

PNQIN AIM

Opioid Use Disorder in Pregnancy

Webinar Series

July 7, 2020

Webinar 10



ODU in Pregnancy Webinars

Monthly Agenda Overview

12:00 - 12:05: Welcome/ Introductions

12:05 - 12:15: Updates from the teams on QI projects + collaborative

12:15 - 12:30: Brief QI teaching, Assignment

Ronald Iverson, MD, MPH – PDSA: Making Adjustments

12:30 - 12:55: Guest Topics: 20 minute presentations + 5 mins for questions

Kelley Saia, MD, FACOG, DABAM – MAT

12:55 - 1:00: Closing/ Final Comments

Webinar Housekeeping

- We will take attendance in the chat box each month – please comment with your name and hospital
- Please mute your lines and avoid placing us on hold, as we will hear your hold music – sometimes beautiful, but also distracting
- Utilize “raise hand” feature to speak
- Please feel free to use the chat box as well
- **We will be recording each session and placing slides on our website after the call**
- We welcome feedback, suggestions about the webinar content and structure!
- Please participate! We want this to be helpful and collaborative!

PNQIN Perinatal Opioid Project Leadership Team

PNQIN

- Fifi Diop (DPH)
- Audra Meadows (BWH)
- Ron Iverson (BMC)
- Mary Houghton (BIDMC)
- Munish Gupta (BIDMC)
- Kali Vitek

Neonatal Folks

- Elisha Wachman (BMC)
- Larry Rhein (UMass)
- Rachana Singh (Baystate)
- Davida Schiff (MGH)
- Alan Picarillo (Maine)
- Eileen Costello (BMC)

Maternal Folks

- Katherine Callaghan (UMass)
- Leena Mittal (MCPAP for Moms)
- Laura Sternberger (Moms Do Care)
- Nicole Smith (BWH)
- Donna Jackson-Kohlin (Baystate)
- Linda Jablonski (Baystate)

Academic and Organizational Partners

- Patrice Melvin (BCH)
- Karla Damus (BU)
- Christina Gebel (MOD)

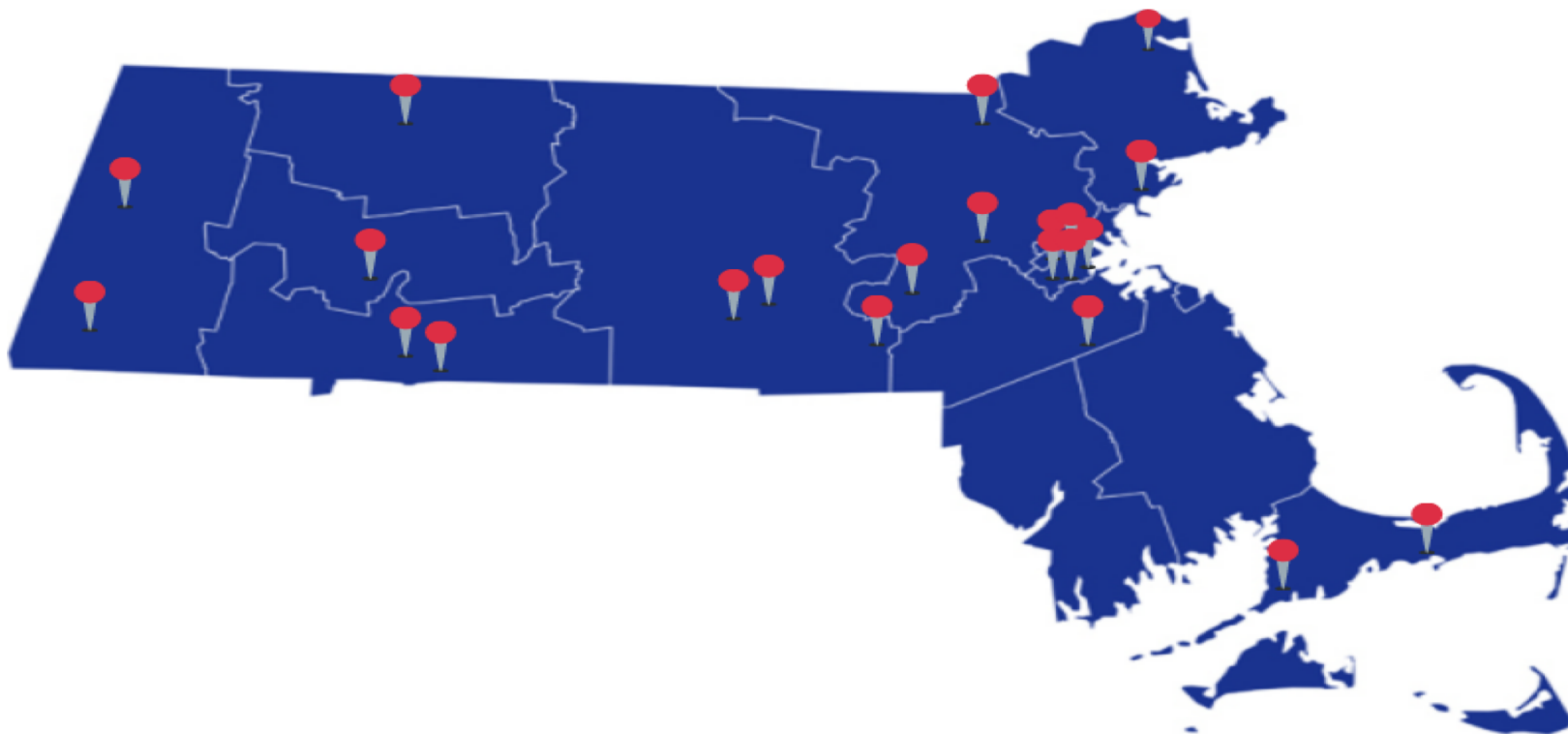
State Partners

- Fifi Diop (DPH and PI of PNQIN Grant)
- Griffin Jones (HPC)
- Michael Kelleher (OHHS)
- Debra Bercuvitz (DPH)
- Abby Taylor (AGO)
- Karen Pressman (BSAS)
- Julia Reddy (BSAS)
- Mary Lutz (DCF)
- Alissa Cruz (MassBIRT)
- Colleen Labelle (BMC)
- Julia Prentice (BLC)
- Natalia Ciesielska (BLC)

Families

- Patricia McDonnell (Baystate)
- Julie Maida
- Meghann Perry
- Ceara McManus (Moms Do Care)

PNQIN AIM Wave I - Who's on the Line?



PNQIN AIM OUD Wave 1 Hospitals

- Anna Jaques Hospital
- Baystate Franklin Medical Center
- Baystate Medical Center
- Berkshire Medical Center
- Beth Israel Deaconess Med Center
- Boston Medical Center
- Brigham & Women's Hospital
- Cape Cod Hospital
- Cooley Dickinson Hospital
- Fairview Hospital
- Falmouth Hospital
- Lowell General Hospital
- Mass General Hospital
- Mercy Medical Center
- Metrowest Med Center
- Milford Regional
- Newton-Wellesley
- North Shore Medical
- Saint Vincent Hospital
- South Shore Hospital
- Tufts Medical Center
- UMASS Memorial

Announcements

- Webinar 10/12, two more to go!
- Process and Structural Measures
 - We will be resuming data collection with the help of Betsy Lehman Center via their REDCap database
- 2-hour Stigma, Bias, and Trauma-Informed Care Training dates are available July-September 2020, please sign up via the link!
 - <https://calendly.com/tictrainings/2hours>
- PNQIN Admin changes – WELCOME Kali
- SMM Data Reports – pilot phase and launch to 22 teams
- Check out our website for updates!
- Give feedback on webinar series

