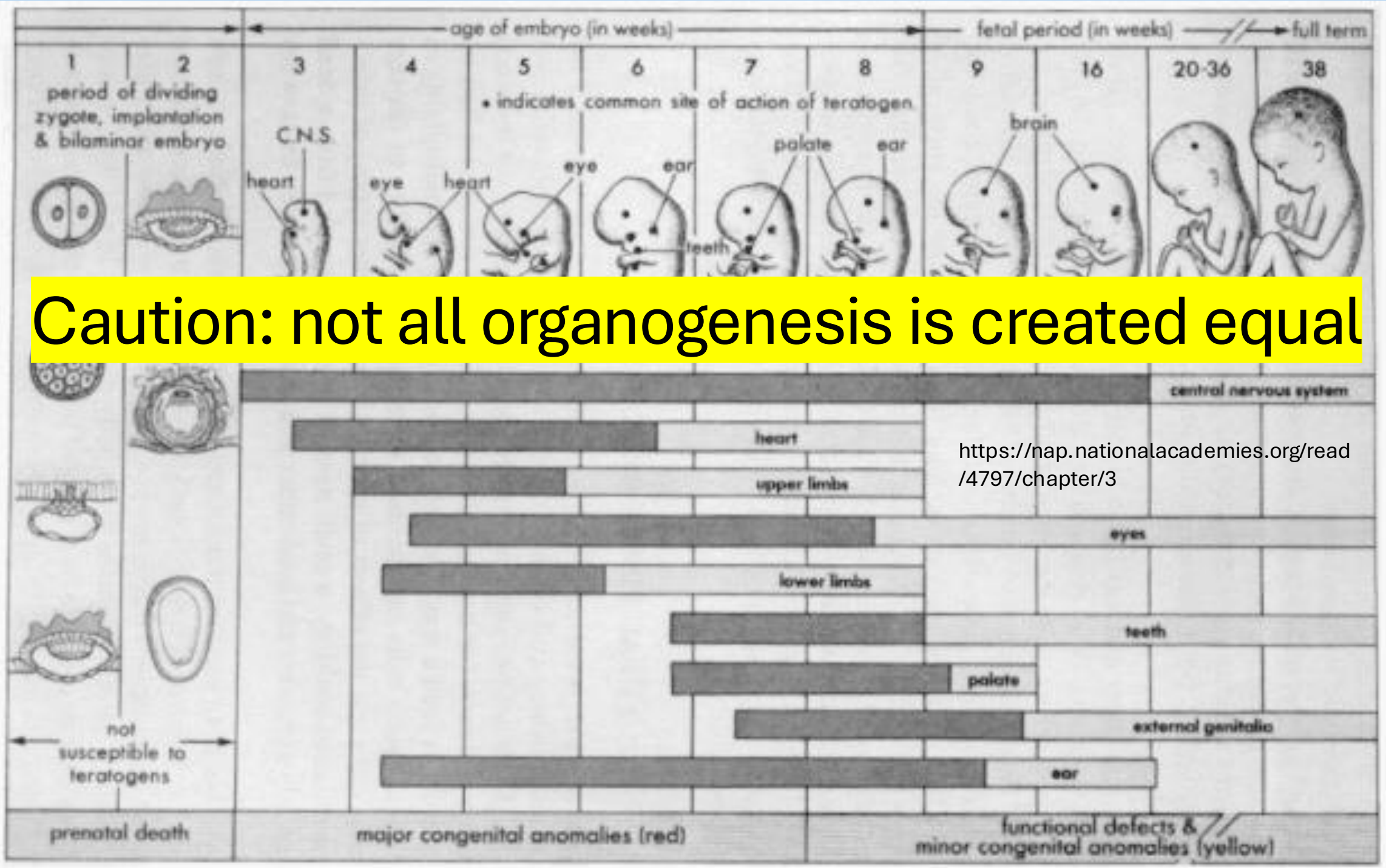


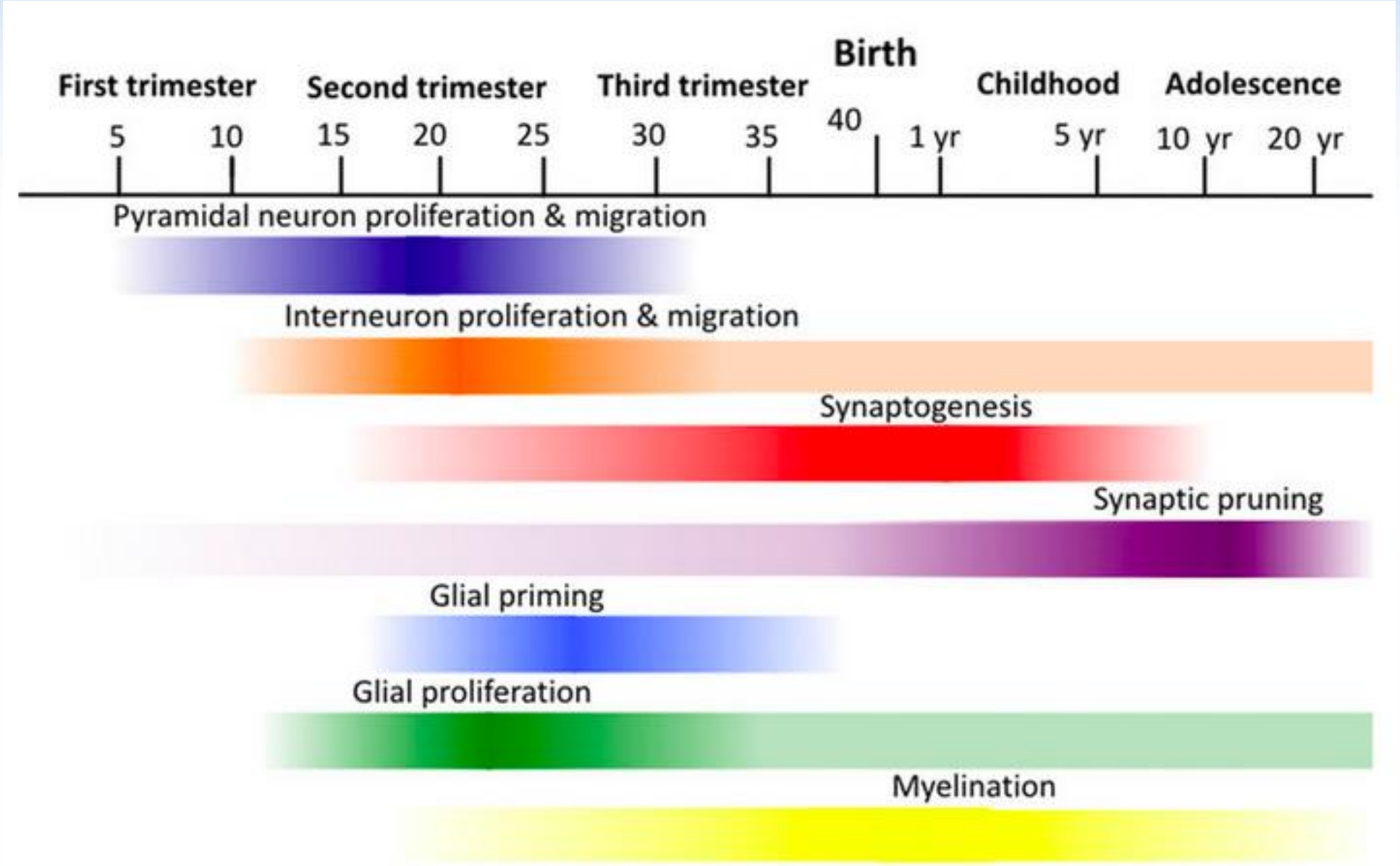
Psychedelics cross the placenta

- IV administered ^{14}C-psilocin readily crosses the placenta and distributes throughout fetal tissues in rats (Law et al 2014)
- IV administered ^{14}C-mescaline readily crosses the placenta and distributes throughout fetal tissues in squirrel monkeys (Taska and Schoolar 1972)
- IV administered ^{14}C-LSD readily crosses the placenta and distributes throughout fetal tissues in mice (Idänpään-Heikkilä and Schoolar 1969)
- SC administered MDMA crosses the placenta and distributes to the fetal brain (and amniotic fluid) in rats (Campbell et al 2006)
- IV administered ketamine crosses the placenta and is found in fetal blood in similar concentrations to maternal blood in ewes (Musk et al 2012)

Probably excreted into breastmilk

- Psilocybin, DMT, mescaline, LSD, MDMA…no data
  - All have some degree of protein binding, especially psilocybin and LSD (decreases transmission via breastmilk) (Khastar et al 2020)
  - All relatively low molecular weight (lower MW -> more likely to be found in breastmilk)
- Ketamine: yes (Wolfson et al 2023)