Available Trainings

- ASAM/ACOG's July Buprenorphine Waiver Trainings
 - July 10th, 17th, and 31st
 - Register: https://www.asam.org/education/live-online-cme/waiver-qualifying-training/ob-gyn-focus?utm_source=ACOG&utm_medium=Today's%20Headlines&utm_campaign=ACOG&utm_term=20TOUD
- MAT Waiver training for Advanced Practice Registered Nurses is offered by Providers Clinical Support System for free!
 - CE credits available
 - Register: <https://pcssnow.org/medications-for-addiction-treatment/waiver-training-for-nurses/>

Webinars, Podcasts, and Videos

- ASAM National Practice Guideline 2020 Focus Update Webinar - Pregnant Women
 - Visit the link for updates on a recording and/or slides from June 30th:
<https://elearning.asam.org/products/the-asam-national-practice-guideline-2020-focused-update-pregnant-women>
- Florida PQC video series on maternal opioid use topics with the AIM states
 - <https://files.constantcontact.com/9648b4fd601/1d443076-3f4f-430d-b60d-1dec5934d5ea.pdf>
 - <https://health.usf.edu/publichealth/chiles/fpqc/morevideos>
- ACOG District II On the Front Line Podcast on Opioid Use Disorder
 - Listen here: <https://www.acog.org/community/districts-and-sections/district-ii/programs-and-resources/medical-education/opioid-use-disorder-in-pregnancy>
- “Engaging Women with OUD in the COVID-19 Crisis” presented by Mishka Terplan, MD, MPH
 - View the webinar recording and slides under the “Archived MORE Presentations and Webinars” tab: <https://health.usf.edu/publichealth/chiles/fpqc/MORE>

Team Updates/Check-In

March-June Update:

- We are working on re-engagement. We have a team meeting scheduled for the morning of 7/7 and are now hoping to focus our Fall Skills Day (virtual or in person) entirely on AIM OUD work. We had hoped our Spring Skills would be this opportunity, but had to cancel for Covid. We are working on rescheduling the many trainings we had set up that had to be cancelled r/t Covid.

Questions:

- We are wondering if any of the hospitals using Epic have had success adding a validated screening tool and if any of the MGB hospitals have an update on if/when the NIDA will be added to our Epic. We would love to avoid a paper tool if possible.

March-June Update:

- Implemented new clinical process including multidisciplinary team meetings; we are working on expanded engagement with our OB practices using tools including video to disseminate information
- Did SBIRT training for MFM practice as we move closer to universal screening (!)
- Developing patient education materials

Team: South Shore Health

March-June Update:

- BSAS approval for SSH
- Group therapy training
- Telehealth visits from 3/2020- Current, some in-clinic visits as well
- Developing OUD prenatal, PP and parenting clinic which will be called SHORE Program (supporting: hope, opportunity, resilience and empowerment) a program within the perinatal behavioral health clinic.
- Hoping to start measuring compliance with screening at 1st prenatal visit and 28 weeks as of August 1st.

Questions:

- How are others managing group therapy? Are some teams doing virtual groups?

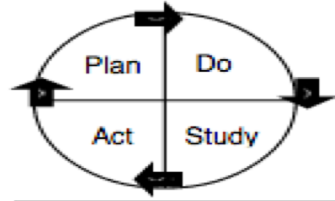
QI Webinar Topics for Next 12 months

| Date | QI Topic |
|---------------|-----------------------------------|
| 7/9/19 | OUD Bundle Components Overview |
| 8/6/19 | Stakeholders |
| 9/3/19 | Developing a Project AIM |
| 10/1/19 | Measures for Improvement |
| 11/5/19 | Key Driver Diagram |
| 12/3/19 | Developing Interventions |
| 1/7/20 | Understanding Run Charts |
| 2/4/20 | Understanding Data Control Charts |
| 3/3/20 | Using the PDSA Cycle |
| 7/7/20 | PDSA: Making Adjustments |
| 8/4/20 | Scale and Spread Up |
| 9/1/20 | Sustainability |

QI Training: PDSA Cycle: Making Adjustments

*Ronald Iverson, MD, MPH
Boston Medical Center*

PDSA worksheet



PDSA WORKSHEET

| | | |
|--|----------------------------|------------------------------------|
| Team Name: Hospital A | Date of test: June 1, 2016 | Test Completion Date: June 3, 2016 |
| Overall team/project aim: By December 2017, to reduce the rate of severe morbidities in women with preeclampsia, eclampsia, or preeclampsia superimposed on pre-existing hypertension by 20% | | |
| What is the objective of the test? To improve access to IV labetalol on the L&D unit. | | |

PLAN:

Briefly describe the test:

Test use of the severe hypertension medication box containing: magnesium sulfate (with tubing, syringes, and needles), labetalol, hydralazine, and calcium gluconate.

How will you know that the change is an improvement?

Feedback from providers and staff on experience with box after use on one patient – does it contribute to improved access and time to treatment?

What driver does the change impact?

Response

What do you predict will happen?

We predict the medication box will improve access to IV hypertensive medication when caring for patient with severe hypertension.

PLAN

| List the tasks necessary to complete this test (what) | Person responsible (who) | When | Where |
|---|--------------------------|--------|------------------------------|
| 1. Gather medication for boxes using appropriate protocol | Jane & John | June 1 | L&D Room 2X |
| 2. Assemble boxes and label all contents individually and list contents on box. | Jane & John | June 1 | L&D Room 2X |
| 3. Mark boxes with a PDSA label so team knows it's part of a test of change | Jane & John | June 1 | L&D Room 2X |
| 4. Notify L&D staff and providers of the box and its location in all rooms. | Jane & John | June 2 | Staff meeting L&D Room 3X |
| 5. Meet with nurse, provider and any other involved staff after first use for feedback. | John | June 3 | L&D Room 3X |
| 6. Develop subsequent PDSA cycle/other action. | Team | June 3 | Team meeting L&D Room 3X |

Plan for collection of data: Qualitative discussion of nurse and provider experience with the box.

DO: Test the changes.

Was the cycle carried out as planned? Yes No

Record data and observations.

Nurse Joan used the box with a patient on June 3. Felt it greatly increased her access to the medications and patient was treated within 45 minutes of confirmed BP. Feedback that box was difficult to open. Questions about how to ensure new box is in place for next case were raised.

What did you observe that was not part of our plan?

We didn't expect packaging to be an issue.

STUDY:

Did the results match your predictions? Yes No

Compare the result of your test to your previous performance:

First test. Previous treatment required additional steps to access medications.

What did you learn?

Medication box helps but needs to be easier to access in an emergency. Plan for restocking needed.

ACT: Decide to Adopt, Adapt, or Abandon.



Adapt: Improve the change and continue testing plan.

Plans/changes for next test: Change box closure type and retest with one patient. Add checking boxes for restocking to the hospital's existing crash cart check list and review status after one box is used with one patient.