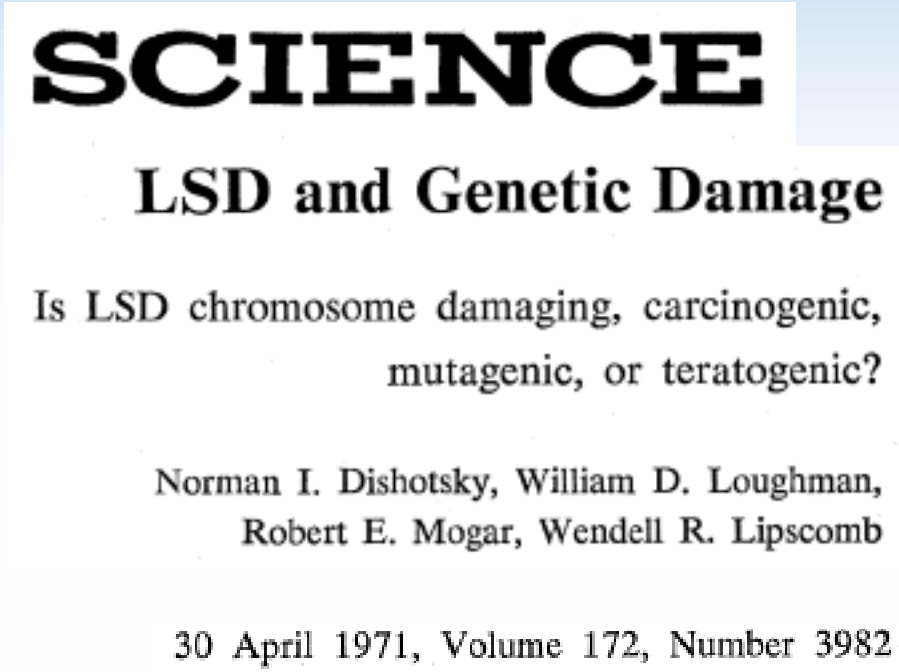

age of embryo (in weeks)
fetal period (in weeks)
full term
1
2
3
4
5
6
7
8
9
16
20-36
38
period of dividing zygote, implantation & bilaminar embryo
• indicates common site of action of teratogen
C.N.S.
heart
eye
heart
eye
ear
teeth
palate
ear
brain
Caution: not all organogenesis is created equal
central nervous system
heart
upper limbs
eyes
lower limbs
teeth
palate
external genitalia
ear
https://nap.nationalacademies.org/read/4797/chapter/3
not susceptible to teratogens
prenatal death
major congenital anomalies (red)
functional defects & minor congenital anomalies (yellow)



Allswede and Cannon 2018

Ayahuasca (dimethyltryptamine aka DMT)

- Centuries of ritual consumption, including by pregnant women and children
- “There is no scientific publication reporting any toxic effects of ayahuasca in pregnant women or in children born from these women” (dos Santos 2013)
- Animal studies (mostly mice and rats) of unclear significance
  - Substantial decrease in survival of pregnant animals at high doses
  - Decreased food consumption of pregnant animals (dose-response curve)
  - Increased incidence of misshapen or incompletely ossified bones (esp skull) – debate as to whether these are “malformations” or “variations” (dos Santos 2013, da Motta 2018)



SCIENCE

LSD and Genetic Damage

Is LSD chromosome damaging, carcinogenic, mutagenic, or teratogenic?

Norman I. Dishotsky, William D. Loughman, Robert E. Mogar, Wendell R. Lipscomb

30 April 1971, Volume 172, Number 3982

Lots of data from the 1950s/60s/70s of unclear significance

- Several, but not all, in vitro studies demonstrated chromosomal damage after exposure to LSD
- Animal studies also with mixed results (heterogeneous study designs)
- Human data was often positive but confounded by lots of other substance use including some known teratogens (e.g., ethanol)
  - Some papers focus on ophthalmologic, limb abnormalities in offspring

MDMA

- Moderate human data suggests increased risk of delayed motor development in offspring (DAISY study, Singer et al 2016)
  - +dose response curve
  - Effect persists after adjusting for several confounding variables
  - Effect persists at least through 2 years of age

- Limited human data suggests:
  - Increased risk of congenital malformations including cardiac malformations (McElhatton et al 1999)