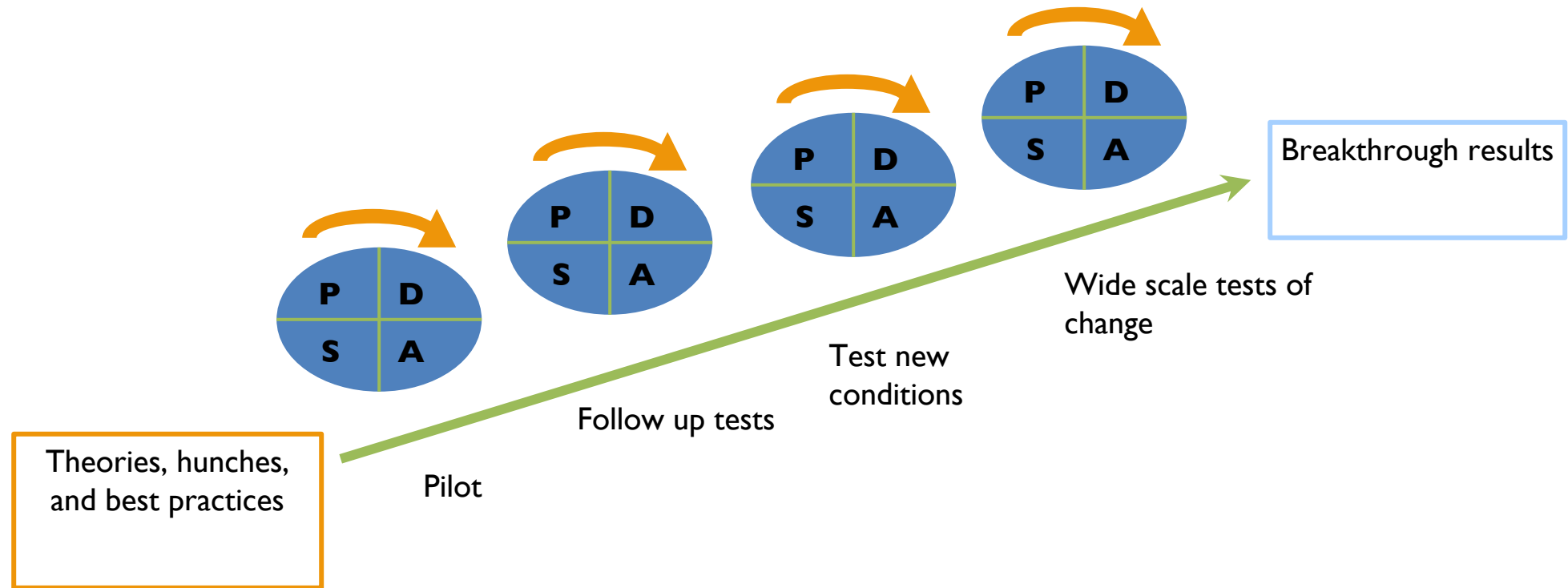


Adopt: Select changes to implement on a larger scale and develop an implementation plan and plan for sustainability



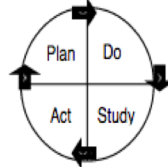
Abandon: Discard this change idea and try a different one

Iterative PDSA Cycles



Make realistic predictions

- Use the data from your first PDSA cycle to adjust your predictions for your second
- Making more informed, data-driven predictions will help you better measure and understand the success or failure rates of your next cycle
- Reevaluate your initial work sheet



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Adopt: Select changes to implement on a larger scale and develop an implementation plan and plan for sustainability

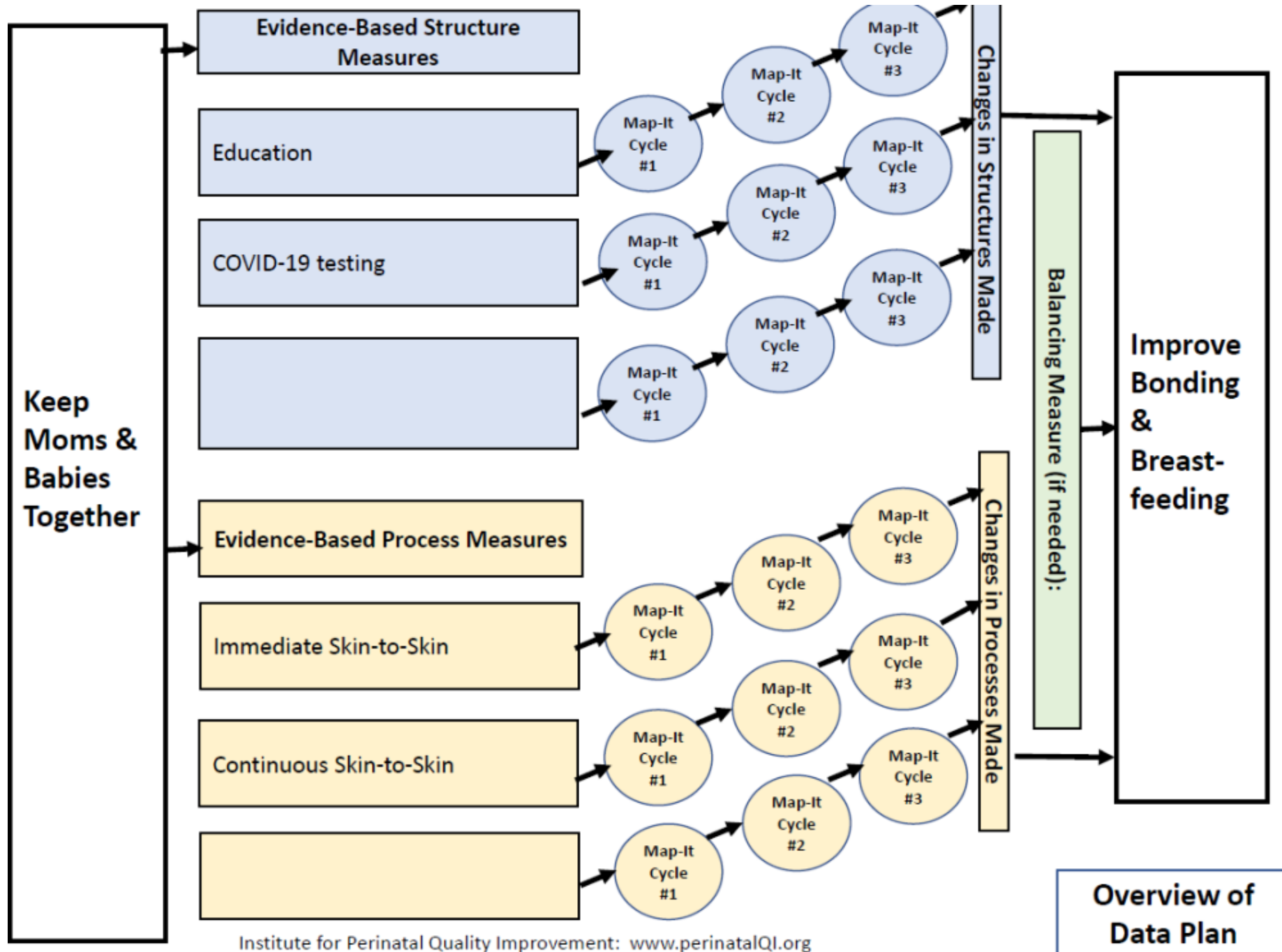
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Plan for collection of data: Qualitative discussion of nurse and provider experience with the box.

SOURCE: www.ilpqc.org ; <https://www.nichq.org/insight/9-tips-moving-one-pdsa-cycle-next>



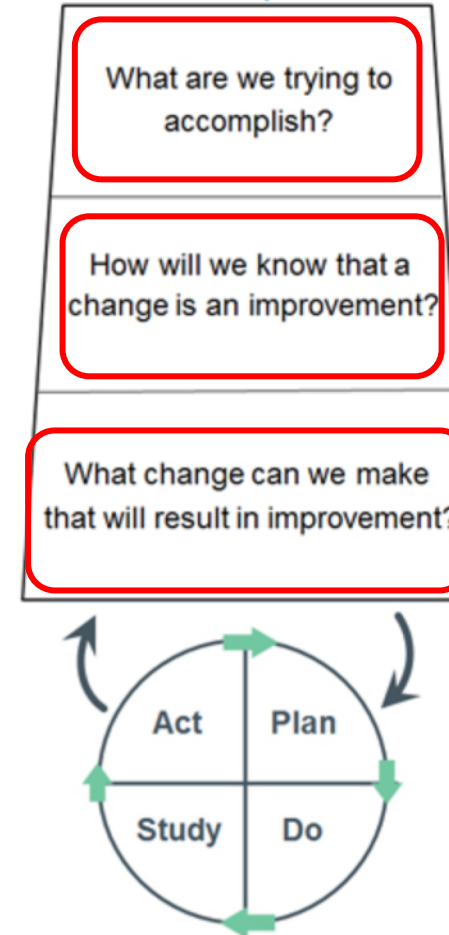
Post-PDSA Cycle Round I - What's Next

- You've finished your first PDSA cycle, which means you have taken an essential step towards driving change.
- Next phase of continuous improvement: your second, third and fourth PDSA cycle, or, as many cycles as needed to reach the final adoption stage
- Utilized following tips to adjust PDSA

Stay on goal

- Modifying an individual test of change—the original PDSA cycle—does not mean your overall project goals should change
- Remember to review your answers to the three fundamental questions and make sure your change modification still supports those goals

Model for Improvement



Setting Aims

The aim should be time-specific and measurable; it should also define the specific population of patients or other system that will be affected.

Establishing Measures

Teams use quantitative measures to determine if a specific change actually leads to an improvement.

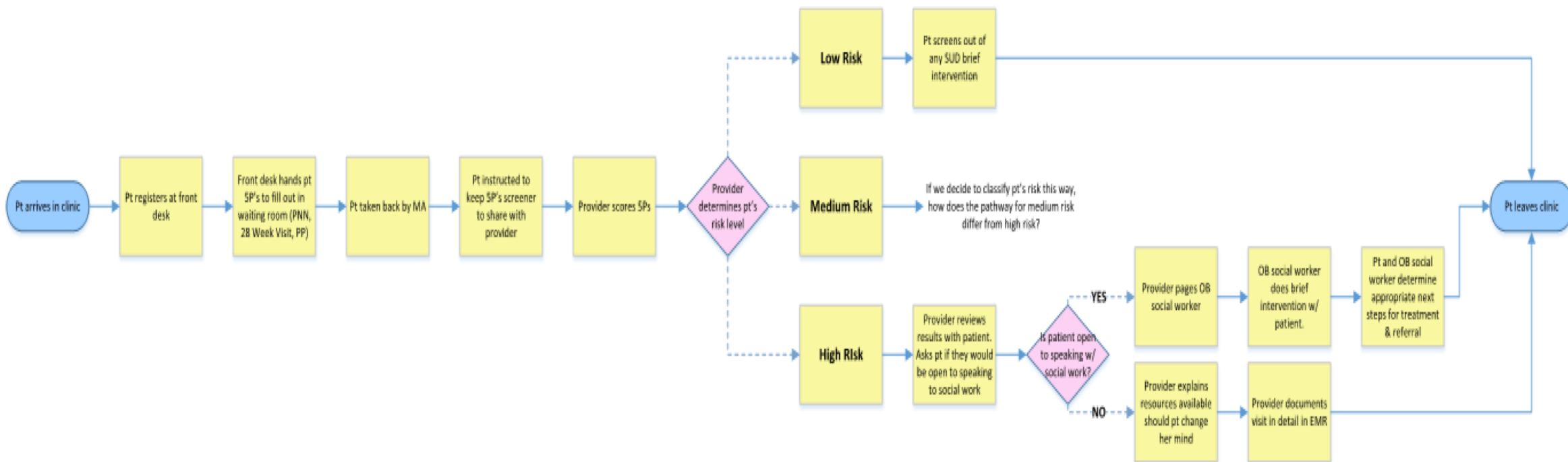
Selecting Changes

Ideas for change may come from those who work in the system or from the experience of others who have successfully improved.

Testing Changes

The Plan-Do-Study-Act (PDSA) cycle is shorthand for testing a change in the real work setting — by planning it, trying it, observing the results, and acting on what is learned. This is the scientific method adapted for action-oriented learning.

SOURCE: <https://www.nichq.org/insight/9-tips-moving-one-pdsa-cycle-next>



Update your learning questions

- New PDSA cycle means creating a new question that your test answers
 - Sometimes, that's a "smaller" aim
 - Don't disregard what you've learned and hope for the best
- Specifically, design a new question that addresses the problem noted in the previous PDSA cycle
- Example: AIM: help patients fill out the 5Ps, get the provider results, and support linkage to next steps
 - PDSA 1 – AIM: Can we get the 5Ps form all the way through the process for one patient? We learned that there was a disconnect from MA to Provider
 - PDSA 2 – AIM: can we help the MA and provider communicate? We learned that yes, we can, but the providers aren't documenting
 - PDSA 3 – AIM: can we help providers document? yes, but they didn't always complete linkage to SW
 - PDSA 4 –AIM: can we support linkage to SW? Yes, by changing the process to communicate with SW team

SOURCE: <https://www.nichq.org/insight/9-tips-moving-one-pdsa-cycle-next>

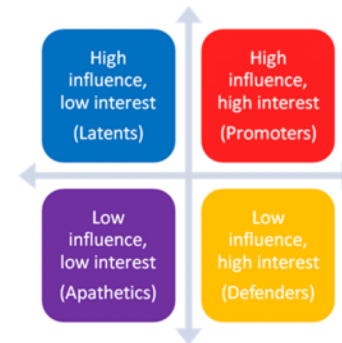
Identify who needs to be notified:

- Change to the initial test will likely impact multiple groups of people
- Meeting with all key stakeholders helps ensure that the adaption will go smoothly during the Do phase of your next PDSA cycle
- Review stakeholder analyses and matrix from first PDSA cycle

Stakeholder Matrix – Example

| Names or Group | Strongly Against | Moderately Against | Neutral | Moderately Supportive | Strongly Supportive |
|------------------------------|------------------|--------------------|---------|-----------------------|---------------------|
| Medical Residents | | | | | X |
| Medicine Attendants | | | X | → | O |
| Emergency Medicine | X | → | | O | |
| Clinical Directors (Nursing) | | | | X | → O |
| Family Medicine | | | | X | |
| Floor Nurses | X | → | | O | |
| Social Workers | | | X | → | O |