Ketamine

- Little human data during pregnancy beyond use of ketamine and esketamine as an analgesic during labor (seems safe for birthing individuals; no data on infant outcomes)
- Mouse data of unclear significance:
  - 5mg/kg ketamine given to pregnant mice led to higher incidence of cardiomegaly, myocardial sarcomere disorganization and decreased heart function in offspring (Yu et al 2023)
  - 15mg/kg and 30mg/kg ketamine given to pregnant mice increased the risk of ADHD and depression-like behaviors in offspring (Zhang et al 2022)
  - 100% of pregnant mice given 60mg/kg ketamine miscarried after a single dose (Zhang et al 2022)


@LateNightSeth
I DONT KNOW WHAT
ANY OF THIS MEANS

- Psychedelics cross the placenta
- Psychedelics are almost certainly excreted in breastmilk
- It is plausible that in utero and/or lactational exposures could lead to fetal/infant harm, but the details (including degree of risk) are fuzzy

Patient Case: ML

- You estimate that patient was approximately 8 weeks gestation at time of ayahuasca use.
- You share with patient the reality of little data known about ayahuansca use in pregnancy within western medical literature, however, there are anthropological reports of use in pregnancy that are overall reassuring.
- Pt inquires about whether she should keep her reservation for second ayahuasca retreat?
- What else do you want to know?

CULTURE > FEATURES

Mommies Who Mushroom

Inside the growing–and, to some, controversial–movement in which parents are using psychedelics to take the edge off modern parenthood.

STORY BY ANDREA STANLEY AND PHOTOGRAPHS BY THOMAS ALBDORF PUBLISHED: APR 11, 2022

SAVE ARTICLE

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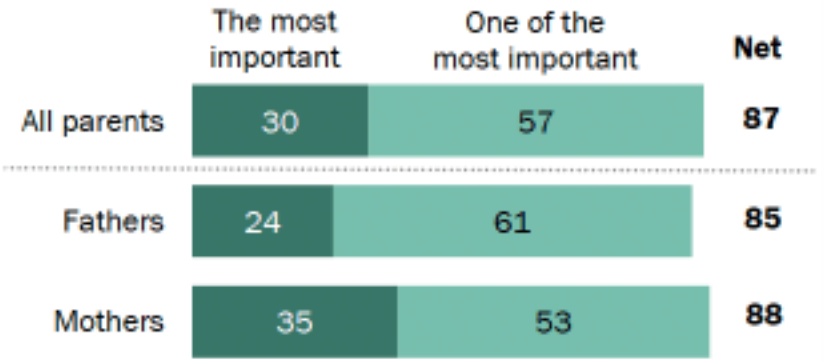
SAVE ARTICLE

"It makes sense; perhaps no one is more in need of a mental-health salve. Because while parenthood is often billed as the ultimate blissed-out euphoria, for many it is where the hemorrhaging of happiness happens. It's a sleep-deprived, tedious, anxiety- riddled road, recently made all the more difficult by the pandemic. Worn down by the malaise of modern parenting, burdened by the traumas they've inherited from their own parents, or disillusioned with a mental-health-care system they feel has failed them, some parents have found an answer in psychedelic substances."

About a third of moms say being a parent is the most important aspect of who they are

% of parents saying being a parent is ____ aspect(s) to who they are as a person



Source: Survey of U.S. parents conducted Sept. 20-Oct. 2, 2022. "Parenting in America Today"

PEW RESEARCH CENTER

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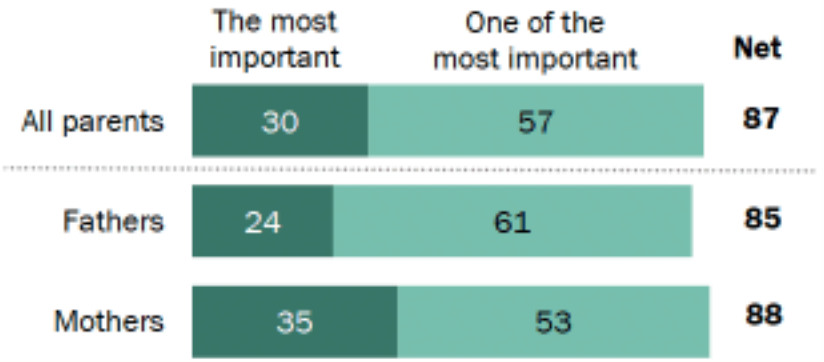