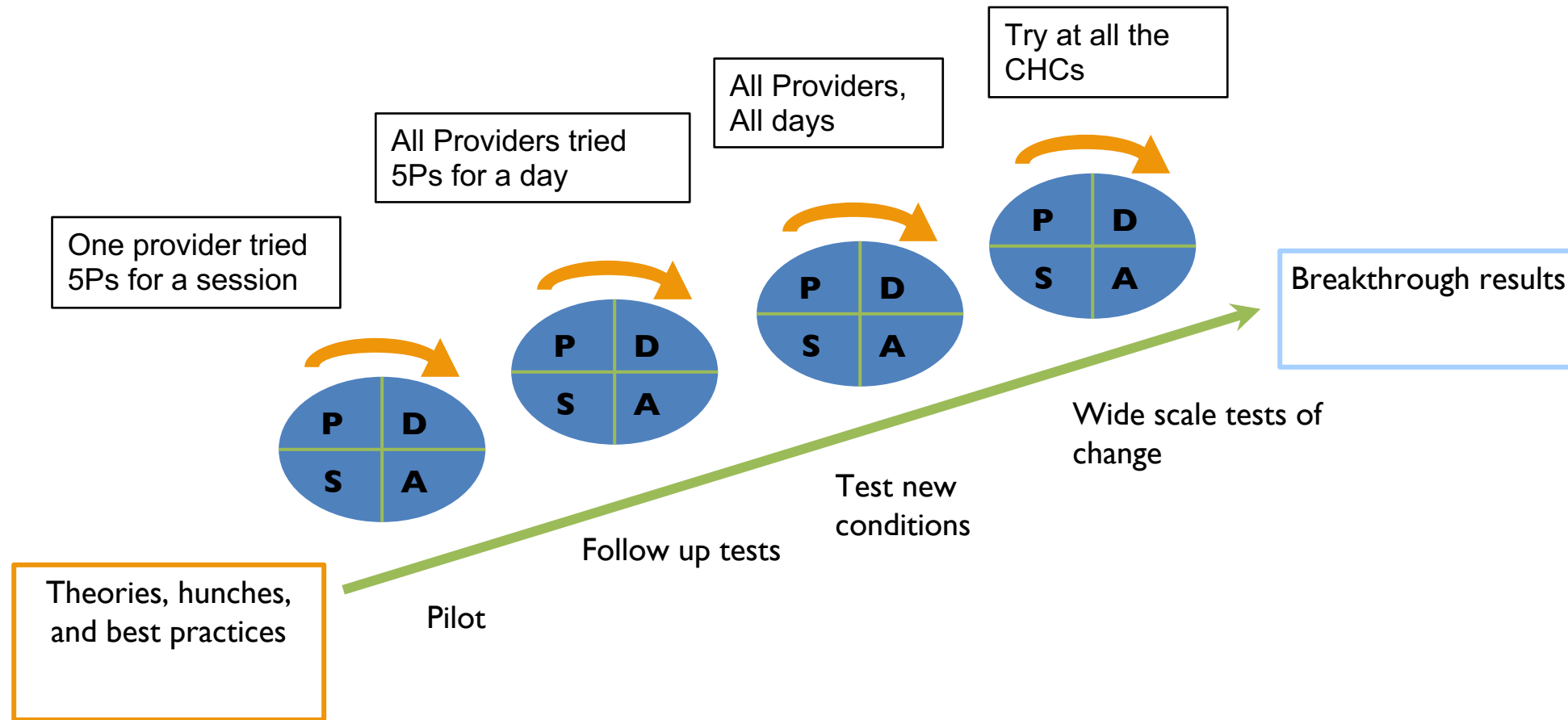
Stakeholder Analysis



- *Promoters* have both great interest in the effort and the power to help make it successful.
- *Defenders* have a vested interest and can voice their support in the community, but have little actual power to influence the effort.
- *Latents* have no particular interest or involvement in the effort, but have the power to influence it if they become interested.
- *Apathetics* have little interest and little power, and may not even know the effort exists.

SOURCE: <https://www.nichq.org/insight/9-tips-moving-one-pdsa-cycle-next>

Iterative PDSA Cycles – Initiation of 5Ps into all Prenatal Clinics



- **Don't abandon too soon:**
 - Don't make the mistake of discarding a promising idea because of poor execution
- **But, don't adopt too soon either:** When we see improvement that is greater than predicted, we can be tempted to adopt it as standard.
 - Remember if there is still room for improvement, keep adapting and start another PDSA cycle
- **Don't repeat the cycle**
 - While this may seem like a given, it can be tempting to re-test the same change if you think the results from the first cycle aren't for sure
 - Even if an anomaly occurs, adapt the model based on the cycle's results
 - In the next cycle, develop a plan for these exceptions so that you are prepared to deal with them when they occur again in the future

Guest Presentations Topics for Next 12 Months

- OUD Screening Options
- Plans of Safe Care
- Linkages to Care
- Caring for Patients with OUD – Using the Checklist
- Centering Patient Voice
- OUD SMM Data
- Equity Consideration in OUD Care
- Early Head Start
- **MAT**
- Pain Relief During Pregnancy, Labor, Surgery, Post-op
- SBIRT Check in

Guest Topics:
MAT

Kelley Saia, MD, FACOG, DABAM
Project RESPECT at Boston Medical Center

OUD in Pregnancy: The Fentanyl Effect

Kelley Saia, MD, FACOG, DABAM

Project RESPECT at Boston Medical Center

MOUD OB Manual

<https://www.bmcobat.org/>

Bmcobat.org → Resources Tab
→ OBAT Clinical Guidelines



GUIDELINES FOR THE
TREATMENT OF OPIOID USE
DISORDER IN PREGNANT AND
PARENTING PATIENTS

PROJECT RESPECT:
SUBSTANCE USE DISORDER IN
PREGNANCY TREATMENT PROGRAM
AT BOSTON MEDICAL CENTER

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Data Brief: Opioid-Related Overdose Deaths among Massachusetts Residents

Massachusetts Department of Public Health

June 2020

<https://www.mass.gov/lists/current-opioid-statistics>

Figure 3. Rate of Confirmed and Estimated Opioid-Related Overdose Deaths, All Intent
Massachusetts Residents: 2000 - 2019

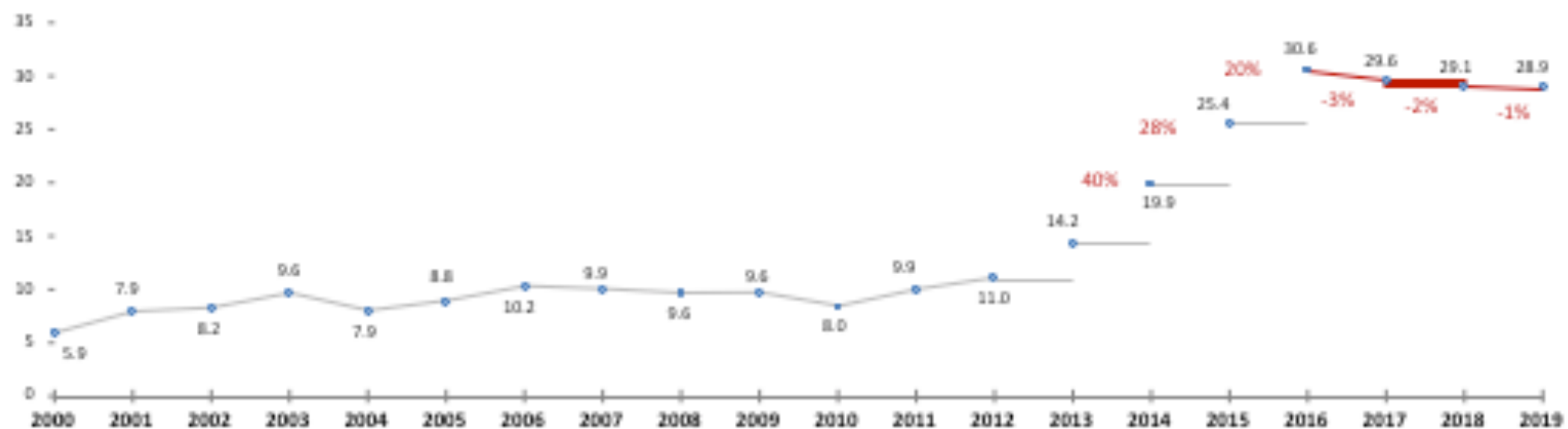


Figure 5. Rate of Confirmed and Estimated Opioid-Related Overdose Deaths and Percent of Confirmed Opioid-Related Overdose

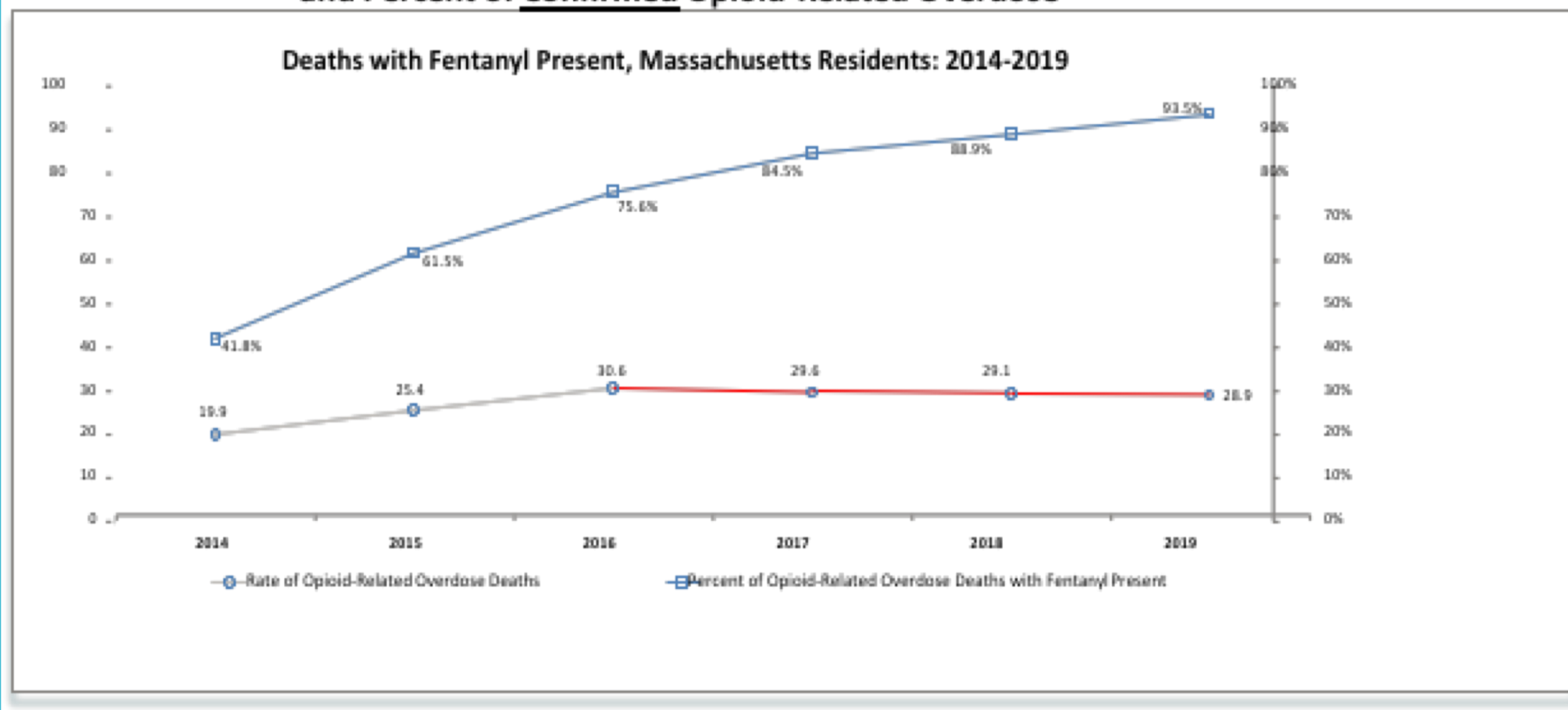
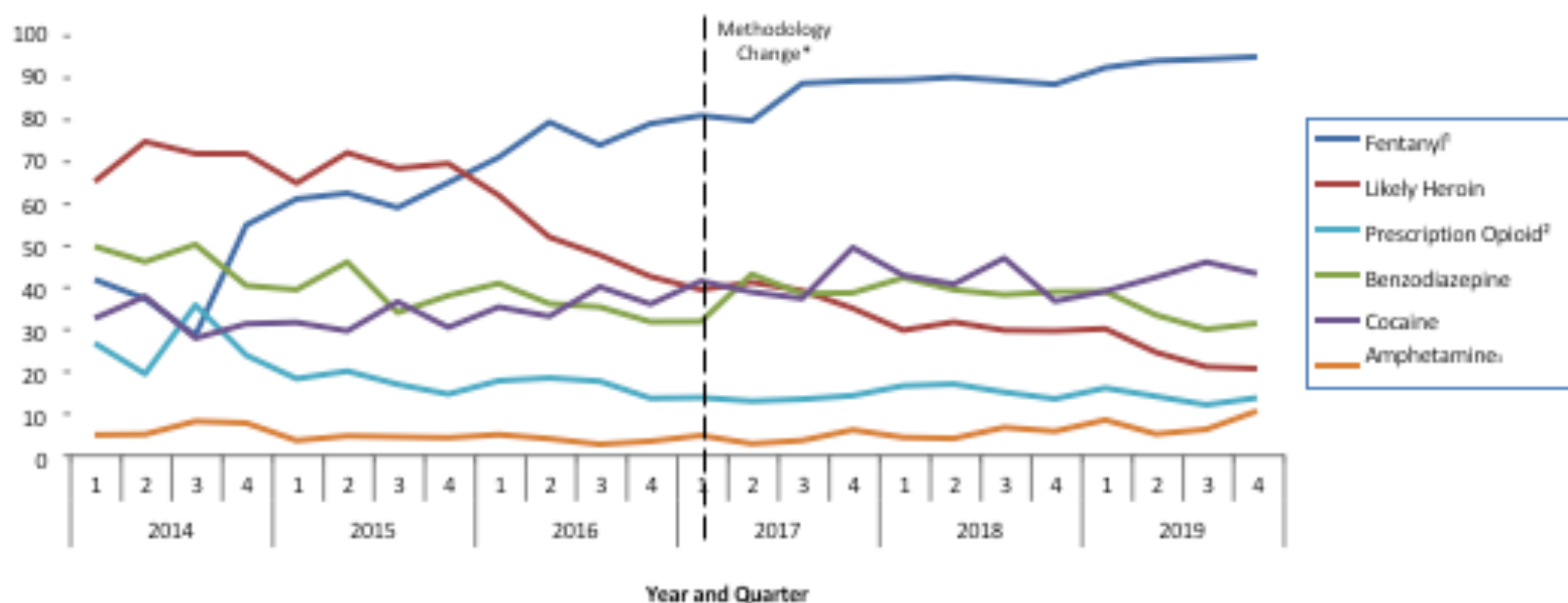


Figure 4. Percent of Opioid-Related Overdose Deaths with Specific Drugs Present
Massachusetts Residents: 2014 - Q4 2019



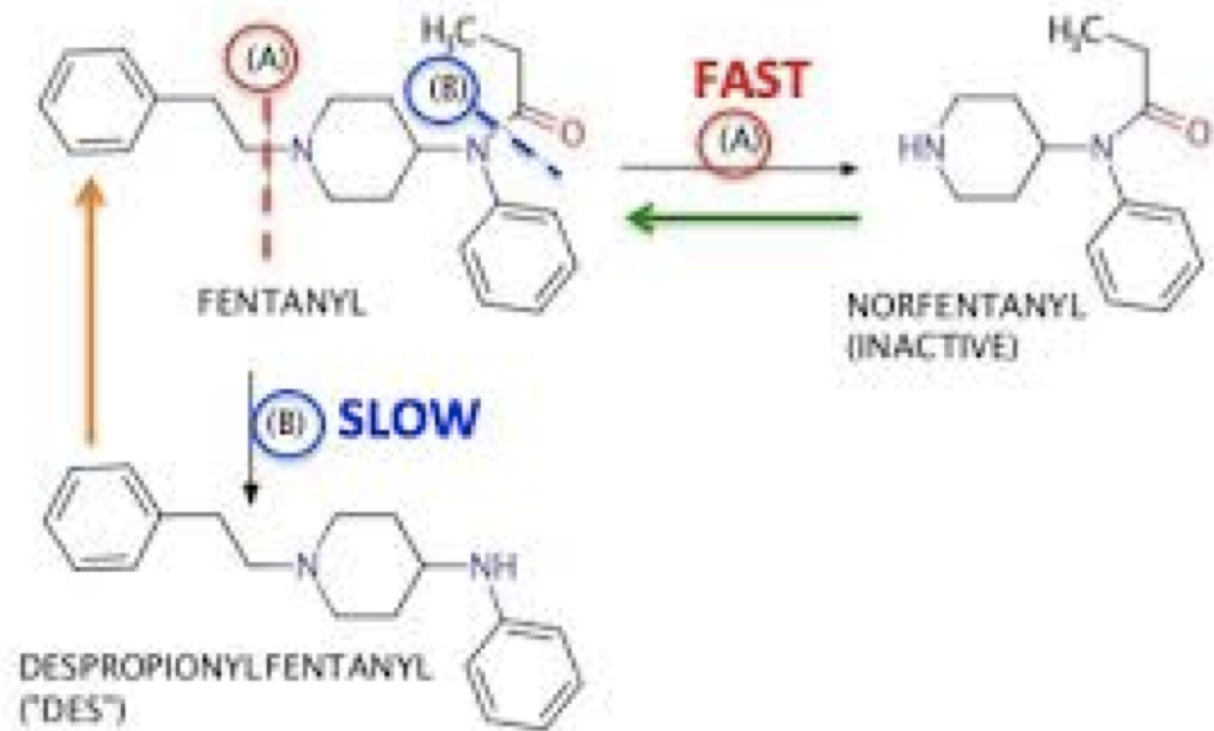
Fentanyl: Its deadly history

- Synthetic opioid (*100x potency of morphine*)
- **1960**: First synthesized by Paul Janseen in Belgium
- **1972**: US FDA approval for treatment of severe pain
- **1980's**: Diversion and misuse by healthcare providers (IV)
- **1990's**: Advent of the transdermal patches for cancer pain
- **2000's**: Illicitly manufactured nonpharmaceutical fentanyl
- **2010's**: "designer-fentanyl" in pill / tablet form (mimic oxy, benzo)
- 22+ identified analogs (majority Schedule I)
 - Sufentanil* 10 times stronger than fentanyl (Schedule II)
 - Butyryl fentanyl*
 - Acetylfentanyl*
 - Carfentanil* 100 times stronger than fentanyl (schedule II)
- Pharmaceutical fentanyl vs. "Street" fentanyl
 - Minimal diversion of transdermal patches or lozenges
 - Fentanyl in Massachusetts is almost entirely illicitly-produced not diverted pharmaceutical fentanyl