Source: Survey of U.S. parents conducted Sept. 20-Oct. 2, 2022.
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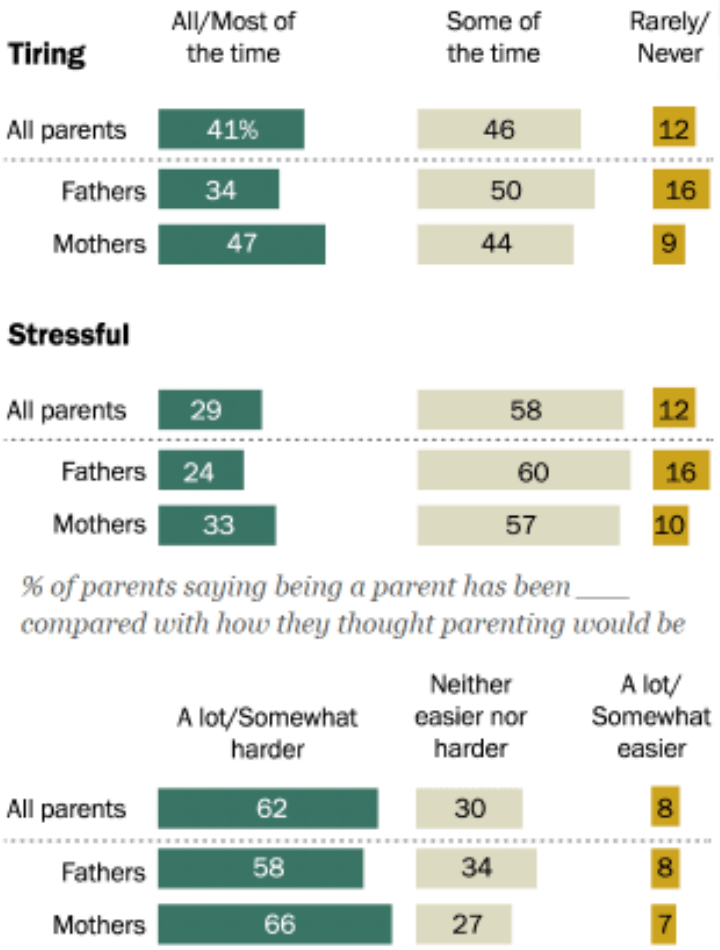
PEW RESEARCH CENTER

Mothers are more likely than fathers to say being a parent is tiring and stressful all or most of the time

% of parents saying they find being a parent to be tiring/stressful ...



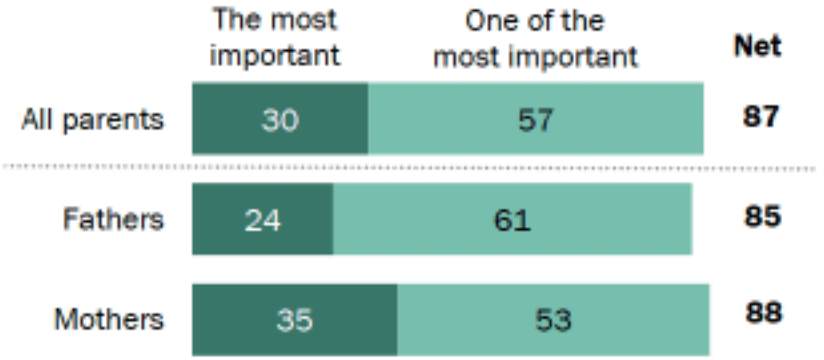
% of parents saying being a parent has been ____ compared with how they thought parenting would be

Note: Share of respondents who didn't offer an answer not shown.
Source: Survey of U.S. parents conducted Sept. 20-Oct. 2, 2022.
"Parenting in America Today"

PEW RESEARCH CENTER

About a third of moms say being a parent is the most important aspect of who they are