Fentanyl: Metabolism and Clearance

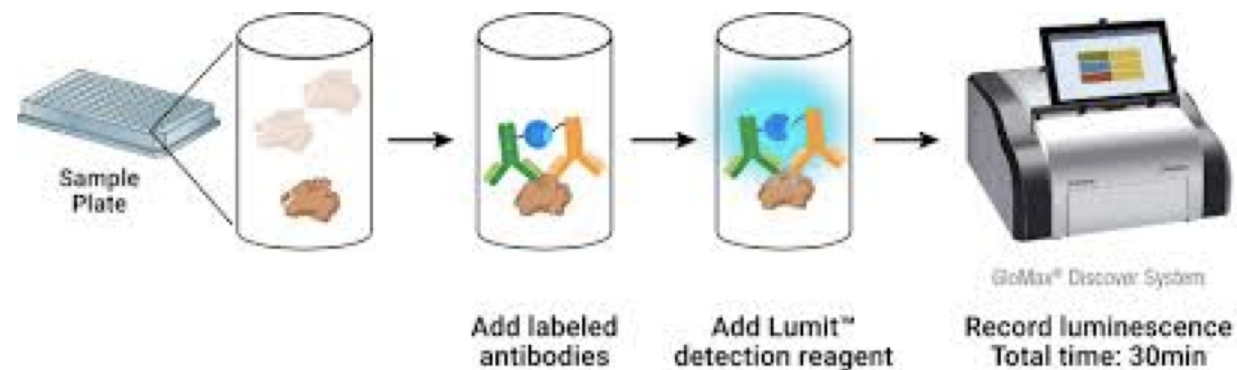
- Metabolized by hepatic cytochrome p₄₅₀ (CYP_{3A4})
- < 10% of parent drug excreted in urine
- >90% excreted as non-toxic, clinically inactive metabolite: ***Norfentanyl***
- Elimination half-life ranges (4-14 hours)
 - Morphine (2-4hours)
 - Highly lipophilic
 - binds strongly to plasma proteins
 - Large volume of distribution
- Clearance affected by
 - Renal / hepatic function
 - Genetic polymorphisms of CYP
 - BMI
 - Medications (SSRIs, antiretrovirals, antiemetics,etc)
- No data on Fentanyl metabolism/ clearance in pregnancy

Fentanyl



Principles of Urine Drug Testing: The Immunoassay

- **Immunoassay:** based on the principles that specific antigens will stimulate very specific (unique) immune responses and that the proteins produced by the immune response, called antibodies, can be used to signal the presence of a target compound in a sample
 - fast and relatively inexpensive
 - Cross-reactivity within drug families
 - Semi-quantitative Immunoassay at BMC
 - Approximately 20% false positive rate for fentanyl
 - “presumptive positive”
 - Confirmatory testing required



Buprenorphine, Urine

NEG

NEG

Comment: THIS IS A SCREENING ASSAY ONLY AND RESULTS ARE REPORTED AS PRESUMPTIVE POSITIVE OR NEGATIVE, USING A CUTOFF CONCENTRATION OF 20 NG/ML. RESULTS ARE TO BE USED FOR CLINICAL EVALUATION ONLY. CONFIRMATION TESTING WAS NOT PERFORMED.

Oxycodone, Urine

NEG

NEG

Comment: THIS IS A SCREENING ASSAY ONLY AND RESULTS ARE REPORTED AS PRESUMPTIVE POSITIVE OR NEGATIVE, USING A CUTOFF CONCENTRATION OF 100 NG/ML. RESULTS ARE TO BE USED FOR CLINICAL EVALUATION ONLY. CONFIRMATION TESTING WAS NOT PERFORMED.

Methadone, Urine

NEG

POS Abnormal

Comment: THIS IS A SCREENING ASSAY ONLY AND RESULTS ARE REPORTED AS PRESUMPTIVE POSITIVE OR NEGATIVE, USING A CUTOFF CONCENTRATION OF 300 NG/ML. RESULTS ARE TO BE USED FOR CLINICAL EVALUATION ONLY. CONFIRMATION TESTING WAS NOT PERFORMED.

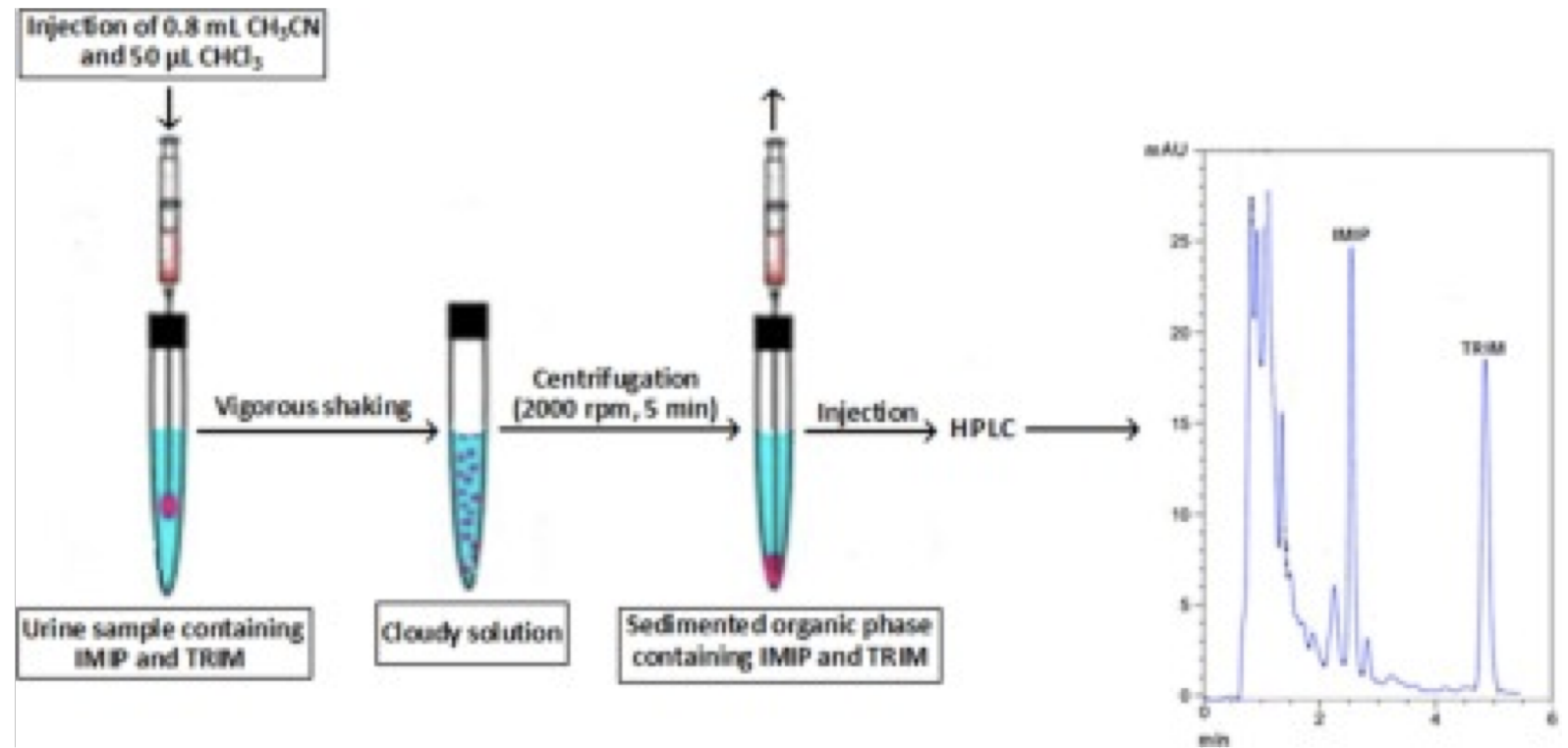
**Fentanyl Presumptive Screen, NEG
Urine**

POS Abnormal

Principles of Urine Drug Testing: GC/LC-MS

Gas or Liquid
Chromatography-Mass
Spectrometry

Individual components in a mixture are first separated followed by ionization and separation of the ions on the basis of their mass/charge ratio



Confirmatory Results

GC-MS

| | Ref Range & Units | | |
|--|------------------------------|-------------|------------|
| | Fentanyl, Urine | <0.50 ng/mL | 38.00High |
| | Norfentanyl, Urine | <0.50 ng/mL | 390.50High |

Case Report

- A 33-year-old G8P₁ with opioid use disorder, hepatitis C, asthma, obesity (pre-pregnancy BMI was 43.59 kg/m²)
- Methadone 90mg
- Protracted fentanyl and norfentanyl detection window
 - Positive norfentanyl on 10 distinct gas chromatography/mass spectrometry
 - Norfentanyl detection 70 days after last use
 - Required a written document summarizing the how to accurately interpret urine drug screens

Urine Drug Testing during Pregnancy

- For the ordering provider
 - **Approach urine testing as a *component* of OUD treatment, not the *focus***
 - an opportunity to confirm treatment success
 - recognize the power test results hold in the legal system
 - **Understand the limits of the tests you order**
 - Confirm accuracy, reliability, recognize processing errors (chain of custody) and availability/ necessity of confirmatory testing
 - **Be the expert on interpretation of results**
 - More complicated than you may think
 - Can confuse medical providers and baffle non-medical systems

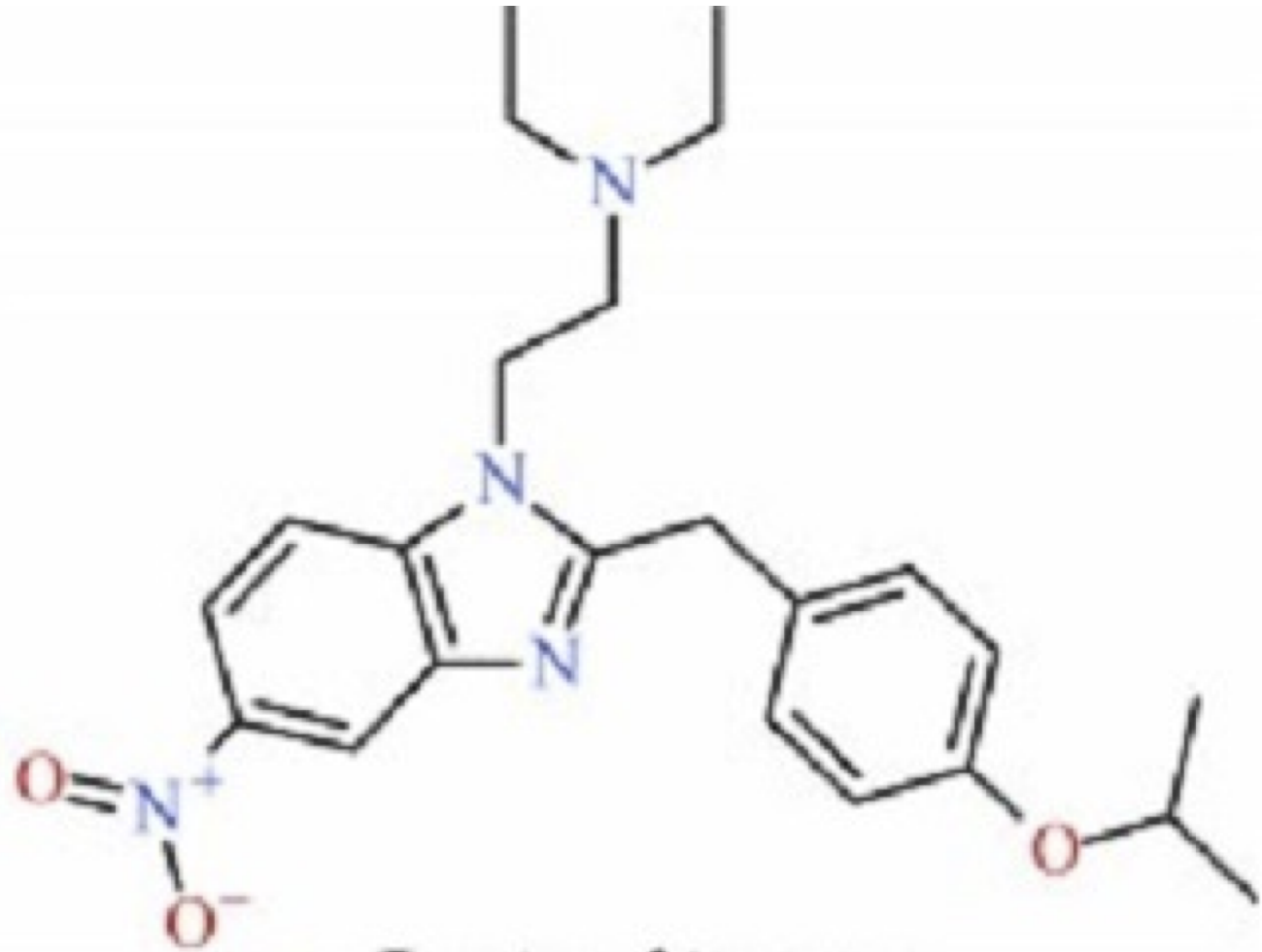
“Iso”

Fall 2019:

Center for Forensic Science
Research & Education issued a
“Potent Synthetic Opioid”
warning for isotonitazene

First synthesized in 1950s

Potency greater than Fentanyl



Isotonitazene

references

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- Harper L, Powell J, Pijl EM. **An overview of forensic drug testing methods and their suitability for harm reduction point-of-care services.** *Harm Reduct J.* 2017;14(1):52. Published 2017 Jul 31. doi:10.1186/s12954-017-0179-5
- Armenian, P., Vo, K. T., Barr-Walker, J., & Lynch, K. L. (2018). **Fentanyl, fentanyl analogs and novel synthetic opioids: a comprehensive review.** *Neuropharmacology*, 134, 121-132.
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- Holmquist, G. L. (2009). **Opioid metabolism and effects of cytochrome P450.** *Pain Medicine*, 10(suppl_1), S20-S29.

Closing Thoughts

- Next Webinar is **Tuesday, August 4, 2020** from 12-1pm EST
- **QI Topic:** Scale and Spread Up
- **Guest Topic:** Pain Relief During Pregnancy, Labor, Surgery, Post-op
- **Assignment:** Register for 2-hour Stigma, Bias, and Trauma-Informed Care Training (<https://calendly.com/tictrainings/2hours>); Register for Buprenorphine Waiver Trainings and share with colleagues
- **Reminders:**
 - Please email or call with questions!

Questions or Concerns?