% of parents saying being a parent is ____ aspect(s) to who they are as a person

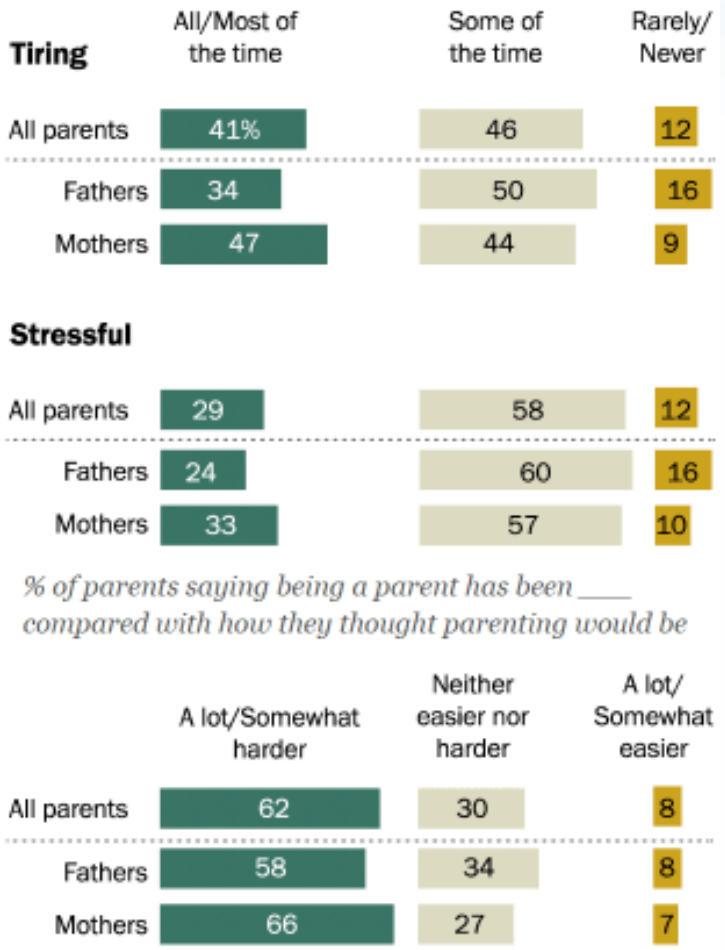


Source: Survey of U.S. parents conducted Sept. 20-Oct. 2, 2022.
"Parenting in America Today"

PEW RESEARCH CENTER

Mothers are more likely than fathers to say being a parent is tiring and stressful all or most of the time

% of parents saying they find being a parent to be tiring/stressful ...



% of parents saying being a parent has been ____ compared with how they thought parenting would be

Note: Share of respondents who didn't offer an answer not shown.
Source: Survey of U.S. parents conducted Sept. 20-Oct. 2, 2022.
"Parenting in America Today"

PEW RESEARCH CENTER

70% of US parents struggling to pay for childcare

act for Early Years

M c S W E E N E Y ' S

INTERNET TENDENCY

Daily humor almost every day since 1998.

NOVEMBER 10, 2022

A PARENT'S TYPICAL DAY, AS ENVISIONED BY MY CHILD'S PRESCHOOL

by RUYI WEN

This is happening, and we should talk about it.

Psychedelic	Use in Pregnancy	Use in Breastfeeding
MDMA	Heavy use alone or with other substances linked to developmental delays and higher birth defect rates. Capable of crossing placenta.	Transfers to breastmilk similar to other amphetamines. May abstain from breastfeeding for 72 hours or 24 hours after a negative urine test.
Psilocybin/psilocin	Anthropologic use reported. Likely capable of crossing placenta.	Transfers to breastmilk. May abstain from breastfeeding for 24–48 hours for safe use.
Ayahuasca	Anthropologic use reported. Observational studies of exposed adolescents show no deficits. Likely capable of crossing placenta.	Transfers to breastmilk. May abstain from breastfeeding for 24–48 hours for safe use.
Ketamine	When used during C-section, may prevent postpartum depression. No studies available in pregnancy.	Case series of four lactating mothers suggests relatively safe use during lactation.
LSD	Concerns for teratogenicity largely refuted. Case reports of birth defects exist.	

Patient Case ML

- MVQ (most valuable question): “What are you hoping to receive from ayahuasca treatment?”
  - What is our patient looking for? Relief from…? Adding meaning…? Connection with others? Connection with self? Spiritual experience?
- Once we understand what our patients are looking for in any given substance, experience, etc, we can work from there to explore:
  - Is it working?
  - What are risks?
  - What are alternatives?
- Keeping patients engaged even if they pursue treatments we do not recommend is essential to preventing harm related to lack of prenatal care!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PSYCHEDELICS TODAY
Rolling Stone
abc nightline

Effects of ketamine and esketamine on preventing postpartum depression after cesarean delivery: A meta-analysis

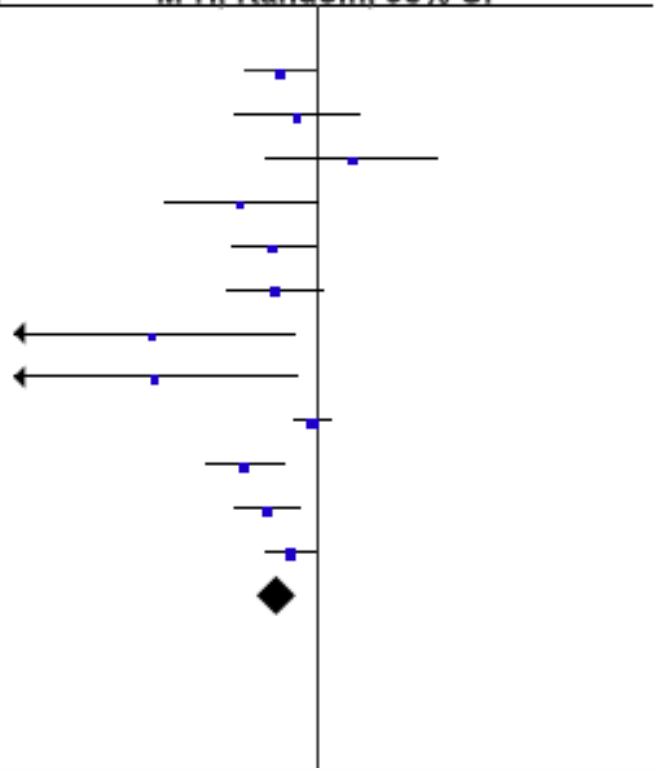
Journal of Affective Disorders 351 (2024) 720–728

Shuying Li [a], Wenqin Zhou [a], Ping Li [a,*], Rongqian Lin [b]

Study or Subgroup	Experimental Events	Experimental Total	Control Events	Control Total	Weight	Risk Ratio M-H, Random, 95% CI
1.1.1 Within 1 week postpartum						
Han 2022	10	122	27	153	5.0%	0.46 [0.23, 0.92]
Liu2023	4	62	6	61	2.8%	0.66 [0.19, 2.21]
Shen 2023	4	102	2	100	1.7%	1.96 [0.37, 10.47]
Wang 2023	2	58	9	57	2.1%	0.22 [0.05, 0.97]
Wang QW 2022	7	69	17	69	4.3%	0.41 [0.18, 0.93]
Wang W 2022 (0.1)	5	38	12	39	3.8%	0.43 [0.17, 1.10]
Wang W 2022 (0.2)	0	40	12	39	0.7%	0.04 [0.00, 0.64]
Wang W 2022 (0.4)	0	39	12	39	0.7%	0.04 [0.00, 0.65]
Xu 2017	41	162	46	163	6.9%	0.90 [0.63, 1.29]
Yang 2023 (2.0)	7	99	29	97	4.5%	0.24 [0.11, 0.51]
Yang 2023（1.0）	11	99	29	97	5.3%	0.37 [0.20, 0.70]
Yao 2020	20	153	35	155	6.1%	0.58 [0.35, 0.96]
Subtotal (95% CI)		**1043**		**1069**	**44.0%**	**0.45 [0.31, 0.67]**
Total events	111		236			

Heterogeneity: $Tau^2 = 0.22$; $Chi^2 = 26.15$, df = 11 (P = 0.006); $I^2 = 58\%$

Test for overall effect: Z = 4.03 (P < 0.0001)



Effects of ketamine and esketamine on preventing postpartum depression after cesarean delivery: A meta-analysis

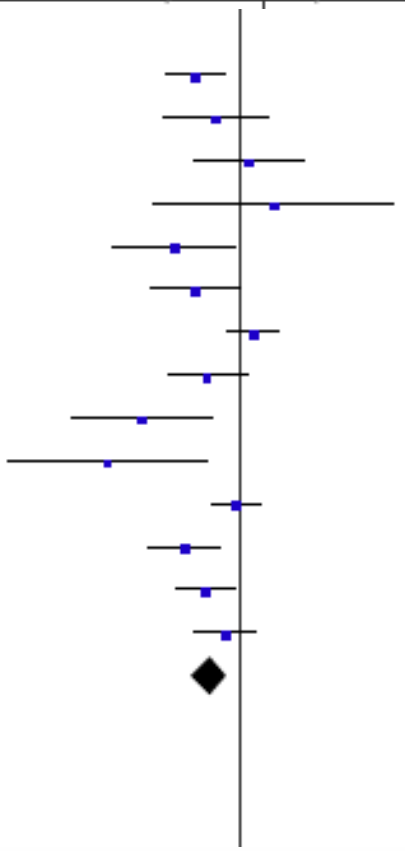
Journal of Affective Disorders 351 (2024) 720–728

Shuying Li [a], Wenqin Zhou [a], Ping Li [a,*], Rongqian Lin [b]

Study or Subgroup	Experimental Events	Total	Control Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
1.1.2 After 4 weeks postpartum						
Han 2022	12	122	37	153	5.5%	0.41 [0.22, 0.75]
Liu2023	5	62	8	61	3.3%	0.61 [0.21, 1.77]
Monks 2022	4	8	3	7	3.1%	1.17 [0.39, 3.51]
Shen 2023	2	102	1	100	1.0%	1.96 [0.18, 21.28]
Wang 2023	3	58	11	57	2.8%	0.27 [0.08, 0.91]
Wang QW 2022	6	69	15	69	4.0%	0.40 [0.16, 0.97]
Wang S 2022	18	32	14	32	6.1%	1.29 [0.78, 2.11]
Wang W 2022 (0.1)	7	38	14	39	4.5%	0.51 [0.23, 1.13]
Wang W 2022 (0.2)	2	40	14	39	2.3%	0.14 [0.03, 0.57]
Wang W 2022 (0.4)	1	39	14	39	1.3%	0.07 [0.01, 0.52]
Xu 2017	26	162	29	163	6.2%	0.90 [0.56, 1.46]
Yang 2023 (2.0)	9	99	27	97	4.9%	0.33 [0.16, 0.66]
Yang 2023（1.0）	14	99	27	97	5.6%	0.51 [0.28, 0.91]
Yao 2020	16	153	22	155	5.5%	0.74 [0.40, 1.35]
Subtotal (95% CI)		**1083**		**1108**	**56.0%**	**0.54 [0.39, 0.77]**
Total events	125		236			

Heterogeneity: $Tau^2 = 0.22$; $Chi^2 = 32.11$, df = 13 (P = 0.002); $I^2 = 60\%$

Test for overall effect: Z = 3.46 (P = 0.0006)



Birth Trauma? Ketamine Treatment Can Help Heal PTSD

GLAMOUR

MOTHERHOOD

Tripping Through Motherhood: How Some Women Are Using Ketamine to Treat Postpartum Depression

For some women standard postpartum depression treatment isn't enough. But are psychedelics the solution?

BY MELISSA WHIPPO AND JULI FRAGA

June 23, 2022

MDMA for Co-occurring PTSD and OUD After Childbirth

University of New Mexico (UNM)

Status and phase

Enrolling | Phase 2

Conditions

Opioid Use Disorder | Stress Disorders, Post-Traumatic

Treatments

Drug: MDMA Assisted Therapy

Study type

Interventional

Funder types

Other

Identifiers

NCT05219175

IUSOU1

MDMA

MDMA (3, 4-Methylenedioxymethamphetamine) has received breakthrough drug status from the FDA for the treatment of PTSD. MDMA is a monoamine releaser and re-uptake inhibitor with indirect effects on neurohormone release. MDMA has a more complex neurochemical mechanism than classical psychedelics involving increased release of serotonin, dopamine, noradrenaline and oxytocin. Activation of the 5-hydroxytryptamine receptor 1A (5-HT1a) and 5-hydroxytryptamine receptor 1B (5-HT1b) receptors decreases feeling of anxiety and depression and reduces amygdala mediated fear response. These effects are accompanied by increased empathy, emotional closeness and compassion. Effects

University of Colorado **Anschutz Medical Campus**

A Study Evaluating the Safety and Effectiveness of RE104, a Psilocybin-like substance, in the Treatment of Patients with Postpartum Depression

This study is testing if a single dose of the psychedelic drug RE104 can help reduce symptoms of moderate-to-severe postpartum depression compared to a placebo in pregnant women aged 18 to 45.

https://researchstudies.cuanschutz.edu/Study/24-0776

#1 cause of pregnancy-associated death in the United States:

#1 cause of pregnancy-associated death in the United States: mental health conditions, driven largely by suicides and unintentional overdoses.

Source: https://www.cdc.gov/media/releases/2022/p0919-pregnancy-related-deaths.html#print

IRB
A Review of Human Subjects Research

Volume 17 Number 2 March-April 1995

Exclusion of Pregnant Women from Research Protocols: Unethical and Illegal

by Jacqulyn Kay Hall

1

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Thank you!

- Questions? Comments? Rude remarks? Email me!
  - Laurie.halmo@childrenscolorado.org